STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

AGENDA

April 11, 2024
Immediately following the Committee on Codes, Regulations, and Legislation Meeting
(Codes scheduled to begin at 10:15 a.m.)

Empire State Plaza, Concourse Level, Meeting Room 6, Albany

I. INTRODUCTION OF OBSERVERS

Jeffrey Kraut, Chair

II. APPROVAL OF MINUTES

February 8, 2024 PHHPC Meeting Minutes

III. REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

A. Report of the Department of Health

James V. McDonald, M.D., M.P.H., Commissioner of Health

B. Report of the Office of Public Health

Ursula Bauer, PhD, MPH, Deputy Commissioner, Office of Public Health

C. Report of the Office of Aging and Long Term Care

Adam Herbst, Deputy Commissioner, Office of Aging and Long Term Care

D. Report of the Office of Primary Care and Health Systems Management

Douglas G. Fish, M.D., Acting Deputy Commissioner, Office of Primary Care and Health Systems Management

E. Report of the Office of Health Equity and Human Rights

Tina Kim, MSPH, Acting Deputy Commissioner, Office of Health Equity and Human Rights

IV. PUBLIC HEALTH SERVICES

Report on the Activities of the Public Health Committee

Jo Ivey Boufford, M.D., Chair of the Public Health Committee

V. HEALTH POLICY

Report on the Activities of the Health Planning Committee

John Rugge, M.D., Chair of the Health Planning Committee

VI. REGULATION

Report of the Committee on Codes, Regulations and Legislation

Thomas Holt, Chair of the Committee on Codes, Regulations and Legislation

For Adoption

23-08 Sections 405.4 & 405.6 of Title 10 NYCRR (General Hospital Medical Staff Recertification)

For Information

23-01 Repeal and Replace of Part 16 of 10 NYCRR (Ionizing Radiation)

VII. PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

A. Report of the Committee on Establishment and Project Review

Peter Robinson, Chair of Establishment and Project Review Committee

APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 2: Applications Recommended for Approval with the Following:

- PHHPC Member Recusals
- Without Dissent by HSA
- Without Dissent by the Establishment and Project Review Committee

CON Application

Acute Care Services - Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	241042 C	St. James Hospital (Steuben County) Mr. Robinson– Recusal	Contingent Approval

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

CON Applications

Acute Care Services - Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	232182 C	White Plains Hospital Center (Westchester County)	Contingent Approval

Residential Health Care Facilities - Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231323 C	St. Mary's Hospital for Children (Queens County)	Contingent Approval

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HSA

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

NO APPLICATIONS

APPLICATIONS FOR THE ESTABLISHMENT AND CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by the Establishment and Project Review Committee

CON Application

Ambulatory Surgery Centers – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	232173 E	Long Island Center for Digestive Health, LLC (Nassau County) Mr. Kraut– Recusal	Approval

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

CON Applications

Home Care Service Agency Licensures

Changes of Ownership

1.	222105 E	Alliance For Health, Inc. (Geographical Service Area: Bronx, Kings, New York, Queens, Westchester, and Richmond Counties)	Approval
2.	222106 E	AccentCare Of New York, Inc. (Geographical Service Area: Bronx, Dutchess, Nassau, Orange, Putnam, Rockland, Suffolk, Ulster and Westchester Counties)	Approval
3.	222108 E	All Metro Home Care Services of New York, Inc. d/b/a All Metro Health Care (Geographical Service Area: Nassau, Queens, and Suffolk Counties)	Approval
4.	222111 E	Allen Health Care Services d/b/a Elara Caring (Geographical Service Area: Dutchess, Nassau, Orange, Putnam, Queens, Rockland, Suffolk, Sullivan, Ulster, and Westchester Counties)	Approval
5.	231047 E	SIAL Acquisition d/b/a The Veranda Assisted Living (Geographical Service Area: Kings, New York, Queens and Richmond Counties)	Approval
6.	231232 E	Jewish Senior Life LHCSA, Inc., d/b/a Jewish Home of Rochester Licensed Home Care (Geographical Service Area: Monroe, Livingston, Orleans, and Wayne Counties)	Approval
7.	231300 E	Community Health And Home Care, Inc. (Geographical Service Area: Broome, Cayuga, Cortland, Schuyler, Tioga, and Tompkins Counties)	Approval

Ambulatory Surgery Centers - Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	232143 E	Saratoga-Schenectady Endoscopy Center, LLC (Saratoga County)	Contingent Approval

Diagnostic and Treatment Centers – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	232201 B	FJ Community Family Corp. d/b/a FJ Community Health Center (Queens County)	Contingent Approval

Midwifery Birthing Center - Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	232163 B	BSD Birthing Center of Rockland (Rockland County)	Contingent Approval

Certificates

Certificate of Amendment of the Certificate of Incorporation

Applicant	E.P.R.C. Recommendation
Ezras Choilim Health Center, Inc.	Approval

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HAS

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

NO APPLICATIONS

VIII. NEXT MEETINGS

June 6, 2024 (NYC)
June 20, 2024 (NYC)

IX. ADJOURNMENT

******Agenda items may be called in an order that differs from above******

State of New York
Public Health and Health Planning Council

Minutes
February 8, 2024

The meeting of the Annual Public Health and Health Planning Council was held on Thursday, February 8, 2024 at 90 Church Street, 4th Floor CR 4 A/B, New York, New York. Mr. Jeffrey Kraut, Chair presided.

COUNCIL MEMBERS PRESENT

Dr. John Bennett	Dr. John Rugge
Dr. Howard Berliner	Dr. Denise Soffel
Dr. Jo Ivey Boufford	Ms. Nilda Soto
Mr. Tom Holt	Dr. Theodore Strange
Dr. Gary Kalkut	Mr. Hugh Thomas
Mr. Jeffrey Kraut	Dr. Anderson Torres
Mr. Scott LaRue	Dr. Kevin Watkins
Dr. Sabina Lim	Dr. Patsy Yang
Ms. Ann Monroe	Commissioner McDonald –Ex-Officio
Mr. Peter Robinson	

DEPARTMENT OF HEALTH STAFF PRESENT

Mr. Amir Bassiri – Albany
Ms. Lynn Baniak – Zoom
Dr. Ursula Bauer – Zoom
Ms. Joanne Criscione – Zoom
Ms. Ashley Cokgoren – Albany
Mr. Jason Corvino – Zoom
Ms. Val Deetz – Zoom
Mr. Vince DiCocco – Albany
Mr. Steven Dziura – Albany
Mr. Kenneth Evans – Albany
Dr. Doug Fish – NYC
Mr. Mark Furnish – NYC
Ms. Shelly Glock – Albany
Ms. Heidi Hayes – Albany
Mr. Adam Herbst – NYC
Dr Eugene Heslin – NYC
Ms. Geraldine Humbert – Zoom
Mr. Jonathan Karmel – Albany
Mr. James Kirkwood – Albany
Ms. Colleen Leonard- NYC
Ms. Karen Madden – Zoom
Mr. George Macko – Albany
Ms. Kathy Marks - NYC
Ms. Johanne Morne - Zoom
Ms. Marthe Ngwashi - NYC
Ms. Stephanie Patton - Albany
Mr. Jason Riegert - Albany
Mr. Mark Schweitzer – Zoom
Mr. Robert Serenka - Albany
Ms. Jackie Sheltry - NYC
Mr. Michael Stelluti -NYC
Ms. Jennifer Treacy - Zoom
Ms. Kazmi Wajiha - Albany

INTRODUCTION

Mr. Kraut called the meeting to order and welcomed Council members, Dr. McDonald, meeting participants and observers.

ELECTION OF OFFICERS

Mr. Kraut opened up the Annual meeting portion of the meeting and motioned to elect Dr. Boufford to serve as the Council's Vice. Chair. Dr. Berliner seconded the motion. The motion carried unanimously. Please refer to pages 1 and 2 of the attached transcript.

APPROVAL OF THE MINUTES OF NOVEMBER 16, 2023

Mr. Kraut asked for a motion to approve the November 16, 2023 Minutes of the Public Health and Health Planning Council meeting. Dr. Berliner motioned for approval which was seconded by Dr. Torres. The minutes were unanimously adopted. Please refer to page 2 of the attached transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Report on the Department of Health

Mr. Kraut introduced Dr. McDonald to give the Report on the Activities of the Department.

Dr. McDonald began his report by acknowledging Black History Month and emphasizing the collective responsibility to address health equity for all, particularly focusing on the systemic racism affecting access to quality healthcare and health outcomes for Black communities. He then discussed various topics covered during budget hearings, highlighting workforce issues as a significant concern across the state. Dr. McDonald expressed hope for legislative changes to streamline processes such as scope of practice regulations, citing examples from other states and proposed legislation aimed at allowing healthcare workers to utilize their training more effectively.

Dr. McDonald discussed declines in COVID-19, flu, and RSV cases across the state, though he highlighted ongoing efforts to track variants and promote vaccine uptake. He also addressed the opioid epidemic, noting the emergence of xylazine as a concerning substance driving mortality rates and proposing regulatory changes to monitor its usage more effectively.

Commissioner McDonald provided updates on healthcare policy initiatives, including the 1115 and 1332 Waivers, which aim to improve access to healthcare services and insurance coverage for New Yorkers. He discussed proposed budget allocations for early intervention programs, emergency medical services, investments in tribal nations' health disparities, and funding for veterans' homes.

Dr. McDonald expressed gratitude for the work of the Public Health and Health Planning Council, Dr. McDonald welcomed questions from members. Dr. McDonald concluded his report. Please see pages 3 through 7 of the attached transcript.

APPROVAL OF THE 2025 PUBLIC HEALTH AND HEALTH PLANNING COUNCIL MEETING DATES

Mr. Kraut asked for a motion to approve the 2025 PHHPC meeting dates. Mr. Thomas motioned for approval which was seconded by Dr. Watkins. The dates were unanimously adopted. Please refer to page8 of the attached transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Report on the Activities of the Office of Aging and Long Term Care

Mr. Kraut welcomed Mr. Herbst to give the Report on the activities of the Office of Aging and Long Term Care.

Mr. Herbst began his report by expressing excitement about providing updates on the Office of Aging and Long-Term Care's initiatives, particularly focusing on the Master Plan for Aging. He highlighted recent legislative developments, including the creation of a new licensure category for the Program for All-Inclusive Care for the Elderly (PACE), which aims to empower seniors to remain in their communities by providing comprehensive care services.

Mr. Herbst then discussed the launch of the Center for Hospice and Palliative Care, emphasizing its role in addressing disparities and barriers to end-of-life care. He outlined various budget proposals aimed at improving long-term care services, such as expanding the scope of practice for healthcare workers, establishing quality reporting metrics for assisted living residences, and enhancing support for families of individuals with dementia through the Special Needs Assisted Living Residents Voucher Program.

Mr. Herbst highlighted efforts to support financially distressed nursing homes through the Vital Access Provider Assistance Program (VAPAP) and ongoing work on the Master Plan for Aging. He emphasized the importance of community engagement and collaboration in developing sustainable recommendations for the Master Plan.

Mr. Herbst addressed inquiries regarding the alternative model of care unit and potential challenges to the Hospital at Home Program at the federal level, reaffirming the state's commitment to transforming healthcare delivery regardless of federal decisions.

Mr. Herbst concluded his report. To see the complete report please see pages 8 through 11 of the transcript.

Report on the Activities of the Office of Health Insurance Programs

Mr. Kraut next introduce Mr. Bassiri to provide an update on the work of the Office of Health Insurance Programs.

Mr. Bassiri, the Medicaid Director at the Office of Health Insurance Programs provided a detailed update on the recent approval of the 1115 Waiver amendment, which occurred on January 9, 2024. He emphasized the extensive negotiation process with the Center for Medicare and Medicaid Services (CMS), lasting approximately fifteen months, culminating in a significant $7.5 billion waiver approval over the next three years, with around 80% of the funding coming from federal sources. This approval represents the largest and most federally funded waiver approved by CMS to date.

Mr. Bassiri outlined the primary goal of the amendment, which aims to fundamentally transform the delivery and payment of Medicaid benefits by integrating social care services with physical and behavioral health services. The focus is on addressing health disparities and inequities across New York State. The waiver amendment builds upon the existing 1115 Waiver structure, which has authorized most of the managed care program since 1997. However, this amendment introduces several new authorities and flexibilities, particularly focusing on health-related social needs services integrated into the managed care benefit package.

Mr. Bassiri continued to explain the waiver's main pillars include the development of social care networks and the integration of health-related social needs, accounting for approximately $4 billion of the total funding. These social care networks will serve as contracting entities responsible for coordinating benefits and services, supporting community-based organizations (CBOs), and integrating them into the Medicaid program's patient flow and reimbursement model. The intention is to establish one social care network per region, with up to five in New York City.

Mr. Bassiri discussed initiatives under the population health improvement and health equity pillar, including the establishment of a statewide health equity regional organization to identify region-specific health equity priorities and support data aggregation. Additionally, there's a focus on enhancing primary care through value-based payment arrangements and aligning with federal primary care transformation models. The waiver also includes funding for financially distressed hospitals, workforce development programs, and loan forgiveness initiatives aimed at addressing workforce shortages in critical healthcare roles. These workforce programs target training and retraining thousands of positions across various healthcare titles and offer loan forgiveness for specific roles in high demand.

Mr. Bassiri concluded his update by mentioning other initiatives tied to the waiver agreement, such as continuous eligibility for Medicaid and child health programs. He invited questions from the members, highlighting the complexity and significance of the waiver amendment and the various measures undertaken to address healthcare disparities and improve Medicaid services across New York State.

Mr. Bassiri concluded his report. To view the complete report, please see pages 11 through 18 of the transcript.

Report on the Activities of the Office of Public Health

Mr. Kraut introduced Dr. Bauer to give the Report on the Activities of the Office of Public Health.

Dr. Bauer provided a detailed update to the council members, highlighting the focus on finalizing the framework for the next cycle of the prevention agenda, which is the state's Health Improvement Plan. The new framework, to be launched in 2025, will guide hospitals and local health departments, along with their community partners, over the next six years.

Dr. Bauer presented two potential frameworks at the PHHPC's Public Health Committee meeting, one of which is a direct continuation of the current plan, while the other takes a more updated approach by formally recognizing and integrating the relationships between the social determinants of health into public health strategies. These determinants include stable housing, transportation, nutrition, access to natural spaces, quality education, and employment opportunities, which are vital for overall well-being. While health departments and hospitals are not directly responsible for addressing these social determinants, they are recognized as root causes of poor public health.

Dr. Bauer explained the updated framework empowers hospitals and health departments to actively partner with communities and invest in initiatives that address these health-related social needs. Dr. Bauer highlighted the importance of aligning the prevention agenda with initiatives such as the 1115 waiver, which aims to transform healthcare delivery and address health disparities.

Dr. Bauer also mentioned the success of the Women, Infants, and Children Program (WIC) chatbot named Wanda, which provides information and referrals to the WIC program. Wanda now offers guidance in Spanish, expanding its reach to more New Yorkers. Additionally, Dr. Bauer noted regulatory updates from the Center for Environmental Health, including modernizing regulations related to ionizing radiation and revising the state's food code to better align with federal standards.

Dr. Bauer's concluded her report and inquired if members had questions. Please see pages 18 and 19 of the attached transcript.

Report on the Activities of the Office of Primary Care and Health Systems Management

Mr. Kraut introduced Dr. Fish to give the Report on the Activities of the Office of Primary Care and Health Systems Management

Dr. Fish provided updates on two key topics during the council meeting. Firstly, discussed the Certificate of Need Program, mentioning Governor Hochul's directive to make

necessary updates to alleviate strain on healthcare providers in the state. These updates include raising financial thresholds that trigger detailed reviews of projects and streamlining the application and approval processes, especially for routine services. Dr. Fish emphasized the need to adapt the Certificate of Need process to respond to changes in the healthcare environment, ensuring it remains effective and efficient within statutory parameters.

Secondly, Dr. Fish provided an update on the statewide healthcare transformation program, which has authorized $1.6 billion through the fiscal year 2024. Of this, $650 million has already been awarded, including funds for projects such as emergency room modernizations and health information technology initiatives. He outlined three requests for applications (RFAs) for the remaining $950 million: $650 million for health information technology, cybersecurity, and telehealth transformation; $50 million for residential and community-based alternatives to traditional nursing home care; and $250 million for transformative healthcare investments prioritizing facilities in severe financial distress. Additionally, Dr. Fish mentioned a proposed Health Care Safety Net Transformation Program in the fiscal year 2025 executive budget, aiming to improve access, equity, quality, and financial sustainability of safety net hospitals.

Dr. Fish concluded his report and invited comments or questions from the Council members. Please see pages 19 through 21 of the transcript.

Report on the Activities of the Office of Health Equity and Human Rights

Mr. Kraut introduced Ms. Kim to give the Report on the Activities of the Office of Health Equity and Human Rights.

Ms. Kim highlighted programmatic updates from the AIDS Institute, including preparations for amendments to the Public Health Law regarding syphilis screening during pregnancy. The AIDS Institute is creating a comprehensive FAQ document to support providers in implementing the new screening requirements. Additionally, efforts to address crystal methamphetamine use include multiyear funding directed to organizations in Western New York and a pilot research study at the University of Rochester focusing on Black men who have sex with men across New York State.

Ms. Kim then shared an update from the Office of Diversity, Equity, and Inclusion, which is conducting training for Department of Health (DOH) staff overseeing boards and councils. The training aims to enhance diversity and inclusion within Department councils and boards, with a focus on updating vetting processes and supporting diversity in decision-making bodies.

Next, Ms. Kim provided an update from the Office of Gun Violence Prevention, highlighting the Governor's announcement of major expansions to combat gun violence and the establishment of a New York State Health Systems for Gun Violence Prevention Task Force. The office is also developing a syndromic surveillance system to publicly report firearm injury data.

Ms. Kim discussed the Mentorship in Medicine and other Health Professions programs from the Office of Minority Health and Health Disparities Prevention. Hofstra University will implement this initiative over the next five years to support economically disadvantaged and underrepresented minority students pursuing careers in medicine and related fields.

Ms. Kim concluded her report and asked if members had questions. Please see pages 21 through 23 of the attached transcript.

PUBLIC HEALTH SERVICES

Mr. Kraut introduced Dr. Boufford to give a report on the recent activities of the Public Health Committee.

Dr. Boufford began her report by providing a detailed historical background and overview of the current Prevention Agenda cycle, emphasizing the importance of its evolution and the need for revisions in the upcoming cycle from 2025 to 2030. Dr. Boufford highlighted that the Prevention Agenda operates in four-to-five-year blocks and has undergone changes in goals and objectives over its cycles. The current cycle, from 2019 to 2024, focuses on five key areas: chronic disease, healthy and safe environments, healthy women, infants, and children, communicable disease prevention, and promoting well-being and preventing mental health and substance use disorders.

Dr. Boufford discussed the process of reviewing the current Prevention Agenda's priorities, progress, and implementation mechanisms, involving key partners such as local health departments, hospitals, and various agencies. Dr. Boufford noted successes in raising the visibility of prevention and fostering collaboration among agencies. However, challenges such as funding issues and the need for greater engagement with social determinants of health were acknowledged.

The discussion also touched on recommendations for the next cycle, including revisiting priorities, reducing the number of objectives, extending reporting cycles, and increasing engagement with social determinants of health. Dr. Boufford emphasized the importance of aligning policies across state agencies to address broader health and aging issues. He concluded by inviting feedback and participation in upcoming meetings to finalize decisions and issue guidance for the next Prevention Agenda cycle.

Dr. Boufford concluded her report. To review the full report and questions and comments from Council members please see pages 23 through 26 of the transcript.

HEALTH POLICY

Mr. Kraut introduced Dr. Rugge to give a report on the recent activities of the Health Planning Committee.

Dr. Rugge began his report by providing an update on the progress made by the Planning Committee of the Public Health and Health Planning Council (PHHPC) in response to concerns raised by the SEMSCO State Emergency Care Service Council regarding lengthy delays in offloading ambulances at emergency department (ED) ramps. Dr. Rugge outlined the analysis conducted, which revealed variability across the state and identified mental health and oral health as areas of particular concern for inappropriate ED visits.

The committee embarked on a series of meetings and workshops to explore opportunities for improvement, drawing inspiration from initiatives in other states. Dr. Sullivan from the Office of Mental Health presented the Comprehensive Psychiatric Emergency Program (CPEP), which aims to redirect 911 calls to more appropriate settings than the ED. Similarly, a program from California was discussed, involving a dental referral agency and RNs to provide immediate care for dental issues over the phone and referral to appropriate dental providers.

Dr. Rugge highlighted the significant components of a draft report prepared by the new director of a new bureau for strategy, Dr. Heslin. These components include EMS reform, behavioral health reform, and dental care reform. The EMS reform proposes establishing EMS zones with oversight by a statewide task force and implementing a state-based system for triage and transport, including community paramedicine with in-home assessments. The report also addresses ongoing behavioral health reform efforts and proposes developing a triage system and new forms of caregiving for dental care, including the use of dental therapists and dental assistants.

Dr. Rugge noted the draft report is nearing completion and will be presented to senior leadership within the Health Department and other agencies, with the aim of bringing it back to the Planning Committee and PHHPC for consideration and review by March or April. Dr. Rugge emphasized the importance of continued collaboration to identify new opportunities for improving healthcare delivery and expressed hope that the efforts of the PHHPC would be instrumental in sparking further discussions and driving meaningful change.

Dr. Rugge concluded his report. To review the full report and questions and comments from Council members please see pages 26 through 28 of the transcript.

REGULATION

Mr. Holt provided the Report of the Committee on Codes, Regulations and Legislation.

Report of the Committee on Codes, Regulation and Legislation

For Emergency Adoption and Adoption

23-07 Amendment of Section 405.45 of Title 10 NYCRR
(Trauma Centers – Resources for Optimal Care of the Injured Patient)

Mr. Holt introduced for emergency adoption and adoption of Amendment of Section 405.45 of Title 10 NYCRR (Trauma Centers – Resources for Optimal Care of the Injured Patient) and motioned for adoption. Dr. Berliner seconded the motion. The motion for emergency adoption carried. Please see pages 28 and 29 of the transcript.

For Adoption

21-21 Amendment of Part 425 of Title 10 NYCRR (Adult Day Health Care)

Mr. Holt introduced for adoption of Amendment of Part 425 of Title 10 NYCRR (Adult Day Health Care) and motioned for adoption. Dr. Yang seconded the motion. The motion for emergency adoption carried. Please see pages 29 of the transcript.

20-22 Amendment of Sections 405.11 and 415.19 of Title 10 NYCRR
(Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements)

Mr. Holt introduced for adoption Amendment of Sections 405.11 and 415.19 of Title 10 NYCRR (Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements) and motioned for adoption. Dr. Yang seconded the motion. The motion for emergency adoption carried. Please see pages 29 and 30 of the transcript.

For Information

24-01 Amendment of Section 405.19 of Title 10 NYCRR (General Hospital Emergency Services Behavioral Health)

23-21 Amendment of Part 300 of Title 10 NYCRR (Statewide Health Information Network for New York (SHIN-NY)

23-08 Amendment of Sections 405.4 & 405.6 of Title 10 NYCRR (General Hospital Medical Staff Recertification)

Mr. Holt stated Amendment of Section 405.19 of Title 10 NYCRR (General Hospital Emergency Services Behavioral Health), Amendment of Part 300 of Title 10 NYCRR (Statewide Health Information Network for New York (SHIN-NY), and Amendment of Sections 405.4 & 405.6 of Title 10 NYCRR (General Hospital Medical Staff Recertification) were presented for information. Please see page 30 of the transcript for members questions and comments.

PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

Mr. Kraut introduced Mr. Robinson to give the Report of the Committee on Establishment and Project Review.

PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

Report of the Committee on Establishment and Project Review

Peter Robinson, Chair, Establishment and Project Review Committee

APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

CON Applications

Acute Care Services- Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231332 C	NYU Langone Hospital-Long Island (Nassau County) Dr. Kalkut – Recusal Dr. Lim - Interest	Contingent Approval
2.	231348 C	Long Island Community Hospital at NYU Langone Health (Suffolk County) Dr. Kalkut – Recusal	Contingent Approval

Mr. Robinson called applications 231332 and 231348. Mr. Robinson noted a conflict and recusal by Dr. Kalkut for both applications and an interest by Dr. Lim for application 231332. Mr. Robinson motioned for approval. Dr. Berliner seconded the motion. The motion carried with Dr. Kalkut's conflicts. Please see page 30 of the attached transcript.

Diagnostic and Treatment Centers – Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231299 C	Weill Cornell Imaging at New York Presbyterian (New York County) Dr. Lim – Interest	Contingent Approval

2.	232063 C	ODA Primary Health Care Network, Inc (Kings County) Dr. Kalkut – Interest	Contingent Approval

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

CON Applications

Acute Care Services- Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231308 C	New York-Presbyterian Westchester (Westchester County)	Contingent Approval
2.	231311 C	Samaritan Medical Center (Jefferson County)	Contingent Approval

Cardiac Services Construction – Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231326 C	Auburn Community Hospital (Cayuga County)	Contingent Approval
2.	231351 C	St. Charles Hospital (Suffolk County)	Contingent Approval

Diagnostic and Treatment Centers – Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231261 C	Weill Cornell Imaging at New York Presbyterian (Kings County)	Contingent Approval
2.	232124 C	Community Health Center of Richmond, Inc. (Richmond County)	Contingent Approval

Mr. Robinson called applications 231299, 232063, 231308, 231311, 231326, 231351, 231261, and 232124. Mr. Robinson noted an interest by Dr. Lim for application 231299 and an interest by Dr. Kalkut for application 232063. Mr. Robinson motions for approval, Dr. Berliner seconds the motion The motion passes. Please see pages 31 and 32 of the transcript.

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HAS

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

NO APPLICATIONS

APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

CON Applications

Ambulatory Surgery Centers – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	222044 B	Sorin Ambulatory, LLC d/b/a Sorin Ambulatory Surgery Center (New York County) Dr. Kalkut - Interest	Contingent Approval

Diagnostic and Treatment Centers – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231114 B	Prime MD Center, LLC (Nassau County) Mr. Kraut – Interest Dr. Lim – Interest	Contingent Approval

Mr. Robinson called applications 222044 and 231114. Mr. Robinson noted for the record an interest by Dr. Kalkut for application 222044 and interests by Mr. Kraut and Dr. Lim for application 231114. Mr. Robinson motions for approval, Dr. Watkins seconds the motion. The motion passes. Please see page 32 of the transcript.

Dialysis Services – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231361 B	Tidal Home Dialysis (Kings County) Mr. LaRue - Interest	Contingent Approval

Mr. Robinson called application 231361 and noted an interest by Mr. Larue. Mr. Robinson motions for approval, Mr. Thomas seconds the motion. The motion passes. Please see page 32 and 33 of the transcript.

Home Care Service Agency Licensures

Changes of Ownership

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231120 E	Health Quest Home Care, Inc. (Licensed)(Geographical Service Area: Dutchess, Orange, Putnam, And Ulster Counties) Mr. Kraut – Recusal	Contingent Approval

Mr. Robinson called application 231120 and noted Mr. Kraut had a conflict and recusal. Mr. Robinson motions for approval, Mr. LaRue seconds the motion. The motion passes. Please see page 33 of the transcript.

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

Ambulatory Surgery Centers – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	232088 E	Sheepshead Bay Surgery Center (Kings County)	Approval

Diagnostic and Treatment Centers – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	232080 B	ALEF Health Center LLC (Richmond County)	Contingent Approval
2.	232106 B	New York Healthcare and Wellness (Bronx County)	Contingent Approval
3.	232133 B	Namo Health Inc (New York County)	Contingent Approval

Mr. Robinson called applications 232088, 232080, 232106, and 232133. Mr. Robinson motions for approval, Dr. Berliner seconds the motion. The motion passes. Please see pages 33 and 34 of the transcript.

Residential Health Care Facilities – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	202035 E	Hilaire Care Network LLC d/b/a Pine Forest Center for Rehabilitation and Healthcare (Suffolk County)	Contingent Approval
2.	222260 B	Oxford Nursing Home (Kings County)	Contingent Approval

Home Care Service Agency Licensures

Changes of Ownership

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	222103 E	Lincare Of New York, Inc. (Geographical Service Area: Albany, Broome, Cayuga, Chemung, Chenango, Clinton, Columbia, Cortland, Delaware, Dutchess, Essex, Franklin, Fulton, Genesee, Greene, Hamilton, Herkimer, Jefferson, Lewis, Livingston, Madison, Monroe, Montgomery, Oneida, Onondaga, Ontario, Oswego, Otsego, Rensselaer, Saint Lawrence, Saratoga, Seneca, Schenectady, Schoharie, Schuyler, Steuben, Tioga, Tompkins, Ulster, Warren, Washington, Wayne, and Yates Counties)	Approval

2.	222104 E	American Outcomes Management, LP (Geographical Service Area: Bronx, Dutchess, Kings, Nassau, New York, Orange, Putnam, Queens, Richmond, Rockland, Suffolk, Sullivan, Ulster, and Westchester Counties)	Approval
3.	231216 E	Tanglewood Manor, Inc. (Geographical Service Area: Allegany, Cattaraugus, Chautaugua, Erie, Genesee, Niagara, Orleans, and Wyoming Counties)	Approval
4.	232021 E	Ideal Care SP LLC (Geographical Service Area: Ulster County)	Approval

Mr. Robinson called applications 202035, 222260, 222103, 222104, 231216, and 232021. Mr. Robinson motions for approval, Mr. Thomas seconds the motion. The motion passes. Please see pages 34 and 35 of the transcript.

Certificates

Certificate of Amendment of the Certificate of Incorporation

Applicant	E.P.R.C. Recommendation
Lake Shore Hospital Foundation, Inc.	Approval
Open Door Family Medical Center, Inc.	Approval

Certificate of Amendment of the Articles of Organization

Applicant	E.P.R.C. Recommendation
Pontiac Nursing Home, LLC	Approval

Restated Certificate of Incorporation

Applicant	E.P.R.C. Recommendation
The Guidance Center of Westchester, Inc.	Approval

Mr. Robinson called the Certificate of Amendment of the Certificate of Incorporation of Lake Shore Hospital Foundation, Inc., the Certificate of Amendment of the Certificate of Incorporation of Open Door Family Medical Center, Inc., the Certificate of Amendment of the Articles of Organization of Pontiac Nursing Home, LLC, and the Restated Certificate of Incorporation of The Guidance Center of Westchester, Inc. Mr. Robinson motioned for approval and Mr. Thomas seconded the motion. The motion passed. See page 35 of the attached transcript.

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HAS

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

NO APPLICATIONS

Mr. Robinson concluded his report. Mr. Kraut thanked Mr. Robinson.

ADJOURNMENT:

Mr. Kraut and the Council members discussed topics for the upcoming strategic retreat. Please see pages 35 through 40 of the transcript.

Mr. Kraut announced the upcoming PHHPC meetings and adjourned the meeting. Mr. Kraut motioned to go into Executive Session to consider a health personnel matter. Dr. Berliner seconded the motion. The public portion of the meeting concluded.

NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
FULL COUNCIL COMMITTEE MEETING
FEBRUARY 8, 2023 9:30 AM
90 CHURCH STREET, 4TH FLOOR, CONFERENCE ROOMS 4A AND 4B, NYC
TRANSCRIPT

Mr. Kraut Good morning. I'm Jeff Kraut. I have the privilege to call to order the meeting of the annual Public Health meeting of the Health Planning Council. Welcome members, participants and observers. I want to remind you that there's an audience viewing this meeting via a webcast. For the public there's a form which you need to fill out to record your attendance in accordance with Executive Law Section 166, you will be able to get that form on www.NYHealth.Gov under Certificate of Need. You can email the completed forms back to Colleen Leonard at the Department of Health. We appreciate your support in having us comply here. Because we're subject to the Open Meeting Law we're broadcast over the internet. Please keep yourselves on mute if you're not speaking. Avoid the rustling of papers. Because we'll pick up everything, particularly side chatter. We're doing synchronized captioning. It's important that we don't speak over one another. The first time you speak, please state your name and briefly identify yourself as a council member or a member of the DOH staff. This will be helpful to the broadcasting company. I just want to remind everybody and encourage those of you who are interested in the work of the council to join the department's Certificate of Need listserv. We regularly send out important council information, notices, dates, agendas, and policy matters on that. There are printed instructions in the reference table on how to join. We also could do so online. Before I start today's meeting, I just want to welcome Dr. Fish. Although he's been here for the committee meetings his first full council meeting. As you know, Dr. Fish replaced Dr. Morley, who retired from state service back in December. Dr. Fish is going to be serving as the Deputy Commissioner for Primary Care and Health Systems Management. You may know Dr. Fish in his other hat is the Chief Medical officer for the Office of Health Insurance Programs and Infectious Disease Physician. He's been with the AIDS Center for the Department of Health Services at Albany Medical Center. Haad the direct delivery of care as a physician and the complexity of doing so within some of the larger providers within the state. Dr. Fish, we welcome you and look forward to working with you. I'm going to conduct the annual meeting first, which we'll vote on appointment of the council's Vice Chair. I will hear a full report from Dr. McDonald, Mr. Herbst, Dr. Bauer, Dr. Fish, Ms. Kim and doctors Boufford and Rugby will provide us updates of their committees. That will be followed by Mr. Holt, who will present the result of the Codes Committee. Finally, Mr. Robinson at the end project review. At the end of that discussion if you were able to stay around, I'd like to talk a little about the retreat that we have planned and some of the topics and ideas and how to structure the day and get some feedback. Just to remember that members of the council about conflicts. We've organized the agenda. Mr. Robinson is going to be batching CON applications. I hope you've taken the time to review the batch on the agenda. If there's any item that you want removed from a batch, please let Colleen know before we begin that consideration and Mr. Robinson gives his report.

Mr. Kraut I'm now going to open up the annual meeting portion of our meeting with the election of a Vice Chair.

Mr. Kraut I would move to elect the council's Vice Chair and to make a motion for Dr. Boufford to continue to serve as Vice Chair. I hope she accepts that honor.

Mr. Kraut You accept, right?

Dr. Boufford Yes.

Mr. Kraut May I have a second?

Mr. Kraut Dr. Berliner.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Thank you.

(Clapping)

Mr. Kraut We are going to maintain our committee membership.

Mr. Kraut She calls every meeting and say, how's he feeling?

(Laughing)

Mr. Kraut We're going to maintain the standing and Ad Hoc Committees, roles, members of the same. We're hoping nominations to the council, as you know there's a couple of pending. I think that we'll revisit the committees and the membership once we are back up to full speed. For now, I think it's best if we just keep them the same. Establishment and Project Review Committee will continue to be Chaired by Mr. Robinson and Vice Chair Dr. Kalkut. Public Health by Dr. Boufford and Vice Chair Dr. Torres. Dr. Rugge will continue to Chair the Health Planning Committee and Ms. Monroe as the Vice Chair. The Committee on Codes, Regulation and Legislation will be Chaired by Dr. Holt and Vice Chair Dr. Yang. The Health Personnel and Professional Relations Committee will be chaired by Mr. Thomas. The Ad Hoc Committee to lead the State Health Improvement Plan Dr. Boufford. I want to thank all the members of the council for the work and dedication of the time you serve on this. It's extraordinary amount of information that we have to consume before each meeting. I know how much time that takes. Hopefully, as we've regained our momentum, I think coming out of COVID and we hope this year will be more productive year for us. There's a lot going on in the state in this exciting time, as you're going to hear a little later from the reports.

Mr. Kraut I'll call, the annual meeting to close.

Mr. Kraut I will open up our meeting of today's meeting.

Mr. Kraut May I have a motion to adopt the November 16th, 2023 PHHPC meeting minutes?

Mr. Kraut I have a motion, Dr. Berliner.

Mr. Kraut A second Dr. Torres.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut That passes.

Mr. Kraut It's my pleasure to invite Dr. McDonald, who is going to update the council about the department's activities since our last meeting.

Dr. McDonald Good morning, Mr. Kraut. It's great to be with you all this morning and joining you today from my office in Albany here at Corning Tower on the 14th floor. You know, as I start my comments, I just want to hope you'll join me in celebrating Black History Month. I'm reminded we all have a role together to implement policies and programs that really do what we can to strengthen health equity for all and eliminate barriers to improving health outcomes for Black New Yorkers. I'm just reflecting on how systemic racism has all too often played a role in reducing access to quality health care and contributing to inequitable health outcomes for communities of color. You know, under the leadership of Governor Hochul, the department will continue working to improve access to quality care and eliminating health disparities as we address the disproportionate impacts that preventable conditions such as maternal mortality, heart disease and diabetes continue to have on our Black community. I want to shift my conversation to cover some topics I covered during our budget hearing. I just want to make sure everybody's hearing sort of these same concepts here. One of the things that's interesting, I traveled a lot across the state this year. I did fifty-nine trips. Went to literally hundreds of community-based organizations, health care facilities, and literally met tens of thousands of people. The issue that really kept coming up every place I went to be the workforce issues. Sometimes I worry we're making this a little bit harder on ourselves then we need to. I sometimes think in New York we're playing soccer uphill when it comes to issues like scope of practice. One of the things I've just noticed is we're different than other states in some areas. I hope this year during the legislative and budget process we can make some of those changes. It's not lost on me that we're one of only eleven states that hasn't joined the Interstate Physician License Compact. We're one of only nine states that hasn't joined the Nurse Licensure Compact. These are in the budget this year as a policy issue. Hopefully, we'll get some traction on those this year. There's also some legislation that came forward this year just to help our health care workers do work they're already trained to do. Just a few examples like certified medication aides. Twenty-four states have allowed them to administer basic medications in long term care settings. I know there's support for that among a lot of our constituents. The other thing I think about is our physician assistant community, the PAs, for example. There are certain settings where after suitable training they could practice independently. Primary care and hospitals are just a couple examples. Another thought that comes to mind is just medical assistance. Forty-nine states allow a medical assistant to give a vaccine. We're the only state that hasn't done that yet. These are just a few examples of where I think we can do some things just to help it a little bit easier for our health care workers to actually practice things that they're already trained to do. I'm going to shift my conversation a little bit to talk about COVID, flu, and RSV. It's one of those things where we are seeing declines in these three viruses across the state regarding hospitalizations in cases, which is a positive thing to see. We did issue a provider advisory last month to health care facilities. We saw a rise in all three cases. Obviously, we're concerned about health care workers and protecting them and keeping them safe. The department through Wadsworth, our state health laboratory continues to track the variants and subvariants. Right now, JN.1 Is the dominant variant

and a little bit different than the Omicron sub variants we dealt with in 2023. I was encouraged by the most recent Morbidity Mortality Weekly Report that looked at vaccine efficacy. So far we're seeing good vaccine efficacy against what's out there. I think that's important. I'm still concerned about the relatively low vaccine uptake we're seeing here. We did send a letter with the state Office of Aging just to remind anyone who can help us with our aging population in particular that are more vulnerable just to make sure they're up to date on all three vaccines. I want to talk about another topic that we covered in our budget proposal, which is just getting to the opioid epidemic, which is a continuing public health concern for the department. It's not just fentanyl that's driving the mortality. We see the rise of xylazine more and more. A veterinary anesthetic. One of the things we put in the proposal this year was to make xylazine a schedule three so veterinarians could still prescribe it like they would any controlled substance but just making it a schedule three, so we could monitor the usage of this and hopefully prevent the diversion of xylazine which is showing up more and more. Xylazine certainly fits the definition of a controlled substance, clearly an issue drug that has the potential for abuse and dependence as we see it showing up in more and more deaths in New York. I'm going to talk a little bit about the 1115 Waiver, though, I know Amir Bassiri is going to talk more about that. I just want to extend my thanks to Amir and his team for three years of just really good work on the 1115 Waiver. Our demonstration is just, I think, another important step in New York as we continue efforts to build a health care system that benefits all New Yorkers. This demonstration bundles a series of comprehensive services to advance health equity, address health disparities, and strengthen access to primary behavioral health care across the state. There's $7.5 billion of funding over the next three years, including $6 billion in new federal funding. I'll let Amir talk more about that later. On a related note, we are waiting for our approval on the 1332 Waiver. We anticipate that getting approved soon by the federal government. Just some of the highlights not going to be increasing the income limit for essential plan eligibility from 200% to 250% of the federal poverty line. That means someone earning $37,650 could obtain this affordable coverage with no premium. This is going to affect another 100,000 Americans getting affordable coverage. In addition, we're proposing that our New York State health marketplace offer subsidies to New Yorkers within comes up to 350% of the federal poverty line who are enrolled in qualified health plans to ensure even more people have access to affordable insurance coverage. One of the other exciting proposals in our budget this year is eliminating cost sharing in both the essential plan and qualified health plans for some chronic disease. Things like office visits, lab work, pharmaceuticals and other supplies will no longer have cost sharing. It's going to affect some chronic conditions. Type two diabetes was one that I think makes sense and comes to mind. There are some others as well. There weren't a lot of investments in this year's budget. It's a challenging budget year, as the Governor's talked about time and again. I was glad to see we were able to do an investment in early intervention. We're making a rate increase, proposing a 5% rate increase across the board and 9% in some rural areas. We do have access to care problems in early intervention. Our timeliness of care numbers isn’t what they should be. I'm glad we're seeing we make this investment as well. There's an important change proposed for emergency medical services. I think a lot of people think of this an essential service right now in our state. It's not an essential service. As a result, response times can vary widely, particularly in some of our rural areas. We're hoping to change that by seeking legislation to make emergency medical services an essential service, creating five emergency medical service zones intended to augment local EMS agencies where the workforce is not quite sufficient. They're also a proposal to establish a first in the nation Paramedic Telemedicine Urgent Care Program to connect rural New Yorkers where paramedics and providers via telemedicine increasing access to care. It's example of a strategy that might reduce unnecessary emergency department visits. Just a couple more topics really quickly. I had several visits this year to

some of the tribal nations. Really, it's very important for me to get out at their invitation and visit with some of the tribal nations. There are some nice investments this year to address health disparities in some of our nations. One thing I'll just talk about is a $4.5 million investment in oral health. One of the things that I remember very distinctly was visiting the Tuscarora Nation, a very lovely people who are very hospitable to me. I really was grateful for their hospitality. That is, I was doing a tour throughout their clinic. They showed me this beautiful dental clinic. It was really state of the art, new chairs, new machine. They didn't have a dentist because they didn't have the funding to hire one. Their members were traveling a good hour, hour and a half to Rochester for dental care. I'm hoping we can do something to help in that regard as well. The last thing I'll just mention, certainly last but not least, is as a veteran myself, I was glad we were able to make an investment in our four veterans' homes. There's $22.5 million this year just to help the veterans' homes as they're recovering from the pandemic still with their enrollment. Quite frankly, admitting people. Our veteran homes can have the resources they need. I know you have a lot of briefings coming from our deputy commissioners and I do want to thank everybody for all that they're doing on our Public Health and Health Planning Council meeting. I know there's a lot of work that goes into this. Not just in this meeting, but in all the other meetings you do. I'm really happy and thankful for all the work you do. I do look forward to coming to the retreat as well. I'm glad you're doing that. I heard you were doing that. I changed my schedule so I could attend as much of it as possible.

Dr. McDonald Let me stop there and see if there's any questions anyone would have for me today.

Mr. Kraut Dr. Soto, then Dr. Kalkut.

Dr. Kalkut Dr. McDonald, thank you for your report.

Mr. Kraut Sorry, I said Dr. Soto first.

(Laughing)

Dr. Soto Nilda Soto, council member. Thank you for your report. My questions are regarding the proposed closure of SUNY Downstate and what are the plans on the impact of the patients in that area? As you probably are aware SUNY Downstate is the only hospital in Brooklyn that does kidney transplants. Where would those patients get their care? I've heard mentioned that one of the places is that people will be the inpatient outpatient be accommodated at Kings County. I wonder with the census already of Kings County how they can accommodate the additional patients from SUNY Downstate. In addition to the patients that's a big training facility. SUNY Downstate Medical School of the seventeen New York state medical schools is the most diverse. They have an additional TPT in other programs. What hospitals in the area meet the criteria to be training facilities? Are they able to bring in additional individuals for their training?

Dr. McDonald Well, I'm glad you asked. I mean, thank you for bringing this up. Obviously, it's an important issue for the area and entirely for the state too. You're right. Downstate Medical Center is a very important training facility. I did talk to Chancellor King just a couple weeks ago. He unveiled a little bit of their transformation plan to me. I'm looking forward to seeing the entire transformation plan. I think you're raising a lot of the important issues, not just access to care, not just where people are going to go. What is the whole area going to hold there? I can't get into a lot of detail about it because we are looking at what this is going to be here. I'm a regulator in this role as well, but obviously very

interested in what the outcome is. I'm really looking forward to seeing a detailed transformation plan to see how it's going to address the medical school, not just the care there as well, but all the high-level services. You gave a great example about kidney transplant services. There's a lot that Downstate does. You need to see how it's going to impact everybody down there. I'm very interested in seeing the full transformation plan. We're looking forward to hearing what their community engagement was and will be, in particular, because I think it's very important that the community be very involved in this. Thank you so much. I'm looking forward to seeing what we can do in this area.

Mr. Kraut Dr. Kalkut.

Dr. Kalkut Thank you.

Dr. Kalkut I have a question about Mount Sinai, Beth Israel and the closure plan for that institution. Can you update us to the degree that you're able to about the status of the discussions with Mount Sinai about a proposed closure of Beth Israel Hospital.

Mr. Kraut Just hold on. Your lawyer here wanted to say something.

Dr. McDonald I'd love my lawyer to say something.

Ms. Ngwashi Good morning. Marthe Ngwashi, attorney at the Department of Health. I just wanted to say for a variety of reasons, including pending litigation, we are not going to be discussing anything about Mount Sinai, Beth Israel and the proposed closure.

Mr. Kraut Dr. McDonald, I don't know if you heard that.

Dr. McDonald I heard it. Marthe did a great job saying the very same thing I was going to say.

Mr. Kraut Good cop, bad cop.

Dr. McDonald No, Martha's always, always---

Mr. Kraut I didn't say she was the bad cop.

(Laughing)

Mr. Kraut I just want to point that out.

Dr. McDonald Thank you.

Mr. Kraut If the rest of the council is not aware there was a lawsuit filed, I believe yesterday, the day before in New York County State Supreme Court by members of the community bringing it to the courts, let me just put it that way. You can read about it in today's paper for those of you were not aware of that.

Mr. Kraut Any other questions?

Dr. Soffel Good morning. First of all, I want to say that the proposal to expand continuous coverage for Medicaid for children is a wonderful step forward for the State of New York. I am delighted to see that we are taking that step. I think it's absolutely great. My question

that I bring to every time I get that opportunity has to do with staffing at the Department of Health and how we are doing in terms of trying to rebuild capacity within the department. I am hearing yesterday we had a wonderful public health committee meeting. We heard about really exciting and ambitious plans for the Office of Public Health. I am concerned about the ongoing challenges of staffing up those and other initiatives.

Dr. McDonald Thank you for acknowledging the team working on coverage for kids 0 to 6. I can tell you as a pediatrician I'm very excited about this as well. As far as staffing goes we're heading in a really good direction. One of the things I often talk about is in 2022 we really much ended the same as we started with the year. We had hired a lot of people, but we lost a lot of people. In 2023, we were positive several hundred people. One of the things I'm excited about though for this year starting in May. I really appreciate Commissioner Hochul's of the Office of Civil Service, but they're going to be expanding the hiring for emergency limited placement program. Almost all of our openings are now going to be something that we can advertise for and hire from without an exam. One of the things we're just running into, quite frankly, is our lists aren't current. I mean, this just affects the entire department. I'm optimistic by the end of calendar 2024 that our entire department is fully staffed. That's my hope for the end of 2024. By the way, I do want to thank Commissioner Andy Ruby, who's done a great job as one of our deputy commissioners administrations. His team has done a great job. We are hiring a lot of people. I think one of the things that I'm really seeing with a lot of the young people we're hiring in particular is people recognize the Department of Health is a positive place to work with a really powerful mission. People are signing up for that. I'm seeing nice enrollments in area. I mean, one of the things we're seeing, we're hiring more nurse surveyors. Of course, they take six to nine months to train, but I'm seeing nice increases in that area, which I'm really happy about too. It reduces our vulnerability when it comes to regulating our license. We're making progress here. I'm really excited about what, civil service is doing. Very, very excited about what can happen in May. Thank you.

Mr. La Rue Good morning. Scott La Rue, a member of the council. First, I wanted to share my enthusiasm with you for the interstate pacts and licensure and as well as the proposal around the MedTech. As you know, the staffing in nursing homes is a very challenging environment. If the average nursing home resident has eight medications at least half of them is over the counter. You do not need an RN to dispense those. It's not allowing the RNs to operate at the highest level of their licenses. It's creating a career ladder for the CNAs to become MedTech. I really am enthusiastic about your proposal in the budget. I hope the legislature, participates in that enthusiasm. Secondly, I just wanted to mention about the staffing regulations and the 3.5 that the legislature passed. I think it was April of 2022. That still has not been funded. I really encourage the executive branch and the department to work with the legislative staff to fund that really necessary mandate but at this point in time it's severely underfunded. I would really encourage some reconsideration on that point. Thank you.

Dr. McDonald Thank you for your feedback. I appreciate it, Mr. La Rue.

Mr. Kraut Any other questions?

Mr. Kraut Well, Commissioner, again, thank you for joining us. Thank you again for agreeing to participate in the retreat. We'll be in coordination with your office as we shape that agenda and appreciate your report. Thank you very much.

Dr. McDonald Thank you so much, everybody.

Mr. Kraut Thank you.

Mr. Kraut There were two things I neglected to do, one during the annual meeting. We have in front of you on your desk a 2025 listing of dates for both our committee meetings and full council meetings and their locations. We need to approve those dates. We make the reservations for the use of facilities in those locations.

Mr. Kraut If I could have a motion to accept the 2025 proposed dates.

Mr. Kraut Mr. Thomas.

Mr. Kraut Second, Dr. Watkins.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut The motion carries.

Mr. Kraut Lastly, I failed to mention that at the end of the meeting we are going to go into an executive session to consider a health personnel matter. Please don't depart before we're able to consider that matter before us.

Mr. Kraut I'm now going to ask Mr. Herbst to give us a report on the activities of the Office of Aging and Long-Term Care.

Mr. Herbst Thank you.

Mr. Kraut Thank you for joining us.

Mr. Herbst Thank you, Mr. Chairman.

Mr. Herbst Good morning, council members. You have to bear with me. I went to the Rangers game the other night. I was very enthusiastic. Went into overtime. I'm blaming the Rangers for me losing my voice. Not for any another reason. Please bear with me while I'm still a little hoarse here. They did win. The Rangers won.

(Laughing)

Mr. Herbst Good morning. I'd like to give some updates today on the wonderful work that the Office of Aging and Long-Term Care has been doing for many months now. Towards the end of my comments, an update on what we're doing at the state on our master's Plan for Aging. Let me start with something that I've discussed a handful of times. I want to give a particular update because we have some news with respect to the program for all-inclusive care for the elderly better known as PACE. When we discussed this at the November meeting the Governor signed into law Article 29EE, which creates an entirely new licensure category for the Certificate of Need review for the PACE program. This program offers a coordinated model of care which features an interdisciplinary team of health care professionals. It provides a comprehensive benefit package that's designed to

empower members to maintain their residence in the community rather than other types of settings like a nursing home, for example. The program encompasses the operation of a PACE center, where members of the PACE program receive a variety of services, including medical care, socialization opportunities, and other PACE services, and adopts capping financing and facilitates the delivery of all-encompassing services that are tailored to the participant's specific needs, which surpasses the limitations imposed by conventional Medicare or Medicaid fee for service plans. What I'd like to update now is that work is being done by the Office of Aging and Long-Term Care in coordination with the Medicaid Office to implement provisions of this law and finalize the regulation, development and the unified application and CON scheduling. We're very excited that applications continue to come in. We're hopeful that over the next several weeks we will have approval to hire additional staff within the Office of Aging and Long-Term Care to help with this new model of unit which will work exclusively on developing the protocols and the review materials for various care models, such as PACE and allow us to carry out the provisions of this law. Until that time, the Article 29EE based licensure process is fully operational. Applicants are now encouraged to apply under the existing process, which includes using Articles 28, 36 and 44. Once the new article 29EE application program becomes operational those applications will be submitted under the existing process will be transitioned to the new Article 29EE review process. We're very excited about this and will bring, I hope, at the next PHHPC cycle some additional ideas with respect to the changes and anticipate the final regulations for the Spring. I also do want to note that CMS must still provide final approval of PACE programs. This law only changes the method that the state conducts its review of the new establishment applications and not the program itself. Next, I'd like to talk about something we're very excited about, which is hospice and palliative care. In the Office of Aging and Long-Term Care we launched the new center for Hospice and Palliative Care, which remains a top priority for us. And the Governor, highlighted in our commitment and the Governor's State of the State. This commitment addresses disparities and access barriers to end of life care. This new center will be led by a director, which is now being posted, if anyone knows good candidates. We'll have active recruitment of about six new roles that will support that director. We're very excited about this new center, which will partner with internal and external stakeholders to assess policies and hospice resource utilization in New York State and across the country. We look forward to educating the public on hospice and palliative care, develop and communicate models, new models of practice, and build strong cross continuum stakeholder relationships. The center will be tasked with examining the underlying reasons for low hospice utilization in New York State. As part of our commitment, we look to develop a public education plan that addresses the trends and increase equity and accessibility of hospice care opportunities in New York State. We also plan to examine palliative care models that concentrate on the early stages of the disease so that we can share model practices that will reduce unnecessary hospitalizations and result in better patient outcomes. Next, I'd like to discuss a few long-term care specific budget highlights that were in this year's executive budget. The executive budget proposes actions that address a stressed workforce, as the Commissioner mentioned, by expanding and providing flexibility and scope of practice that would allow, as Mr. La Rue pointed out, for certified medication aides with the appropriate experience, training and competency to administer certain medications in nursing homes. The executive budget also sets forth a comprehensive plan of amendments for the Public Health Law that expands access to care in the home through the Hospital at Home Program, which would authorize inpatient care at home and would enable the state to develop a Medicaid rate to support this innovative model of care. This expansion would be accompanied by changes to the Public Health Law 2805 that will encourage additional collaborations and service delivery. It's our goal that the programs and initiatives such as these will address service gaps and

community health care needs by expanding these types of providers who are transforming and expanding the way the care is delivered. In addition, the executive budget is seeking to improve the quality and transparency of assisted living residences by establishing quality reporting metrics and accreditation. We look forward to further discussion with the PHHPC and with our industry partners on this important initiative. Finally, another strong and important long term care proposal in the executive budget would support families and informal caregivers of individuals with various forms of dementia by strengthening the Special Needs Assisted Living Residents Voucher Program, better known as SNALR by clarifying that the voucher must be used to subsidize SNALR costs and promulgating regulations that govern this program. We will enable consumers to make informed decisions regarding the care their loved ones, while ensuring funding remains available to support the care that they need. Given the history of the waiting list and the growing interest in the SNALR voucher program, we strongly look forward to supporting this proposal. Next, just very briefly, I'd like to just give some highlights of the OALTC, the Office of Aging Long-Term Care Nursing Home Quality and Support, which has been tremendously busy. First, the team has been working to support financially distressed nursing homes. We've been working to hold our partners to ensure that they provide the right type of documentation if they want to receive the funding through the state, both, including a $50 million grant for funding allocated through alternative models of traditional nursing home care. The statewide four RFA was released on January 9th. I want to remind people that regarding the RFA for this, it is due February 14th, just next week. Responses will be posted publicly on or around early March. We anticipate awards to be announced in this Fall. The primary purpose of an additional funding is the VAPAP program, a vital access provider program to provide short term financial assistance to distressed nursing homes while they are thoughtfully planning for the future of their facility. The department continues to accept applications of the VAPAP applications on a rolling basis. Since the program's inception, we have been awarding many nursing homes VAPAP funding to ensure they are providing the short-term financial need. Finally, the Master Plan for Aging, an important initiative that the Governor signed into law in December 2022. We have been very busy developing a transformative and sustainable set of recommendations that will go into the state's first Master Plan for Aging. We look forward to providing this final master plan later this year. What we've been doing is going around the state to different communities, different churches, synagogues and mosques, different aging communities, schools, different networks and having town halls and listening sessions so we can hear from various communities, every community, for that matter, what their interests are in participating with respect to the Master Plan for Aging. We also have a statewide survey that's been tremendously informative. I encourage everyone on this council and everyone listening today to fill out that survey, which is on the Master Plan for Aging website. We have printed copies if you'd like to get those as well. We have been learning so much about this master plan of what the state really is desiring. It transforms beyond just health care. There are so many other areas of public health prevention agenda. Thank you, Dr. Boufford, for your participation and partnership. There is housing. There is transportation. There is technology. There are so many different areas that we are including into our Master Plan for Aging to help our aging. All of us are aging. Our aging community and our disability communities. We're very excited about providing updates to this council and other councils over the course of the year as we finalize our final Master Plan for Aging report. One thing I do want to highlight is that although the report is going to be due this year it's not like we're simply handing a document in and then saying we're done. Rather, this is just the beginning. This report once it's handed to the Governor and distributed to the public will enable us to look forward ten years out. We have developed a special unit within the Department of Health and our partners in State Office of Aging and other state agencies to ensure that the program and the services and all of the ideas that are being

put together in this master plan will be sustainable, will be carried out and ensure they are a live document for many years to come. We anticipate much work to be done not just this year, but over the next ten years as a result of our final report. We're very excited, enthusiastic with all of your participation to see that this plan is successful and fruitful for many years to come for all of us as we age in the state of New York. Thank you very much.

Mr. Kraut Thanks so much, Mr. Herbst.

Mr. Kraut Questions?

Mr. Kraut That was a really good report.

Mr. Kraut Yes, Mr. La Rue.

Mr. La Rue Good morning. In your written report, you mentioned the alternative model of care unit. Could you expand on that a little bit, please?

Mr. Herbst Sure.

Mr. Herbst Under Mark Furnish to my rights lead, we have created this new unit that will help us with our PACE programs, with our hospice programs, and all of our licensure matters. This unit will be dedicated exclusively to ensuring that PACE applications, for example, get carried through and are not sidetracked with other work that Mark's team is working on. We have created a dedicated staff to focus exclusively on the work that I highlighted in this report.

Mr. Kraut Ms. Monroe.

Ms. Monroe Thank you, Adam.

Ms. Monroe Yesterday I read that the federal government might be rescinding its approval of hospital at home because of lack of use and lack of accountability, all kinds of reasons. Have you heard that? What might we do in New York if, in fact, that actually comes to pass?

Mr. Herbst Thank you, Ms. Monroe.

Mr. Herbst I have not heard that, actually. I do anticipate that no matter what happens at the federal government we in the state of New York are looking forward to transforming the way care is delivered, which is outside the walls of the hospital. We think that there is quite a bit of interest and need from our state partners, in the hospital systems and the patients to see that this is scaled up. We will continue to make sure that the Hospital Health Program is successful, irrespective of what the federal government is going to do. We are working with Amir's team, like I mentioned, to ensure that there is some type of rate there from the Medicaid program. We are working on all cylinders to make sure that this program is scaled.

Ms. Monroe Thank you.

Mr. Herbst Thank you.

Mr. Kraut Thank you so much.

Mr. Kraut Now going to call on Mr. Bassiri to give a report on the Office of Health Insurance Programs.

Mr. Bassiri Thank you, Jeff, and nice to be with you this morning.

Mr. Bassiri My name is Amir Bassiri. I am the Medicaid Director at the Office of Health Insurance Programs at DOH. I want to give an update specifically on our recent approval for the 1115 Waiver amendment, which occurred January 9th of this year. As Commissioner McDonald said, it has been a long process, taking a village to get to where we are. We were negotiating with the Center for Medicare and Medicaid Services for about fifteen months on this amendment. Ultimately, we landed, with a $7.5 billion waiver approval over the next three years with about 80% of the waiver being federally funded. It is in concert with other waiver amendments that CMS has approved nationally. This is the largest they've approved. This is the most federal funding they've provided. We do have less time, traditionally. I'll talk a little bit about that and how we're mitigating against that. We're very, very excited to finally be here. The goal of this amendment is to fundamentally change the way we pay for and deliver Medicaid benefits and integrate social care services, along with our physical and behavioral services to address some of the health disparities and inequities throughout the state. By way of background, the 1115 Waiver, I know many of you are familiar with it. New York has a unique structure. We've had most of our managed care program authorized under this 1115 Waiver since 1997. The last big demonstration you're all familiar with. This is not a demonstration. It's an amendment. We have our current demonstration and process. It is between March 31st of 2022 to March 31st of 2027. We're amending that 1115 to incorporate several new authorities and flexibilities, but primarily health related social needs services that we are integrating into the managed care benefit package. We've added a goal to our amendment specifically around health equity. We view this as from the Medicaid programs perspective our strategic plan to address health equity. We don't intend for it to be time limited. This is something we intend to be a permanent fixture and how we do business and some of the delivery system reforms. There are three main pillars of the waiver. It is dense and wide. There are three main major pillars starting with development of social care networks and integration of health-related social means. That is about $4 billion of this seven and a half. It's the core focus. It's the research question that both New York and other states and the federal government are evaluating and hoping to evaluate thoroughly to assess whether inclusion of these benefits and funding from Medicaid will improve overall population health and reduce or be equivalent to current spending on medical services. It's a very ambitious goal, and one that we are going to have to work in rapid fashion to actually measure within the next three years. We have done extensive planning and preparation. We do have some things that are currently publicly available like our request for application to award these new social care networks currently in the application process. I'll talk a little bit about that. The social care networks are the core focus. One of the newer entities that we intend to establish in the Medicaid delivery system. They build upon a lot of the things that we have done. However, there's an evolution that has taken place. These are intended to be contracting entities taking on fiscal responsibility, coordination of benefits and services and HIT and HIE related functions to support community-based organizations and other health care providers for geographic regions throughout the state and serve as the basis for bringing community-based organizations into both the patient flow and the reimbursement model of the Medicaid program. These social care networks. We are planning to have one per region with New York City heading up to five. We will see what comes in. We are very much encouraging partnerships given the scope of

responsibility of these organizations. There is some of the work happening throughout the state. It would not be statewide. Organizations are going to have to come together to be able to stand up the infrastructure quickly and support their CBO and other health care partners. We intend for that to happen by August is our goal to have everything set up and funding to flow to these entities. Everything will begin in terms of their service delivery through a standardized, uniform screening and referral tool. That tool is very, very important to some of the things Jim spoke about earlier and our ability to evaluate outcomes and benefits of these services. There is going to be every Medicaid member, regardless of managed care or fee for service will have and go through a social care screening assessment. That assessment will flow through these networks. They will go to the State Health Information Network, health plans. They will trigger and identify what services an individual would benefit from or be eligible for. Everyone, regardless of what that assessment says will have access to what we're defining as level one case management services, which would be some linkages to existing state and federal programming, benefits and services, certain populations, more vulnerable populations, those that are in the health home eligibility criteria, pregnant persons and children, those being discharged from incarceration will be eligible for higher level or level two health related social needs services. That includes nutritional services, groceries, pantry stocking, home delivered meals, cooking classes, things of that nature, as well as transitional housing, supportive services, tenancy supports even rent and board for a temporary period of time, medical respite services and other linkage and care coordination services to get people into stable housing or transitional housing while we place them in permanent supportive housing. We're very, very excited about that. There's a whole suite of services. We're planning to do a very detailed webinar next week where you can see a lot of this information. There are some details in our current RFA for the social care network. You can see the data infrastructure and how we've thought about building this new entity and why we believe we've done it in a way that is intentionally done so that these entities are permanent fixtures and how we do business in Medicaid. There are some other health related social needs services that are new, including transportation. Medicaid normally pays for either emergency or non-emergency transportation, limited to access to medical appointments. This would be new transportation services to connect to social benefits and social care providers, which is a new service that would be included in this package. That is the core focus and primary funding of the waiver and one of the first pillars. There are some other very large initiatives under two pillars. I'll start first with population health improvement and health equity. We were able to secure funding for a statewide health equity regional organization. This will not be a government entity. It will be an independent entity that will be responsible for doing some of the regional planning and engagement of stakeholders to identify region specific health equity priorities and needs. They will also be working to support data aggregation of this new social care data with some of our other health medical data in the Medicaid data warehouse, as well as census data and other data sources to really enrich the information that we have on our members, who they are, what they need, if they're getting what they need, and what the outcomes of those referrals and services are. Will also be supporting and developing new value-based payment arrangements that could be funded and included in some of our managed care funding after the waiver depending on what type of innovation works and what stakeholders are saying is addressing some of the health equity priorities of any particular region, whether it's maternal health or behavioral health. They will do a lot of planning activities in that regard. There's also a very large primary care focus of this waiver. We work very closely with CMS, as well as the center for Medicare and Medicaid Innovation. Their primary care models that have recently been announced. We're trying to align where appropriate and also just catch up because as the State of New York as well as many other states have fallen behind in terms of the percentage of primary care in the health care dollars. We

have a very robust infrastructure through DSRIP and the PCMH program. We see very good outcomes in the PCMH program. The federal government is interested in aligning Medicare primary care transformation in accordance with what Medicaid has done. PCMH is going to be that link both for upcoming and new Medicare investments as well as statewide Medicaid investments that we have in this year's budget and which would roll out starting next year with an enhanced PMPM for both adults and children differential enhancement to really focus on increasing our investment in primary care and streamlining some of the quality improvement activities to align with what Medicare is doing in some of their new models. There is also a large policy change and unique demonstration Downstate that is outlined in the waiver. It is tied to the funding we were able to secure for financially distressed hospitals in the Downstate region. It is up to $2.2 billion. It serves as a bridge in many ways towards a new way of financing hospitals under a global budget demonstration. That is also in relation to a Medicare demonstration that would start in 2027. It is a voluntary model. Other hospitals can and we encourage them to participate if the state applies later this Summer. The funding is specifically for distressed hospitals is to stabilize and help prepare for the rebalancing of care from inpatient settings to ambulatory care settings in partnership with primary care providers and other community-based providers with total cost of care, accountability and population health outcomes that we hope to improve upon. The last component is workforce. This is very unique that we were able to secure workforce funding in this. There is no other 1115 Waiver approved in this cycle that has funding for workforce in this way. There are two primary workforce programs starting with that career advancement pathways training programs, which will be also leveraging existing infrastructure created under DSRIP through our workforce investment organizations, which had initially been established with a long-term care focus. We are really targeting to work with more sophisticated and more comprehensive that have expanded beyond only supporting long term care workforce and that have the capability and relationships, partnerships with educational institutions and employers to do healthcare training for nursing titles, for mental health practitioners, and new social care providers like community health workers and peer support navigators to support that social care infrastructure that we're building through the waiver. We hope to train or retrain at least 18,000 positions across various titles. It is going to be very challenging, but we are very excited about the opportunity and have been working closely with some to identify best practices and their capability. The other component that is much different than a training program is a small piece of loan forgiveness that is being targeted in a very specific way to titles for which we have a dearth of availability in the Medicaid program and widespread access issues such as psychiatrist, dentist, pediatric nurse specialist, primary care physicians. We are going to have some opportunities for loan forgiveness under the condition that anyone who receives loan forgiveness would commit to a service area requirement that they work at a Medicaid enrolled provider that serves at least 40% Medicaid and uninsured for at least four years. There is a large commitment. The loan forgiveness amounts are pretty significant with up to $300,000 for a psychiatrist. There are some additional initiatives. I think I heard Ann mention one that I'll just touch on. It's not specifically in this waiver. It's tied to the agreement, which is continuous eligibility. Medicaid and child health plus up to the age of 6. We have a pending amendment right now. We have some upcoming public forums. I'm happy to get information to the council. We'd love you to attend and encourage comments, but I've been talking for a while now. I need a sip of water. I'm sure you have many questions. I'm happy to pause.

Mr. Kraut Well, thank you very much. Congratulations on getting it to this point on the field and little over the goal line. As you know, we've been asking for this kind of presentation for a little while. Until the documents became public, it was difficult to have this conversation. That's why I'm giving them all the time they need to kind of go through these.

I think this is something we're going to be hearing about and talking through. Our role is somewhat limited. You're starting to see the framework of how health policy alignment is going where they're making the money and the investment and everything else kind of has to change behind that in order for this to be successful.

Mr. Kraut I'll open it up for questions.

Mr. Kraut Doctor Ortiz.

Mr. Ortiz Just more of a comment. It was great to hear you talk about workforce as Dean of a School of Nursing. In looking at the ability to create tracks for future nurses to progress from CNA to LPN to RN into advanced practice. I just hope that your office has the ability to work with State Ed and Office of Professions in a very seamless and transparent manner. There are many challenges to the regulations. There are three nurse associates in the Office of Professions who each interpret all the regulations differently. As past President of the State Council of Nursing Deans, I heard many, many frustrations and many emails from nursing deans trying to do unique and creative programs that would streamline and shorten the pathway. The regulations seem to stand in that way. Anything you can do, we be happy to help, of course. I just wanted to put that comment out there.

Mr. Bassiri Thank you for the comment. I think as you heard Commissioner McDonald earlier, it's something we're very focused on. We have engaged SCD. We are not necessarily asking them for any special flexibility with respect to these training programs. It is something we're very focused on more broadly.

Dr. Boufford Amir, congratulations on really hard work and continuing to focus on population health. I have two questions. One, is really about the social care network development. One of the learnings, I think, in DSRIP and other areas is A, that many nonprofits who are providing social services, the kind of supports that you want for complex patients do not have the capacity to scale up their ability to deliver services. That's one part. The second part is the degree to which developing networks takes time. I mean, there's a good example in Brooklyn. There's been sort of three, four or five years now with a very robust network of community health centers involved there. I think the time frame you're talking about of hitting the ground in August really raises two questions. One is, is there a potential for investment in administrative fiscal as well as staffing capacity in nonprofits as part of the funding ask that people would make not just bringing people on or beginning to sort of have a target number? The second question was just, what's the role of health plans in all this? It seems to me, ironically, they of all entities would have the greatest interest in integrating health and social care and managing patient costs. They seem to be kind of an afterthought. Those are my two questions. Thanks.

Mr. Bassiri Great questions.

Mr. Kraut We have a second by Dr. Bennett.

Mr. Bassiri You reminded me. I glossed over the health plan’s role. It's not insignificant. It's certainly not an afterthought. This is actually a lesson learned from the DSRIP waiver, where I think we acknowledge that not having health plans is integral to the delivery is why we haven't seen some of the lasting impacts of the policy reforms once the incentive funding is gone. We actually have put health plans very much front and center. They will have a very large role in supporting the networks, in ensuring that we can adequately measure and evaluate how these screenings and referrals, what the result is, whether

people are improving or reducing health care utilization as a result of receiving these services. They are going to be very involved start to center with all aspects of the 1115 Waiver with the exception of, I think the workforce investment organizations, although we do have some reporting that we use to do with the health plan. They are certainly front and center. They will have a very large role. Some of the health plans have actually done a lot of this work from the screening and assessment standpoint. I'm sure Dr. Bennett will mention what --- done. We are really taking what we've built and what we've learned from what's happening to try and just scale statewide and fill gaps because health plans can't do it alone. The networks can't do it alone. Together, we think we can fill some of the gaps and target health equity improvement for some of our more vulnerable members.

Mr. Kraut Dr. Bennett.

Mr. Bassiri I had mentioned there's $4 billion for both the infrastructure for the networks and the services. $500 million is for the infrastructure, capacity building, training, CBOs support, organizing, outreach are all eligible funding streams within that $500 million. We know this is going to take a lot of work. It will take a lot of partnerships. There are parts of this state that are further along and have really built on what the successes of DSRIP were to take it further. I would say different regions are at different places. We're working as quickly as possible. We want to leverage the federal funding as quickly as we can. We know that people have been preparing and planning and expecting this to happen. Some of that work has started.

Dr. Bennett Thank you for those comments. We're pleased to see it. As you said, if we want to get long term benefit from this investment you need to have this centered around the health plans. The one thing that concerns me, and I don't know whether it'll be an issue or not, is that because we basically were excluded from really the first DSRIP program there wasn't really much in the way of increased costs of administration. I'm always worried about unintended, unfunded mandates because that'll put a further strain as you very rightly said, we're doing a lot of this. We already have links with most of the community benefit organizations in the Capital Region. Our people are in there where they have EMRs we're connecting to them. We've already made a lot of these investments. We're not unique. Well, maybe we are. We like to think we are. Others have done similar things. I just would hope that as this rolls out that the department be conscious of not giving us an unfunded mandate where there's we have to do something new that we can't really afford.

Mr. Bassiri Thanks for the question, Dr. Bennett. Very much top of mind. This will not be an unfunded mandate. I will tell you that the rates will be actuarially sound. I assure you that. We are also planning to use vehicles like state directed payments and other things of that nature that have administrative funding components to them. We know this is not easy work. For a plan like yours I think it's well positioned to be very effective quickly and get reimbursed for things. You're probably not reimbursed for today.

Dr. Bennett Thank you.

Mr. Kraut Dr. Torres.

Dr. Torres I wanted to pause earlier in making a comment only because I was waiting to hear your presentation. It was an honor and exciting to host the MPA meeting in one of the community sites. Interestingly enough, there were also other groups and individuals that wanted to also comment on the waiver and use the MPA forum to do so as they saw an

impact on the aging, community as well. I just wanted to make that point. Thank you for the clarification and more discussions coming in the future.

Mr. Kraut I'll give the final question to Dr. Kalkut.

Dr. Kalkut Thank you. Congratulations, Amir. I'm Gary Kalkut from the council. Could you comment briefly, if you can, on data infrastructure to track screenings and referrals health related social need referrals? The data during DSRIP was a keystone to improve.

Mr. Bassiri This is the thing I'm the most excited about. What we put the most, I think time planning and effort into is the social care data infrastructure and its change, both, at the provider level as well as the statewide level. There's a lot of this in the social care request for application that is publicly available in terms of the visuals. You can understand and see the architecture in a much clearer way. The assessments will be done primarily by community-based organizations and or health care providers that have the capability to do them. They'll flow through the social care networks. We have focused very much so...I know not everybody loves this, but on standardizing that information. It is not going to be perfect because we know that this is a nascent market. A lot of people think they know and have the best screening tool to assess a member's social care needs. Ultimately, if we don't have uniform and standardized data we will never be able to evaluate what works and what doesn't. We would have that standard. That is where everything starts. It flows through the social care networks. It will be housed in a data lake and connected to the SHIN-NY. We will have access to integrating that data with other Medicaid data in the warehouse. Through our partners, both in the SHIN-NY and the state, we would be able to integrate that data and release it to the regions or more publicly in a way that we can monitor and evaluate what's working in which regions, where and when. I'm summarizing it pretty rudimentary. There is a lot behind it. There is no other state, even the other 1115 Waivers who are doing this type of work. They haven't built infrastructure on the data exchange like we have. They don't have the benefits of a statewide HIE like we have. We are really trying to leverage the infrastructure that exists such that this can continue in perpetuity and in a way that it will continuously improve and help us evaluate whether it's working and whether it's cost effective.

Mr. Kraut I made a mistake. I gave Dr. Kalkut the last question on the left side of the room. I'm going to give on the right side of the room to Ms. Monroe.

Ms. Monroe I'll make this quick.

Ms. Monroe Thank you for that explanation. One of the things I think we learned in DSRIP is to follow the money. I'd like to just ask you a dollar comes into you and down at the other end of this whole transaction is a person who needs a ride. How does that dollar flow down to that person?

Mr. Bassiri It's a great question. We'll actually go through this fund flow, Ms. Monroe, in a public webinar next week. We are going to establish a per member per month premium for the social care services. That's going to be challenging in the first year because there is no historical information to base that premium on.

Ms. Monroe Does that go to the health plan or to the social care network?

Mr. Bassiri It goes to the health plan, and it is directed to the social care network through a state directed payment, meaning we will be able to follow it from health plan to social

care network. The social care network is responsible for a lot. One of which is establishing a fee schedule for these different services with the CBOs. It would be a fee for service like fee schedule for services. The service you described would be on that fee schedule. They would coordinate the referral to that provider based on that member's screening and assessment form. If the referral was paid, the service was provided, the provider would be paid for that transportation.

Ms. Monroe By whom?

Mr. Bassiri By the social care.

Ms. Monroe Okay.

Mr. Bassiri The social care network will be paying their network of community based and other health care providers directly.

Mr. Kraut I would just tell you, as we move from what's written on paper to reality, I'm sure a lot of the questions will get answered. As Mr. Bassiri said, the webinars that are scheduled, I would encourage everybody to watch them. Colleen, I'll ask you to send those links out to the board members. Thank you very much.

Mr. Kraut Now, I'd like to introduce Dr. Bauer to give a report on the activities of the Office of Public Health.

Dr. Bauer Thank you so much.

Dr. Bauer Good morning, council members. The Office of Public Health is looking forward this year to finalizing the framework for the next cycle of the prevention agenda the state's Health Improvement Plan. When we launched the new prevention agenda framework in 2025 hospitals and local health departments, along with their community partners will be using that new framework to plan their work over the six years of the cycle. Yesterday at the meeting of PHHPC's Public Health Committee OPH presented two potential frameworks, one of which is a direct descendant of the current plan, mirroring the existing priorities and focus areas, and one that takes an updated approach to advancing public health by more formally recognizing and integrating into our strategies the known relationships between the vital conditions or the social determinants of health that we all need to thrive. Those are the things we've just heard about in terms of the 1115 waiver, stable housing, transportation, good nutrition and include things like safe, natural spaces, quality education, living wage and so forth. All of those, as we know, through our work with social determinants of health are an even greater force for health than even health care. While health departments and hospitals are not responsible for addressing conditions like poverty and low high school graduation rates and so forth we've long recognized those conditions as the root causes for poor public health. The updated framework, which was under discussion with the Public Health Committee yesterday takes the recognition of that relationship a step further and empowers and exhorts hospitals and health departments to actively partner, to invest in communities and help address these health-related social needs. There were questions yesterday from the Public Health Committee about how hospitals and health care organizations can do that. We have just heard how the health care delivery system can transform, can partner with the community, can work with community organizations to really change the trajectory for patients and for community

members. It's really exciting to hear now about the 1115 waiver and how that will be moving forward and potentially how the prevention agenda can align with and support that work. I'll refer council members to our OPH written report for our office of Public Health updates. I will call your attention, though, to the success of our WIC chat bot known as Wanda, who has been providing information and referring New Yorkers to the WIC program. This year just launched, last month Wanda now offers all of that guidance information and referral in Spanish. We're looking forward to expanding our reach for the WIC program. I'll also note included in the report the Center for Environmental Health has several regulatory updates underway, including modernizing the regulations related to ionizing radiation and revising the state's food code, which, of course, we're doing in sync with the Department of Agriculture and Markets with the goal of better aligning with the federal government's model Food Code. Those are a handful of updates from the Office of Public Health. Thanks very much.

Mr. Kraut Great.

Mr. Kraut Thank you.

Mr. Kraut I have a question. It's not a question. It's just a recollection. I believe the prevention agenda has to get approved by the council in order to be adopted. At some point in the future, as it comes through the Public Health Committee it will get presented here at one of our meetings for adoption. My recollection is we have to do that in order to recertify for the state and stuff like that. I know we're going to hear from Dr. Boufford as well.

Mr. Kraut Do you have comments for Dr. Bauer? Any comments? Questions?

Mr. Kraut Thank you. Thank you so much.

Mr. Kraut I'll now turn to Dr. Fish to give a report on the Office of Primary Care and Health Systems Management.

Dr. Fish Thank you.

Dr. Fish Good morning, council members and guests. It's a real privilege to be with you here today in this role. Thank you, Mr. Kraut, for the kind introduction earlier today. Just a friendly amendment. I'm acting in the acting capacity Acting Deputy Commissioner role of the Primary Care and Health Systems.

Mr. Kraut You think you're acting.

(Laughing)

Dr. Fish I'm learning a lot. I've spent my last nine years, as you mentioned in the Office of Health Insurance Programs working with them here in the Medicaid program. That's been a real privilege. Just a couple of comments. Just two topics that I'll touch on today in the interest of time. One is, the Certificate of Need Program. Governor Hochul announced in her State of the State Address that to alleviate strain on both providers in the state she'll instruct the department to make necessary updates to the state's Certificate of Need Program, such as raising financial thresholds that qualify a project for more detailed review and streamlining the application and approval processes, including for what are now routine services. Project cost thresholds were last raised in 2017, and construction costs

have escalated as we all know. Updating the Certificate of Need process will help to ensure that it continues to advance its objectives as responsive to a changing health care environment focuses the department and the Public Health and Health Planning Council resources on issues and projects of greatest impact and is a streamlined and expeditious as possible within the parameters of the statutory authority. The second topic is just an update on the statewide health care transformation program. A total of $1.6 billion is authorized through fiscal year 2024 for statewide health care transformation programs and our statewide efforts. $650 million of the statewide four appropriation has already been awarded, including $450 million for statewide three projects and $200 million for emergency room modernizations. $950 million remain to be awarded under three requests for applications just announced under the statewide four and five programs as follows: first $650 million for health information technology, cybersecurity, and telehealth transformation projects through statewide four and five funds through our Office of Quality and Patient Safety. That was released on January 2nd with applications due March 13th of this year. Second, $50 million for residential and community-based alternatives to traditional nursing home care through statewide four funds released a January 9th with applications due April 9th. $250 million for facilities to drive transformative healthcare investments with priority given to facilities in severe financial distress using statewide four funds. This was released also on January 9th with applications due March 26th. Separate from these statewide RFAs the council should also note that a new Health Care Safety Net Transformation Program for hospitals is proposed in the fiscal year 2025 executive budget under Health and Mental Hygiene Part S. The Executive Budget Bill language authorizes and directs the State Comptroller to transfer up to $500 million of funds from statewide four and five to fund this program. The goal is to improve access, equity, quality and outcomes while increasing the financial sustainability of our safety net hospitals. With that, I'll just wrap up and see if there are any comments or questions.

Mr. Kraut Any questions for Dr. Fish?

Dr. Soffel I have one very quick question. I'm sorry, Jeff.

Mr. Kraut No, it's okay.

Dr. Soffel I’m just a little bit confused about the dollar flows here because as I'm reading the report and what you just said is that there's still $950 million remaining under four and five and it's been allocated in three different buckets, but then somehow $500 million more is going to go to this new health care safety net transformation program?

Dr. Fish That's correct. An additional $500 that's proposed in the budget this year.

Dr. Soffel So this is new money?

Dr. Fish This would be new dollars, yes.

Dr. Soffel It's not being transferred from four and five?

Dr. Fish No, it's, not part of the original $1.6 billion. That's correct. It's separate.

Dr. Rugge Actually, I think that it's not new money. I think it's actually money that had been previously not spent. It's being reappropriated from other unspent funds into that particular bucket that he would not know that because it was before his time.

Dr. Fish Thank you.

Mr. Kraut Every time you issue an RFP it's new money as far as people are concerned.

(Laughing)

Mr. Kraut As long as you get to spend it.

Dr. Fish Thank you.

Mr. Kraut Thank you so much.

Mr. Kraut I'm now going to ask Miss Kim to give a report on the activities of the Office of Health Equity and Human Rights Management.

Mr. Kraut Ms. Kim.

Ms. Kim Thank you.

Ms. Kim Good morning, almost most good afternoon to the council. I'm delighted to provide you with updates on progress to date with work that is happening in the Office of Health Equity and Human Rights. My name is Tina Kim. I'm the Acting Deputy Commissioner for the Office of Health Equity and Human Rights. First, I wanted to highlight a few programmatic updates from the AIDS Institute. The Department of Health is preparing for amendments to the Public Health Law to go into effect May 3rd, which will require a syphilis test during the third trimester of pregnancy, in addition to testing at the time of the first examination. The AIDS Institute is creating a frequently asked questions document and communicating with providers on needs to support the implementation of syphilis screening during pregnancy in the third trimester. The frequently asked questions will include information about existing and new requirements for the screening to ensure that there's a single comprehensive document for New York State providers. We will continue to monitor and work with providers as this law goes into effect later in May. The AIDS Institute is also continuing its efforts to address the harmful impact of crystal methamphetamine use. The AIDS Institute has directed multiyear funding to Trillium Health and Evergreen Health to address crystal meth use in the Western New York Region. This funding complements the great efforts of partners at the New York City Department of Health and Mental Hygiene that they offer through the five New York City boroughs. The University of Rochester also received one year funding to conduct a pilot research study to learn about the current impact of crystal methamphetamine use, specifically among Black men who have sex with men across New York State. The AIDS Institute convened and successfully conducted two community virtual discussions, which held space for education and awareness to talk about the impact of crystal methamphetamine use in communities, and in particularly communities that often experience societal political marginalization. We will be continuing those efforts through the course of 2024. I do have an update that we were not able to include in our written report, but I'm happy to share verbally. This is an update from the Office of Diversity, Equity and Inclusion. The Office of Diversity, Equity and Inclusion within the Office of Health Equity and Human Rights will be conducting a training for DOH staff this Tuesday. This is for staff that are overseeing boards and councils within the Department of Health. As you all may know, the department oversees a convening of over forty advisory boards and councils. The objective of the ODEI training, titled Enhancing DOH Councils and Boards Through Diversity and Inclusion is to provide DOH board and council liaisons and

affiliates with knowledge and understanding of diversity and inclusion updates related to vetting processes, defining diversity and inclusion and its alignment to DOH boards and council, reviewing and education on current and innovative practices, support and resources for board and council education, outreach and improvement, and identifying next steps towards working with each DOH council and board and the staff to oversee them. The Director of the Office of Diversity, Equity and Inclusion continues to serve as a DNI liaison, responsible for now reviewing all incoming DOH council and board candidates. This is towards the goal of increasing diversity within the boards of counsel that are responsible for making key decisions impacting New Yorkers. We believe that increasing diversity and representation on those boards and councils will be critical to further inform the decisions that come out of those important bodies. We will continue to partner with our colleagues and the council operations team to ensure that we try and do our best to increase diversity as much as possible. I have a quick update from the office of Gun Violence Prevention. Many of you all may have read in the State of the State 2024 book the Governor announced major expansions to combat gun violence. We were particularly excited to see the Office of Gun Violence Prevention here within the Department of Health highlighted within that book. As you know, there was a state agency, Division of Criminal Justice Services that is mainly responsible for public safety strategies and efforts. As you all know, the Governor had announced through Executive Order declaring that gun violence is a public health crisis and specifically, created the Office of Gun Violence Prevention within the Department of Health to undertake a preventive public health approach to mitigating and ultimately reducing gun violence. As announced in the 2024 State of the State book, many of you may be already aware of this and invested, as many of you have hospital-based violence mitigation programs already in place. The State of the State announcement, one of the pieces was talking about a New York State Health Systems for Gun Violence Prevention Task Force. It will be comprised of representatives from hospitals, hospital systems and hospital associations that will contribute to conversations impacting hospital-based setting. The establishment of this task force is underway. The intention is that this membership will build support from leadership and hospital-based settings to promote implementation of recommended solutions to address and mitigate gun violence. Also, in the 2024 State of the State, the Office of Gun Violence Prevention, in partnership with stakeholders and experts across the Department of Health will develop a syndromic surveillance system to house data and publicly put out data related to firearm injury. The Office of Gun Violence Prevention will manage the data, maintain the outputs, conduct trend analysis, and defend the findings in a public dashboard, which I know many community stakeholders have asked about and are interested in seeing. We are very excited to be able to deliver that. We continue to partner with Amir's team and the Office of Health Insurance Programs to provide guidance and technical support to clinicians and community organizations related to hospital violence intervention programs. We are continuing that work. Lastly, from the Office of Minority Health and Health Disparities Prevention, I wanted to provide a quick update on the mentorship in medicine and other health professions program. This is a program that specifically supports activities and approaches designed to contribute towards the reduction of barriers by promoting an increase in the number of economically disadvantaged and underrepresented minority students who would like to pursue professional careers in medicine and health related areas. We are delighted to share that we issued award and non-awardee letters to applicants in recent weeks related to the mentorship and medicine competitive opportunity. Hofstra University will be implementing the initiative for the next five years, starting this May. This program will be supported by local assistance funding that is coming in through the Office of Minority Health and Health Disparities Prevention. This will continue to support existing pathway programs. With that,

I'm happy to close with the update from the Office of Health Equity and Human Rights. I'm happy to answer any questions you may have.

Mr. Kraut Thank you so much.

Mr. Kraut Dr. Soffel.

Dr. Soffel Good afternoon, Tina. It's good to see you. Question about the Health Equity Impact Assessments. Have you started to receive Certificates of Need that include the Health Equity Impacts? What's the status of that?

Ms. Kim Yes. The department has received a number of Certificate of Need applications that came with and required a Health Equity Impact Assessment. The Health Equity Impact Assessment unit within the office is one of various review units within the department that leads to the overall comprehensive review of Certificate of Need application. We are part of the process. We anticipate that in future PHHPC meetings there will be presentation of applications that will include review of the Health Equity Impact Assessment. I am happy to share that we, we are in receipt of Health Equity Impact Assessments from Certificate of Need applications but unable to kind of disclose further. There's not just our review, but there's other reviews that are happening concurrently for those applications. They are very much in process.

Mr. Kraut Dr. Soto.

Dr. Soto Thank you very much for your presentation. I have a question on the last item that you brought up in terms of support to increase the diversity of physicians and health care providers from disadvantaged and diversity groups. Do you have a sense what is the criteria of the individuals who will be eligible for this? In part, the reason I'm asking you this, because I used to direct science technology entry program that right now is being sued because of the eligibility requirements for that program.

Ms. Kim I can certainly circle back with you on specific eligibility criteria when it comes to individual applicants. The focus of the mentorship in medicine and other health professions program is specifically to support institutions that are kind of increasing students' awareness and pursuit of careers in health care, including behavioral health, STEM education programs,, science, technology, engineering and mathematics. I know that there's a specific focus on which types of programs fall under the parameters of this mentorship and medicine program. I'm happy to circle back with the specific eligibility criteria.

Mr. Kraut Thank you very much, Ms. Kim.

Mr. Kraut I'll now turn to Dr. Boufford to give us a report on the activities of the Public Health Committee.

Mr. Kraut Dr. Boufford.

Dr. Boufford I'm not going to repeat what was said earlier by Dr. Bauer, but I wanted to give you a little bit of background because I think this will be coming back to the council. Just historical background. The first thing is that this is the fourth cycle of the prevention agenda. It initially started 2008, and it's been done in sort of four-to-five-year blocks. The current sort of approach is 2019 to 2024. The next one will be what we're planning now is

will be 2025 to 2030. That's important. There have been changes during those cycles, I think from the initial cycle of having ten goals, the current one is five and truly tried updating the objectives, etc. There has been also a really effective dashboard on reporting. The key partners in the currently operate prevention agenda have been local health departments working with hospital leadership, bringing as many people locally as they can, as many stakeholders to the table, including business, nonprofits, academic institutions, etc. The goals for the current prevention agenda were really based on the state health assessment, which identified four basic goals. The fifth one was added, which were the causes, the highest causes of preventable mortality in the state. They were picked as, chronic disease, healthy and safe environment, healthy women, infants and children's and communicable disease prevention. Because of working directly with the Office of Mental Health, OASAS on the drug policy and NYSOFA. In the current model, the fourth goal was added, which was promoting well-being and preventing mental health and substance use disorders because the Department of Health doesn't have authority over that activity. The health department and OASAS joined together, really starting back in 2019 or 2018 before the COVID. Now, all this was sort of interrupted in COVID, although interestingly, and I think we've had these presentations in the Public Health Committee, local health departments continued to report what was going on in addition to COVID, and we had some panels and other things going back a couple of years. That's kind of the way of background. This next cycle would be a new sort of six-year cycle, which we would be creating, really by the Fall of 2024 ideally to have guidance drafted that could then go out for whatever implementation is going to take place. Over the last few months, and I want to give credit to my colleagues on the Public Health Committee who've been working over the Summer and over a number of times during the Fall with the Ad Hoc Committee. What we've been doing is reviewing the priorities that exist, progress against goals and metrics and the implementation mechanisms for the current prevention agenda. We've had updates from staff. We had panels from our partner agencies; NYSOFA, OMH and OASAS. I want to mention the Department of State that's been particularly interesting and involved around the economic development issues on, smart growth as well as environmental justice. They've been very involved. We also had a panel with NYSACHO and Greater New York and HANYS who really talked also about the prevention agenda. We invited them to really talk about strengths and weaknesses, because we want to inform, the design of the next generation. Our last meeting before Christmas we had a presentation from, the Master Plan on Aging, which also has a subcommittee on prevention and health, which we're watching that crosswalk because one of the goals of the prevention agenda initially, which I think we all agreed was not well met was really incorporating aging in the various objectives. There was an objective there for over 50 but that's not the group that we're talking about in the master plan. The mechanism was each local partnership identifies two of the five areas of the state goals that they wish to work on and address a health disparity. I think there's been a good sense of what worked and what didn't work. Generally, I think it just to summarize the response from the various meetings and discussions we've had is the prevention agenda was seen to be very important and very positive in raising the visibility and importance of prevention. Many of our sister agencies indicated that they have started units to focus on prevention within mental health and behavioral health and others that they had not had prior to their collaboration on the prevention agenda. There also have been some counties and local partnerships with counties and hospitals that have been very successful bringing multiple stakeholders together, getting community engagement and really working through the entire process, which is setting goals. I'm looking at Dr. Watkins. Setting goals, designing evidence-based implementation and evaluating that implementation. It's been a problem for others. It's been an unfunded initiative. That's been one of the issues. Similarly, one of the areas that had begun to happen but wasn't as fully developed as we hoped going forward. The new

model was really linking the local infrastructure on area offices on aging, the local and regional infrastructure, which is basically sort of federal pass through in some ways on mental health and behavioral health with local health departments and having them begin to work together with local health departments and hospitals. Again, as always, things have worked well or not so well. The other, piece of the current activity was really encouraging hospitals and local health departments to work together on submitting their local plan. Using the Health Department's required annual health needs assessment, health assessment and then building together their choices of initiatives, as well as other local issues that they might be working on. After about ten years, we have about a 45% overlap between what's going on between the partnerships between health departments and local hospitals. A part of the question that's here is, is there a more effective vehicle for really pushing that collaboration a little bit more strongly in the next cycle? The last area we looked at was, and I think these are recommendations for change, some of which, link directly to what Dr. Bauer mentioned, that we want to revisit the priorities to see if they are, in fact, the appropriate ones. We want to... Obviously, some of that will come from the updated State Health Assessment, which is just being completed. It's going to be presented at the next Ad Hoc Committee meeting. Total consensus on reducing the number of objectives. Obviously, they have to be revised because they were not... I think, now been fully revised in the last couple of weeks but had lagged. Lengthening the cycle of reporting. A local health department had felt that three-year report was really too short. They wanted a cycle of either maybe annual updates, but a six-year opportunity to really embed the changes they wanted to make. As Dr. Bauer alluded to, greater engagement on the issue of social determinants of health. It's important to realize in public health that the evidence base for social determinants, and I am not talking about social service supports to complex patients. I'm talking about social determinants of health, which have to do with conditions in communities in which people live. Healthy housing is an important issue for a patient that has complexity and is houseless. The issue is, can we deal with policies that fix housing stock in communities or greenspace or other things? Health in all policies. Exactly. What are the other questions going forward because of this interest in broader engagement in social determinants of health is that there has been since 2018 a mechanism an Executive Order that Governor Cuomo issued, and Governor Hochul has actually referred to and endorsed to have all agencies in New York state government look at their policies, their procedures and their contracting relative to the health effects and or the effects on healthy aging. That's sort of been in place since 2018 and was reinforced in creating the Master Plan on Aging that Governor Hochul issued. Obviously that group had been constituted. It was co-chaired by the Commissioner and individuals from the Governor's Office. It was obviously interrupted by COVID. The last meeting was scheduled to be March of 2020 and didn't happen. That mechanism is there. It was a really a focus of a lot of the questions yesterday that the health department and hospitals have a role, certainly a critical role to play. If you're focusing specifically on health problems they have a bigger role, relatively speaking, perhaps then beginning to address some of the broader social determinants, which are very, very important. The discussion we were having yesterday is it's very clear of what they can do. How might they be encouraged to do that again without financial incentives or others. I'm going to continue to make this distinction between social care services and social determinants of health, which are from the point of view of the prevention agenda different. Similarly, how could we bring other agencies in? There was a really nice report on the kinds of evidence base that interventions hospitals can make that health departments obviously can make. We know broader sort of nonprofits are very involved in all this. To deal with policy chains on food, for example, or food security, AG and Markets is an agency that needs to be involved and green space, parks and recreation and others. That's kind of where we ended the discussion yesterday, which I think is really important. I just want to thank my committee members for asking

really good questions. Part of it is really developing this and how will the connections be made and how will the metrics be developed for social determinants focus on a new model of the prevention agenda? We have a meeting of the Ad Hoc Committee on the 22nd of February. I encourage anyone to come. We'll get the feedback from that group, which is officially the sort of public advisory group to the prevention agenda. We've talked tentatively about having another cycle of Public Health Committee and Ad Hoc in April to sort of see where we go with drafting since we need to get some decisions made and bring back to the PHHPC, so that there's plenty of time in the Fall for developing the guidance and issue to get to local leadership. Thank you.

Dr. Boufford I'm happy to take any questions.

Mr. Kraut That meeting in February on the 22nd will be in Albany. I'll repeat that again.

Dr. Boufford Other issue, just very quickly, the Public Health Committee has historically picked an issue of importance, public health issue of importance to work on. You'll recall we really worked hard on the maternal mortality question about seven or eight years ago and I think, can take some credit for launching the focus on maternal mortality after that. We have picked public health workforce not daunted by challenges. This year we heard from the new Office of Public Health Workforce, and we heard from the leadership of that group. I want to mention her name, Keshana Owens-Cody, who presented. She's kind of really organizing her office and presenting her plans for staffing up in some of the areas are going to work on. We're developing that with them. Thank you.

Mr. Kraut Just as a point of history, the last time we adopted the prevention agenda was in 2018. That was to run through the end of 2024. That's the timing issue Dr. Boufford spoke about.

Mr. Kraut Any questions for Dr. Boufford?

Mr. Kraut Thank you. I know this will become... We're going to have to devote a significant time to review that agenda with the full council after its recommended to us after the Ad Hoc Committees meet. That'll probably be early/late Spring.

Dr. Torres I just want to say something. That there are many elements of this that plays into the social care network.

Mr. Kraut It's beyond just the social care. It really goes back to the health, when ee talked about the health in all policies.

Dr. Boufford You're right. I think one of the five areas identified for attention in the new and the proposal that came from the department was really looking at health care quality and access to care. That could align very well. The prevention agenda has historically kind of stopped at the clinical door and tried to deal with the other environmental issues and where people live and go back to but that is on the table for potentially more work in that space in the new proposal.

Mr. Kraut Thanks so much.

Mr. Kraut Dr. Rugge is going to give a report on the Health Planning Committee.

Dr. Rugge Quick brief update thanks to Colleen Leonard and Jeff Kraut on behalf of the planning committee of this council. It was one year ago that Dr. Morley brought to PHHPC concerns raised by SEMSCO State Emergency Care Service Council regarding untoward lengthy delays of offloading ambulances at the ED ramp sometimes for hours. An analysis showed there's a lot of variability across the state. Further analysis showed there were two areas of particular concern that seemed inappropriate to go to the ED; mental health and oral health because it really can't be treated very effectively there. That led to a series of committee meetings, but also committee workshops trying to learn what are the opportunities, what can we learn from elsewhere around the state and around the nation. Starting with Dr. Sullivan as Commissioner of Office of Mental Health, describing CPEP, Comprehensive Psychiatric Emergency Program based on turning 911 calls into 988 calls and instead of simply having the ambulance go to the one place, find a more appropriate and develop a more appropriate setting. That's been supported by gubernatorial support and gradually expanding around the state. Then we came to oral health and hit upon a California example or program with 911 calls for dental problems referred to a dental referral agency and RNs supported by a backup dentist to find immediate care over the telephone and then referral to a more appropriate setting among dental providers. Again, I'm hoping that what happened was the interest of our planning committee that questions were raised. The queries help to guide where to go next with all this. What's been happening for a number of months now is lots of hard work by staff. Coming back to us as the new director of a new bureau for strategy. Of course, Dr. Heslin, looking to prepare a report that would be informative and precedent setting in terms of how we reform the structure and the delivery of health care. This draft report, as I understand it, has three significant components. One is EMS reform, how to make sure that a 911 call simply does not automatically lead to an ambulance taking somebody to the emergency department when it may not be helpful. In this case, Governor Hochul has jumped ahead of us. The executive budget there's a proposal for establishing five EMS zones with oversight by an EMS statewide task force, supported by appropriate reimbursement through the Medicaid program. Using this to establish a paramedic program the ET3 federal program, of which the New York state was a participant was canceled by the state in December. Triage and transport. Because there was very little sign up, but now it's been redesigned and reformulated into a state supported state-based system. One that will include the use of community paramedicine with in-home assessments, not in hospital assessments. That's number one. Number two, continued BHS reform, behavioral health reform. The question is how can PHHPC and its planning committee be helpful in understanding what new twists could be applied to their program and be supportive? Number three is back to dental care. How can we develop a triage system for a new referral service? How can we develop new forms of caregiving, specifically considering the use of dental therapists and dental assistants in new ways? What we're doing in primary care with physician assistants. Developing partnerships for referrals to federally qualified health centers and dental training programs, dental schools. With all this, the report is in draft. It is about ready within days to go to senior leadership within the Health Department and other agencies. With a timetable of hopefully March, perhaps more like April, hopefully not longer than that. Then to come back to the Planning Committee and to PHHPC for consideration and review and for the proposals. Along with that major priority is to say this was a start in terms of how this council can be helpful in terms of restructuring our delivery system. What's next? Starting at the unloading offloading ramp of the E.R. is kind of poetic, I like to say. Now the question is, where do we go next by way of making health care more effective given all those new technologies, all the new programs we have been undertaking? Hopefully along the way, the work of us as PHHPC members has been helpful in some way in terms of stimulating interest, sparking this discussion, and that we will be helpful going forward in identifying new opportunities and helping our real experts, the people working hard at this

to explore the options and settle on new courses. Let's hope we will work together and realize that we are the Public Health and Health Planning Council.

Mr. Kraut You know, it's interesting I'm going to talk a little about this. We're going to devote a session of the full council to obviously the prevention agenda, as I said, and another session to the recommendations coming out of the Health Planning Committee, which I will adjust the agenda to make sure we give it ample time to be discussed.

Mr. Kraut Ms. Monroe.

Ms. Monroe As Vice Chair of the committee I've really been pleased along with John about the progress of this report. I am as enamored as anyone about new ideas to address the problem. I also want to make sure this report defines the problem. Is it the same everywhere? Is it regional? Is one region stronger than another? Is it children? Is it adults? Is it Medicare? Is it Medicaid? Who are the payers? In addition to great new ideas about fixing the problem, I'm really hoping that this report will also define and describe the problem. I wanted to add that to what John said, because that's kind of our ying and yang of the Health Planning Committee. I don't expect a response today, but I do hope that there's a true description and definition of the problem.

Dr. Strange I will respond. That might take another year.

(Laughing)

Dr. Strange I will say is very important is that because we did this, even though the report isn't out, when you look at the executive budget, we had five scope of practice issues in this year where we had thirty last year. Large EMS package. A very strong section in dental. We focused on something with Public Health Council. We brought together and used Public Health Council as a convening tool, gathered information. Got outside input. Amazingly, two of five major areas that are in executive budget are there. I would say congratulations.

Mr. Kraut Thank you.

Dr. Rugge Another quick observation that health care is like the same everywhere. I mean, the EMS squads are so different from one another, so fractured, so diverse, profit/not for profit, government based, private based and working together to how to regularize and more standardization so we have one standard of high quality everywhere. That's our project.

Mr. Kraut That's great.

Mr. Kraut Thank you very much.

Mr. Kraut I'm going to turn to Mr. Holt now to give a report on the Codes, Regulation and Legislation Committee.

Mr. Holt Good afternoon. At the February 8th committee meeting on Codes, Regulations and Legislation, we reviewed six codes, one for emergency and full adoption, two for adoption and three for information only. They were all recommended for adoption by the full council. The first one was for both emergency adoption and full adoption trauma centers, resources of optimal care of the injured patient. Department presented the trauma

centers resource of optimal care of the injured patient, proposed regulation to the Committee on Codes for emergency adoption and adoption. They are available to the council should there be any questions of the members. I so move.

Mr. Kraut He so moves.

Mr. Kraut I have a second Dr. Berliner.

Mr. Kraut Any questions from council members?

Mr. Kraut I'll call for a vote.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstention?

Mr. Kraut Motion carries.

Mr. Holt Next for adoption at this morning's meeting, we had the adult day health care code presented by Ms. Heidi Hayes, Ms. Stephanie Paton and Ashley Corcoran of the department. They presented that proposed regulation to the Committee on Codes. They are available to the council should there be any questions. I move the adoption of this code regulation.

Mr. Kraut I have a motion.

Mr. Kraut I have a second by Dr. Yang.

Mr. Kraut Are there any questions from the council?

Mr. Kraut I'll call for a vote.

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Motion carries.

Mr. Holt Third, we had the hospital in a nursing home PPE requirement. Jaclyn Sheltry and Jonathan Karmel of the department presented the hospital and nursing home PPE requirements and proposed regulation to the Committee on Codes for adoption. They're available to the council members should there be any questions. I move the adoption of this regulation.

Mr. Kraut I have a motion.

Mr. Kraut May I have a second?

Mr. Kraut Dr. Yang.

Mr. Kraut Any questions?

Mr. Kraut All those in favor?

Mr. Kraut Opposed?

Mr. Kraut Abstention?

Mr. Kraut The motion carries.

Mr. Holt Finally, we had three, codes for information only for the council, general hospital, emergency services, behavioral health. The statewide health information network of New York, Adult Day Health Care and General Hospital Medical Staff Recertification. Those will come back to the council for further consideration at a future date. That completes this morning's report.

Mr. Kraut Thank you very much, Mr. Holt. For those of you who were present for Codes, there was a very robust conversation on them. It was a very good meeting.

Mr. Kraut Mr. Robinson is going to give the report of the actions of Establishment and Project Review Committee.

Mr. Robinson Thank you very much.

Mr. Robinson As Mr. Kraut said at the beginning of the session, we go through batches at full council for this application. One last call for anybody that wants to pull an application out for more extensive discussion. Otherwise, I'm going to proceed with the batches.

Mr. Robinson Thank you.

Mr. Robinson For these first two, I'm asking Dr. Kalkut or leave the room. Calling application 231332C, NYU Langone Hospital, Long Island, Nassau County. I'm also noting an interest by Dr. Lim to certify a new extension clinic for ambulatory surgery at 1440 Northern Boulevard, Manhasset. Department and committee recommend approval with conditions and contingencies. Application 231348C Long Island Community Hospital and NYU Langone and Suffolk County to certify a new extension clinic for ambulatory surgery at 196 Main Street in Patchogue. Also, the department recommends approval with contingencies, as did the committee. I move those two applications.

Mr. Kraut I have a motion.

Mr. Kraut I have a second, Dr. Berliner.

Mr. Kraut Any questions?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Robinson Please have Dr. Kalkut return.

Mr. Robinson Next batch for applications for diagnostic and treatment centers. Application 231299C, Weill Cornell Imaging at New York Presbyterian in New York County. Interest by Dr. Lim. Certify a new imaging extension clinic at 575 Lexington Avenue. Department and committee recommend approval with conditions and contingencies. Application 232063C, ODA Primary Health Care Network Inc in Kings County. Noting an interest by Dr. Kalkut. Certify a new extension clinic at 251 Wallabout Street, Brooklyn, and certify medical services, notably primary care, medical services and other medical specialties and optometry. The department and the committee recommend approval with conditions and contingencies. Application 231308C, New York Presbyterian Westchester, in Westchester County. Certify new extension clinic for ambulatory surgery at 1111 Westchester Avenue White Plains. Department and committee recommend approval with conditions and contingencies. 231311C, Samaritan Medical Center, Jefferson County. Certifying five psychiatric beds and performing requisite renovations. Department and committee recommend approval with conditions and contingencies. Application 231326C, Auburn Community Hospital in Cayuga to certify cardiac catheterization and PCI and perform renovations to an existing interventional radiology suite. Department and committee recommend approval with conditions and contingencies. Application 231351C, Saint Charles Hospital in Suffolk County, certifying cardiac cath, adult diagnostic cardiac cath, electrophysiology and cardiac cath PCI and perform renovations to create a new cardiac cath lab. Department recommends approval with conditions and contingencies, as did the committee. Application 231261C, Weill Cornell Imaging at New York Presbyterian and Kings County to certify a new extension clinic.

Mr. Robinson Thank you.

Mr. Robinson Brooklyn. Go Brooklyn!

(Laughing)

Mr. Robinson Department and committee recommend approval with contingencies. I don't know why my tongue tied up on that. 232124C, Community Health Center of Richmond Inc in Richmond County certify a new extension clinic located at 104 New Dorp Plaza in Staten Island. This is a HERSA funded safety net application. Department and committee recommend approval with conditions and contingencies. I move that back.

Mr. Kraut May I have a second?

Mr. Kraut Dr. Berliner.

Mr. Kraut Any questions?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions.

Mr. Kraut The motions carry.

Mr. Robinson Batching applications for ambulatory surgery centers. 222044B, Sorin Ambulatory LLC doing business as Sorin Ambulatory Surgery Center in New York County to establish and construct a multi-specialty ambulatory surgery center at 120 Wall Street. An interest by Dr. Kalkut. Approval is recommended with conditions and contingencies with an expiration of the operating certificate five years from the date of issuance. The committee similarly recommended that. Application 231114B, Prime MD Center LLC in Nassau County. Noting interests by Dr. Lim and Mr. Kraut to establish and construct a new DNTC at 1,000 Railroad Avenue and Woodmere. Department and committee recommend approval with conditions and contingencies. That's the batch that I move now.

Mr. Kraut Doctor Lim, before I do it, are you abstaining on it?

Dr. Lim No, I'll be voting.

Mr. Kraut You'll be voting with an interest.

Mr. Kraut I have a motion.

Mr. Kraut May I have a second?

Mr. Kraut I have a second, Dr. Watkins.

Mr. Kraut Any questions on this?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Robinson Thank you.

Mr. Robinson 231361B, Title Home Dialysis in Kings County. Noting an interest by Mr. La Rue. Establish and construct a new DNTC at in Brooklyn and certify home hemodialysis training and support and home peritoneal dialysis training and support. Department recommends approval with conditions and contingencies, as does the committee. I so move.

Mr. Kraut I have a motion.

Mr. Kraut Do I have a second?

Mr. Kraut Mr. Thomas.

Mr. Kraut Any questions?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Robinson Mr. Kraut is leaving the room with this next application.

Mr. Robinson Application 231120E, Health Quest Home Care Inc license. The geographic area is broad. This is to transfer ownership interest above the parent level. The department and the committee recommend approval. Madam chair, I so move.

Dr. Boufford Do I have a second?

Dr. Boufford Thank you, Mr. La Rue bumping out Dr. Berliner.

Dr. Boufford Any comments/questions from the council?

Dr. Boufford All in favor?

All Aye.

Dr. Boufford Any opposed?

Dr. Boufford Any abstentions?

Dr. Boufford Motion passes.

Dr. Boufford Invite Mr. Kraut back into the room.

Mr. Robinson Application 232088E, Sheepshead Bay Surgery Center in Kings County. Transferring 5% ownership interest from a deceased shareholder to an existing shareholder. Department and committee recommend approval with conditions. Application 232080B, ALEF Health Center, LLC in Richmond County to establish and construct a new DNTC at 3777 Richmond Avenue in Staten Island. Department and committee recommend approval with conditions and contingencies. Application 232106B, New York Health Care and Wellness in the Bronx to establish a new DNTC at 3005 Grand Concourse in the Bronx. Department and committee recommend approval with conditions and contingencies. 232133B, Nemo Health Inc in New York County establishing construct a new diagnostic and treatment center by converting a private practice at 651 Academy Street in New York, Manhattan. Department and committee recommend approval with conditions and contingencies. I make a motion for that batch.

Mr. Kraut I have a motion.

Mr. Kraut May have a second?

Mr. Kraut Dr. Berliner.

Mr. Kraut Any questions?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Robinson Thank you.

Mr. Robinson Application 202035E, Hilaire Health Care Network LLC doing business as Pine Forest Center for Rehabilitation and Health Care in Suffolk County to establish Hilaire Care Network LLC as the new operator of the seventy-six-bed residential health care facility located at 9 Hilaire Drive in Huntington. Currently operated as Hilaire Rehab and Nursing. Department and committee recommend approval with a condition and contingencies. Application 222260B, Oxford Nursing Home in Kings County. Relocate the facility from 144 South Oxford Street, Brooklyn to a new building to be constructed at 2832 Linden Boulevard in Brooklyn and transfer 15% ownership interest from one deceased member to two existing members. The department here recommended approval with conditions and contingencies as did the committee. Changes of ownership here for Home Health Agency licensure. 222103E, Lynn Care of New York Inc and with a broad geographic service area transferring 100% ownership interest from the current owner to a new shareholder LLC. Department and committee recommended approval. Application 222140E, American Outcomes Management LP, again transferring 100% partnership interest from the current partners to a new LLC partner. Department and committee recommend approval. Application 231216E, Tanglewood Manor Inc a broad service area noting an interest by Dr. Watkins. Transferring 100% ownership interest to a new shareholder LLC. Department recommends approval as did the committee. 232021E, Ideal Care SP LLC a broad geographic service area. Transfer 73% ownership interest from one withdrawing member and one existing member to two existing members and one new member. Department recommends approval as did the committee. I'll make a motion for that batch.

Mr. Kraut Have a motion.

Mr. Kraut A second Mr. Thomas.

Mr. Kraut Any questions?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Robinson Thank you.

Mr. Robinson These are certificates of amendment for the certificate of incorporation. Lake Shore Hospital Foundation Inc. Department and committee recommend approval. Open Door family Medical Care Inc. Department and committee recommend approval. Certificates of amendment of the Articles of Organization for Pontiac Nursing Home LLC. Department and committee recommend approval. And recently stated Certificate of Incorporation for the Guidance Center of Westchester Inc. Department and committee recommend approval. I move that batch.

Mr. Kraut I have a motion.

Mr. Kraut I have a second, Mr. Thomas.

Mr. Kraut Any questions?

Mr. Kraut All those in favor?

All Aye.

Mr. Kraut Opposed?

Mr. Kraut Abstentions?

Mr. Kraut The motion carries.

Mr. Robinson That concludes the report of the Establish and the Project Review Committee.

Mr. Kraut Thank you very much, Mr. Robinson. Very efficiently done.

Unknown Take a breath.

(Laughing)

Mr. Kraut Nobody go anywhere if you can hold on. We are going to go into an Executive Session in a moment to discuss a health personnel matter. I want to talk about the retreat for a second to give you a sense of it. It's scheduled for the evening of May 8th, where we would arrive and have dinner and have a speaker. I'll talk a little about that in a moment. Spend the entire day on Thursday starting at about breakfast going to the end of day. The issue is what do we kind of focus in on and use this productively? There are so many subjects to speak about just look at today's discussion. Recognizing this is public health and health planning. There are two things. One, we are going to spend time on public health and the prevention agenda in the course of a meeting. I promised one of the

meetings has to go over the things Dr. Boufford and Dr. Bauer spoke about. The second is we're going to come back and look at health planning and the recommendations here. Knowing those things are going to be discussed in a meeting, I kind of move those to the side. If you remember, we've been trying to hold a retreat for quite a bit of time. A lot of you wrote to me and commented as we started thinking about the next one. I had all your comments from the previous ones, which I reviewed. There was a consensus, at least at the time is let's focus on issues that are going to come before us and that we've had trouble having... We've never had adequate time to understand. One of them is the changing nature of health care, the different models, the different organizational structures, the different governance structures. Dr. Berliner gave a great talk many years ago about all these changes that were occurring. I think we would start with a speaker. I don't know if it'll be Dr. Berliner, but, you know, maybe. He volunteers. He's cheap at least, or inexpensive.

(Laughing)

Mr. Kraut You know, the other thing is the Commissioner is going to be joining us and obviously wants to talk about the policy agenda for the Department of Health and the role of the PHHPC. One of the things that we approved many years ago and we've never gotten feedback on...and in light of certain the hospital closure activity in our marketplace is the evolution of the kind of freestanding emergency departments and they're evolution. Because you've also approved them with beds and you've approved them with other services attached thinking that we kind of review the regulatory framework, but also invite in two or three operators, some downstate, and make sure we have rural, so we see different dimensions. Ms. Monroe kind of made this a really important theme. She's absolutely right. Just don't come and talk to us. We want to make the presentations tight and then let us ask questions and get involved in what the implications might be for future projects that are coming our way or, frankly, regulatory reform, which I'll come back to in a moment. The second issue is the issue of aging, but not as wide ranging as Mr. Herbst provided. I mean, we have struggled with long term care projects coming in here, specifically character and competence. The structure that's happening, the current looking and investigations that are going on, not to say we're going to talk about the investigations, but they've raised a lot of issues. How is that going to come back here when we look at establishment into the future? To structure a conversation about that. I think the Medicaid waiver, as you heard today has far reaching consequences, whether from now until May I don't know if much will change from what Mr. Bassiri said, but really focusing in on those aspects of the waiver that have implication in regulation or health equity. I think the department and some of the staff have to kind of work to focus the question. I think for us to sit and not have a conversation about how we're bridging the equity issue from the regulatory framework. Dr. Soffel brought up the health equity impact. We may have one by then. It may raise issues of the process we're going to use. I'm not sure exactly how we would do that, but I think that merits conversation. Spend the last two hours, if this is structured correctly to go through some of the regulatory reforms that have been proposed in CON and the operations of the council. We have new mandatory members that are supposed to be appointed. I doubt they'll be appointed by the time we meet, but if they are identified. I'd certainly invite them as guests, as we would members of the public so they kind of here this. Spend the balance of time on what's focusing the PHHPC agenda for the upcoming year to eighteen months. For us to look at things that we've said, this is like ridiculous. We should change this rule or regulation and try to have stuff for us to read beforehand, focus the questions that we're going to try to come out so we're clear about at the end of this agenda. What we had done last time is we created an agenda of items that we wanted to look at during following the retreat and then we ran into COVID. COVID

opened up a lot of issues. What I would like to do is I need to have more conversation with the department, because I've gotten some feedback but not broad. I'll reduce this in a note to everybody to kind of comment and give out a draft agenda. I'm very mindful of what Ms. Monroe said is we don't want just people talking to us without the opportunity to discuss among ourselves. How does that feel as a good starting point?

Mr. Kraut Dr. Bennett.

Dr. Bennett as I listen to what you said, I'm trying to think of how much time all that's going to take.

(Laughing)

Mr. Kraut Yes, I've worked out some timing issues.

Dr. Bennett Talking about a lot of things.

Mr. Kraut Well, one of them may drop out.

Dr. Bennett Question without any firm opinion. Is it too much in one day?

Mr. Kraut Well, I honestly I've heard myself say it and as I said it, I think it's too much. I'd rather on the side of leaving time for conversation than packing this. If you find this beneficial, we might be able to have a second retreat without necessarily having an overnight, because there is, you know, obviously an expense and logistics to do this. If we find that if we then say that then what we need is part of our agenda setting a kind of a Spring and Fall meeting, then that's what we do.

Dr. Boufford One, I think it sounds like you've touched on the key points. I think there is one other source of information which might be areas we've worked on in the past that didn't go anywhere. I think some of the world is changing, but this sort of integration, the Health Planning Committee had done work on integration of behavioral health and sort of physical health care and dealing with the regulatory implications of that or legislative implications. It kind of hit the wall at that point. There's still a lot of conversation. Some of these pilots are getting over that barrier. I think the issue of routine questions of why we can't do better there. Revisiting that that happened. That was one thing. I'll think of the other one in a minute.

Mr. Kraut To that point actually---

Dr. Boufford Dr. Boufford speaking away from mic.

Mr. Kraut Yeah.

Dr. Boufford --- I think.

Mr. Kraut Actually, I think Dr. Lim, the most recent exchange on the regulatory framework to permit this to happen. During COVID we had tremendous flexibilities to do things. We lost those. Some of those need to come back. I think within the context of regulatory flexibility may be looking at how you try to do that. Again, we have to just the timing.

Mr. Kraut Dr. Strange.

Dr. Strange I think there's a lot on that agenda. One of the overarching elements of this whole thing and the commission brought this up is the workforce issue. Because none of this can be accomplished without workforce being addressed in this whole thing.

Mr. Kraut Again, I'm trying to focus the things under our purview. This council every year has made a statement that what we would love to do is have a joint task force with state education to address those issues. I would absolutely endorse that if there was a practical pathway to do it. I think that has a legislative directive to do. Maybe that's what comes out of our agenda setting is that this becomes a high priority issue for us to not be passive, but maybe to be more focused in advocacy.

Mr. Kraut Yes, Dr. Berliner and Dr. Kalkut and then Dr. Soffel.

Dr. Berliner I must say that I stand behind no one in my support for public health and the public health agenda and the public health part of PHHPC.

Mr. Kraut Right.

Dr. Berliner We do have a health planning component also that doesn't directly relate to public health, although it's adjacent to it. What we found during COVID was that our health system in New York State was both fiscally and structurally unprepared for a pandemic. To my knowledge, and I may be wrong about this. If it happens tomorrow, we're back in the same position. If it's not a respiratory condition, we may be in even worse condition. I think it would be useful for us to discuss what could New York do ro deal with a potential pandemic? Does it need more beds? Does it need different beds? Does it need different health care settings? This directly relates to workforce. Y

Mr. Kraut Like I said, I just fill up days.

Dr. Berliner Absolutely. We can look at the small stuff, but we should also kind of not ignore the big stuff.

Dr. Kalkut I agree that what you've already went through is probably too much. I'll just pile on for a moment. Came up a couple of weeks ago and I think it's come up repeatedly is the technology and space requirements things moving into the ambulatory space. Surgery centers we talked about two weeks ago, but we've talked about before. What's happening with DNTCs. Again, I think would be important. Maybe that's in phase two or the second day or the fourth day or the two weeks.

(Laughing).

Dr. Kalkut I think all of that and I think the technology is going to drive this further and further out of the hospital into the community.

Dr. Soffel Thank you.

Dr. Soffel As the newest member of the council until we get our new members, I want to sort of reflect on what has been the most challenging and frustrating for me as I have learned the role of this council. It's kind of interrelated. The first half of it is how the department defines need when we are looking at Certificate of Need and that that's in many cases a kind of mushy, not terribly well defined exercise that especially as we see

emerging types of businesses coming out into the health care sphere that we don't have a good criteria for evaluating whether those services are actually needed and how they reflect and respond to communities. Sort of the flip side of that is we look at each Certificate of Need on its own. We don't seem to have an opportunity to step back and look at a bigger picture, a broader context. Where is the health care delivery system in New York State going? Is that where we as a council believe it should be going? How do we affect that process of change? I don't quite know where that goes in the agenda, but it feels to me like how PHHPC can effectively respond to changes in the delivery system and provide our wisdom and insight into where it should be going.

Mr. Kraut I think you've expressed the struggle we've had. I mean, it's not just being a new member. I mean, we've always had to contend with that, but it is an issue. That's why I'm trying to focus it on areas that we absolutely have impact as opposed to where we want to have impact. That's the challenge within the time frame. It's not to say we wouldn't take that up. I think that's our objective long term.

Mr. Kraut Dr. Boufford.

Dr. Boufford I want to go back to Howard's intervention on emergency preparedness, because we spent a lot of time with all these repeated emergencies whatever's. Just going back again to what we have done at one point when we did a sort of review with our colleagues from Primary Care, Public Health and others around COVID response. The results of that review were that it was totally hospital focused. There were other issues that should have been dealt with. I am assuming that there has been an after-action discussion which we've had not reported to us. It might be just to bring Howard's point concretely. It could be in one of these meetings. It doesn't have to be on the retreat. I think we haven't heard the after-action results of what happened as a consequence of what we learned from COVID about planning for the next time?

Mr. Kraut I think you'll find that at least one aspect of the system, the kind of the emergency first point to contact drills is pretty ready if that happens again. The issue is what we don't control is the government's response to it. I even suspect that'll change relative to other.

Mr. Kraut I'm going to get it out. You'll have an opportunity. I'll reflect on some of the comments. I'll send something in draft once I've had an opportunity to sit with the department.

Mr. Kraut I got to move on because we're going to lose. We have to make a vote.

Mr. Kraut The Ad Hoc Committee to lead the State Health Improvement Plan is going to convene in February on the 22nd in Albany. The next regularly scheduled committee day is March 28th. The full council is going to convene on April 11th. Both meetings again will be held in Albany.

Mr. Kraut I'd like to adjourn the public portion of the Public Health and Health Planning council meeting and have a motion to adjourn and then convene an Executive Session to consider a health personnel matter.

Mr. Kraut May I have a motion?

Mr. Kraut I have a second.

Mr. Kraut All those in favor?

Mr. Kraut We're going to adjourn the public session.

Mr. Kraut We are now going to go into Executive Session.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law section 2803, sections 405.4 and 405.6 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraph (4) of subdivision (b) of Section 405.4 is amended to read as follows:

The hospital shall have an organized medical staff that operates under bylaws approved by the governing body.

* * *

(b) Organization.

* * *

(4) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with the provisions of this Part and the New York State Public Health Law. Following the initial appointment of medical staff members, the medical staff shall conduct periodic reappraisals of its members, on at least[,] a [biennial] triennial basis.

Subparagraph (i) of paragraph (7) of subdivision (b) of Section 405.6 is amended to read as follows:

(b) The activities of the quality assurance committee shall involve all patient care services and shall include, as a minimum:

* * *

(7) the committee shall oversee and coordinate the following:

(i) the establishment of a medical, dental and podiatric staff privileges review procedure through which credentials, physical and mental capacity, and competence in delivering health care services are reviewed at least [biennially] triennially as part of an evaluation of staff privileges and in accordance with section 405.4 of this Part. These procedures shall include the collection of the following information from a physician, dentist or podiatrist prior to granting or renewing professional privileges or association in any capacity with the hospital:

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 2803 of the Public Health Law (PHL) authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities, including hospitals.

Legislative Objectives:

PHL Article 28 assures the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. Specifically, PHL section 2800 specifies that "hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article."

PHL section 2803(2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Needs and Benefits:

The proposed regulations will benefit Article 28 general hospitals by lengthening the requirement to review the credentials of medical staff from every two years to every three years, which will reduce administrative burdens and provide consistency by aligning with a recent revision by The Joint Commission to its credentialing and privileging standards applied to its Advanced Diagnostic Imaging, Ambulatory Surgical Center, Critical Access Hospital, and Hospital accreditation programs.

Costs for Regulated Entities:

There are no anticipated costs to regulated parties (PHL Article 28 general hospitals), insofar as the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Cost to State and Local Government:

There are no anticipated costs to regulated parties, including general hospitals owned and operated by State or Local governments, insofar as the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Cost to the Department of Health:

There are no anticipated costs to the Department of Health.

Local Government Mandates:

This regulation does not impose a local government mandate.

Paperwork:

Regulated entities will be required to maintain documentation that they have satisfied the minimum recredentialing review of medical staff as articulated in the proposed regulations.

However, the proposed regulations do not require new or additional paperwork requirements, insofar as existing regulations at 10 NYCRR sections 405.4 and 405.6 currently require Article 28 general hospitals to maintain records relating to their review of medical staff qualifications; the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Duplication:

The proposed regulation does not duplicate any federal, state, or local law.

Alternatives:

Alternatives include not amending the regulations or requiring a recredentialing period of a length other than every three years (triennially). However, the Department finds that neither alternative is viable. The proposed regulations align with a recent change by The Joint Commission to revise its credentialing and privileging standards applied to its Advanced Diagnostic Imaging, Ambulatory Surgical Center, Critical Access Hospital, and Hospital accreditation programs. Therefore, the Department finds that the triennial recredentialing timeframe proposed in these regulations—as opposed to the current (biannual) or an alternative timeframe—will provide consistency to regulated facilities, as it will align with standards applied by this national hospital accreditation organization to many of the Article 28 general hospitals in New York State.

Federal Requirements:

Federal Conditions of Participation at 42 CFR 482.22(a)(1) require medical staff to "periodically conduct appraisals of its members." The federal Centers for Medicare & Medicaid Services (CMS) has stated in a letter to The Joint Commission that "[p]eriodic review would be

consistent with local laws or national practice." Therefore, the proposed regulatory requirement for triennial reviews is consistent with existing federal regulation.

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

Contact Person: Ms. Katherine E. Ceroalo
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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS

No Regulatory Flexibility Analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, nor does it require any new reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or new, significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendments, that it will not have an adverse impact on jobs and employment opportunities.

SUMMARY OF EXPRESS TERMS

The regulatory proposal would repeal and replace all sections within Part 16 of Title 10 of the New York Codes, Rules and Regulations (NYCRR), as described in more detail below.

Section 16.1 is updated to correct references to other agencies and persons exempted under Title 10 of the Code of Federal Regulations (CFR) Part 30.

Section 16.2 is updated to include numerous new definitions used in 10 CFR Part 30, as well as other definitions related to new technologies, updated units and clarification of terms.

Section 16.4 updates appendix references, including changing the reference from 10 NYCRR Part 16 to application sections within 10 CFR Part 30.

Section 16.5 updates responsibilities for radiation safety to include acceptance testing and annual program review requirements.

Section 16.6 makes updates to the requirements for evaluating prior occupational doses and removes provisions on planned special exposures. The term “eye dose” is replaced by “lens dose.”

Section 16.7 updates dose limits for members of the public to reflect current Title 10 CFR references and outdated language is removed or updated.

Section 16.10 is amended to update inspection schedules, add Certified Radiation Equipment Safety Officer (CRESO) program requirements, and update requirements for surveys and testing of sealed sources.

Section 16.11 is updated to reflect changes in terminology for personnel monitoring and to clarify dose limits.

Sections 16.12, 16.13 and 16.15 are all updated to reflect 10 CFR Part 30 references instead of references to 10 NYCRR Part 16, as well as to clarify the actual language and phrasing used within these sections.

Section 16.14 is updated to require recording of high patient doses from fluoroscopy and notification of referring physician and instructions to patient.

Sections 16.16 and 16.17 are updated for compatibility with 10 CFR Part 30 requirements.

Section 16.19, concerning limitations on application of radiation to humans, is updated to reflect changes in the use of radioactive materials especially therapeutic sources.

Section 16.22 is updated to remove the requirement for mammography screening programs to teach breast self-examination.

Section 16.23 is updated to require quality assurance (QA) programs for advanced modality dental and podiatry, to require radiation safety policies regarding patient fluoroscopy doses and neonatal imaging, to update specifications for modern imaging modalities, and to update breast imaging QA requirements.

Section 16.24 is updated to reflect updates to QA requirements and verification of radiation therapy treatments.

Section 16.26 is updated to incorporate by reference the current federal regulation from the U.S. Nuclear Regulatory Commission (NRC).

Sections 16.40 and16.41 are updated to reflect new fee schedules and to incorporate NYS Department of Labor (DOL) fee categories.

Section 16.50 is updated to correctly reference the New York City Department of Health and Mental Hygiene (NYC DOHMH), change registration periods to allow more flexibility, and include commercial requirements previously listed within DOL regulations.

Section 16.51 is updated to include several items in the prohibited uses of radiation equipment, and half-value layer tables were updated to be current with federal manufacturing requirements (21 CFR Part 1020) for equipment listed in sections 16.52 through 16.70 of Title 10 of the NYCRR.

Sections 16.52, 16.54 and 16.55 are updated to include specifications for hand-held units and Cone Beam Computed Tomography (CBCT) as well as updates to filtration requirements. Requirements for gonadal shielding have also been removed.

Section 16.53 is updated to include changes for handheld intra-oral radiographic equipment.

Section 16.58 is updated to include new specifications for display of air kerma and minimum source to skin distance, to be consistent with federal manufacturing requirements (21 CFR Part 1020).

Sections 16.60 and 16.61 are updated to reflect current technologies and therapy equipment operated at potentials over and below 60 kV.

Section 16.65 is a new section regarding CBCT quality assurance, physicist testing, and accreditation requirements.

Section 16.101, concerning licensure, is updated to incorporate references to the CFR. Although no additional requirements are being added, elements of 10 CFR Part 31 and the Appendices to Part 16 are now included herein.

Section 16.102 is updated to add a paragraph on authorizing the Department to inspect a facility prior to the issuance of a license and adds a paragraph requiring an emergency plan for licensees that possess large amounts of dispersible radioactive material. This was previously codified in DOL regulations under 12 NYCRR Part 38. This section also adds conditions for consortiums to share accelerator produced isotopes.

Section 16.103, concerning licensing requirements for radioactive materials, incorporates by reference various provisions within 10 CFR Parts 30, 40, and 70 for licensing requirements. Currently these requirements are only incorporated into license conditions but not NYS regulations.

Section 16.104 adds requirements on portable gauge security, consortiums, and breakthrough limits for generators.

Section 16.109 adds reciprocity agreement provisions with other Agreement States, which were previously codified in DOL regulations within 12 NYCRR Part 38. This new section will also allow a licensee to pay a fee to work in New York for up to 180 days each year, instead of only allowing licensees to work 30 days each year but at no charge.

Section 16.112 is updated to add requirements for increased security for certain amounts of radioactive material, as required by 10 CFR Part 37.

Sections 16.113 and 16.114 add requirements for decommissioning and financial assurance.

Section 16.123 updates medical use requirements for specific licenses for certain medical uses of byproduct materials, to be compatible with Federal regulations.

Section 16.124 is a new section that adds manufacturing requirements for licenses to manufacture or transfer certain items containing radioactive material.

Section 16.125 is a new section that adds additional requirements for the manufacture, preparation or transfer for commercial distribution of medical drugs containing radioactive material.

Section 16.126 adds a new requirement for sealed source and device registration.

Section 16.127 adds a new section governing licenses for industrial radiography as well as radiation safety requirements for industrial radiographic operations.

Section 16.128 adds a new section for well logging.

Section 16.129 adds a new section for panoramic irradiators.

Pursuant to the authority vested in the Commissioner of Health by section 7 of Part B of Chapter 58 of the Laws of 2006, Part 38 of Title 12 (Labor) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby repealed, and pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 225 of the Public Health Law, sections 16.0 through 16.200 of Part 16 of Title 10 (Health) of the NYCRR are hereby repealed and replaced, to be effective upon filing a Notice of Adoption in the New York State Register, to read as follows:

Part 16 - Ionizing Radiation

Section 16.0 Introductory note.

This Part applies to all radiation equipment and radioactive material within the jurisdiction of the New York State Department of Health. Sections of this Part set forth under the heading "General Provisions" (sections 16.1-16.26) contain provisions applicable to radiation equipment operators and persons in possession of radioactive materials, including general radiation protection requirements.

Sections of this Part set forth under the heading "Radiation Equipment" (sections 16.50-16.63) contain the registration provisions for radiation equipment and general and additional radiation protection requirements applicable only to specific radiation equipment.

Sections of this Part set forth under the heading "Licensing of Radioactive Materials" (sections 16.100-16.123) contain the licensing provisions for radioactive materials, i.e., byproduct

material, source material, special nuclear material in quantities not sufficient to form a critical mass, naturally occurring radioactive materials, and accelerator-produced radioactive material. Section 16.150, "Radon testing and reporting", contains provisions applicable to firms performing radon measurements and mitigations in the State of New York.

Section 16.200, "Material incorporated by reference," provides a list of federal rules and regulations also related to the regulation of ionizing radiation.

GENERAL PROVISIONS

16.1 Applicability and inapplicability of this Part.

(a) Applicability. Except as otherwise provided in subdivision (b) of this section, this Part applies to any person who transfers, receives, possesses or uses any radiation source in this State. The types of installations to which this Part is generally applicable are described in the definition of "radiation installation" in section 16.2 of this Part.

(b) Inapplicability.

(1) This Part does not apply to any common or contract carrier operating within this State to the extent that such carrier is subject to regulation as provided for by law by the United States Department of Transportation or other agencies of the United States or agencies of the State of New York, other than the Department of Health, having jurisdiction.

(2) The licensure requirements contained in sections 16.100 through 16.110 and sections 16.120 through 16.123 of this Part shall not apply in a county, part-county or city health district having a population of more than 2,000,000 people, provided that such health district has established its

own substitute licensure requirements with respect to radiation sources located within such health district and transferred, received, possessed or used by persons other than the State and its institutions or other facilities and provided that such substitute licensure requirements are submitted to the State Department of Health prior to their effective date and are acceptable to the State Department of Health as consistent with the corresponding requirements of this Part.

(3) Persons described in 10 CFR 30.12 & 30.13, are exempt from this Part to the same extent provided for in 10 CFR 30, as revised and implemented in full on October 16, 2020.

(4) All discharges of wastes to the environment are subject to the provisions of the Environmental Conservation Law with particular reference to Article 17 (water pollution control), Article 19 (air pollution control) and Article 27 (collection, treatment and disposal of refuse and other solid waste) thereof, and to all pertinent rules and regulations of the State Department of Environmental Conservation, including its permit requirements.

(c) Communications. Except as otherwise provided for in this Part or authorized by the department, all applications, notifications or other communications filed pursuant to this Part shall be addressed to the New York State Department of Health, Bureau of Environmental Radiation Protection, Empire State Plaza, Albany, NY 12237, by telephone (518) 402-7550, facsimile (518) 402-7554 or email to berp@health.ny.gov. Registrants and licensees that are authorized to operate pursuant to Article 28 of the Public Health Law may comply with adverse event reporting required by this Part by electronic filing with the department via the New York Patient Occurrence and Tracking System (NYPORTS).

16.2 Definitions.

(a) As used in this Part, unless the context indicates otherwise, the terms below shall have the following meanings:

(1) “A_1” means the maximum activity of special form radioactive material permitted in a Type A package. “A_2” means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed or may be derived in accordance with the procedure prescribed in 10 CFR 71 appendix A, as revised and implemented in full on November 30, 2021.

(2) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(3) "Accelerator-produced radioactive material" means any material made radioactive by a particle accelerator.

(4) "Acceptance Test" is an evaluation of medical equipment and software to verify proper function prior to clinical use. Acceptance testing includes but is not limited to image quality, radiation dose, and radiation protection.

(5) "Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

(6) "Activity" means the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(7) “Acute” means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

(8) "Adult" means an individual 18 or more years of age.

(9) "Agreement State" means any state with which the United States Nuclear Regulatory Commission or the United States Atomic Energy Commission has entered into an effective agreement under section 274b of the Atomic Energy Act of 1954, as amended.

(10) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(11) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:
(i) in excess of the derived air concentrations (DACs) specified in appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002, or
(ii) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(12) “Air kerma” or “AK” means kerma in air (see definition of Kerma (under paragraph (99) of this subdivision.)

(13) “Air kerma rate” or “AKR” means the air kerma (see definition of Kerma (under paragraph (99) of this subdivision) per unit time.

(14) “Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(15) “ALARA” (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this Part as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

(16) “Alert” means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

(17) "Aluminum equivalent" means the thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.

(18) "Annual limit on intake" or “ALI” means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002.

(19) "Annually" means either at intervals not to exceed 1 year or, once per year at about the same time each year (plus or minus 1 month).

(20) "Assigned Protection Factor” or “APF” means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly trained and fitted users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(21) "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators (SAR’s) and self-contained breathing apparatus (SCBA) units.

(22) “Authorized licensing authority” means the New York State Department of Health, the New York City Department of Health and Mental Hygiene, an Agreement State, or the United States Nuclear Regulatory Commission.

(23) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material (which have not been technologically enhanced) including radon (except as a decay product of source or special nuclear material); and global radioactive fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from radioactive materials (source, byproduct or special nuclear material) regulated by an authorized licensing authority.

(24) "Becquerel" or “Bq” means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (s^{-1}).

(25) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this Part, "radiobioassay" is an equivalent term.

(26) "Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and

adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(27) “Broad scope license” or “specific license of broad scope” means a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purposes. This type of license is subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee’s radiation safety committee.

(28) “Byproduct material” means:

(i) any radioactive material, except special nuclear material, yielded in, or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(ii) the tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes; however, underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(iii) any discrete source of radium-226 produced, extracted, or converted for extraction for use for a commercial, medical, or research activity;

(iv) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity;

(v) any discrete source of naturally occurring radioactive material, other than source material, that is extracted or converted after extraction for use in a commercial medical or research activity that the Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security is extracted or converted after extraction for use in a commercial, medical, or research activity.

(29) "Calendar quarter" means not less than 12 consecutive weeks or more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method used to determine calendar quarters for purposes of this Part except at the beginning of a calendar year.

(30) “Calibration” means the determination of:

(i) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(ii) the strength of a source of radiation relative to a standard.

(31) "C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship.

Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

(32) “Certified radiation equipment safety officer" or “CRESO” means an individual who meets the requirements in section 16.10(d) of this Part and who holds an unexpired certificate as a radiation equipment safety officer issued by the department.

(33) "CFR" means Code of Federal Regulations.

(34) "Class" or “lung class” or “inhalation class” means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days.

(35) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(36) "Collimator" means a device or mechanism by which the x-ray or gamma-ray beam is restricted in size.

(37) “Commissioner" means the Commissioner of Health of the State of New York.

(38) "Committed dose equivalent" or "$H_{T,50}$" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(39) "Committed effective dose equivalent" or "$H_{E,50}$" is the sum of the products of the weighing factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

(40) "Cone" means a device used to indicate beam direction and to establish a minimum source-surface distance. It may or may not incorporate a collimator.

(41) "Consortium" means an association of medical use licensees and a positron-emission tomography (PET) radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a medical facility.

(42) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

(43) “Controlled area” means any area the access to which is controlled for the purpose of protecting individuals from exposure to radiation and radioactive material but shall not mean any area used as residential quarters.

(44) "Controlled area" as used in this Part is synonymous with "restricted area."

(45) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(46) "Curie" means a unit of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations per second (2.22×10^{12} disintegrations per minute).

(47) "Declared pregnant worker" means a person who has voluntarily informed the licensee or registrant, in writing, of their pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant worker withdraws the declaration in writing or is no longer pregnant.

(48) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.

(49) "Decommissioning plan" means a written document that includes the licensee's planned procedures and activities for decommissioning of the facility or site.

(50) "Deep dose equivalent" or "H_d" which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(51) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(52) "Department" means the New York State Department of Health and includes its duly authorized representatives, except for the reference to 10 CFR 30.12, as revised and implemented on November 30, 2021, in section 16.1 of this Part, for which Department means the U.S. Department of Energy.

(53) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 percent by weight of the total uranium present.

(54) "Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of this Part, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in table 1, column 3, of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002.

(55) "Derived air concentration-hour" or “DAC-hour” means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may use 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(56) “Discrete source” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(57) "Diagnostic type protective tube housing" means x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed 1 millisievert (100 milliroentgens) in one hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.

(58) "Diaphragm" means a device or mechanism by which the x-ray or gamma-ray beam is restricted in size.

(59) “Disposable respirator” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator

are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(60) “Distinguishable from background” means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

(61) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. For purposes of this Part, "radiation dose" is an equivalent term.

(62) “Dose area product” or “DAP” is the absorbed dose multiplied by the area irradiated. Units are expressed as $Gy \cdot cm^2$.

(63) “Dose commitment” means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

(64) "Dose equivalent” or “H_T” means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(65) "Dose limits" means the permissible upper bounds of radiation doses established in accordance with this Part. For purposes of this Part, "limits" is an equivalent term.

(66) "Dose monitor unit" or "DMU" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(67) "Dosimetry processor" means a person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(68) "Effective dose equivalent" or "H_E" is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).

(69) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(70) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(71) “Explosive materials” means any chemical compound, mixture, or device which produces substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(72) “Exposure” means either:

(i) being exposed to ionizing radiation or to radioactive materials; or

(ii) the quotient of dQ by dm where “dQ” is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “dm” are completely stopped in air. The special unit of exposure is the roentgen R. One roentgen is equal to 0.000258 coulomb per kilogram of air.

(73) “Exposure rate” means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

(74) “External dose” means that portion of the dose equivalent received from any source of radiation outside the body.

(75) “Extremity” means hand, elbow, arm below the elbow, foot, knee and leg below the knee.

(76) "Facility" means the location within one building, vehicle, or under one roof and under the same administrative control:

(i) at which the possession, use, processing or storage of radioactive material is or was authorized; or

(ii) at which one or more radiation-producing machines or radioactivity-inducing machines are installed or located. "Facility" may also mean multiple such locations at a site or part of a site.

(77) "Filter" means material placed in the useful beam to change beam quality in radiation producing equipment.

(78) "Filtering facepiece (dust mask)" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(79) "Final status survey" means the survey of the facility or site after decommissioning activities have been completed during which the determination is made by the licensee that the facility or site meets the department’s release criteria.

(80) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(81) "Fit Test" means the use of a protocol to qualitatively evaluate the fit of a respirator on an individual.

(82) “Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities” means nuclear reactors, nuclear fuel reprocessing plants, uranium

enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

(83) “General License” means a license issued pursuant to the terms and conditions of sections 16.101 or 16.103 of this Part. General licenses are effective without the filing of an application with or the issuance of a licensing document by the department.

(84) “Gray” or “Gy” means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram. One gray is equal to 100 rad.

(85) “Half value layer” or “HVL” means the thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the exposure rate by one-half.

(86) “Health officer having jurisdiction” means the commissioner or the commissioner’s designee, or the chief executive officer of the appropriate county or part-county health department or the New York City Department of Health and Mental Hygiene, or the director of a state, regional, area or district office of public health.

(87) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(88) "High radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose

equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates. For purposes of this Part, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.

(89) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(90) “Human use” as used in this Part is equivalent to “medical use”.

(91) “Image receptor” means any device which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformation. Image receptors may include but are not limited to radiographic film with or without cassette, a phosphorescent screen, a computed radiography system (CR), a direct digital radiography system (DR), or scintillation camera.

(92) “Individual” means any human being.

(93) "Individual monitoring" means the assessment of:

(i) dose equivalent:

(*a*) by the use of individual monitoring devices or

(*b*) by the use of survey data; or

(ii) committed effective dose equivalent:

(*a*) by bioassay or

(*b*) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

(94) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this Part, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescent dosimeters (OSLDs), pocket ionization chambers, and personal (lapel) air sampling devices.

(95) “Inherent filtration” means the filtration permanently in the useful beam: it includes the window of the x-ray tube and any permanent tube or source enclosure.

(96) “Inspection” means an official examination or observation including, but not limited to, reviews of records, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the department.

(97) “Interlock” means a mechanical, electrical or software barrier or device, arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(98) “Internal dose” means that portion of the dose equivalent received from radioactive material taken into the body.

(99) “Kerma” means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus K = dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

(100) “Kerma Area Product” or “KAP” is the air kerma multiplied by the corresponding X-ray beam cross-sectional area. Units are expressed as $Gy \cdot cm^2$.

(101) “Kilovolt” or “kV” means a unit of electrical potential equal to 1000 volts. “Kilovolt peak” or “kVp” means the crest value in kilovolts of the potential difference of a pulsating generator. When only one-half of the wave is used, the value refers to the useful half of the wave.

(102) “Lead equivalent” means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(103) “Leakage radiation” means all radiation coming from within the source or tube housing except the useful beam.

(104) "Lens dose equivalent" or “LDE” applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm2).

(105) "License" means a radioactive material license issued by the department in accordance with the regulations adopted by the department. There are two types of licenses: general and specific. Unless otherwise specified, the type of license referred to in this Part will be a specific license

(106) “Licensed material” means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by an authorized licensing authority.

(107) “Licensed Medical Physicist” or “LMP” means an individual who is authorized to practice medical physics in the appropriate subspecialty pursuant to article 166 of the Education Law. In addition, an “Authorized Medical Physicist” or “AMP” means a licensed medical physicist who meets the requirements of paragraph 16.123(b)(1) of this Part.

(108) “Licensee” means any person who is licensed by the department in accordance with this Part or one who possesses any radioactive material that is subject to the licensure requirements of this Part.

(109) “Limits” has the same meaning as dose limits as defined in paragraph (65) of this subdivision.

(110) "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(111) “Lost or missing licensed material” means licensed material whose location is unknown by the licensee. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot by readily traced in the transportation system.

(112) “Lot Tolerance Percent Defective” means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

(113) “Medical use” means the intentional internal or external administration of ionizing radiation to human beings under the order or direction and supervision of individuals specified in section 16.19 of this Part.

(114) “Member of the public” means any individual except when that individual is receiving an occupational dose.

(115) “Minor” means an individual less than 18 years of age.

(116) “Monitoring” means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this Part, radiation monitoring and radiation protection monitoring are equivalent terms.

(117) “Monitor Unit” has the same meaning as Dose Monitor Unit as defined in paragraph (66) of this subdivision.

(118) “Natural radioactivity” means radioactivity of naturally occurring nuclides.

(119) “Nationally tracked source” is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in appendix E of 10 CFR 20, as revised and implemented in full on December 19, 2002. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(120) "Negative pressure respirator (tight fitting) " means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(121) “Nonstochastic effect” means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of this Part, a “deterministic effect” is an equivalent term.

(122) "NORM" means any naturally occurring radioactive material. It does not include accelerator produced, byproduct, source, or special nuclear material.

(123) “Nuclear Regulatory Commission” or “NRC” means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

(124) “Occupational dose” means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, as revised and implemented on August 14, 2007, from voluntary participation in medical research programs, or as a member of the public.

(125) “Operator” means any person conducting the business or activities carried on within the radiation installation or having by law the administrative control of a radiation source whether as owner, lessee, contractor or otherwise.

(126) “Package” means the packaging, together with its radioactive contents, as presented for transport.

(127) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium as energies usually in excess of 1 MeV. For purposes of this definition, "accelerator" is an equivalent term.

(128) “Person” means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of the State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, but shall not include federal government agencies.

(129) “Personnel monitoring equipment” has the same meaning as individual monitoring devices, as defined in paragraph (94) of this subdivision.

(130) "Phantom" means an object behaving in essentially the same manner as components of human anatomy, in both material and shape appropriate for the purpose, with respect to absorption or scattering of the ionizing radiation in question.

(131) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(132) "Possess" means to acquire or take responsibility for radiation sources without regard for ownership.

(133) "Powered air-purifying respirator” or “PAPR” means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(134) “Professional practice" means the practice of medicine, dentistry, podiatry, osteopathy or chiropractic.

(135) “Professional practitioner” means any individual licensed or otherwise authorized under State Education Law to practice a profession.

(136) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(137) "Principal activity" means an activity authorized by the license which is essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activity incidental to decontamination or decommissioning are not principal activities.

(138) “Principal individual” means a person primarily or ultimately liable.

(139) “Protective apron” means an apron made of radiation attenuating material(s), used to reduce exposure to radiation.

(140) “Protective barrier” means a barrier of radiation attenuating materials(s) used to reduce useful beam and/or stray radiation to the degree required to assure compliance with sections 16.6 and 16.7 of this Part.

(141) “Protective glove” means a glove made of radiation attenuating material(s) used to reduce radiation exposure.

(142) "Public dose" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose, dose received from background radiation from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, as revised and implemented on August 13, 2007, or equivalent, or dose from voluntary participation in medical research programs.

(143) "Qualitative fit test” or “QLFT” means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

(144) “Quality factor” or “Q” means the modifying factor (listed in tables 1004(b).1 and 1004(b).2 of 10 CFR 20.1004, as revised and implemented on May 21, 1991) that is used to derive dose equivalent from absorbed dose.

(145) "Quantitative fit test" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(146) "Quarter" has the same meaning as Calendar Quarter, as defined in paragraph (29) of this subdivision.

(147) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray). One millirad equals 0.001 rad.

(148) "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of this Part, ionizing radiation is an equivalent term. Radiation, as used in this Part, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

(149) "Radiation Area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.
(150) "Radiation equipment" means any equipment or device that can emit radiation by virtue of the application thereto of high voltage.

(151) "Radiation installation" means a place, facility or mobile unit where radiation equipment, in operable condition or intended to be used, is located or used, or where radioactive material is

transferred, received, possessed or used including generally a hospital; medical, dental, chiropractic, podiatry, or veterinarian institution, clinic or office; industrial facility; educational institution; commercial, private or research laboratory performing diagnostic procedures or handling equipment or material for medical use; or any trucking, storage, messenger or delivery service establishment. Radiation installation shall include, whether or not it is specially stated above, any place, facility or mobile unit where radiation is applied intentionally to a human. The limits of the contiguous radiation installation area shall be as designated by the operator.

(152) “Radiation safety officer” shall mean a principal individual who, under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with section 16.5 of this Part and who is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program.

(i) For human use radiation equipment installations, the radiation safety officer (RSO) shall be:

(*a*) a professional practitioner as defined in section 16.2 of this Part, practicing within their professional practice as defined in this section; or,

(*b*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of radiation sources in the installation, or, an individual with equivalent training and experience as determined by the department.

(ii) For non-human use radiation equipment installations, the radiation safety officer shall be:

(*a*) a veterinarian for veterinary installations; or,

(*b*) a physicist certified by the American Board of Health Physics, the American Board of Radiology, or, an individual with equivalent training and experience as determined by the department; or,

(*c*) a researcher determined by the institution as qualified by training and experience for installations using only x-ray diffraction and fluorescence analysis equipment.

(iii) For licensed non-human use radioactive materials installations, the radiation safety officer shall be:

(*a*) an authorized user named on the radioactive materials license issued by this department; or,

(*b*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of use of radioactive material in the installation, or, an individual with equivalent training and experience as determined by the department; or

(*c*) an individual who, under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with section 16.5 of this Part and who is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program.

(iv) For a license that authorizes human use, the radiation safety officer shall be

(*a*) an individual that meets the training and experience requirements in paragraph 16.123(b)(10) of this Part; and

(*b*) an individual who is also:

(*1*) an authorized user named on the radioactive materials license issued by this department or;

(*2*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of use of radioactive material in the installation; or

(*3*) an individual with equivalent training and experience as determined by the department.

(153) “Radiation source” means any radioactive material or any radiation equipment.

(154) “Radioactive material” means any solid, liquid, or gas that emits radiation spontaneously.

(155) “Radioactivity” means the transformation of unstable atomic nuclei by the emission of radiation.

(156) “Radiobioassay” has the same meaning as bioassay, as defined in paragraph (25) of this subdivision.

(157) "Radon" means the radioactive noble gas radon 222.

(158) “Reference man” means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(159) “Registrant” means any person who is registered with the department or is legally obligated to register with the department pursuant to this Part.

(160) “Registration” means registration with the department in accordance with this Part.

(161) “Rem” is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem=0.01 sievert).

(162) “Research and development” means:

(i) theoretical analysis, exploration, or experimentation; or

(ii) the extension of investigative findings and theories of scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

(163) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee’s control. This includes all radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of this Part.

(164) “Respiratory protective device” means an apparatus, such as a respirator, used to reduce an individual’s intake of airborne radioactive material.

(165) “Restricted area” means any area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters. "Restricted area" as used in this Part is synonymous with "controlled area."

(166) “Roentgen” means the special unit of exposures. One roentgen R equals 2.58×10^{-4} coulombs per kilogram of air (see definition of Exposure (under paragraph (72) of this subdivision)).

(167) “Sanitary sewerage” means a system of public sewers for carrying off waste and refuse, but excluding sewage treatment facilities, septic tanks and leach fields owned or operated by the licensee or registrant.

(168) “Scattered radiation” means radiation whose direction has been altered during passage through matter. (It may have been modified also by a decrease in energy.)

(169) “Sealed source” means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the

most severe conditions which are likely to be encountered in normal use and handling.

(170) "Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration certificates, maintained by the Nuclear Regulatory Commission (NRC), that summarize the radiation safety information for sealed sources and devices, and describe the licensing and use conditions appropriate for the product.

(171) "Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(172) "Shallow dose equivalent" or "Hs", which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2).

(173) "Shutter" means an adjustable device fixed to the radiation source housing to intercept or collimate the useful beam.

(174) "SI" means an abbreviation of the International System of Units.

(175) "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(176) "Site" means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials.

(177) “Site area emergency” means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

(178) “Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

(179) “Source material” means:

(i) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(ii) ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

(180) “Source of radiation” means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

(181) “Source-skin distance” or “source-surface distance” means the distance measured along the central ray from the center of the front surface of the source (x-ray focal spot or sealed radioactive source) to the surface of the irradiated object.

(182) “Special form radioactive material” means radioactive material which satisfies the following conditions:

(i) it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(ii) the piece or capsule has at least one dimension not less than 5 millimeters (0.197 inch); and

(iii) it satisfies the additional requirements specified in section 71.4, Special form radioactive material, of 10 CFR 71, as revised and implemented in full on November 30, 2021 (see section 16.200 of this Part).

(183) “Special nuclear material” means:

(i) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(ii) any material artificially enriched by any of the foregoing but does not include source material.

(184) “Special nuclear material in quantities not sufficient to form a critical mass” means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum

of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(185) "Specific License" means a license for byproduct material issued pursuant to sections 102 through 123 of this Part. A specific license also means a similar license issued by the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission or any Agreement State.

(186) “State” means the State of New York, unless the context of this Part clearly indicates that a different meaning is intended.

(187) “Stochastic effect” means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of this Part, probabilistic effect is an equivalent term.

(188) “Stray radiation” means the sum of leakage and scattered radiation.

(189) "Supplied-air respirator" or "SAR" or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(190) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements or calculations of levels of radiation or concentrations of radioactive material present.

(191) "Therapeutic type protective tube housing" means:

(i) for x-ray therapy equipment not capable of operating at 500 kVp or above, an x-ray tube housing so constructed that the leakage radiation at one meter from the source does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential; or

(ii) for x-ray therapy equipment capable of operation at 500 kVp or above, an x-ray tube housing so constructed that leakage radiation at one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.

(192) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(193) “Total effective dose equivalent” or “TEDE” means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(194) “Unrestricted area” means an area, access to which is neither limited nor controlled by the licensee or registrant.

(195) “U.S. Department of Energy” means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and transferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

(196) “Unrefined and unprocessed ore” means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

(197) “Use” as used in radioactive materials licenses means to employ or apply radioactive materials for the licensed purpose. It shall include instruction of, and responsibility for, technical

and support staff members. It does not include training others in the techniques of use of radioactive materials for the purpose of qualifying for licensure. In licenses authorizing human use of radioactive materials “use” will also include:

(i) ordering or directing the administration of radiation of radioactive materials to humans, including the method or route of administration;

(ii) actual use of, or direction of, technologists or other paramedical personnel in the use of, radioactive material;

(iii) regular review of the progress of patients receiving therapy and modification of the originally prescribed dose as warranted by the patient's reaction to radiation therapy.

(198) “Useful beam” means the radiation that passes through the source or tube-housing port and the aperture of the collimating device when the exposure switch or timer is activated.

(199) "User seal check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check. For purposes of this Part “fit check” is an equivalent term.

(200) "Very high radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates. (Note: At very high doses received at high dose

rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

(201) "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in subparagraphs (ii), (iii), and (iv) of the definition of byproduct material set forth in this section.

(202) "Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive wastes.

(203) "Week" means 7 consecutive days starting on Sunday.

(204) "Weighting factor" or "W_T" for an organ or tissue means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12

Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[1]
Whole Body	1.00[2]

[1] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[2] For the purpose of weighting the external whole-body dose (for adding it to the internal dose), a single weighting factor, w_T=1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(205) “Whole body” means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(206) "Worker" means an individual engaged in activities under a license or registration issued by the department and controlled by a licensee or registrant but does not include the licensee or registrant.

(207) “Working level” or “WL” means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 130,000 MeV of potential alpha particle energy.

The short-lived radon daughters are, for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

(208) “Working level month” or “WLM” means an exposure to 1 working level for 170 hours. (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.)

(209) “Year” means the period of time beginning in January used to determine compliance with the provisions of this Part. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

16.3 Granting exemptions or variations. The department may upon either the application of any interested person or the department's own initiative, grant an exemption or variation from any requirement of this Part when the department finds that such exemption or variation will not result in an undue danger to life and property from radiation hazards.

16.4 Exemption of certain radiation sources from the requirements of this Part. Any person is hereby exempted from the requirements of this Part to the extent that such person transfers, receives, possesses, installs, operates or uses:

(a) Any of the radioactive materials~~,~~ or items containing radioactive material in accordance with the provisions in 10 CFR 30.14, 30.15, 30.18, 30.19, 30.20, 30.21(a), (b) and (d), 30.22(a), , all

as revised and implemented in full on October 16, 2020, and 10 CFR 40.13, as revised and implemented in full on January 14, 1961.

(b) Radiation equipment constructed so that it cannot emit radiation at a level greater than 0.005 mGy (0.5 milliroentgen) per hour, measured two inches or five centimeters from the surface, and averaged over an area of 1.55 square inches or 10 square centimeters as certified by the manufacturer of the device; provided, however, that such exemption shall not apply to the testing or servicing of such equipment during its production.

(c) Radiation equipment during its storage, shipment, retail sale or other similar use during which such equipment is not connected to a voltage source and does not emit radiation.

16.5 Responsibility for radiation safety. No person shall operate or permit the operation of a radiation installation, nor shall the person operate, transfer, receive, possess, or use or permit the operation, transfer, receipt, possession or use of any radiation source unless that person:

(a) achieves occupational doses and doses to members of the public as low as is reasonably achievable (ALARA). Such effort shall include, to the extent practicable, the use of procedures and engineering controls which are based on sound radiation protection principles;

(b) develops, documents, and implements a radiation protection program commensurate with the scope and extent of the radiation activities engaged in by the radiation installation. This program shall be designed to ensure compliance with the provisions of this Part;

(c) provides a radiation safety officer as described in section 16.2 of this Part. The radiation safety officer shall be delegated authority to ensure the implementation of this radiation protection program and shall be responsible for the day-to-day conduct of the program;

(d) provides for a radiation safety committee to administer the radiation protection program in hospitals, and broad scope licensees and in accordance with section 16.123(d) of this Part. The committee shall include the facility operator or a person with the authority to act on behalf of the facility operator, and representation from departments within the facility where radiation sources are used. The committee shall approve all uses of radiation-producing equipment and radioactive materials within the facility, shall review the activities of the radiation safety officer annually, and shall review the radiation protection program at least annually. The committee, or a subcommittee, shall also oversee the administration of a quality assurance program, as required by subdivision (e) of this section;

(e) provides a quality assurance program for diagnostic and therapeutic uses of radiation producing equipment and radioactive materials pursuant to sections 16.23, 16.24 and other applicable sections of this Part;

(f) ensures that all personnel involved in planning for or administering radiation doses to humans, or in the use of radiation producing equipment or radioactive materials for other purposes, are supervised, and are instructed as described in subdivision (c) of section 16.13 of

this Part, and are competent to safely use such radiation equipment or other radiation sources and services;

(g) ensures that radiation equipment is used only for those procedures for which it is designed;

(h) ensures that acceptance testing of all medical and chiropractic diagnostic equipment, and treatment and planning equipment for radiation therapy, and all associated software, is performed before first use of such equipment on humans by an individual competent to perform such testing and approved by a licensed medical physicist. Such testing will also be performed following reassembly or major upgrade; and

(i) conducts, or causes to be conducted, an annual review of the radiation protection program content and implementation.

16.6 Occupational dose limits.

(a) Occupational dose limits for adults

(1) No person shall transfer, receive, possess, or use any radiation source so as to cause any individual adult to receive an occupational dose from all sources of radiation that exceeds any of the following limits:

(i) An annual limit, which is the more limiting of:

(*a*) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(*b*) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.50 Sv (50 rem).

(ii) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are: [note that any reference to eye dose is equivalent to lens dose]

(*a*) A lens dose equivalent of 0.15 Sv (15 rem), and

(*b*) A shallow dose equivalent of 0.50 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

(2) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of the skin receiving the highest exposure.

(i) The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purposes of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of the individual monitoring are unavailable.

(ii) When a protective apron is worn pursuant to section 16.58 of this Part, by physicians during x-ray fluoroscopic procedures and monitoring is conducted as specified in section 16.11(b)(1) of this Part, the effective dose equivalent for external radiation may be determined for these individuals as follows:

(*a*) When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(*b*) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(3) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(4) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week. (*See* footnote 3 of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002).

(5) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. The licensee or registrant shall determine the occupational radiation dose received during the current year. In complying with this requirement, a licensee or registrant may accept a record of the occupational dose that the individual received during the current year, or from the individual's employer(s) for work involving radiation exposure during the past year, that discloses the nature and the amount of any occupational dose that the individual received during the current year.

(b) Compliance with requirements for summation of external and internal dose.

(1) If the licensee or registrant is required to monitor pursuant to both subdivisions (a) and (d) of section 16.11 of this Part, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to subdivisions (a) or (d) of section 16.11 of this Part, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph (2), and the conditions in paragraphs (3) and (4) of this subdivision. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(i) the sum of the fractions of the inhalation ALI for each radionuclide; or

(ii) the total number of derived air concentrations-hours (DAC-hours) for all radionuclides divided by 2,000; or

(iii) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50}, that is, $W_T H_{T,50}$ per unit intake for any organ or tissue.

(3) Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.
(4) Intake through wounds or absorption through skin. The licensee or registrant shall evaluate and account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this paragraph.

(c) Determination of external dose from airborne radioactive material.
(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud (*See* 10 CFR 20 appendix B, footnotes 1 and 2, as revised and implemented in full on March 14, 2023).
(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(d) Determination of internal exposure.
(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under section 16.11 of this Part, take any of

the following measurements as may be necessary for timely and appropriate detection and assessment of intake of radioactivity by individuals:

(i) concentrations of radioactive materials in air in work areas; or

(ii) quantities of radionuclides in the body; or

(iii) quantities of radionuclides excreted from the body; or

(iv) combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in section 16.26 of this Part, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

(i) use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and

(ii) upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(iii) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide (*See* 10 CFR 20, appendix B, as revised and implemented in full on March 14, 2023) to the committed effective dose equivalent.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in subparagraphs (ii) or (iii) of paragraph (1) of this subdivision, the licensee or registrant may

delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by sections 16.15(b) or 16.15(c) of this Part. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(i) the sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from 10 CFR 20, appendix B, as revised and implemented in full on March 14, 2023, for each radionuclide in the mixture; or

(ii) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

(i) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in subdivision (a) of this section and in complying with the monitoring requirements in section 16.11(d) of this Part; and

(ii) the concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

(iii) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(8) When determining the committed effective dose equivalent, the following information may be considered:

(i) In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(ii) For an ALI and the associated DAC is determined by the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in 10 CFR 20, appendix B, table 1, as revised and implemented in full on March 14, 2023. The licensee or registrant may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALIs, the licensee or registrant shall also demonstrate that the limit in clause (a)(1)(i)(b) of this section, is met.

(e) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in subdivision (a) of this section.

(f) Dose equivalent to an embryo/fetus.

(1) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant worker, does not exceed 5 mSv (0.5 rem). (*See* section 16.14(d) of this Part for recordkeeping requirements).

(2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant worker so as to satisfy the limit in paragraph (1) of this subdivision.

(3) The dose equivalent to an embryo/fetus shall be taken as the sum of:

(i) the deep dose equivalent to the declared pregnant worker; and

(ii) the dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant worker during the entire pregnancy period.

(4) If by the time the worker declares pregnancy to the licensee or registrant, the dose to the embryo/fetus exceeded 5 mSv (0.5 rem), the licensee or registrant shall be deemed to be in compliance with paragraph (1) of this subdivision if the additional dose equivalent to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

16.7 Radiation dose limits for individual members of the public.

(a) Dose limits for individual members of the public.

(1) Each licensee or registrant shall conduct operations so that:

(i) the dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 10 CFR 35.75, as revised and implemented on August 13, 2007, does not exceed 0.02 mSv (0.002 rem) in any one hour; and

(ii) the total effective dose equivalent to individual members of the public from the licensed operation, or registered equipment operation, does not exceed 1 mSv (0.1 rem) in a year, exclusive of dose contribution from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under

10 CFR 35.75, as revised and implemented on August 13, 2007, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with section 16.8 of this Part.

(2) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(3) Notwithstanding subparagraph (ii) of paragraph (1) this subdivision, a licensee may permit visitors to an individual who cannot be released, in accordance with 10 CFR 35.75, as revised and implemented on August 13, 2007, to receive a radiation dose greater than 0.1 rem (1 mSv), but not exceeding 0.5 rem (5 mSv) if the authorized user, as defined in section 16.123 of this Part, has determined before the visit that it is appropriate.

(4) A licensee or license applicant may apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(i) demonstration of the need for and the expected duration of operations in excess of the limit in subdivision (a) of this section;

(ii) the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit;

(iii) the procedures to be followed to maintain the dose as low as is reasonably achievable; and

(iv) any additional information requested by the department.

(5) The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

(6) If radioactive materials are released into the air or water by any person in such a manner that the radioactive materials may be reconcentrated in the environment or may be added to any other

radioactive materials released to the environment, the department may restrict the release by such person to assure that the limits set forth in this Part are not exceeded.

(b) Compliance with dose limits for individual members of the public.

(1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in subdivision (a) of this section.

(2) A licensee or registrant shall maintain records of measurements and calculations used to demonstrate compliance with the annual dose limit in subdivision (a) of this section.

(3) A licensee shall show compliance with the annual dose limits in subdivision (a) of this section by;

(i) demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

(ii) demonstrating that:

(*a*) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in 10 CFR 20, appendix B, table 2, as revised and implemented in full on March 14, 2023; and

(*b*) if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

16.8 Waste disposal. Disposal and transportation of radioactive waste shall be governed by the New York State Department of Environmental Conservation as set forth in 6 NYCRR Parts 380 and 381.

16.9 Professional practitioners and related provisions.

(a) Nothing in sections 16.6 through 16.16 of this Part shall limit any human use of radiation in diagnostic or therapeutic procedures pursuant to section 16.19 of this Part, provided that with respect to use on humans of radioactive material, such use is in accordance with a specific or general license issued under this Part, or an exemption therefrom.

(b) Each professional practitioner who administers, inserts, or implants an amount of radioactive material into a patient in such quantities that the patient cannot be released under 10 CFR35.75, as revised and implemented on August 13, 2007, shall require that the patient wear a wrist band. The wrist band shall bear the radiation symbol, the quantity and type of radioactive material administered, inserted or implanted and the date on which such quantity was measured.

(c) Radioactive cadavers.

(1) If any patient containing radioactive material, which was administered for therapeutic purposes, dies it shall be the responsibility of the physician who pronounces such patient as dead to notify immediately the physician in charge of the case or their designated representative.

(2) No person shall commence any autopsy on any cadaver that contains radioactive material in a quantity that exceeds five millicuries, which was administered for therapeutic purposes, without first having consulted with and being advised by the radiation safety officer for the licensee or, if

they are not available, the physician responsible for the administration of the radioactive material. If neither is available, their designated representative may serve.

(3) A radioactivity report on every cadaver containing more than five millicuries of radioactive material which was administered for therapeutic purposes, shall be completed by the radiation safety officer or the physician responsible for the administration of the radioactive material or their designated representatives. The report must include: the name and address of the hospital; the name of the deceased; the name, address and telephone number of the next of kin; the name, address and telephone number of the funeral home to which the deceased will be sent; the radionuclide involved, the approximate activity on the day of the report and the physical form; the location of the radioactive materials in the body and the external rate at the body surface closest to the source; the precautions to be observed during autopsy or handling of the body by the funeral director; and the name of the person who prepared the form. This report shall accompany the body (whether autopsied or not) when it is surrendered to the funeral director. The licensee shall retain a copy of the radioactivity report for a period of three years for review by the department.

(d) Provide notification of suspected radiation related illness as required by section 16.15(f) of this Part.

16.10 Inspections, surveys, checks and tests; vacating installations; securing radiation sources.

(a) Each person who possesses any radiation source shall make, or cause to be made, the applicable surveys required under this section and such additional surveys as may be necessary for them to comply with other sections in this Part, to determine the magnitude and extent of

radiation levels and concentrations or quantities of radioactive material in areas including the subsurface, and as the department may direct in order to evaluate the extent of the radiation hazard or potential radiation hazards of the radiation levels and residual radioactivity detected that may be present. Each person who possesses any radioactive material not in a sealed source for which surveys are required shall provide or have available appropriate calibrated and operable instruments capable of detecting and measuring radiation and radioactive contamination. Records of surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning in accordance with this Part.

(1) Any radiation installation subject to the registration requirements of section 16.50(a) of this Part shall be inspected periodically to assure compliance with this Part and the maintenance of radiation exposures as far below the limits set forth in this Part as is reasonably achievable. Inspections shall be made at a frequency as specified in subparagraph (i) of this paragraph, The inspection shall be performed in a manner, and reported in writing on a form, prescribed by the department. The person who makes the inspection shall include in such report all recommendations necessary to accomplish compliance with this Part, and to reduce radiation exposure as far below the limits set forth in this Part as reasonably achievable. The inspection shall be made by the department, the New York City Department of Health and Mental Hygiene or, as the department shall direct, by the appropriate county or part-county health officer having jurisdiction or by a certified radiation equipment safety officer. Such county or part-county health officer or the New York City health commissioner shall make the inspection only under an inspection program that is certified by the department in writing as approved and in effect. They may make the inspection or have it made by a duly authorized representative approved for

such purpose by both such health officer and the department. The operator of an installation required to be inspected by a certified radiation equipment safety officer, shall be solely responsible for having all such required inspections made.

(i) The department shall establish a schedule of inspection frequencies and make this available to regulated entities and other interested parties. This schedule may be adjusted for cause or administrative purposes by the department. Initial inspections should occur within the first year of operations.

(ii) The CRESO (certified radiation equipment safety officer), or the health officer having jurisdiction, as the case may be, shall furnish the inspection report, signed by the person who made the inspection, to the operator of the installation and a copy thereof to the department in accordance with the instructions of the prescribed form.

(2) Radiation installations wherein radioactive materials are handled or installed which will have any readily accessible area in which there is reasonable expectation that a radiation level will exist in excess of two millirems in any one hour shall be surveyed during the initial operation and whenever any change is made in the installation or its use that might increase the radiation level to which a person could be exposed.

(3) Accessible areas and equipment within radiation installations wherein radioactive material not contained in a sealed source is handled or installed shall be surveyed at least once a month for radioactive contamination unless a shorter interval is specified in a license issued pursuant to this part. Radioactive contamination of surfaces shall be kept ALARA using Appendix 16-A, Table 7 of Part 16 of Title 10 (Health) of the NYCRR.

(4) Depleted uranium components, and each sealed or plated sources, containing radioactive material other than Hydrogen-3, with a half- life greater than 30 days and in any form other than

gas, shall be tested for leakage prior to initial use and at successive intervals thereafter not to exceed six months or a longer interval as specified in the sealed source and device registry, except as noted below:

(i) That each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months or as specified in the sealed source and device registry.

(ii) Notwithstanding the periodic leak test required by this paragraph, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta, neutron, and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

(iii) Except for alpha sources, the periodic leak test required by this paragraph shall not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer. In the absence of the delivery of a certificate by the transferor to the transferee indicating that a test pursuant to the applicable provisions of this Part was made within six months prior to the transfer, the source shall not be used until tested for leakage.

(5) Additional requirements for leak tests:

(i) If there is reason to suspect that a sealed source might have been damaged, or might be leaking, such source shall be tested for leakage before further use.

(ii) The test sample shall be taken from selected accessible surfaces of the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored. For teletherapy and/or irradiator sources, the selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used treatment cone or beam collimating device.

The test sample shall be taken with the source in the "off" position the leak test technique shall be capable of detecting:

(*a*) the escape of radon at the rate of 37,000 Bq (0.001 microcuries) or more per 24 hours for sealed radium sources; or

(*b*) 185,000 Bq (0.005) microcurie or more of removable radioactivity from all other sealed sources and depleted uranium shields, collimators, etc. Detection of a leak in any sealed source in excess of the sensitivity levels set forth in this paragraph shall result in immediate suspension in the use of such source until such source is decontaminated and repaired or disposed of in accordance with section 16.8 of this Part. Records of leak test results shall be kept in units of microcuries per test sample and maintained for inspection by the department.

A leaking source report shall be submitted to the department for each source found to be leaking in excess of the above sensitivity levels within five days of detection of the leak and shall describe the equipment involved, the test results, and the corrective action taken. The reporting requirements are listed in section 16.15(e) of this Part.

(6) Protective devices such as interlocks, safety switches, fume hoods, filters and trapping devices for radioactive gases, shall be tested regularly and maintained in good repair and proper operating condition.

(b) Each person shall perform surveys of the area wherein radioactive material is or has been stored as necessary to demonstrate to the department that the area of the licensee’s facility meets the criteria in section 16.28 of this Part for unrestricted release. This does not apply to decommissioning of buildings or license termination.

(c) Each person who possesses any radiation source shall secure such source against its unauthorized removal from its place of storage or use. The following additional restrictions apply to noncontrolled areas:

(1) Radiation sources stored in a noncontrolled area shall be stored in a locked facility in the original shipping container, or a container providing equivalent radiation protection. Such a facility may be a cabinet, a safe or a room, providing the facility is locked at all times when no activities are in progress relating to the use of the radiation sources.

(2) Radiation sources in a noncontrolled area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

(3) Security requirements for portable moisture density gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(d) Certified Radiation Equipment Safety Officer (CRESO). A certification as a radiation equipment safety officer shall be issued by the department. Eligibility for renewal of a certificate shall be based on a work record as a certified radiation equipment safety officer that is in conformance with the regulations of the department. The certificate may be revoked for cause by the department on due notice.

(1) The requirements for certification as a radiation equipment safety officer are as follows:

(i) at least 18 years of age at the time of application; and

(ii) good moral character; and

(iii) graduation from a regionally accredited college or university, or one recognized by New York State, with a bachelor's degree in physical or natural science, mathematics or engineering; or four years of satisfying full-time paid experience in radiation protection or control; or an equivalent combination of the education and experience specified in this clause; and

(iv) successful completion, after meeting the requirements of subparagraphs (i), (ii), and (iii) of this paragraph, of an examination prescribed by the department; and

(v) at least three years of satisfactory full-time paid experience in radiation protection or control including at least one year of experience dealing with radiation equipment, with the provision that up to two years of graduate training in physical or natural science, mathematics or engineering, may be substituted on a year for year basis for the required experience except for the one year of experience in radiation protection or control dealing with radiation equipment. Verification of employment, experience, and education must be provided upon department request.

(vi) Individuals must have available calibrated test equipment appropriate for the types of equipment inspected. Records of calibration must be submitted to the department as requested.

(2) The department may accept in lieu of the requirements of subparagraphs (iii) and (iv) of paragraph (1) of this subdivision a certificate in radiation protection or control issued by the American Board of Health Physics, the American Board of Radiology or the American Board of Medical Physics.

(3) A person meeting all requirements of paragraph (1) of this subdivision except the experience or experience substitute requirement of subparagraph (v) of paragraph (1) may be certified as a radiation equipment safety officer with the restriction that they perform surveys only under the

supervision of a certified radiation equipment safety officer who meets the requirements of subparagraph (v).

(4) The Radiation Safety Officer for a facility may not act as CRESO for the same facility.

(e) Instrumentation. Each person required to perform a survey by this Part shall be provided with or have available appropriate calibrated and operable instruments capable of detecting and measuring radiation.

(f) Radiation equipment-surveys. Every installation and mobile source wherein radiation equipment is to be used shall be surveyed during the initial operation of such equipment and whenever any change is made in such installation or mobile source or in its use that might increase the radiation level to which an individual could be exposed. When vibrations or other physical conditions exist in such installations or mobile sources which may cause changes in the protective features, surveys shall be made at least every six months.

16.11 Personnel monitoring.

(a) External radiation sources. Each licensee and registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee or registrant. Each person who possesses any radiation source shall supply and require the proper use of appropriate, calibrated and operable individual monitoring devices by:

(1) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in paragraph (1) of section 16.6(a) of this Part; and

(2) minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv); Minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in section 16.6 of this Part; and

(3) declared pregnant worker likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem) (Note: All of the occupational doses in section 16.6 of this Part continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.); and

(4) individuals entering a high or very high radiation area, or operating fluoroscopy equipment; and

(5) as required by section 16.119 of this Part for individuals conducting industrial radiography operations (10 CFR 34.47, as revised and implemented on March 18, 2020) and as required by section 16.120 of this Part for irradiator operators (10 CFR36.55, as revised and implemented on March 18. 2020)

(b) A person supplying personnel monitoring devices to individuals as required by subdivision (a) of this section shall ensure that the individuals wear such devices as follows:

(1) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure.

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to section 16.6(h)(1) of this Part, shall be located at the waist under any protective apron worn by the woman.

(3) An individual monitoring device used for monitoring the lens dose equivalent shall be located at the neck outside any protective apron worn by the individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities shall be worn on the extremity likely to receive the highest exposure. The device shall be oriented to measure the highest dose to the extremity being monitored.

(c) All personnel monitoring devices, except for direct and indirect reading dosimeter and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and which are supplied pursuant to subdivision (a) of this section, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(1) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximate the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(d) Intake of radioactive material. Each licensee shall perform all appropriate measurements of those specified in section 16.6(d)(1) of this Part which will enable them to determine the

occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in 10 CFR 20, appendix B, table 1, columns 1 and 2, as revised and implemented in full on March 14, 2023.

(2) Minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

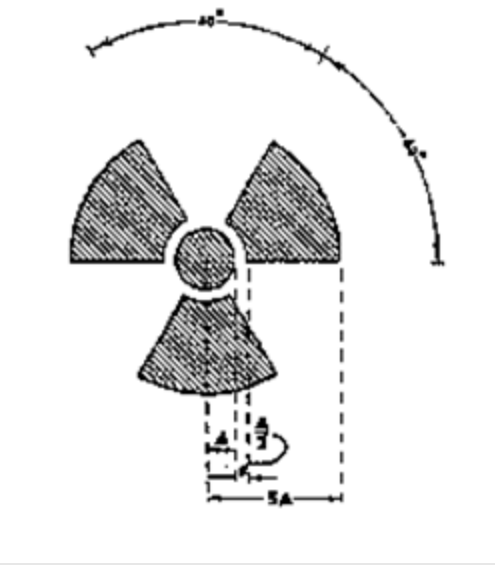
(3) Declared pregnant worker likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

16.12 Radiation symbol, signs, labels, and control devices.

(a) Standard radiation symbol. Unless otherwise authorized by the department, the symbol prescribed by this section shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design and shall be as illustrated below:

(1) Cross-hatched area is to be magenta, or purple, or black.

(2) The background is to be yellow.



(3) Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of subdivision (a) of this section, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(4) Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this Part, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(b) (1) Posting requirements.

(i) Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA".

(ii) Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

(iii) Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA".

(iv) Posting of airborne radioactivity areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA".

(v) Posting of areas or rooms in which licensed material is used or stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

(2) Exceptions to posting requirements.

(i) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

(*a*) the sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Part; and

(*b*) the area or room is subject to the licensee's or registrant's control.

(ii) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to paragraph (1) of this subdivision provided that the patients that could be released from licensee control pursuant to section 16.123 of this Part.

(iii) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(iv) A room or area is not required to be posted with a caution sign because of the presence of a diagnostic x-ray system used solely for healing arts purposes.

(c) Labeling of containers and radiation equipment.

(1) The licensee or registrant shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(3) Each registrant shall ensure that radiation equipment is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

(4) Exemptions to labeling requirements. A licensee or registrant is not required to label:

(i) containers holding licensed material in quantities less than the quantities listed in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023; or

(ii) containers holding licensed material in concentrations less than those specified in 10 CFR 20, appendix B, table 3, as revised and implemented in full on March 14, 2023; or

(iii) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Part, (e.g., laboratory containers, such as beakers, flasks, and test tubes, used transiently in laboratory procedures (i.e., for a period of a few hours) in the presence of an authorized user); or

(iv) containers when they are in transport and packaged and labeled in accordance with the regulations of the United States Department of Transportation; or

(v) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(vi) installed manufacturing or process equipment, such as chemical process equipment, piping, and tanks.

(d) Control of access to high radiation areas.

(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(i) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem)

in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

(ii) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(iii) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by paragraph (1) of this subdivision for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee or registrant may use alternative methods for controlling access to high radiation areas found by the department to be effective at accomplishing such control.

(4) The licensee or registrant shall establish the controls required by paragraphs (1) and (3) of this subdivision in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with section 16.17 of this Part, provided that:

(i) the packages do not remain in the area longer than 3 days; and

(ii) the dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are

personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this Part and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(7) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in this paragraph if the registrant has met all the specific requirements for access and control specified in other applicable sections of this Part, such as those regulating x-ray equipment in the healing arts and particle accelerators.

(e) Control of access to very high radiation areas.

(1) In addition to the requirements in paragraph (2) of this subdivision, the licensee or registrant shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to irradiators as described in subdivision (f) of this section.

(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in paragraph (1) of this subdivision if the registrant has met all the specific requirements for access and control specified in other applicable sections of this Part, such as those regulating radiation equipment in the healing arts or particle accelerators.

(f) Control of access to very high radiation areas -- irradiators.

(1) This subdivision applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. This subdivision does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create a radiation level of 5 Gy (500 rad) or more in 1 hour at 1 meter in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(i) Each entrance or access point shall be equipped with entry control devices which:

(*a*) function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(*b*) permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(*c*) prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

(ii) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subparagraph (2)(i) of this subdivision:

(*a*) the radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(*b*) conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(iii) The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(*a*) the radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(*b*) conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(iv) When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of shielding to a level at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

(v) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subparagraphs (iii) and (iv) of this paragraph.

(vi) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

(vii) Each area shall be controlled by use of such procedures and devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(viii) Prior to the first individual's entry into each very high radiation area after any use of the source of radiation, the area shall be checked by a radiation measurement. The area may not be used unless the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

(ix) The entry control devices required in subparagraph (i) of paragraph (2) of this subdivision shall have been tested for proper functioning. (*See* section 16.14(f) of this Part for recordkeeping requirements).

(*a*) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(b) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(c) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(x) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(xi) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such procedures and devices as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of paragraph (2) of this subdivision which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of paragraph (2) of this subdivision, such as those for the automatic control of radiation levels, may apply to the department for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in paragraph (2) of this subdivision. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(4) The entry control devices required by paragraph (2) and (3) of this subdivision shall be established in such a way that no individual will be prevented from leaving the area.

(g) Unnecessary use of signs and labels. Cautionary signs and labels shall not be used except as required by subdivisions (b) and (c) of this section.

16.13 Notices, instructions and reports to workers; inspections.

(a) Purpose and scope. This section establishes requirements for notices, instructions and reports by radioactive materials licensees or radiation-producing equipment registrants to individuals engaged in work under a license or registration, and options available to such individuals in connection with inspections of the activities and facilities of licensees or registrants by the department or health officer having jurisdiction to ascertain compliance with the provisions of this Part, orders and licenses issued thereunder regarding radiological working conditions.

(b) Posting of notices to workers.

(1) Each licensee or registrant shall post current copies of the following documents:

(i) the regulations of this Part;

(ii) the radioactive materials license and conditions or documents incorporated into the license by reference and amendments thereto, or the certificate of registration;

(iii) the operating procedures (including emergency procedures) applicable to work under the license or registration; and

(iv) any notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued pursuant to the provisions of the Public Health Law, and any response from the licensee or registrant.

(2) If posting of a document specified in paragraph (1) of this subdivision is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(3) A current copy of "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

(4) Documents, notices or forms posted pursuant to this section shall be conspicuous, be replaced if defaced or altered, and appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from assigned work locations to which the document applies.

(5) Department documents shall be posted within two working days after receipt of the documents from the department; the licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting violations, if any, has been completed, whichever is later.

(c) Instructions. All individuals likely to receive an occupational dose or frequenting any portion of a restricted area shall be provided instruction as specified in this subdivision. In determining those individuals subject to the requirements of this subdivision, licensees and registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed and/or registered facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace. Individuals described under this Part shall be:

(1) kept informed of the storage, transfer or use of radioactive material, of radiation-producing equipment or of radiation in such portions of the restricted area;

(2) instructed in the operating procedures applicable to work under the license or registration and the health protection problems associated with exposure to such radioactive material,

radiation equipment, or radiation, in precautions or procedures to minimize exposure, in the purposes and functions of protective devices employed, and required to demonstrate familiarity with such precautions, procedures and devices;

(3) instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of this Part and licenses and/or registrations for the protection of personnel from exposures to radiation, radiation equipment, or radioactive material occurring in such areas;

(4) instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of the department regulations and licenses or unnecessary exposure to radiation or radioactive material;

(5) instructed in the appropriate response to warnings made in the event of any unusual occurrence of malfunction that may involve exposure to radiation or radioactive material; and

(6) advised as to the radiation exposure reports which workers must be given or may request pursuant to subdivision (d) of this section.

(7) The extent of these instructions required under this subdivision shall be commensurate with the nature and level of the likely exposure and with potential radiological health problems in the restricted area. Instruction shall be given before an individual begins work likely to result in receiving an occupational dose or before an individual begins work in a restricted area and at least annually thereafter. Records documenting individual worker instruction shall be maintained for inspection by the department for a period of three years.

(d) Notification and reports to individuals.

(1) Radiation exposure data for an individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this subdivision. The information reported shall include

data and results as shown in records maintained by the licensee or registrant pursuant to subparagraphs (i) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part. Each notification and report shall be in writing and include appropriate data, such as the name of the licensee or registrant, the name of the individual, the individual's identifying information together with the individual's exposure information and contain the following statement: "This report is furnished to you under the provisions of Part 16, New York State Sanitary Code, and should be preserved for further reference."

(2) Each licensee or registrant shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to subparagraphs (i) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part.

(3) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall:

(i) be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later;

(ii) cover, within the period of time specified in the request, each calendar year in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation producing equipment registered with the department;

(iii) contain the results of any dose to the embryo/fetus and include any calculations and analysis of radioactive material deposited in such individual's body, including any bioassay or other medical evaluation services of which records are required by subparagraphs (ii) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part; and

(iv) include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to section 16.15 of this Part to report to the department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide to the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the department.

(5) At the request of any worker who has been engaged in a work assignment in an area restricted by a licensee or registrant for purposes of radiation protection, and who is terminating employment in such work assignment in the current year, the licensee or registrant shall provide a written report of the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified current year. The report shall be provided to the worker or the worker's designee at termination, and if the final determined personnel monitoring results are not available at that time, a written estimate of that dose shall be provided in the interim. Estimated doses shall be clearly indicated as such.

(e) Inspections; presence of representatives of licensees or registrants and workers during inspection.

(1) Each licensee or applicant for a license or registrant, shall afford the department or health officer having jurisdiction during hours of operation the opportunity to inspect:

(i) the radiation source and the installation, institution, establishment, premises or facilities at which such source is located, possessed, stored or used;

(ii) each record required to be maintained by this Part.

(2) During an inspection, the licensee or registrant shall conduct, or permit the department or health officer having jurisdiction to conduct, such tests as the department or health officer may require, including but not limited to tests of:

(i) any radiation source and the installation, institution, establishment, premises or facilities at which such radiation source is located, possessed, stored or used; and

(ii) the personnel monitoring equipment referred to in section 16.11 of this Part and any other equipment, instrument or devices used in connection with the location, possession, storage or use of such radiation source.

(3) During an inspection, the department or health officer having jurisdiction may consult privately with workers as specified in subdivision (f) of this section. The licensee or registrant may accompany department inspectors or health officer having jurisdiction during other phases of an inspection.

(4) If, at the time of inspection, an individual has been authorized by the workers to represent them during inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the worker's representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(5) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in subdivision (c) of this section.

(6) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(7) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant--for example, a consultant to the licensee or registrant or to the workers' representative--shall be afforded the opportunity to accompany inspectors during the inspection of physical working conditions.

(8) Notwithstanding the other provisions of this section, inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information or radioactive materials quantities of concern, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

(f) Consultation with workers during inspections.

(1) Inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of department regulations, registrations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection any worker may privately bring to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violations of this Part, or license condition, or an unnecessary exposure of an individual to radiation from licensed radioactive material or registered radiation equipment under the licensee's or registrant's control. Any such notices in writing shall comply with the requirements of paragraph (1) of subdivision (g) of this section.

(3) The provisions of paragraph (2) of this subdivision shall not be interpreted as authorization to disregard instructions provided pursuant to subdivision (c) of this section.

(g) Requests by workers for inspections.

(1) Any worker or representative of workers who believes that a violation of this Part or of license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the department. Any such notice shall:

(i) be in writing;

(ii) set forth the specific grounds for the notice; and

(iii) be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the department no later than at the time of inspection, except that, upon the request of the worker giving such notice, their name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the department, except for good cause shown.

(2) If, upon receipt of such notice, the department determines that the complaint meets the requirements set forth in paragraph (1) of this subdivision and that there are reasonable grounds to believe that the alleged violation exists or has occurred, the licensee or registrant shall afford the department or health officer having jurisdiction, during routine hours of operation or at other reasonable times, opportunity to conduct an inspection. Inspection pursuant to this section need not be limited to matters referred to in the complaint or allegation.

(3) No licensee or registrant shall discharge, or in any manner discriminate against, any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under this Part or has testified or is about to testify in any such proceeding, or because of the exercise by such worker on behalf of himself or others of any option afforded by this Part.

(h) Inspections not warranted; informal review.

(1) If the department determines, with respect to a complaint under subdivision (g) of this section, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the department shall notify the complainant in writing of such determination. The complainant may obtain an informal review of such a determination by submitting a written statement of position with the department who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the department, who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the department may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, department shall affirm, modify or reverse the initial determination of the department and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefore.

(2) If the department determines that an inspection is not warranted because the requirements of paragraph (1) of subdivision (g) of this section have not been met, it shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of paragraph (1) of subdivision (g) of this section.

(i) Each person who possesses any radiation source shall, when necessary or desirable in order to aid in determining the extent of any individual's occupational exposure to a radiation source, comply with orders from the department directing such person to make available to such

individual bioassay services or other appropriate medical evaluations and to furnish to the department and the health officer having jurisdiction a copy of the reports of such services.

16.14 Records

(a) General provisions.

(1) Each licensee or registrant shall use the SI units: becquerel, gray, sievert and coulomb per kilogram, or the special units: curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part, with the exception that information on shipment manifests as required by 10 CFR20.2006(b), as revised and implemented on October 1, 2007, shall be recorded in the SI units.

(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Part, such as, total effective dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(3) Form of records. Each record required by this Part shall be legible throughout the specified retention period. The record shall be the original or the record may also be stored in electronic media with the capability for producing retrievable, legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications shall include pertinent information, such as stamps, initials, and signatures.

(4) The discontinuance of or curtailment of activities does not relieve any person who possesses any radiation source of responsibility for retaining all records required by this Part.

(b) Records of radiation protection programs. Unless otherwise specified in license condition or regulation, records shall be maintained for a minimum of three years.

(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

(i) the provisions of the program; and

(ii) audits and other reviews of program content and implementation.

(2) The licensee or registrant shall retain the records required by subparagraph (i) of paragraph (1) of subdivision (b) of this section until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by subparagraph (ii) of paragraph (1) of subdivision (b) of this section for three years after the record is made.

(3) The licensee or registrant shall maintain safeguards sufficient to prevent tampering with and loss of records and shall have adequate procedures or systems in place to ensure the security and integrity of all data and records and have plans to recover from events of data tampering and ensure continuity of care.

(c) Records of surveys.

(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by sections 16.10(a) and 16.16(b) and (c) of this Part. The licensee or registrant shall retain these records for three years after the record is made.

(2) The licensee or registrant shall retain each of the following records until the department authorizes the disposition of these records:

(i) records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(ii) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(iii) records showing the results of air sampling, surveys, and bioassays required pursuant to section 16.26(c)(1)(iii)(a) and (b) of this Part; and

(iv) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(3) Upon termination of the license or registration, the licensee or registrant shall ensure that all occupationally monitored employees are provided their most recent and final exposure reports.

(4) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by section 16.10(a)(4) of this Part shall be kept in units of becquerel or microcuries and maintained for inspection by the department.

(d) Records of individual monitoring results.

(1) Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to section 16.11 of this Part, and records of doses received during accidents and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of this Part need not be changed. These records shall include, when applicable:

(i) the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

(ii) the estimated intake or body burden of radionuclides, see section 16.6(b) of this Part; and

(iii) the committed effective dose equivalent assigned to the intake or body burden of radionuclides; and

(iv) the specific information used to assess the committed effective dose equivalent pursuant to section 16.6(d) of this Part; and

(v) the total effective dose equivalent when required by section 16.6(b) of this Part; and

(vi) the total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(2) Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in this subdivision at least annually.

(3) Recordkeeping format. The licensee or registrant shall maintain the records specified in this subdivision on US NRC's "Occupational Radiation Exposure Record for a Monitoring Period", or in clear and legible records containing all the information required by such form.

(4) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(5) The licensee or registrant shall retain each required form or record until disposition is authorized by the department.

(6) Upon termination of the license or registration, the licensee or registrant shall provide dosimetry records and/or bioassay data to the individuals who were monitored.

(e) Records of dose to individual members of the public:

(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. (*See* section 16.7(a) of this Part).

(2) The licensee or registrant shall retain the records required by this subdivision until disposition is authorized by the department.

(f) Records of testing entry control devices for very high radiation areas.

(1) Each licensee or registrant shall maintain records of tests made pursuant to section 16.12(f)(2)(ix) of this Part on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(2) The licensee or registrant shall retain the records required by this subdivision for three years after the record is made.

(g) Records of transfer, or receipt of radioactive materials.

(1) Each licensee shall maintain accurate and complete written records for each transfer or receipt of radioactive materials including radioactive waste.

(i) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years or as directed by the department, following transfer or disposal of the material.

(ii) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a provision of this Part, or other applicable regulations, dictates otherwise.

(iii) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the department terminates each license that authorizes disposal of the material.

(2) The licensee shall retain each record that is required by this or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward records of disposal of licensed material made under section 16.8 of this Part to the department.

(4) If licensed activities are transferred each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer disposal records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(5) Prior to license termination, each licensee shall forward the records required by the Part for decommissioning to the department.

(h) Records of Patient Fluoroscopy Doses

(1) When a patient's skin dose from a fluoroscopic procedure exceeds 2 Gy (200 rad), the facility will record the dose in the patient's medical record along with an unambiguous identification of those areas of the patient's skin that received the dose. Such identification may be through diagram or narrative description.

(2) When a patient skin dose from a fluoroscopic procedure is equal to or greater than 3 Gy (300 rad):

(i) The facility will monitor the patient for skin reactions for at least 1 year.

(ii) The patient's referring physician will be notified and provided information regarding management of skin reactions.

(iii) The patient will receive written follow-up instructions that informs them how to identify skin reactions, how to notify the facility, how to arrange for follow-up.

(iv) The patient should have sufficient knowledge to alert providers.

16.15 Reports.

(a) Reports of stolen, lost, or missing licensed or registered sources of radiation.

(1) Telephone reports. Each licensee or registrant shall report to the department by telephone as follows:

(i) Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023.

(ii) Within 7 calendar days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023, that is still missing.

(iii) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation equipment.

(iv) Immediately after the discovery of an event that prevents immediate protective action necessary to avoid exposures to radiation or radioactive materials which could exceed the regulatory limits, or releases of radioactive material which could exceed regulatory limits; due to an event such as an explosion, or toxic gas release.

(2) Written reports. Each licensee or registrant required to make a report pursuant to this subdivision shall, within 30 days after making the telephone report, make a written report to the department setting forth the following information:

(i) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form, manufacturer, model

and serial number for the device and/or source, and the estimated current activity of the source; and, for radiation equipment, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and other pertinent information as requested by the department.

(ii) A description of the circumstances under which the loss or theft occurred.

(iii) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved.

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas.

(v) Actions that have been taken, or will be taken, to recover the source of radiation.

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(3) After filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within 30 days after the discovery of such information.

(4) The names of individuals who may have received exposure to radiation must be stated only in a separate and detachable portion of the report.

(b) Notification of incidents.

(1) Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(i) an individual to receive:

(a) a total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(b) a lens dose equivalent of 0.75 Sv (75 rem) or more; or

(c) a shallow dose equivalent to the skin or extremities of 2.5 Gy (250 rad) or more; or

(ii) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(2) Twenty-four hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(i) an individual to receive, in a period of 24 hours;

(a) a total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(b) a lens dose equivalent exceeding 0.15 Sv (15 rem); or

(c) a shallow dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rem); or

(ii) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hotcells or process enclosures.

(3) The licensee or registrant shall prepare each report filed with the department pursuant to this subdivision so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(4) Licensees or registrants shall make the reports required by paragraphs (1) and (2) of this subdivision by means indicated in section 16.1(c) of this Part.

(c) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

(1) Reportable events. In addition to the notification required by subdivision (b) of this section , each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(i) incidents for which notification is required by section 16.15(b) of this Part;

(ii) doses in excess of any of the following:

(*a*) the occupational dose limits for adults in section 16.6(a) of this Part;

(*b*) the occupational dose limits for a minor in section 16.6(e) of this Part;

(*c*) the limits for an embryo/fetus of a declared pregnant worker in section 16.6(f) of this Part;

(*d*) the limits for an individual member of the public in section 16.7(a) of this Part;

(*e*) any applicable limit in the license or registration;

(iii) Levels of radiation or concentrations of radioactive material in:

(*a*) a restricted area in excess of applicable limits in the license or registration;

(*b*) an unrestricted area in excess of 10 times the applicable limit set forth in this Part or in the license or registration, whether or not involving exposure of any individual in excess of the limits in section 16.7(a) of this Part.

(2) Contents of reports.

(i) Each report required by this subdivision shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(*a*) estimates of each individual's dose; and

(*b*) the levels of radiation and concentrations of radioactive material involved; and

(*c*) the cause of the elevated exposures, dose rates, or concentrations; and

(*d*) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, and associated license or registration conditions.

(ii) Each report filed pursuant to paragraph (1) of this subdivision shall include for each individual exposed: the name and status as minor or adult. With respect to the limit for the embryo/fetus in section 16.6(f) of this Part, the identifiers should be those of the declared pregnant worker. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(3) All licensees or registrants who make reports pursuant to this subdivision shall submit the report in writing to the department.

(d) Notifications and reports to individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in section 16.13 of this Part.

(2) When a licensee or registrant is required pursuant to section 16.15(c) of this Part to report to the department any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the department and shall comply with the provisions of section 16.13 of this Part.

(e) Reports of leaking or contaminated sealed sources. If a sealed source is determined to be leaking or contaminated, a report shall be filed within five days with the department describing the equipment involved, the test results and the corrective action taken. The information must include device make and model, source make, model, serial number, isotope, and the activity and date for which the activity was determined and other information as requested by the department.

(f) Each professional practitioner who treats or diagnoses any suspected radiation illness shall report in writing to the department within seven days after such treatment or diagnoses, the fact thereof and the full name, address and age of the individual. Included in this reporting requirement are patients who have developed clinical symptoms as a result of contact with radioactive jewelry or other consumer products.

(g) Radioactive materials licensees and general license registrants shall report events described in 10 CFR 30.50(a), (b), (c)(1) and (c)(2), as revised and implemented on October 16, 2020; 10 CFR40.60(a), (b), (c)(1) and (c)(2), as revised and implemented on October 16, 2020; and 10 CFR70.50(a) and (b), as revised and implemented on October 16, 2020, to the department instead of to the NRC.

(h) Licensees and registrants authorized for medical use shall furnish reports of medical events as required by sections 16.25 and 16.123 of this Part.

(i) Reports of transactions involving nationally tracked sources.

(1) Each licensee who manufactures, transfer, receive, disassemble, or dispose of a nationally tracked source shall comply with 10 CFR 20.2207, as revised and implemented in full on August 9, 2021.

(j) Immediately report to the department any exceedance of external radiation standards for packages, as specified in section 16.16(d) of this Part.

16.16 Procedures for picking up, receiving, and opening packages.

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the Type A(2) quantities specified in 10 CFR71.4 as revised and implemented on

November 30, 2021, and appendix A of 10 CFR 71 as revised and implemented in full on November 30, 2021, shall make arrangements:

(1) to receive the package when the carrier offers it for delivery; or

(2) to receive notification of the arrival of the package at the carrier's terminal and to pick up the package expeditiously.

(b) Each licensee shall:

(1) Monitor the external surfaces of a package Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 as revised and implemented on July 11, 2014, and 172.436-440 as revised and implemented on December 20, 1991, for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR71.4 as revised and implemented on November 30, 2021.

(2) Monitor the external surfaces of a package Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 as revised and implemented on July 11, 2014, and 172.436-440 as revised and implemented on December 20, 1991, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR71.4 as revised and implemented on November 30, 2021, and appendix A to 10 CFR 71 as revised and implemented on November 30, 2021.

(c) Each licensee, upon receipt of a package containing radioactive material in quantities described in subdivision (a) of this section, or any package that shows evidence of damage or leaking shall monitor the external surfaces of the package for radioactive contamination, shall survey all packages for radiation levels and shall make other surveys as may be required by

section 16.10 of this Part. The licensee shall perform the monitoring as soon as practical after receipt of the package, but not later than three hours after the package is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and the department, by telephone, if packages, other than those transported by exclusive use vehicle, are found to have any of the conditions in paragraphs (1) and (2) of this subdivision. Notification to the department shall be made by means indicated in section 16.1(c) of this Part.

(1) Removable radioactive contamination in excess of the limits specified in 49 CFR173.443 as revised and implemented on July 11, 2014, [0.01 microcuries (22,000 dpm) (0.37 KBq) per 100 square centimeters on the external surfaces of the package]; or

(2) External radiation levels [at 1 meter from the external surface of the package in excess of 0.01 rem (10 mrem) (0.1mSV) per hour] in excess of the limits in 10 CFR71.47 as revised and implemented on September 28, 1995.

(e) Each licensee shall:

(1) Establish and maintain written procedures for the safe opening of packages in which radioactive material is received that include consideration given to special instructions for the type of package being opened.

(2) Ensure that the procedures are followed.

16.17 Packaging and Transportation of Radioactive Material.

(a) Any person performing packaging, preparation for shipment, and transportation of radioactive material shall comply with the provisions of the following federal regulations, which

are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 71, Packaging and Transportation of Radioactive Material, as revised and implemented in full on November 30, 2021, except as follows:

(1) Sections 71.0, 71.1, 71.2, 71.6, 71.7, 71.9, 71.10, 71.11, 71.12, 71.14(b), 71.19, 71.31, 71.33 through 71.36, 71.38, 71.39, 71.41, 71.51 -71.81, 71.85(a)-(c), 71.91(b), 71.93, 71.95, 71.99, 71.100, 71.101(c)(2), 71.101(d)-(f), and 71.107-71.125 are excluded.

(2) Any reference to the “Commission”, “NRC”, “NRC Regional Office” or any other organizational unit thereof shall be deemed to be a reference to the New York State Department of Health, except for when used in 71.5(b), 71.17(b), (c)(3), and (e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c)(1)(iii), (c)(3)(ii) and (iii), and (f), and 71.101(c)(1).

(3) In section 71.89 “10 CFR 20.1906(e)” is replaced with “10 NYCRR 16.16”.

16.18 Surrender of radioactive material; sealing of radiation equipment.

Notwithstanding any exemption set forth in this Part:

(a) The department may, by rule, regulation, license condition or order, impose upon any person possessing a radiation source such requirements, in addition to those set forth in this Part, as it deems appropriate or necessary to protect the public health and safety and to minimize danger to life and property from radiation hazards.

(b) The department may by order require the removal through an authorized transferee or the surrender to the department of any radioactive material by any person who is not able or equipped, or who fails, to observe with regard to such radioactive material such radiation protection standards as are established by the department, or who uses such radioactive material in violation of law or this Part or order of the department or in a manner other than as set forth in

a license issued therefor by the department. Such person shall decontaminate any premises which may have been contaminated with radioactive material as a result of his activities to such radiation levels as the department may specify. The expenses incidental to such transfer, surrender, and/or decontamination shall be borne by such person responsible for the source.

(c) The department may by order require radiation equipment sealed, with an official New York State Department of Health seal or other suitable method, when such equipment is used by any person who is not able or equipped, or fails to observe with regard to such radiation equipment such radiation protection standards as are established by the department, or who uses such radiation equipment in violation of law or this Part or order of the department. Radiation equipment sealed by the department pursuant to this subdivision shall not be unsealed without prior authorization by the department.

16.19 Limitations on application of radiation to humans.

(a) Diagnostic x-ray equipment. No individual other than a professional practitioner, as defined in section 16.2(a) of this Part; a physician's assistant working under the authority of a physician in accordance with article 37 of the Public Health Law; or, a certified nurse practitioner working in accordance with article 139 of the Education Law, within a practice agreement with a physician, or under the authority of a Medical Director or Medical Board in an article 28 facility, shall direct or order the application of radiation from radiation equipment to a human being. No individual other than a professional practitioner; or an individual licensed and registered or exempted under article 35 of the Public Health Law, and operating within their scope of practice or, a student currently enrolled in an approved program of study in radiologic technology, and under direct supervision by a professional practitioner or licensed and registered radiographer;

shall position patients, set techniques or apply such radiation to a human being. Such direction or order to apply, or application of, radiation shall be in the course of the practitioner's professional practice and shall comply with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(1) Dental assistants may operate dental radiographic equipment for dental x-ray procedures only under the supervision of a licensed dentist pursuant to the applicable provisions of section 89.30 of this Title and of section 3516 of the Public Health Law.

(b) Radiation therapy (external beam and brachytherapy) equipment. No individual other than a qualified physician shall direct or order the application of radiation from therapy equipment to a human being. No individual other than an Authorized User, named on a radioactive materials license for uses specified in 10 CFR sections 35.400, 35.600 and 35.1000, as revised and implemented in full on November 14, 2022, shall direct or order the application of radioactive material or radiation from radioactive material for therapeutic purposes to a human being. Nor shall any individual other than a qualified physician, or a licensed and registered radiation therapist or a student currently enrolled in an approved program of study in radiation therapy technology, and under direct supervision of a qualified physician or licensed radiation therapist; position patients, set techniques or apply radiation therapy to a human being. Such direction or order to apply, or application of, radiation shall be in compliance with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(c) Radioactive materials. No individual other than a physician who is an Authorized User, named in a radioactive materials license issued pursuant to section 16.100 of this Part, or a physician under the Authorized User’s supervision shall direct or order the use of radioactive materials specified in 10 CFR sections 35.100, 35.200, 35.300 or 35.1000 or sealed sources for

diagnosis specified in 10 CFR 35.500 to a human being, as revised and implemented in full on November 14, 2022. Nor shall anyone other than these individuals, or an individual working under their direction or order, or a licensed and registered nuclear medicine technologist, as defined in article 35 of the Public Health Law, or student currently enrolled in an approved program of study in nuclear medicine technology, and under direct supervision by a professional practitioner or licensed and registered nuclear medicine technologist; administer radioactive materials to a human being. Such direction or order, or administration of radioactive materials or radiation shall be in the course of the physician's practice and shall comply with the practitioner's professional practice and shall comply with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(d) The use of body scanning equipment for security screening. No individual, except as described in article 35 of the Public Health Law and section 16.70 of this Part, shall apply radiation to humans for purposes of security screening.

16.20 Hearings.

(a) On disapproval of applications. If the department disapproves any application for license filed pursuant to section 16.102 of this Part:

(1) The department will conduct a hearing if the applicant files with the department a written petition within 30 days after receipt of such notice of disapproval, and the petition:

(i) asserts that such disapproval was, and the respect in which it was, improper; and

(ii) requests a hearing.

(2) Having determined to conduct a hearing on the issues raised in an applicant's petition, the department will give written notice by personal delivery or by certified or registered mail to the

applicant at least 20 days prior to such hearing, informing that person that they may be present and heard at the hearing.

(b) On amendment, suspension or revocation of licenses; imposition of additional requirements; transfer or surrender of radioactive material. Except in any case of willfulness or in which the public health or safety requires otherwise, or in which an administrative correction is required, the department shall not amend, suspend or revoke any license pursuant to section 16.107 of this Part, or impose additional requirements on the possessor of a radiation source or require the transfer or surrender of radioactive material pursuant to section 16.18 of this Part without first:

(1) notifying in writing such licensee or person of the facts or conduct which may warrant such amendment, suspension, revocation, additional requirement, transfer or surrender, and giving such licensee or person a reasonable opportunity to demonstrate or achieve compliance with all lawful requirements; and

(2) conducting a hearing if the licensee or person files with the department a written petition within 30 days after receipt of such notice, and the petition:

(i) asserts that such amendment, suspension, revocation, additional requirement, transfer or surrender would be, and the respects in which it would be improper; and

(ii) requests a hearing.

(3) giving written notice by personal delivery or by certified or registered mail to the licensee or person at least 20 days prior to any hearing ordered pursuant to paragraph (2) of this subdivision. Such notice will inform the licensee or person that they may be present and heard at the hearing. The requirements in subdivision (b) of this section may be waived upon consent of the licensee or their authorized representative.

16.21 RESERVED.

16.22 X-ray screening; general requirements; mammography.

(a) General requirements. This applies to each person or operator that provides x-ray screening to a target population when there is no individual order for each procedure.

(1) All screening shall be performed under the supervision of a licensed practitioner pursuant to section 89.2(a) of this Title.

(2) The screening program operator shall establish and maintain a referral system for communicating findings to the patient's primary care provider in a timely fashion.

(3) The screening program operator shall establish and maintain a referral system for patients with suspicious findings or disease when the patient does not report having a primary care provider.

(4) The screening program operator shall annually review the program to determine the appropriateness of continuing screening and report the findings of that review to the department.

(5) A prospective screening program operator shall apply to the department and submit information prior to operation indicating how the operator will comply with paragraphs (1) through (4) of this subdivision.

(6) The screening program operator shall prepare and submit to the department within 15 days of a request, a report that includes the following information for a requested time period:

(i) the total number of patients screened by diagnosis;

(ii) the total number of suspicious findings or disease;

(iii) the total number of patients referred for follow-up for each suspicious finding or disease diagnosed.

(b) Mammography. The following requirements for mammography screening are in addition to those in paragraphs (1) through (5) of subdivision (a) of this section.

(1) All mammographic images shall be interpreted by a qualified physician.

(2) Baseline mammography images shall be maintained for ten years.

(3) The screening program operator shall perform an annual analysis of false positive and false negative findings for cases where the data can be obtained.

(4) The facility shall prepare and submit to the department an annual report including:

(i) total number of individuals screened by age group;

(ii) total number of patients referred for follow-up by age group; and

(iii) results of the analysis of false-positive findings.

16.23 Quality assurance programs for diagnostic facilities.

(a) A quality assurance program is a system of plans, actions, reviews, reports and records whose purpose is to ensure that diagnostic facilities achieve consistent high-quality imaging and other diagnostic results, while maintaining radiation output and personnel doses within limits prescribed by the department.

(1) Each radiation facility conducting diagnostic x-ray, fluoroscopy, cone beam CT, CT and/or radioactive materials procedures, excepting intraoral dental, panoramic dental, podiatric x-ray, and veterinary facilities, shall implement a quality assurance program including at a minimum:

(i) the adoption of a manual containing written policies and procedures for radiation protection and describing the facility's quality assurance program. Policies and procedures must be consistent with the types of equipment and services provided, including but not limited to, use of gonad or scoliosis shielding; personnel monitoring; protection of pregnant workers and patients;

and holding of patients. The quality assurance manual must describe the various processing, generator and systems quality control tests appropriate for the types of equipment and services provided in sufficient detail to ensure that they will be performed properly;

(ii) the performance of quality control tests and the correction of deficiencies as specified in the quality assurance manual;

(iii) the maintenance of equipment records for each diagnostic imaging system, containing test results, records of equipment repairs and other pertinent information;

(iv) the provision of a formalized in-service training program for employees, including, but not limited to, quality assurance and radiation safety procedures;

(v) the measurement of radiation output at the point of skin entry for common X-ray examinations;

(vi) the measurement of the amount of activity of each dose of a radiopharmaceutical administered to a patient;

(vii) the calculated absorbed dose for diagnostic procedures involving radioactive materials;

(viii) the recording of patient doses from fluoroscopy;

(ix) patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 – 2013), NCRP Report 168, or equivalent standard.

(x) the provision of the information described in subparagraphs (v), (vi), and (vii) of this paragraph to any patient upon request; and

(xi) the conduct of an ongoing analysis of repeated, rejected or misadministered diagnostic studies which is designed to identify and correct problems and to optimize quality.

(xii) Each radiation facility conducting medical imaging studies and storing the imaging data electronically, shall implement a quality assurance program that includes written policies and procedures to ensure continuity of care for electronic images that is consistent with that provided for hardcopy imaging studies including assessment of backup of images and at least an annual testing of the system.

(2) Quality Assurance for Digital Imaging Acquisition Systems. Each radiation facility using digital imaging systems, excepting dental, podiatric and veterinary facilities, shall follow quality assurance (QA) and quality control (QC) protocols for image processing in addition to section 16.23(a)(1) of this Part. Acceptance testing and the radiation safety survey shall be completed and documented before first human use.

(i) Equipment Test Records shall be maintained for each unit in operation. Exposure indicator numbers for typical exams and image retakes shall be trended and kept for three years. If the manufacturer does not provide target numbers and tolerances, QC numbers for tests shall be trended to establish control limits.

(ii) Quality Control Records for Equipment. Test Records shall be maintained and available for review for quality control test equipment that requires calibration. Quality Control Records may be maintained in either hardcopy or softcopy format but shall be available for review during inspections.

(iii) Equipment Monitoring.

(*a*) All automated tests recommended by the manufacturer shall be run at the recommended frequency.

(*b*) The following tests shall be performed and documented on non-cassette based (also referred to as direct read or DR) systems using the manufacturer's phantom or a phantom acceptable to the department:

(*1*) Characterization of the beam (kVp, thickness and type of attenuation, mAs, other necessary information).

(*2*) Exposure index number calibration verification.

(*3*) Establish exposure index target values (for anatomic regions or exam type).

(*4*) Low contrast test.

(*5*) Contrast scale test.

(*6*) Spatial resolution test.

(7) Uniformity test.

(*8*) Geometric accuracy test.

(*9*) Artifact test.

(*10*) Signal-to-noise ratio (on raw images).

(*11*) Contrast-to-noise ratio (on raw images).

(*12*) Number of bad pixels test (if the system is capable).

(*13*) Automatic Exposure Control (AEC) verification.

(*c*) The following tests shall be performed and documented on cassette based (also referred to as computed radiography or CR) systems using the manufacturer's phantom or a phantom acceptable to the department:

(*1*) Characterization of the beam (kVp, thickness and type of attenuation, mAs, other necessary information).

(*2*) Establish exposure index target values (for anatomic regions or exam type).

(*3*) Low contrast test.

(*4*) Contrast scale test.

(*5*) Spatial resolution test.

(*6*) Uniformity test.

(*7*) Geometric accuracy test.

(*8*) Signal-to-noise ratio (on raw images).

(*9*) Contrast-to-noise ratio (on raw images).

(*10*) Image plate (IP) artifact test.

(*11*) IP dark noise test.

(*12*) Laser jitter.

(*13*) Primary erasure.

(*14*) Automatic Exposure Control (AEC) verification.

(*15*) System Linearity & Sensitivity.

(iv) Primary Diagnostic Monitors (PDM). Each primary diagnostic monitor shall be tested per the manufacturer's quality control requirements. At a minimum the following tests shall be performed and documented:

(*a*) Visual test pattern evaluation (TG-18QC, SMPTE, or equivalent).

(*b*) DICOM calibration of the Grayscale Standard Display Function (GSDF).

(*c*) Maximum luminance output.

(*d*) Minimum luminance output.

(*e*) Luminance ratio of maximum to minimum.

(*f*) Evaluation of viewing conditions.

(v) Laser Printers. Each printer, if used for primary interpretation or for patient records or referral, shall be tested per the manufacturer's quality control requirements and shall be of diagnostic quality. At a minimum the following tests shall be performed and documented.

(*a*) Download and print the SMPTE pattern.

(*b*) Measure the density of the 10%, 40%, and 90% patches.

(*c*) Determine and plot the Mid-density using the density at the 40% patch (MD) and Lower-density (LD) using the density at the 90% patch.

(*d*) Determine and plot Density Difference (DD) subtract the density at the 40% patch from the density of the 10% patch.

(vi) Neonatal imaging. Neonatal intensive care units must develop a QA program which includes the following protocols:

(*a*) establishing a technique chart for neonatal imaging including, at a minimum, specific techniques for chest and abdomen, along with corresponding direct or indirect determination of entrance skin dose; and

(*b*) an annual training program for Licensed Radiographic Technologists (LRTs) for conducting neonatal imaging; and

(*c*) a protocol for the proper use of neonatal collimation; and

(*d*) each facility must conduct an annual report on the compliance with the facility's neonatal QA program and forward such report to the facility radiation safety committee for review.

(vii) Imaging of children. Each registrant that conducts x-ray imaging of children must establish specific techniques at least for 1-year old, 5-year-old and 10-year-old children, specific to PA chest and abdomen x-ray studies. Additionally, the entrance skin exposure must be directly or

indirectly determined for the latter studies and posted in the facility along with the technique chart wherever it is reasonable to expect that children of such an age group can be x-rayed.

(b) Breast imaging quality assurance. Each facility performing breast imaging examinations that are not regulated by the U.S. Food and Drug Administration's Mammography Quality Standards Act, shall ensure that the breast imaging system is optimized to provide consistent, high-quality imaging. A breast imaging system includes the x-ray control, x-ray generator, x-ray tube, image receptor and all components of the imaging process. The facility shall use a breast equivalent phantom approved by the department to monitor image resolution. The breast phantom contains test objects which represent low density areas and microcalcifications which are related to the imaging of breast lesions. A test object is either a mass, fiber, or speck set.

(1) No breast imaging shall be performed unless the minimum manufacturer specifications and or the minimum criteria established by the American College of Radiology (ACR) for breast phantom imaging are met.

(2) All facilities shall optimize the breast imaging systems used and determine the breast phantom test object resolution of the system prior to performing breast imaging. The number of test objects resolved is the reference image the facility shall use for comparison during periodic testing. Under any conditions, if during the testing required under subdivision (a) of this section, the system is found to have lost the ability to resolve two test objects previously visible in the reference image, the facility shall investigate the reason and optimize the system.

(3) Diminished phantom test object resolution and facility follow-up.

(i) Whenever the phantom image indicates that the breast imaging system fails to meet the minimum test object resolution defined in paragraph two of this subdivision the facility shall

investigate the reason. Correction to achieve the minimum level shall be completed prior to performance of breast imaging.

(ii) In addition, if it is found that breast imaging has been performed while minimum requirements were not met the investigation shall include:

(*a*) a review of phantom images to determine at which point the image resolution fell below the minimum; and

(*b*) a review, by a panel of physicians selected by the department for this review, of breast images performed since the last phantom image that was identified as meeting the minimum level. Physicians selected for the panel must be certified in diagnostic radiology by the American Board of Radiology or the American Osteopathic Board of Radiology or have equivalent qualifications and will be selected for addition to this panel in consultation with the New York State Radiological Society. Members of the panel are deemed volunteers in service to the department within the meaning of paragraph (a) of subdivision one of section 17 of the Public Officers Law and, in lieu of expenses, shall be compensated by the department at the prevailing departmental per diem rate. The cases chosen for review shall include images from the range of studies performed by the facility which the panel ascertains to be sufficient to determine that the clinical images are of diagnostic quality. A record of the review and findings shall be maintained for inspection.

(iii) If images are identified by the physician conducting the review as nondiagnostic, the facility shall, within 5 business days, notify:

(*a*) the referring physician, or other authorized referring practitioner as defined in subdivision (a) of section 16.19 of this Part, or the patient, if not referred by a practitioner, of the need for follow-up; and

(*b*) the department of the results of the investigation and follow-up contacts.

(iv) A record of the results of the investigation and actions taken to correct any deficiency shall be maintained for review by the department for a period of three years.

16.24 Quality assurance programs for the use of radiation for therapy in humans.

(a) External beam therapy and brachytherapy. Each licensee or registrant authorized to administer external beam therapy or brachytherapy to human beings shall implement a quality assurance program to systematically monitor, evaluate, and document radiation therapy services to ensure consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissues, minimal exposure to personnel, and adequate patient monitoring aimed at determining the end result of the treatment. Each such licensee or registrant shall meet or exceed all quality assurance criteria described in this subdivision.

(1) Each licensee or registrant shall adopt, maintain, and implement a quality assurance manual that includes policies and procedures that ensure quality of patient care and safety of patients and other personnel. The manual must include procedures to ensure the following:

(i) Each patient's medical record shall be complete, accurate, legible, and shall include the patient's initial clinical evaluation, treatment planning data, treatment execution data, clinical assessments during treatment, a treatment summary, and plan for subsequent care. Treatment related data shall be recorded in the patient's medical record at the time of each treatment.

(ii) A written and dated order or prescription for the medical use of radiation or radioactive material shall be made for each patient in accordance with subdivisions (b) and (c) of section 16.19 of this Part. The order or prescription shall be signed or approved electronically by a board-certified radiation oncologist or qualified physician who restricts their practice to radiation

oncology. Changes to the initial prescription or written directive shall be signed and dated clearly.

(iii) The accuracy of treatment plan data and any modifications to treatment plan data transferred to a radiation treatment delivery system shall be verified by qualified clinical staff prior to patient treatment.

(iv) The treatment plan shall be reviewed and approved prior to the start of treatment and after any change ordered by a board-certified radiation oncologist or qualified physician who restricts their practice to radiation oncology.

(v) Set up shall be verified and documented by a radiation therapy technologist prior to every treatment session and set up shall be verified and approved by the radiation oncologist prior to:

(*a*) the first treatment and;

(*b*) prior to treatment for any changes to the initial treatment plan and;

(*c*) during the course of the treatment at frequencies consistent with the written directive and treatment protocol.

(vi) A radiation therapy technologist or physician shall obtain clarification before beginning a patient's treatment if any element of the order or other record is confusing, ambiguous, erroneous, or suspected of being erroneous.

(vii) Each patient's identification shall be verified by at least two different means and matched to the treatment plan at the console, by a radiation therapy technologist or physician prior to each treatment.

(viii) Each patient's response to treatment shall be assessed by a board-certified radiation oncologist or other qualified physician in the active practice of external beam therapy and/or

brachytherapy at least weekly. Unusual responses shall be evaluated as possible indications of treatment errors and recorded in the patient's medical record, investigated, and resolved.

(ix) The medical records of patients undergoing fractionated treatment shall be checked for completeness and accuracy by the licensed medical physicist or their designee at intervals not to exceed six fractions, and the completion of the course of radiation therapy.

(x) Radiation treatment plans and related calculations shall be checked, consistent with the written policy and the conditions of the license, by a licensed medical physicist or their designee for accuracy before 25 percent of the prescribed dose for external beam therapy or 50 percent of the prescribed dose for brachytherapy is administered, except the check shall be performed prior to treatment for: any single fraction treatment; any fractional dose that exceeds 300 cGy or 700 monitor units; or when the output of a medical therapy accelerator or treatment machine exceeds 600 monitor units per minute or 600 cGy per minute during treatment.

(*a*) If a treatment plan and related calculations were originally prepared by a licensed medical physicist or authorized medical physicist, it may be rechecked by the same individual using a different calculation method. (*b*) Treatment plans and related calculations prepared by others must be checked by a licensed medical physicist or their designee using procedures specified in the registrant's or licensee's treatment planning procedures manual required pursuant to paragraph (2) of this subdivision, and who has received training in use of the manual pursuant to paragraph (2) of this subdivision.

(xi) A board-certified radiation oncologist or other qualified physician shall assess patient’s response to treatment during the course of treatment and at the completion of radiation therapy. Unusual responses shall be evaluated as possible indications of treatment errors and recorded in

the patient's medical record, investigated, and resolved. Plans and evidence of follow up care shall be documented in the medical record.

(xii) All equipment and other technology used in planning, guiding, and administering radiation therapy shall function properly and safely, and shall be calibrated properly and repaired and maintained in accordance with the written policy and the manufacturer's instructions. The equipment and technology that is subject to such quality control includes but is not limited to: computer software and hardware including upgrades and new releases; equipment used to perform simulation/treatment planning; dosimetry equipment; equipment used to guide treatment delivery, including but not limited to ultrasound units, kV and mV imaging equipment and monitors that are used to view patient imaging studies; and personnel radiation safety equipment. Data communication between various systems, including but not limited to treatment planning systems, treatment delivery systems, and data networks/storage media, shall be evaluated and tested to ensure accurate and complete data transfer.

(xiii) Quality control tests performed on equipment and technology used in planning and implementing radiation treatment shall be documented, including:

(*a*) detailed procedures for performing each test;

(*b*) the frequency of each test;

(*c*) acceptable results for each test;

(*d*) corrective actions taken;

(*e*) record keeping and reporting procedures for test results including the tester’s name, signature, and date of the test; and

(*f*) the qualifications are specified for the individual(s) conducting the test and for the person who reviews test data.

(xiv) Test results that exceed tolerances/limits shall be immediately reported to the licensed medical physicist or authorized medical physicist.

(xv) Records for all maintenance, repairs, and upgrades of equipment and technology shall be maintained for at least five years.

(xvi) Errors or defects in technology or equipment, including computer hardware and software, shall be reported to the technology or equipment manufacturer and to the United States Food and Drug Administration (MedWatch) as soon as possible and in no event more than 30 days of discovery, and records of equipment errors and reports required by this clause shall be maintained for review by the department for at least three years.

(xvii) External beam therapy equipment calibration/output required by section 16.60(c)(1) or 16.61(b)(1) of this Part shall be verified by an independent means and records of such measurements shall be retained for review by the department for at least three years.

(xviii) Patients with permanent brachytherapy implants shall be provided with instructions to take radiation safety precautions, as required by section 16.123(e)(4) of this Part (incorporating 10 CFR 35.75, as revised and implemented on August 13, 2007) and the licensee's radioactive materials license, after being released from the licensee’s facility.

(xix) All personnel involved in planning or administering radiation therapy shall be credentialed. Credentialing shall include verifying that all professional staff are appropriately licensed, including medical physicists and radiation therapy technologists. Records of credentialing shall be maintained during the period in which the credentialed person provides services to the licensee or registrant and for three years thereafter. In the cases of new or complex high fractional dose therapy, staff (in additional to radiation therapists) required at the therapy console should be clearly identified in a written policy and properly trained.

(xx) Any unintended deviation from the treatment plan that is identified shall be evaluated and corrective action to prevent recurrence shall be implemented. Records of unintended deviations and corrective action shall be maintained for audits required by paragraph (3) of this subdivision and for review by the department.

(xxi) There shall be a process to ensure quick and effective response to any radiation therapy related recalls, notices, safety alerts, and hazards.

(xxii) A registrant providing mobile therapeutic radiation machine services shall, at each location of service, comply with all requirements specified in section 16.24 of this Part, as applicable. The registrant shall have policies and procedures to assure proper operation of the device on each day of clinical use, consistent with the registrant’s written policy, manufacturer's guidelines, and established professional body guidelines.

(2) Each licensee or registrant shall adopt and maintain a radiation treatment manual that includes the calculation methods and formulas to be used at the facility (including the methods for performing the checks of treatment plans and related calculations as required in paragraph (1) of this subdivision). The treatment planning manual may be part of the quality assurance manual required by paragraph (1) of this subdivision. The radiation treatment manual shall be included in training given pursuant to subdivision (c) of section 16.13 of this Part to facility staff who will participate in treatment planning. Each licensee or registrant shall ensure that a licensed medical physicist or authorized medical physicist prepares or reviews and approves a procedures manual describing how radiation therapy treatment planning is to be performed at the licensee’s or registrant's facility and reviews the treatment planning manual at least annually. This review must include all parts of the system including both software and physical components and any new modality or protocols.

(3) Each licensee or registrant shall implement written procedures for auditing the effectiveness of the radiation therapy quality assurance program that include the following:

(i) Audits shall be conducted at intervals not to exceed 12 months by a licensed medical physicist or authorized medical physicist, and also by a physician, both of whom are in the active practice of the type of radiation therapy conducted by the licensee or registrant.

(ii) The licensee or registrant shall ensure that the individuals who conduct the audit prepare and deliver to the licensee or registrant a report which contains an assessment of the effectiveness of the quality assurance program and makes recommendations for any needed modifications or improvements.

(iii) The licensee or registrant shall promptly review the audit findings, address the need for modifications or improvements, and document actions taken. If recommendations are not acted on, the licensee or registrant shall document the reasons therefor and also alternative actions taken to address the audit findings.

(iv) Each licensee or registrant shall maintain for review and inspection by the department complete written records relating to quality assurance and audit activities. Audit records shall be maintained for at least six years.

(v) The findings of the audit shall be presented to the RSC or in facilities exempt from having an RSC, the RSO shall review and document.

(4) Accreditation in Radiation Oncology. Each registrant or licensee providing radiation therapy using radioactive material authorized under 10 CFR sections 35.400, 35.600 or 35.1000 (other than radiopharmaceuticals), as revised and implemented in full on November 14, 2022, or radiation equipment under sections 16.60 or 16.61 of this Part shall:

(i) maintain accreditation in radiation oncology by an accrediting organization that is approved by the department;

(ii) for a newly licensed or registered practice, submit an application for accreditation to an organization listed in subparagraph (i) of this paragraph no later than six months after patient treatments begins. Within 18 months after start of patient treatments, the licensed or registered practice shall earn and maintain accreditation in radiation oncology by such organization;

(iii) upon addition of a radiation oncology modality that did not fall under an existing accreditation, the registrant or licensee shall notify the department within 14 days and follow the requirements to obtain accreditation by the accrediting organization and as directed by the department;

(iv) notify the department within 14 days upon notice of the outcome of the accreditation survey;

(v) registrants, licensees, and practices where service is provided by physicians and surgeons who are not radiation oncologists, and whose practices do not qualify for an accreditation survey by an organization specified in subparagraph (i) of this paragraph, shall have an annual audit specified in paragraph (3) of this subdivision performed by a physician and a licensed medical physicist or authorized medical physicist, both in active practice of such modalities and who have not provided clinical services at the practice during the period for which they perform the audit.

(b) Radiopharmaceutical therapy. A quality assurance program for radiopharmaceutical therapy is a system of plans, actions, reviews, reports and records whose purpose is to ensure a consistent and safe fulfillment of the written directive or dose prescription by the authorized user.

(1) Each licensee who uses radiopharmaceuticals for therapy in humans shall implement a quality assurance program which includes at a minimum:

(i) the adoption of a manual containing written policies and procedures designed to assure effective supervision, safety, proper performance of equipment, effective communication, and quality control. These must include procedures to assure that:

(*a*) each patient's evaluation and intended treatment by an authorized user is documented in the patient's record;

(*b*) a written, signed and dated order for medical use of radioactive material is made in accordance with subdivision (c) of section 16.19 of this Part;

(*c*) all orders and other treatment records are clear and legible;

(*d*) staff will be instructed to obtain clarification before treating a patient if any element of the order or other record is confusing, ambiguous or suspected of being erroneous;

(*e*) each patient's response to treatment is assessed by a physician knowledgeable in radiopharmaceutical therapy and that unusual responses are evaluated as possible indications of treatment errors; and

(*f*) complete treatment records containing data recorded at the time of each treatment are maintained.

(2) Each licensee shall ensure that all equipment used in planning and administering radiopharmaceutical therapy is designed for the intended purpose and is properly functioning; is properly calibrated and is maintained in accordance with the manufacturer's instructions and the quality assurance program described in the licensee or registrant's quality assurance manual.

(3) Each licensee shall: audit the radiopharmaceutical quality assurance program at intervals not to exceed 12 months to assess the effectiveness of the program; document the audit and any modifications or improvements found to be needed; institute corrective actions and

improvements as indicated by the audit findings; and present the finding of audit to the RSC or in facilities exempt from having an RSC to the RSO for review and approval.

16.25 Misadministration or Medical Event.

(a) A medical event or a misadministration are equivalent terms for purposes of this Part. A medical event shall be the administration of:

(1) A radiopharmaceutical or radiation from a source other than the one ordered.

(2) A radiopharmaceutical or radiation to the wrong person.

(3) A radiopharmaceutical or radiation by a route of administration or to a part of the body other than that intended by the ordering physician.

(4) An activity of a radiopharmaceutical for diagnostic purposes that differs from the activity ordered by more than 50 percent.

(5) An activity of a radiopharmaceutical for therapeutic purposes that differs from the activity ordered by more than 10 percent.

(6) A therapeutic radiation dose from any source other than a radiopharmaceutical or brachytherapy source such that errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent.

(7) A therapeutic radiation dose from a brachytherapy source such that errors in computation, calibration, treatment time, source activity, source placement or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent.

(8) In a therapeutic radiation course consisting of more than 5 fractions, the administered dose in an individual treatment or fraction that differs from the dose ordered for that individual treatment or fraction by 50 percent or more, or a dose deviation of 20 percent or more in 5 consecutive fractions. In a treatment course of 5 or fewer fractions, dose deviations of 20 percent or more in any one fraction.

(i) Instances when the administered dose is less than the prescribed dose due to machine interruption or patient decision or inability to complete the treatment are not deemed medical events. However, machine performances resulting in incorrect dose administration shall be investigated and reported to the manufacturer if warranted and corrective actions documented pursuant to section 16.24(a)(1)(xvi) of this Part.

(9) A CT scan is performed on the wrong person.

(10) A CT scan is performed on the wrong body part.

(11) A CT scan that results in damage to an organ, organ system or results in hair loss or erythema as determined by a physician.

(b) Records and Reports of medical events or misadministrations.

(1) Diagnostic medical events or misadministrations.

(i) Records of medical events as defined in subdivision (a) of this section which involve diagnostic procedures, and the corrective actions taken pursuant to subparagraph (ix) of paragraph (1) of subdivision (a) of section 16.23 of this Part, shall be retained for three (3) years.

(ii) If such a medical event in a dose to the patient exceeding 5 rem (0.05 Sv) to the whole body or 50 rem (0.5 Sv) to any individual organ, or the administration of iodine-131 or iodine-125 in the form of iodide, and in a quantity greater than 30 microcuries, the licensee or registrant shall

notify the department in writing within 15 days and make and retain a record pursuant to paragraph (3) of this subdivision.

(iii) A medical event described in paragraphs (9), (10) or (11) of subdivision (a) of this section, shall be reported to the Bureau of Environmental Radiation Protection (Bureau) within 15 days of occurrence. All other diagnostic events may be entered into NYPORTS or otherwise documented for facilities not subject to article 28 requirements.

(2) Therapy medical events or misadministrations.

(i) When a medical event described in paragraphs (5), (6), or (7) of subdivision (a) of this section, in which the percentage of error is less than 20 per cent is discovered the licensee or registrant shall immediately investigate the cause and take corrective action.

(*a*) The licensee or registrant shall make and retain a record of all therapy medical events or misadministrations described in this subparagraph. The record shall contain all the information called for in paragraph (3) of this subdivision and shall be retained for six years.

(ii) When a therapy medical event described in paragraphs (a)(1), (2), (3) or (8) of this section is discovered; or when a medical event described in paragraphs (a)(5), (6) or (7) of this section in which the percentage of error is equal to or greater than 20 percent is discovered; the licensee or registrant shall notify the department by telephone. The licensee or registrant shall also notify the referring physician of the affected patient and the patient, of any therapy medical event described in this subparagraph, with the exception of medical events described in paragraphs (a)(1) and (8) of this section. When it is not medically advisable to give such information to the patient, the information shall be made available to the patient's responsible relative or guardian on the patient's behalf. These notifications must be made within 24 hours after the medical event is discovered. If the referring physician, patient, or the patient's responsible relative or guardian

cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as practicable. It is not required that the patient be notified without first consulting the referring physician; however, medical care for the patient shall not be delayed.

(iii) Within 7 days after an initial therapy medical event report, the licensee or registrant shall send a written report to the bureau. The written report must contain the name of the licensee or registrant; the information called for in paragraph (3) of this subdivision; and whether the licensee or registrant notified the patient or the patient's responsible relative or guardian.

(3) Each licensee or registrant shall maintain a record of each reportable medical event for six years. The record must contain the names of all individuals involved in the event (including the treating physician, allied health personnel, the patient, and the patient's referring physician), the medical record number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and actions taken to prevent recurrence.

(4) Within seven days after an initial therapy medical event report made pursuant to subparagraph (ii) of paragraph (2) of this subdivision, the licensee or registrant shall provide the patient a written report with a copy to the patient's referring physician. The report shall contain a brief description of the event, the effect on the patient including any change in the patient's health status which resulted or could result from the medical event, and recommendations for the appropriate course of treatment or follow-up. If it is not medically advisable to give such information to the patient, the report shall be made available to the patient's responsible relative or guardian on the patient's behalf and documented in the patient's treatment record.

16.26 Respiratory protection and controls to restrict internal exposure restricted areas.

(a) Any person using respiratory protection and controls to restrict internal in exposure restricted areas shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 20, subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," as revised and implemented in full on December 19, 2002, except as follows:

(1) Any reference to the "Commission" or "NRC" shall be deemed to be a reference to the New York State Department of Health.

16.40 Fees.

(a) General requirement. Unless exempt under subdivision (b) of this section, no person shall establish, maintain or operate a radiation installation with radiation equipment, that is subject to the registration requirements of section 16.50 of this Part, or hold a radioactive materials license as required pursuant to the licensing requirements of section 16.100 of this Part, except upon payment of the applicable fees prescribed in this section and section 16.41 of this Part.

(b) Exemptions.

(1) Agencies of the State of New York and its political subdivisions, except for hospitals and higher education academic institutions operated by such agencies, are exempt from the payment of any of the fees prescribed in this section and section 16.41 of this Part.

(2) Any operator of a radiation installation that is registered with the New York City Department of Health and Mental Hygiene or any person that holds a radioactive material license issued by the New York City Department of Health and Mental Hygiene, pursuant to sections 16.50(j) and 16.1(b)(2) of this Part, is exempt from paying the fees prescribed in this section and section 16.41 of this Part, unless they also hold a registration certificate or a radioactive material license

issued by the department for which fees are applicable. In the latter case, the applicable fees for the activities registered or licensed by the department shall be assessed.

(c) Payment of fees.

(1) Each application for a radiation installation registration or for a new radioactive material license, shall be accompanied by a remittance of the full amount of the applicable annual fees prescribed in section 16.41 of this Part. Annual fees for each subsequent year shall become due on each anniversary date thereafter, determined by the date of original registration or license issued.

(2) Any operator of a radiation installation who holds a current radiation installation registration certificate issued pursuant to this Part or any person who holds a current radioactive material license issued pursuant to this Part, shall pay the prescribed annual fee as billed by the department. Payment of fees shall be made within the 30-day period immediately following the billing date.

(3) The payment of all fees prescribed by this Part shall be by check or money order made payable to the New York State Department of Health.

(d) Prorating fees. For administrative purposes, the department may alter the fee due date and charge a fee for a period greater or less than one year. In such case the amount of the fee due will be prorated to correspond to the length of the period covered by the bill.

(e) No refund policy. Except in those cases where the department has determined that a payment of fees is not required, no fees, or portions thereof, paid to the department pursuant to this Part shall be refundable.

(f) Failure to pay prescribed fee. If an applicant for a license or registration fails to remit with such application the full amount of the fees as prescribed by this Part, the department will not

process the application and will notify the applicant that the application will not be processed unless fees are first paid. The department may revoke, suspend or amend a registration or radioactive material license in whole or in part for failure to pay all prescribed annual fees due.

(g) Registration fees charged by New York City Department of Health and Mental Hygiene. Provided that a written schedule of the registration fees to be charged by the New York City Department of Health and Mental Hygiene, has been submitted, in the manner prescribed, to, and approved by, the State Commissioner of Health, the New York City Department of Health and Mental Hygiene is authorized to charge within its jurisdiction registration fees as so approved. The State of New York or any political subdivision thereof or any agency or instrumentality of either are exempt from the payment of such fees.

(h) Fees charged by local health departments. Provided that a written schedule of the fees to be charged, together with a written analysis of the estimated costs of its radiation protection regulatory program, has been submitted to and approved by the State Commissioner of Health, the New York City Department of Health and Mental Hygiene or, as the department shall direct, the appropriate county or part-county health officer having jurisdiction that inspects installations with radiation equipment under a program of inspection certified by the State Department of Health, or any county, part-county or city health district that licenses and inspects radioactive materials in accordance with section 16.1(b)(2) of this Part, is authorized to charge adequate and reasonable fees for inspection, licensing and/or other radiation protection services rendered, as applicable, not exceeding the estimated costs of such services, except that, with the approval of the State Commissioner of Health, one or more of such services may be rendered without charge. The State of New York or any political subdivision thereof or any agency or instrumentality of either are exempt from the payment of such fees.

(i) Fees charged by certified radiation equipment safety officers. A certified radiation equipment safety officer shall not charge, or propose to charge, a fee for an inspection in excess of a fair and reasonable amount as determined by the department. Such officer shall furnish to the department, upon request, information as to fees charged or proposed to be charged by the officer. Such fees shall not exceed the estimated cost of services.

(j) Fees paid prior to the effective date of this section. Facilities that had paid fees which cover a period that extends beyond the effective date of this section, shall be responsible for the difference between the prorated amount of any fee previously paid for such period and that due under this section for such period.

16.41 Fee schedule.

Effective upon adoption, the annual fees assessable shall be as prescribed in this section.

(a) Registration fees. Except for entities exempt from fees under section 16.40(b)(1) of this Part, the annual registration fee for radiation installations required to be registered shall be as listed in this section.

(b) Fee categories for radiation installations required to be registered with the department. For the purpose of assessing annual fees, all radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part are categorized in one of the following six categories:

Category I: Radiation installations with any five or more of the modalities listed below.

Category II: Radiation installations with three or four of the modalities listed below.

Category III: Radiation installations with two of the medical modalities listed below.

Category IV: Radiation installations with one of the medical modalities listed below and annual patient workload of 750 examinations or more.

Category V: Radiation installations with one of the medical modalities listed below and annual patient workload of less than 750 examinations, and all other radiation installations with one or two of the non-medical modalities listed below except as listed under Category VI.

Category VI: Dental, podiatric, bone densitometry or veterinary installations.

The modalities to be used in determining the fee category for radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part are:

Medical Modalities: radiography, fluoroscopy, computed tomography, angiography, stereotactic breast biopsy systems, and Grenz/orthovoltage therapy, utilized in humans.

Non-medical Modalities: radiography, fluoroscopy, analytical equipment (including electron microscopes, fluorescence analysis and x-ray diffraction equipment), gauges and other commercial device not otherwise listed here, and computed tomography and particle accelerators that are not utilized on humans.

(c) Fee schedule for radiation installations routinely inspected by the department. All radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part that are not exempt from fees under section 16.40(b) of this Part and that are routinely inspected by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed annual fees according to the following schedule:

Category I radiation installations: $ 2600

Category II radiation installations: $ 1800

Category III radiation installations: $ 1250

Category IV radiation installations: $ 550

Category V radiation installations: $ 325

Category VI radiation installations: $ 100

(d) Fee schedule for radiation installations routinely inspected by a county or part-county health officer or by a certified radiation equipment safety officer. All radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part that are not exempt from fees under section 16.40(b) of this Part and that are routinely inspected by a county or part-county health officer having jurisdiction, as the department shall direct, under a program certified by the department, or by a certified radiation equipment safety officer as directed by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed an annual fee according to the following schedule:

Category I radiation installations: $ 600

Category II radiation installations: $ 450

Category III radiation installations: $ 300

Category IV radiation installations: $ 125

Category V radiation installations: $ 65

Category VI radiation installations: $ 25

(e) Fee categories for non-commercial, radioactive material licensees and radiation installations that use accelerators in medical therapy. For the purpose of assessing annual fees, all persons holding radioactive material licenses issued by the department and all radiation installations that are required to be registered with the department, pursuant to section 16.50(a) of this Part and

that use accelerators in medical therapy are categorized in one or more of the following six categories:

Category I: Persons issued a broad scope medical license.

Category II: Persons issued a broad scope academic or broad scope research and development license.

Category III: Persons issued a specific license which allows the use of radioactive materials for both nuclear medicine and brachytherapy, or a license which authorizes the operation of a nuclear pharmacy at an institution or a pharmaceutical production cyclotron.

Category IV: Radiation installations operating a medical therapy accelerator and/or persons issued a specific license which authorizes the use of radioactive materials in nuclear medicine, brachytherapy, mobile nuclear medicine service, teletherapy (including Co-60 teletherapy and gamma knife), research and development, academic uses, veterinary medicine or large irradiators.

Category V: Persons issued a specific license which authorizes the use of radioactive materials in a clinical laboratory, lead paint analyzers, mobile nuclear medicine sites, leak tests, equipment calibration, self-shielded irradiators, diagnostic sealed sources, and any other use not included in categories I through VI as listed in this subdivision.

Category VI: Persons issued a specific license for use of radioactive materials in gas chromatographs.

(f) Radioactive materials/medical therapy accelerator fee schedule.

(1) Except for entities exempt from fees under section 16.40(b) of this Part, all persons that hold radioactive material licenses issued by the department and all radiation installations that are required to be registered with the department and that use accelerators in medical therapy shall be assessed annual fees according to the following schedule:

Category I: $ 9600

Category II: $ 6200

Category III: $ 2400

Category IV: $ 1500

Category V: $ 600

Category VI: $ 120

(2) When more than one fee category as described in section 16.41(e) of this Part applies, the fee which corresponds to the highest applicable category will be assessed, provided, however, that separate Category III fees will be assessed to any person that holds a license to operate a nuclear pharmacy or a pharmaceutical production cyclotron for each type of these uses that applies, in addition to any other categories of fees that apply; and radiation installations or licensees that provide teletherapy (Co-60, gamma knife or a medical therapy accelerator) services or veterinary medicine services, or use radioactive materials in large irradiators, or, except for Category I or II licensees, use radioactive materials in research and development, will be assessed Category IV fees for each type of these uses that applies, in addition to any other categories of fees that apply. If a person that holds a radioactive material license is also the operator of a radiation installation that uses an accelerator in medical therapy and the licensed activities are conducted at such installation, the licensed radiation installation shall be considered as one and the same entity for purposes of assessing fees described under section 16.41(e) of this Part.

(g) Fee categories for commercial radioactive material licensees. For the purpose of assessing annual fees, all persons holding radioactive material licenses issued by the department shall be categorized in one or more of the following six categories:

Category I: Persons issued a specific license which authorizes the use of radioactive material for cyclotron operations, industrial radiography - fixed facility only, industrial radiography - temporary job sites (may include fixed), licenses of broad scope not otherwise specified (NOS), manufacturing NOS, manufacturing of radioactive products - broad scope, nuclear laundry, nuclear pharmacy operations, open irradiator (> 1MCi), research and development - broad scope, waste broker, waste disposal facility (active), or waste services NOS.

Category II Persons issued a specific license which authorizes the use of radioactive material for commercial distribution of radioactive products, decontamination and decommissioning service, distribution of radioactive medical products, distribution of radioactive products NOS, manufacturing of radioactive medical products – limited scope, manufacturing of radioactive products – limited scope, open irradiator (>10,000 Ci <1MCi), research and development – limited scope (>1 Ci), waste disposal facility (inactive), waste processing or repackaging, or well logging and tracer studies

Category III Persons issued a specific license which authorizes the use of radioactive material for device installation, maintenance and repair service, full health physics consulting service, leak test and calibration service, medical system service, moisture/density gauge, open irradiator (<= 10,000 Ci), redistribution of

radioactive products, research and development – limited scope (<1 Ci), sealed or unsealed sources NOS, services NOS, and well logging (sealed sources only).

Category IV Persons issued a specific license which authorizes the use of radioactive material for analytical laboratory (radioactive sample analysis), calibration service, fixed gauges, gauges NOS, leak test service, portable X-ray fluorescence analyzer, possession incident to exempt distribution (NRC E-license), and self-shielded irradiators.

Category V Persons issued a specific license which authorizes the use of radioactive material for Analytical instruments NOS, demonstration and sales of radioactive products, gas chromatograph, or storage only pending disposal.

(h) Annual fee schedule for commercial radioactive materials licenses.

Category I $3600

Category II $3000

Category III $2400

Category IV $1800

Category V $ 600

(i) Generally licensed devices. A non-refundable fee in the amount of $120, payable to the department, shall be submitted with each registration of a generally licensed device.

(j) Additional fees.

A non-refundable fee for commercial licenses shall be submitted to the department according to the following schedule:

(1) Fee for the review of decommissioning plan submitted in accordance with section 16.113 of this Part shall be $2,500.

(2) Fee for sealed source and device certificate application review shall be $1,500.

(3) Fee for reciprocity shall be 50% of the commercial license fee by category (i.e., category 1 reciprocity will be $1800 for 6 months).

RADIATION EQUIPMENT

Introductory note: Sections under this heading contain the registration and transfer notification provisions for radiation equipment and general and additional radiation protection requirements applicable only to specific radiation equipment.

16.50 Registration of installations with radiation equipment; notification of transfer of radiation equipment.

(a) No person shall establish, maintain or operate any radiation installation at which is located or used any radiation equipment in operable condition or intended to be used, unless such installation has been registered as evidenced by a current certificate of registration issued to the operator thereof by the department or has been registered in an alternate manner accepted by the department in accordance with subdivision (j) of this section. Radiation equipment exempted from the requirements of this Part under section 16.4 is exempt from the registration requirement.

(b) Radiation installation application for registration, as described in subdivision (a) of this section shall be made by the operator thereof, to the department on a written form and in a manner prescribed by the department. This must be done 30 to 60 days prior to: a new installation of equipment, an existing installation certificate expiration date (renewal), and any changes in ownership, operation status, or location.

(c) The department may withhold, suspend, or revoke a certificate of registration if it finds that:

(1) the information submitted in the application is incorrect or incomplete; or

(2) the fees for registration and/or the certificate have not been paid as required; or

(3) the installation is, has been or will be established, maintained or operated in violation of the State Public Health Law, the State Sanitary Code (Chapter I of this Title) or any other applicable law, rule, regulation or order; or

(4) the certificate has not been issued correctly.

(d) A certificate of registration shall be issued for a limited period of time extending from the date of issuance to the date of expiration as specified on the certificate.

(e) The certificate of registration issued for a radiation installation to the operator thereof shall expire upon:

(1) the expiration date specified on the certificate; or

(2) revocation by the department; or

(3) a change of the operator; or

(4) a change in location of the radiation installation if it is not a mobile unit; or

(5) a change in the name of the installation; or

(6) the discontinuance of the installation.

(7) failure to pay the required fee by the specified date.

(f) A certificate of registration shall not be transferable or assignable except as approved by the department.

(g) An unexpired certificate of registration issued for a radiation installation shall be conspicuously posted at the installation and made available by the operator, upon request, to the department, the health officer having jurisdiction, or other person or agency making a survey of the installation pursuant to paragraph (1) of subdivision (a) of section 16.10 of this Part.

(h) The certificate of registration shall not imply endorsement or approval by the department and shall not be used to advertise or promote business.

(i) The operator of a radiation installation shall keep correct and complete the information submitted in his application for registration by reporting to the department in writing within 10 days any change affecting such information.

(j) The department may accept, in lieu of registration with the department, registration with the New York City Department of Health and Mental Hygiene. Acceptance of registration may be done only for radiation installations surveyed under an inspection program conducted by the New York City Department of Health and Mental Hygiene as described in paragraph (1) of subdivision (a) of section 16.10 of this Part. As a condition of the department's acceptance of registration pursuant to this section, the registering agency shall furnish to the department in writing, at such times and in such form as the commissioner may prescribe, pertinent information concerning the registration of each and every radiation installation registered by the agency. The information furnished to the department shall cover at least those items contained in the department's application form for registration of a radiation installation.

(k) The distributor, retailer or other agent who sells, leases, transfers, loans or installs X-ray or fluoroscopic equipment or other radiation equipment subject to the registration requirements of this section shall notify the department in writing within 10 days after making such sale, lease, transfer, loan, or installation on, and in accordance with the instructions of, a form prescribed by the department.

(l) No person shall make, sell, lease, transfer, loan, or install radiation equipment subject to the registration requirement of this section or the supplies used in connection with such equipment unless such supplies and equipment, when placed in operation and used, will meet the requirements of this Part.

(m) Every distributor or retailer of radiation equipment, or agent thereof, or radiation consultant, who installs, tests, or otherwise services radiation equipment shall be registered with the commissioner on a form prescribed by them. Registration shall be made prior to undertaking such installation, testing, or servicing. Such distributors, retailers, agents, or consultants shall, while engaged in installation, testing, or other servicing of radiation equipment, comply with the requirements of this Part.

16.51 General requirements for and prohibited uses of radiation equipment.

(a) General requirements. All radiation equipment shall meet any applicable specific provision of the sections of this Part set forth under the heading "Radiation Equipment" (section 16.50 to 16.70), and all possession or use thereof shall comply with the requirements of sections of this Part set forth under the heading "General Provisions" (section 16.1 through 16.20), and any other requirement imposed by the department. Radiation equipment which is not intended to be used must be made inoperable to the satisfaction of the department by dismantling or sealing with an official New York State Department of Health seal or other suitable method; and shall not be unsealed or restored to operable condition without prior authorization by the department.

(b) Prohibited uses and activities include the following:

(1) non-image intensified fluoroscopic equipment which has not been certified in accordance with 21 CFR 1020 as revised and implemented in full on January 20, 2023. (*See* section 16.200 of this Part);

(2) shoe-fitting fluoroscopic devices;

(3) intra-oral fluoroscopy used in dental examinations;

(4) photofluorographic equipment;

(5) the sale of gold jewelry which is known by the owner to be contaminated with radioactive materials, except for sale to the department;

(6) body composition assessment or analysis not under the direction and order of an authorized individual pursuant to section 16.19 of this Part;

(7) exposure of human beings for demonstration purposes;

(8) hand-held fluoroscopic devices.

(c) Beam Quality *Half-value layer (HVL)*. The HVL of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in Table 1 in paragraph (c)(1) of this section under the heading "Specified Dental Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading "I--Other X-Ray Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and under the heading "II--Other X-Ray Systems," for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in Table 1 in paragraph (c)(1) of this section, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to ensure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

Table 1

X-Ray Tube Voltage (kilovolt peak)	Measured Operating	Minimum HVL (mm of aluminum)		
Designed Operating Range	Potential	Specified Dental Systems[1]	I--Other X-Ray Systems[2]	II--Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1]Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2]Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

[3]All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

16.52 Electrical hazards.

(a) All radiation equipment, except equipment used solely in research and development, installed in a radiation installation shall, where applicable, be listed by the Underwriters Laboratories Inc., or shall comply with The National Electrical Code of the National Fire Protection Association (NFPA), as implemented by NFPA70: National Electric Code 2023, which is hereby incorporated by reference, or an equivalent safety standard.

(b) Existing equipment employing uninsulated or bare overhead conductors moved to a new location or registered as a new installation under section 16.50 of this Part shall be certified as being free of electrical hazards.

(c) Certification by a duly constituted local authority that the installation is free of electrical hazards shall be acceptable.

16.53 Dental radiographic installations.

(a) Intraoral Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide at least the same degree of protection as is required of the tube housing.

(3) The diameter of the useful beam at the face of the patient shall not exceed three inches.

(4) A cone or spacer frame shall provide a source-skin distance of not less than seven inches with equipment operating above 50 kVp or four inches with equipment operating at 50 kVp or below for intra-oral radiography.

(5) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(6) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type, and where protective barriers are required shall be so arranged that it cannot be operated outside the shielded area.

(7) Each installation shall be so arranged that the operator can stand at least six feet from the patient, the X-ray tube, and the useful beam during exposure. A protective barrier shall be provided where the operator cannot stand at least six feet away from the patient, the X-ray tube and the useful beam during exposures.

(8) The tube head shall remain stationary when placed in the exposure position.

(b) Conditions for operation of equipment.

(1) The film or image receptor shall not be held by the dentist or technician during the exposure.

(2) Only the patient shall be in the useful beam.

(3) Neither the tube housing, pointer nor cone shall be handheld during the exposure.

(4) Only persons required for the radiographic procedure shall be the radiographic room during the exposure.

(5) For extra-oral radiography, the x-ray film used as the recording medium during the x-ray examination shall show substantial evidence of cut-off (beam delineation).

(c) Special installations.

(1) Panoramic installations are dental installations which consist of a tube head with a collimator providing a narrow (12mm) useful beam and an extra-oral film carrier which are interlocked in their motion about the patient.

(i) Equipment.

(*a*) The protective tube housing shall be of diagnostic-type.

(*b*) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the tube housing.

(*c*) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(*d*) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type.

(*e*) Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six feet from the patient, the X-ray tube, and the useful beam.

(ii) Conditions for operation of equipment. Only the patient shall be in the useful beam.

(2) Handheld X-ray devices - portable dental X-ray devices which are used in dentistry for taking intraoral radiographs. The devices are battery-powered, portable and designed to be used when held in the hands of the operator during exposure. Only units that are FDA approved and have been reviewed and approved by the department may be used in New York State.

(i) Equipment.

(*a*) The protective tube housing shall be of diagnostic type.

(*b*) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide at least the same degree of protection as is required of the tube housing.

(*c*) For intra-oral radiography the diameter of the useful beam at the face of the patient shall not exceed three inches.

(*d*) A cone or spacer frame shall provide a source-skin distance of not less than seven inches with equipment operating above 50 kVp or four inches with equipment operating at 50 kVp or below for intra-oral radiography.

(*e*) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(*f*) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type, the handheld unit shall be operated with the scatter shield in place.

(*g*) Each installation shall be so arranged that the operator can stand behind the X-ray tube, and the useful beam during exposure.

(*h*) The unit shall only be operated by authorized personnel who have been trained in the operation of the device.

(*i*) When not in use the handheld unit must be secured to prevent inadvertent exposures or use by unauthorized personnel.

(*j*) The backscatter shield shall be in place.

(3) Cone Beam CT (CBCT) – the requirements of section 16.65 of this Part shall apply.

16.54 Veterinary radiographic and fluoroscopic installations.

(a) Fixed radiographic, CT, CBCT installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(iii) The images shall show substantial evidence of cut-off (beam delineation).

(iv) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(v) A device shall be provided which terminates the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type and shall be so arranged that it cannot be operated outside a shielded area.

(2) Structural shielding.

(i) Control apparatus for the radiographic equipment shall be located in an adjacent room or in a fixed booth within the same room provided such booth is composed of radiation shielding to a minimum height of seven feet. The control booth either shall be so arranged that the radiation has to be scattered at least twice before entering the booth, or shall be provided with a protective door that is interlocked in such a way that the X-ray tube(s) cannot be energized unless the door is in the closed position.

(ii) The operator shall be able to see the animal patient by means of a mirror or through a window of lead equivalent sufficient for the required protection and so placed that the operator is always in a shielded position.

(3) Conditions for operation of equipment.

(i) Only persons required for the X-ray procedure shall be in the X-ray room during the exposures.

(ii) When an animal patient must be held in position during exposures, mechanical supporting or restraining devices shall be used. Animal patients or image receptors shall be held only under extreme conditions when clinically necessary. Individuals holding animal patients or image receptors shall wear protective gloves having at least 0.5 mm lead equivalent, a protective apron of at least 0.25 mm lead equivalent, and shall keep all parts of their body out of the useful beam. The exposure of any individual used for holding animals shall be monitored. Pregnant women and persons under 18 years of age shall not hold animal patients or films under any conditions.

(b) Portable or mobile radiographic installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(iii) The X-ray images shall show evidence of cut-off (beam delineation).

(iv) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(v) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(vi) A dead-man type of exposure switch shall be provided with a cord sufficiently long so that the operator can stand at least six feet from the animal patient, the X-ray tube, and the useful beam.

(2) Conditions for operation of equipment.

(i) No person shall be regularly employed to support or hold animals or film during X-ray exposures.

(ii) When an animal must be held in position during exposures, mechanical supporting or restraining devices shall be used. Individuals should hold animals only when clinically necessary under extreme conditions. Such individuals shall wear protective gloves having at least 0.5 mm lead equivalent, a protective apron of at least 0.25 mm lead equivalent, and shall keep all parts of his body out of the useful beam. The exposure of any individual used for holding animals shall be monitored. Pregnant women and individuals under 18 years of age shall not hold animals under any conditions,

(c) Fluoroscopic installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Equipment shall be so constructed that the entire cross section of the useful beam is always intercepted by a primary protective barrier (usually a lead glass screen or image intensifier assembly) irrespective of the panel screen distance. For conventional fluoroscopes, this requirement may be assumed to have been met if, when the collimating system is opened to its fullest extent, an unilluminated margin is left on all edges of the fluorescent screen regardless of the position of the screen during use.

(*a*) Collimators, and adjustable diaphragms, or shutters used to restrict the size of the useful beam shall provide the same degree of protection as is required of the tube housing.

(*b*) The exposure shall automatically terminate when the barrier is removed from the useful beam.

(*c*) With the fluorescent screen 14 inches from the panel of the tabletop, the exposure rate two inches beyond the viewing surface of the screen shall not exceed 30 mR/hr for each roentgen per minute at the tabletop with the screen in the useful beam without a patient and with the fluoroscope operating at the highest potential employed.

(iii) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(iv) The fluoroscopic exposure switch shall be of the dead-man type.

(v) Mobile fluoroscopic equipment is subject to the following additional requirements:

(*a*) in the absence of a tabletop, a cone or spacer frame shall limit the source-to-skin distance to not less than 12 inches;

(*b*) image intensification shall always be provided;

(*c*) it shall be impossible to operate a machine unless the useful beam is intercepted by the image intensifier.

(2) Conditions for operation of equipment.

(i) Protective gloves and aprons of at least 0.25 mm lead equivalent each shall be made available and shall be worn by the fluoroscopist during every examination.

(ii) Unless measurements indicate that they are not needed protective gloves and protective aprons of at least 0.25 mm lead equivalent each shall be worn by the physician, nurse, technician and all other persons within the fluoroscopic room.

(iii) Only persons needed in the fluoroscopic room shall be present during the exposure.

(iv) The fluoroscopic room shall be free of extraneous light that interferes with the examination.

(d) Special installations.

(1) Handheld X-ray devices.

(i) The requirements of paragraph 16.53(c)(2) of this Part shall apply.

(ii) “Animal” shall replace “human being” or “patient”

16.55 Podiatric radiographic installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type and where protective barriers are required shall be so arranged that it cannot be operated outside the shielded area.

(6) Each installation shall be arranged so that the operator can stand at least six feet from the patients, the X-ray tube and the useful beam during exposure. A protective barrier shall be provided when the operator cannot stand at least six feet away from the patient, the X-ray tube and useful beam during exposures.

(b) Conditions for operation of equipment.

(1) No person shall hold film during the exposure.

(2) Only persons required for the radiographic procedure shall be in the radiographic room during exposure.

(c) Special Installations.

(1) Handheld X-ray devices,

(i) The requirements of paragraph 16.53(c)(2) of this Part shall apply for patient anatomy limited to the foot.

(ii) The handheld unit is operated with the manufacturer's stand.

(2) Cone Beam CT – the requirements of section 16.65 of this Part shall apply.

16.56 Radiographic installations excluding dental, veterinary, and podiatric installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(6) A dead-man type of exposure switch shall be used and so arranged that it cannot be operated outside a shielded area. Exposure switches for "spot-film" devices used in conjunction with fluoroscopic equipment are excepted from this shielding requirement.

(7) The tube head shall remain stationary when placed in the exposure position.

(b) Structural shielding.

(1) Except for mammography systems, control apparatus for the radiographic equipment shall be located in an adjacent room or in a fixed booth within the same room provided such booth is composed of radiation shielding to a minimum height of seven feet. The control booth either shall be so arranged that the radiation has to be scattered at least twice before entering the booth, or shall be provided with a protective door that is interlocked in such a way that the X-ray tube(s) cannot be energized unless the door is in the closed position.

(2) The operator shall be able to see the patient by means of a mirror or through a window of lead equivalent sufficient for the required protection and so placed that the operator is always in a shielded position.

(3) Provision shall be made for the operator to communicate with the patient from a shielded position.

(c) Conditions for operation of equipment.

(1) No person shall be regularly employed to hold patients or image receptors during exposures, nor shall such duty be performed by any individual occupationally exposed to radiation during the course of their other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices shall be used whenever possible. If patients or image receptors must be held by an individual, that individual shall be provided with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent. No part of the attendant's body shall be in the useful beam. The exposure of any individual used for holding patients shall be determined. Pregnant women and persons under 18 years of age shall not hold patients under any conditions.

(2) Only persons required for the radiographic procedure shall be in the radiographic room during exposure; and, except for the patient, all such persons shall be equipped with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent.

16.57 Portable, bedside or mobile X-ray equipment excluding dental, veterinary and podiatric equipment.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(6) All mobile, portable or beside equipment shall be provided with cones or metal frames so that the minimum source to skin distance is at least 12 inches.

(7) The exposure switch shall be of the dead-man type and shall be provided with a cord sufficiently long that the operator can stand at least six feet from the patient, the X-ray tube and the useful beam.

(b) Use. If a mobile unit is used routinely in any location, it shall be considered a fixed installation, and shall meet the requirements of section 16.56 of this Part.

(c) Conditions for operation of equipment.

(1) No person shall be regularly employed to hold patients or image receptors during exposures, nor shall such duty be performed by any individual occupationally exposed to radiation during the course of their other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices shall be used. If patient or image receptors must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent. No part of the attendant's body shall be in the useful beam. The exposure of any individual used for holding patients shall be monitored. Pregnant women and persons under 18 years of age shall not hold patients under any conditions.

16.58 Fluoroscopic installations excluding veterinary installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Equipment shall be so constructed that the entire cross section of the useful beam is always intercepted by the primary protective barrier irrespective of the position.

(i) Collimators and adjustable diaphragms or shutters used to restrict the size of the useful beam shall provide the same degree of protection as is required of the tube housing.

(ii) The exposure shall automatically terminate when the barrier is removed from the useful beam.

(3) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(4) Fluoroscopic exposure switch shall be of the dead-man type.

(5) Source-skin distance.

(i) Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 cm. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing.

(ii) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application

that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing.

(6) Fluoroscopy equipment shall not be operated for human use unless a cumulative timing device, activated by the fluoroscope exposure switch, is functioning. It shall indicate the passage of a period of irradiation, not exceeding five minutes, either by an audible signal or by temporary interruption of the irradiation.

(7) The exposure rate as measured, at no less than 70 kVp in the mode of least magnification with the image intensifier at 40 cm above the tabletop or over table fluoroscopy tube at a source to image distance normally used for an average patient, with a patient phantom composed of 1 and 1/2 inches of Type 1100 aluminum in a 7 inch square or an equivalent device in the fluoroscopic beam shall not exceed 5 roentgens per minute except during recording of fluoroscopic images or during activation of optional high level control. The maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 88 mGy per minute (10 roentgens per minute) except as follows:

(i) Equipment manufactured before May 19, 1995 and certified in accordance with 21 CFR 1020 as revised and implemented in full on January 20, 2023, (see section 16.200 of this Part) and having an optional high level control is limited to a maximum output of 44 mGy per minute (5 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 176 mGy per minute (20 roentgens per minute).

(ii) Certified equipment manufactured after May 19, 1995 with automatic exposure rate and having an optional high level control is limited to a maximum output of 88 mGy per minute (10 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 roentgens per minute.

(iii) Certified equipment manufactured after May 19, 1995 without automatic exposure rate is limited to 44 mGy per minute (5 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 176 mGy per minute (20 roentgens per minute).

(8) Primary protective barriers shall provide the following protection:

(i) For uncertified equipment, with the image intensifier 36 cm (14 inches) from the tabletop, the exposure rate two inches beyond the image intensifier shall not exceed 5uGy/hr (30 mR/hr) for each roentgen per minute at the tabletop with the intensifier in the useful beam without a patient and with the fluoroscope operating at the highest potential available for use.

(ii) For certified equipment, the exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 0.33 uGy per hour (two milliroentgens per hour) at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each 0.01 Gy per hour (roentgen per minute) or entrance exposure rate.

(9) The high contrast resolution of the fluoroscopic system shall be capable of resolving a minimum mesh number of 24 for the center of the beam and 20 for the edges using a test tool

composed of 8 groups of copper or brass mesh screening ranging from 16 to 60 lines/inch set in plastic or an equivalent device.

(10) The low contrast performance of the fluoroscopic system shall be capable of resolving a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and a patient equivalency phantom or an equivalent device.

(11) Radiation therapy simulation systems shall be exempt from the requirements of paragraphs (2), (6), (7) and (8) of this subdivision provided that:

(i) the systems are designed and used in a manner such that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(ii) systems which do not meet the requirements of paragraph (6) of this subdivision are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(b) Conditions for operation of equipment.

(1) The operator of the installation shall make and record the outputs made pursuant to paragraph (7) of subdivision (a) of this section, where the center of the useful beam enters the patient during routine fluoroscopy and cinefluoroscopy, at annual intervals or more frequently if outputs are found to exceed the limits defined in this section.

(2) Other than tabletop mini C-arms, protective garments of at least 0.25 mm lead equivalent each shall be worn by the physician, nurse, radiologic technologist and all other persons within the fluoroscopic room.

(3) Only persons needed in the fluoroscopic room shall be present during the exposure.

(4) The cumulative fluoroscopic time must be reset for each new patient.

(5) Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

(i) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

(ii) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

(iii) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

(iv) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users according to 21 CFR 1020.30(h)(6)(iii) as revised and implemented on January 20, 2023.

16. 59 Computed Tomography (CT) equipment.

(a) Definitions

(1) “Computed tomography (CT)” scan and “computerized axial tomography (CAT)” scan refer to an imaging procedure that uses x-rays to create cross-sectional images of the human body.

(2) “Computed tomography dose index” (CTDI) means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan where the dose profile is centered around z = 0 and for a multiple tomogram system, the scan increment between adjacent scans is nT;

z = position along a line perpendicular to the tomographic plane;

D (z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan

(3) “CT x-ray system” is technology that is used to perform CT scans and includes but is not limited to, a control panel, image display device, gantry, x-ray tube, collimating device with filters, high voltage transformer and a data acquisition system.

(4) “CT scanner” refers to technology used to perform and interpret CT scans and includes, but is not limited to, a control panel, gantry, high voltage generator, x-ray tube, table and display devices that are used for image interpretation.

(5) “CTDI100” is the dose measurement made with a 16 cm diameter (head/pediatric body) or a 32 cm diameter (body) acrylic phantom. The measurements are made utilizing a 100 mm long pencil ionization chamber. Readings are made with the ion chamber in both the center (axial or central dose) position and near surface slots of the phantom (the peripheral dose).

(6) “CTDIW”, the weighted or blended dose, is calculated by adding together two-thirds of the CTDI100 peripheral dose with one-third of the CTDI100 axial or center dose. (CTDIW = 2/3 CTDI100 peripheral + 1/3 CTDI100 axial or center). CTDIW represents an average dose in the x and y planes.

(7) “CTDIVOL” represents the integrated dose over the total volume that is irradiated, CTDIVOL = (1/PITCH) x (CTDIW), where “Pitch” is defined as the table travel per rotation divided by the collimation of the x-ray beam. CTDIVOL represents the average dose in the x, y and z planes.

(8) "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors.

(9) "CT dosimetry phantom" means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethyl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole-body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.

(10) “Dose length product” (DLP) is defined as the CTDIvol times the irradiated length of the body for the whole series of images that are taken during a CT scan.

(11) “Picture Archiving and Communication System (PACS)” is a medical imaging technology that provides access to and storage for medical images from multiple modalities. It is comprised of an image acquisition system, display, network and data storage or archiving system.

(12) "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

(13) "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram or a series of tomograms.

(14) "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

(15) “Technique” means the settings selected on the control panel of the equipment and may include the position of the x-ray tube, image intensifier and patient.

(16) “Technique chart” means a chart that lists the standard settings and positions for a given technique.

(17) “Tomogram” is an image of a tissue plane or section of tissue.

(18) "Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

(19) "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(b) CT X-Ray System Equipment Requirements.

(1) Each control panel and gantry of a CT x-ray system shall include visual signals that indicate to the operator of the CT x-ray system whenever x-rays are being produced and when x-ray production is terminated, and, if applicable, whether the shutter is open or closed.

(2) Each CT x-ray system shall be equipped with a control that allows the operator of the CT x-ray system to terminate the x-ray exposure at any time during a scan, or series of scans, when the exposure time is greater than one-half second duration.

(3) Each CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence.

(4) Each CT x-ray system shall include a clearly and conspicuously labeled emergency shutoff button or switch.

(5) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation by the operator prior to the initiation of another scan.

(c) Patient communication and viewing requirements.

(1) Each CT x-ray system shall be equipped to allow two-way aural communication between the patient and the operator at the control panel.

(2) Each CT x-ray system shall be equipped with windows, mirrors, closed-circuit television, or an equivalent to permit continuous visual observation of the patient during CT scanning by the CT operator from the control panel.

(3) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

(d) Calibration.

(1) Each registrant shall ensure that the calibration of the radiation output of each CT x-ray system that it operates is performed by, or under the direction of, a licensed medical physicist.

(2) Each registrant shall maintain and make available for review by the department, on the premises of its radiation installation where a CT x-ray system is located written procedures for the appropriate calibration of the CT x-ray system.

(3) After initial installation, the CT x-ray system shall be calibrated prior to its use on human beings and recalibrated at least within every 14 months thereafter. Any change or replacement of components of a CT x-ray system which could cause a change in the radiation output will require

a recalibration within 30 days of component installation by a licensed medical physicist operating within their scope of practice.

(4) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. This system shall have been calibrated either by the National Institute of Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) and traceable to NIST. The calibration shall have been performed within the previous 24 months and after any servicing that might have affected system calibration.

(5) CT dosimetry phantom(s) shall be used in determining the radiation output of each CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(i) Any effects on the doses measured because of the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(ii) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(iii) The requirements of subparagraphs (i) and (ii) of this paragraph can also be met by using an alternative method of radiation measurement and calculation published in the peer-reviewed scientific literature and acceptable to the department.

(6) Records of calibrations performed shall be maintained for a period of three (3) years at the radiation installation where the CT is located.

(e) Quality Assurance Testing

(1) Each registrant shall maintain a Quality Assurance (QA) manual that shall contain written procedures for all testing and shall meet the requirements specified in this section and section 16.23(a)(1) of this Part. The CT Quality Assurance procedures shall have been developed under the direction of a licensed medical physicist or radiologist.

(2) The QA procedures shall incorporate the use of one or more image quality dosimetry phantoms, or the phantom supplied by the original equipment manufacturer which have the capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CT Number for water or other reference material. All these image quality parameters shall be evaluated at least annually by a licensed medical physicist.

(3) Written records of the QA checks performed by the registrant shall be maintained for review by the department for a period of at least three (3) years.

(4) QA checks shall include the following:

(i) Images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations. The images shall be retained as photographic copies or as electronic copies stored within the CT x-ray system or stored on the PACS.

(ii) Dose assessment for the most common CT examinations that are performed on the system for which reference levels have been published by the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM) or the National Council on Radiation Protection and Measurements (NCRP) for pediatric heads, pediatric abdomens, adult heads and adult abdomens.

(iii) An evaluation of image quality.

(f) Operating Procedures and Policies

(1) The CT x-ray system shall not be operated on a human being except by a physician or by a radiologic technologist licensed pursuant to article 35 of the Public Health Law who has been specifically trained in its operation.

(2) The registrant shall ensure that each CT x-ray system has a radiation protection survey or other measurement and assessment of exposure to persons in controlled and non-controlled areas made at the time of installation. Additional radiation protection surveys shall be done after any change in the radiation installation or equipment which might cause a significant increase in radiation hazard.

(3) Each CT x-ray system shall have available at the control panel written information regarding the operation and calibration of the CT x-ray system. Such information shall include:

(i) dates of the latest calibration and QC checks and the location within the facility where the results of those tests may be obtained;

(ii) instructions on the use of the CT dosimetry phantom(s) including a schedule of QC tests that are appropriate for the system as determined by the manufacturer, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(iii) a current set of default protocols are available at the control panel (either electronically or as a document) which specifies for each routine examination the CT conditions of operation and the slice thickness, spacing between slices and/or pitch;

(iv) a list of techniques optimized for the body part being imaged to obtain a quality image and to ensure that the lowest amount of radiation is used as consistent with good medical practice.

(4) If the QC testing on the CT x-ray system identifies that a system operating parameter has exceeded a tolerance as specified in the Quality Assurance manual, use of the CT x-ray system on patients shall be limited to those exceptions permitted by established written instructions of the licensed medical physicist or radiologist. Upon completion of corrective action, the QC testing shall be repeated to verify that the system is back within tolerance.

(5) Each registrant performing CT scans on human beings shall ensure that for each scan, the radiation dose delivered by the scanner to a reference phantom or the dose received by the patient is saved and recorded. The dose delivered shall be recorded as Computed Tomography Dose Index volume (CTDIvol), dose length product (DLP) or other dosimetry metric published in the peer reviewed scientific literature and acceptable to the department. The dose received by a patient shall be recorded as organ dose or other dosimetry metric published in the peer reviewed scientific literature and acceptable to the department.

(6) The displayed dose shall be verified on an annual basis by or under the supervision of a licensed medical physicist to ensure that the equipment manufacturer's displayed dose is within 20% of the measured dose.

(7) Each current registrant that performs diagnostic CT scans on human beings shall be accredited by a nationally recognized accreditation program that is acceptable to the department. A facility performing CT that loses their existing accreditation or a registrant or licensee that fails to obtain accreditation must report this fact within 30 days to the department. New licensees or registrants will have 18 months to become accredited, but must demonstrate that they have initiated the accreditation process within 90 days of the start of operations. New units at existing registrations and replacement units will begin accreditation as soon as possible but no later than 90 days following installation.

(8) Each registrant that performs CT scans on human beings shall establish and implement a policy and a procedure to ensure that:

(i) a request for a CT scan originates from a physician or other authorized health care practitioner familiar with the patient's clinical condition; and

(ii) the request includes sufficient information to demonstrate the medical indication for the CT examination and allow for the proper performance and interpretation of the CT scan.

(g) Exemptions – CT equipment used exclusively for attenuation correction, biopsy, guiding or delivering treatment planning does need to meet the accreditation requirements of this section.

16.60 Therapy equipment operated at potentials over 60 kVp.

(a) Equipment.

(1) The protective tube housing shall be of therapeutic type.

(2) Fixed diaphragms or cones used to restrict the useful beam shall be so constructed as to provide the same degree of protection as is required of the tube housing.

(3) Adjustable or removable beam limiting diaphragms or cones shall not transmit more than five percent of the useful beam at the maximum kilovoltage and with the maximum treatment filter.

(4) The filter system shall be so arranged as to minimize the possibility of error in filter selection and alignment. The filter slot shall be so constructed that the radiation escaping through it does not produce an exposure exceeding one roentgen per hour at one meter, or if the patient is likely to be exposed to radiation escaping from the slot, 30 roentgens per hour at two inches (five centimeters) from the external opening. Each removable filter shall be marked with its thickness and material.

(5) It shall be possible for the person operating the controls of the therapeutic equipment to determine from the operating position what filters are in place in the equipment. Filters shall be so mounted as to prevent their movement during the treatment.

(6) The X-ray tube shall be secured so that it cannot move in respect to the housing aperture. A mark on the exterior of the tube housing is recommended to indicate the focal spot.

(7) Adequate devices shall be provided to secure the tube housing during stationary portal treatment.

(8) An easily discernible indicator which shows whether or not X-rays are being produced shall be on the control panel.

(9) A suitable exposure control device (e.g. an automatic timer, exposure meter or dose meter) shall be provided to terminate the exposure automatically after a preset time interval or preset exposure or dose limit. Means shall be provided for the operator to terminate the exposure at any time.

(10) Equipment utilizing shutters to control the useful beam shall have a shutter position indicator on the control panel.

(b) Structural shielding.

(1) The protective barriers for all therapy equipment operating at voltages above 60 kVp shall not be removable.

(2) The control panel for all therapy equipment operating at voltages above 150 kVp shall be located outside the treatment room.

(c) Conditions for operation of equipment.

(1) The beam output shall be calibrated prior to the use of the apparatus for treating humans. Calibration shall be performed by an individual who is currently licensed by the New York State

Department of Education as a Medical Physicist – Therapeutic Radiology. The method of calibration used shall be in accordance with procedures recommended by the American Association of Physicists in Medicine for the energy and type of radiation employed. Calibration shall be made at least annually. Recalibration, however, shall be made after each tube replacement and after any changes or replacements in the generating apparatus, or changes or updates in computer programs which govern or interact with the functions of the machine, and which could change the X-ray output.

(2) No person other than the patient, shall be permitted to remain within the therapy room while the generator is in operation.

(3) Every entrance to a therapy room in which equipment is capable of operating above 150 kV shall be protected by interlocks to insure that during the production of X rays no person can enter the therapy room without turning off the radiation equipment. Interlocks shall be so arranged that irradiation equipment cannot be started again without manually resetting the controls.

(4) Windows, mirror systems, or closed-circuit television viewing screens shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position.

(5) Provision shall be made for oral communication with the patient.

(6) In addition to the interlocking controls, there shall be installed signals which are readily observable or discernible near the outside of all access doors to indicate the production of X rays.

(7) No therapy vault shall be able to be closed from inside the therapy vault.

(8) Instructions for emergency response, contact information for manufacturer's technical assistance, radiation oncologist, medical physicist and the RSO should be posted at the control console.

16.61 Therapy equipment operating at potentials of 60 kVp and below.

(a) Equipment. All provisions of subdivision (a) of section 16.60 shall apply except that the leakage five centimeters from the surface of the tube housing shall not exceed 0.1 roentgen per hour.

(b) Conditions for operation of equipment.

(1) The output of the X-ray generator shall be calibrated prior to the use of the apparatus for treating humans. Calibration shall be performed by an individual who is currently licensed by the New York State Department of Education as a Medical Physicist – Therapeutic Radiology. The method of calibration used shall ensure accurate delivery of the prescribed dose under all conditions of use. Calibrations shall be made at least annually. Recalibration, however, shall be made after each tube replacement and after any changes or replacements in the generating apparatus which could change the x-ray output.

(2) If the tube must be hand-held during irradiation, the operator shall wear protective gloves and a protective apron of no less than 0.5 mm lead equivalent.

(3) The operator shall be able to observe and communicate with the patient during irradiation.

(4) Equipment having an output of more than 1,000 roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the main disconnect switch in addition to the control panel switch.

(5) When operating equipment constructed with beryllium or other low filtration windows, the operator shall insure that the useful beam is blocked at all times except when actually being used.

(6) Instructions for emergency response, contact information for manufacturer's technical assistance, radiation oncologist, medical physicist and the RSO should be readily available. at the location of use of the device

16.62 Industrial Radiography.

Use of x-ray based Industrial Radiography equipment shall follow the requirements of section 16.119 of this Part, as applicable.

16.63 Miscellaneous and special types of radiation producing equipment. Types or uses of radiation producing equipment not specifically covered by this Part and not exempted in section 16.4 of this Part, and such other types or uses of radiation producing equipment as may be designated by the department shall be governed by special inspection or surveys by the department. Such special inspections or surveys by the department shall, with respect to the radiation producing equipment so inspected or surveyed, substitute for the inspections required by paragraph (1) of subdivision (a) of section 16.10 of this Part.

16.64 RESERVED.

16.65 Cone Beam Computed Tomography (CBCT).

Cone Beam Computed Tomography – Cone beam computed tomography (or CBCT, also referred to as C-arm CT, Cone beam volume CT, or flat panel CT) is a medical imaging technique consisting of x-ray computed tomography where the x-rays are divergent, forming a cone.

(a) Equipment

(1) The protective housing shall be of diagnostic type.

(2) X-ray activation controls shall be mounted in a protected area and situated so that the operator is required to remain in the protected area during the entire exposure.

(3) Each control panel and CBCT system shall include visual signals that indicate to the operator of a system whenever x-rays are being produced and when x-ray production is terminated.

(4) Each CBCT x-ray system shall be equipped with a control that allows the operator of the CBCT system to terminate the x-ray exposure at any time during a scan, or series of scans.

(5) Each CBCT system shall include a clearly and conspicuously labeled emergency shutoff button or switch.

(6) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CBCT conditions of operation by the operator prior to the initiation of another scan or series of scans.

(7) Each CBCT system shall be equipped to allow the operator at the control panel to maintain view of the patient by means of a window or mirror and two-way aural communication.

(b) Quality Assurance Program shall include:

(1) Identification of the facility New York State registration identification number.

(2) Identification of the make and model of the unit.

(3) Identification of the staff trained to perform QC testing and patient care.

(4) Identification of the licensed medical physicist.

(5) The most recent licensed medical physicist survey.

(i) Copies of the licensed medical physicist surveys shall be kept on file electronically or on paper for a period of three years.

(6) Documentation of preventive maintenance and service records, including any corrective actions.

(7) The provision of a formalized in-service training program for employees, provided prior to use on patients and thereafter annually, including:

(i) Basic radiation principles and safety.

(ii) Machine model specific training.

(iii) Displays and systems used for viewing.

(iv) Documentation of initial and annual training completion shall be maintained for a period of three years and available upon request.

(v) The practitioner shall attest in writing to employee completion of initial and annual training for each qualified employee allowed to operate the CBCT.

(vi) Examinations shall be performed only when clinically indicated and by written order of the practitioner.

(vii) No person shall be regularly employed for the purpose of imaging training demonstrations. This means that no person shall be imaged for the express purpose of testing or demonstrating the equipment.

(8) Eighteen months after the effective date of this Part, each current registrant that performs diagnostic CBCT scans on human beings shall be accredited by a nationally recognized accreditation program that is acceptable to the department. A facility performing CBCT scans that loses their existing accreditation or a registrant or licensee that fails to obtain accreditation must report this fact within 30 days to the department. After the effective date of this Part new licensees or registrants will have 18 months to become accredited and must demonstrate that they have initiated the accreditation process within 90 days of the start of operations.

(c) Cone Beam CT Quality Control program.

(1) Test requirements may vary from manufacturer to manufacturer. Each cone beam CT unit shall be tested to the manufacturer's requirements, or a QC test program shall be developed in consultation with the New York State licensed medical physicist if not provided by the manufacturer. Requirements include:

(i) Phantom test device from the manufacturer (FDA 21 CFR subchapter J section 1020.33 as revised and implemented in full on January 20, 2023) capable of QA/QC test completion as directed by the manufacturer or licensed medical physicist.

(ii) Documentation of QC test results and completion, including any system used for image viewing.

(2) Quality Control testing performed by a New York State licensed medical physicist:

(i) Initial acceptance testing, testing after a major repair, software upgrade, or change to any part of the system affecting unit output and patient dose, and annual testing thereafter shall be performed by a New York State licensed medical physicist, consistent with currently accepted professional standards. Physicist testing shall include but not be limited to:

(*a*) Calibration of the CBCT unit. The radiation output calibration of a CBCT x-ray system shall be performed with a calibrated dosimetry system. This system shall have been calibrated either by the National Institute of Standards and Technology (NIST) or by an American Association of Physicists in

Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) traceable to NIST. The calibration shall have been performed within the previous 24 months and after any servicing that may affect system calibration.

(*b*) Dose area product (DAP) or (KAP).

(*c*) Dose to pediatric and adult patients for the most common exam techniques.

(*d*) CT number for water or other reference material.

(*e*) Low and high contrast resolution.

(*f*) Noise.

(*g*) Scan localization accuracy.

(*i*) Artifacts.

(*j*) Field of View.

(*k*) Scatter measurements performed within 30 days of installation.

(*l*) Documentation of the area exposure results from an NVLAP approved laboratory at the console or operator location for a duration of one year.

(3) Registrant QC testing responsibilities shall include:

(i) Daily or days of CBCT patient imaging:

(*a*) Equipment function indicators, mechanical, and other safety checks.

(*b*) Film processing or digital system QC, if applicable.

(*c*) CT number for water and bone.

(*d*) Field uniformity.

(*e*) Artifacts.

(*f*) Repeat or rejected patient images shall be monitored and include the reason for patient image repeat or reject.

(ii) Weekly:

(*a*) Image viewing system software and hardware – as applicable.

(iii) Ongoing:

(*a*) Repeat reject analysis as determined by section 16.23(a)(1)(xi) of this Part.

(4) Each registrant shall maintain and make available for review by the department, on the premises of its radiation installation where the CBCT system is located, written procedures for appropriate calibration of the CBCT x-ray system.

(d) Additional Requirements.

(1) Each patient record shall document exposure or dose area product (DAP) or air kerma (AK) (DAP or AK where indicated, system may display DAP or AK for each examination).

(2) Pediatric and adult patients' most common exam technique and the resulting dose, as determined annually by the licensed medical physicist, shall be displayed at the operator console.

(3) The CBCT system shall not be operated except by an individual who has been specifically trained in its operation.

16.66 RESERVED.

16.67 RESERVED.

16.68 RESERVED.

16.69 RESERVED.

16.70 Use of Body Scanning.

(a) This section shall not apply in cities having a population of two million or more.

(b) Practitioners licensed under article 35 of the Public Health Law and unlicensed personnel employed at a local correctional facility may utilize body imaging scanning equipment that applies ionizing radiation to humans for purposes of screening inmates committed to such facility, solely in connection with the implementation of such facility's security program and in accordance with the provisions of this Part.

(c) Definitions.

(1) “Body imaging scanning equipment" or "equipment" means equipment that is specifically manufactured for security screening purposes and utilizes a low dose of ionizing radiation, with a maximum exposure per scan equal to or less than 10 uSv (1 mrem), to produce an anatomical image capable of detecting objects placed on, attached to or secreted within a person's body. The utilization of body imaging scanning equipment is for purposes of screening inmates committed to such facility, in connection with the implementation of such facility's security program.

(2) "Local correctional facility” shall mean a local correctional facility as defined in Correction Law section 2(16).

(3) “Equipment operator” or “operator” means personnel employed at the local correctional facilities that have successfully completed a training course approved by the department.

(4)"Screening" means the sum of radiation exposures or scans necessary to image objects concealed on all sides of the body as intended by the system design under normal conditions.

(d) Equipment use and installation requirements.

(1) Prior to the equipment’s first use on humans at a specific physical location or upon any major repairs that could influence image quality or exposure:

(i) body imaging scanning equipment purchased or installed at a local correctional facility must be registered with the department, in accordance with section 16.50 of this Part; and

(ii) a radiation protection survey, shielding evaluation and verification of image usefulness for detecting foreign objects must be completed by a licensed medical physicist.

(2) Equipment must have a clearly marked restricted area and one or more indicators when a scan is in process that is clearly visible to all security screening system operators and anyone approaching the restricted area.

(3) Equipment must be periodically inspected by the department as described in section 16.10 of this Part.

(4) Equipment must be tested by a licensed medical physicist annually to verify the equipment is operating as designed.

(5) The facility must maintain a policy and procedure manual describing equipment operations and body scanning procedures. Records and associated facility policies shall be maintained and available upon request by the department. The policy and procedure manual must include the following items:

(i) operating procedures appropriate for the specific equipment and intended scan types;

(ii) policy prohibiting the use of the equipment on individuals who are not inmates;

(iii) policy regarding the determination of pregnancy that has been approved by the jail physician;

(iv) emergency contact information in the event the equipment overexposes any individual or there is equipment related failure that potentially requires service prior to scanning other inmates;

(v) requirements for exposure records to be provided to an inmate upon release or transfer to another facility; and

(vi) exposure per scan for each scan protocol used.

(6) Records and documentation of the program operation shall be maintained in accordance with section 16.14 of this Part and shall include, at a minimum, the following:

(i) the number of times the equipment was used on inmates upon intake, after visits, and upon the suspicion of contraband, as well as any other event that triggers the use of such equipment;

(ii) the average, median, and highest number of times the equipment was used on any inmate, with corresponding exposure levels;

(iii) the number of times the use of the equipment detected the presence of drug contraband, weapon contraband, and any other illegal or impermissible object or substance; and

(iv) the number of times an inmate has been scanned.

(e) Exposure limits and reporting requirements

(1) No person other than an inmate of a local correctional facility shall be exposed to the useful beam and then only by an individual that has met the provisions of subdivision (f) of this section.

(2) Limits on the use of equipment exposure to inmates are:

(i) no more than fifty percent of the annual exposure limits for non-radiation workers as specified by applicable regulations, not to exceed 0.5 mSv (50 mrem);

(ii) inmates under the age of eighteen shall not be subject to more than five percent of such annual exposure limits, not to exceed 0.05 mSv (5 mrem); and

(iii) pregnant women shall not be subject to scanning at any time.

(3) The following events shall be reported to the department in writing within 30 days:

(i) incidents or any injuries or illness resulting from the use of such equipment or reported by persons scanned by such equipment; and

(ii) exposure that exceeds the limits set forth in this Part.

(f) Training Requirements.

(1) Every equipment operator shall receive initial operator training, to be provided by the equipment manufacturer or their approved representative, or another source approved by the department.

(2) The contents of the initial operator training must include radiation safety, equipment operations, exposure and exposure limits for occupational exposed staff and inmates; applicable regulations; and facility policies and procedures.

(3) Initial operator training must be documented and available for review by the department upon request. Such documentation must include the names of the presenter or sources, attendees, dates and contents of the training.

(4) Every equipment operator shall receive annual refresher training, to be provided by the equipment manufacturer or their approved representative, or another source approved by the department. Such training shall meet the requirements listed in paragraphs (1), (2) and (3) of this subdivision and include any changes to the policies and procedures manual or updates to the regulations.

LICENSING OF RADIOACTIVE MATERIALS

Introductory note: The sections under this heading contain the licensing provisions for radioactive material, i.e., byproduct material, source material, special nuclear material in quantities not sufficient to form a critical mass naturally occurring radioactive material, and accelerator produced radioactive material.

16.100 Overall licensing requirements for radioactive material.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use or transfer any radioactive materials only in accordance with a specific license issued by the department or as allowed in subdivisions (b) or (c) of this section.

(b) A specific license is not required for persons who comply with all applicable requirements for a general license as set forth in section 16.101 of this Part.

(c) A specific license is not required for persons who comply with all applicable requirements to qualify for an exemption as set forth in section 16.4 of this Part or other exemptions provided for in this Part or for the removal of source material from its place of deposit in nature.

16.101 General licenses

(a) This section establishes:

(1) general licenses for the possession and use of radioactive material;

(2) a general license for ownership of radioactive material;

(3) registration requirements for certain devices;

(4) a limit of no more than one millicurie of gamma-emitting radioactive material in a sealed source, where gamma radiation is the emission of interest, and no more than one millicurie of strontium 90 or any transuranic radionuclide per device that may be possessed or used under a general license, and;

(5) terms, conditions and limitations.

(b) Any person who possesses or uses radioactive material under a general license shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 31, General Domestic Licenses for Byproduct Material, as revised and implemented in full on July 23, 2008, except as follows:

(1) Sections 31.1-31.4, 31.11, 31.5(c)(13)(i), (ii) and (iv), and 31.21-31.23 are excluded.

(2) Any reference to the “Commission”, “NRC”, “Director”, “Office of Nuclear Material Safety and Safeguards”, “NRC Regional Office” or any other office thereof shall be deemed to be a reference to the New York State Department of Health, except for when used in sections 31.8(c)(2) and 31.11(d)(2).

(3) Reporting required in 10 CFR 31.5, as revised and implemented in full on July 23, 2008, other than reports of import or export, shall be submitted to the department by means specified in section 16.1(c) of this Part, instead of to the NRC by method listed in 10 CFR30.6(a) as revised and implemented in full on October 16, 2020.

(4) Upon receipt of any fixed measuring, gauging or controlling devices that contain radioactive material not exceeding the limits specified in subdivision (a) of this section, each person shall register the device with the department on a form prescribed by the department and accompanied by the required fee. Each address for a location of use represents a separate general licensee and requires a separate registration and fee. Portable or mobile measuring, gauging or controlling devices containing radioactive material are not applicable under this paragraph and thereby require a specific license under 16.100 of this Part.

(5) Any reference in 10 CFR 31 as revised and implemented in full on July 23, 2008, to the import or export of radioactive material is under the direct and exclusive jurisdiction of the NRC.

(c) Any person who is licensed pursuant to section 16.123 of this Part for medical use is also authorized to use radioactive material described in 10 CFR31.11(a) as revised and implemented in full on November 14, 1968, under the conditions of such specific license without filing for a general license registration.

16.102 Applications for specific licenses.

(a) An application for a specific license for any radioactive material shall be filed in duplicate on, and shall contain completely and accurately all information called for by, a form prescribed by the department. The application may incorporate by clear and specific reference information contained in any previous application, supplementary statement, notification or report filed with the department.

(b) At any time subsequent to the filing of an application for a license and before the termination of a license issued in response thereto, the department may require the applicant to submit one or more supplementary statements containing additional information to enable the department to determine whether such application should be approved or denied, or whether a previously issued license should be amended, suspended or revoked.

(c) Each application or supplementary statement shall be signed by either the applicant personally or a person duly authorized by the applicant to sign for and on the applicant's behalf.

(d) A single application may apply for more than one license or for a license covering more than one radioactive material.

(e) The applicant shall permit the department to perform an onsite inspection or inspections prior to issuance of a license in order to verify information provided in the license application and any supplemental application information.

(f) Applications submitted without the fee specified in section 16.41 of this Part will not be processed until the department receives payment in full.

(g) As provided by section 16.114 of this Part, certain applications for specific licenses filed under this Part must contain a proposed decommissioning funding plan or a certification that financial assurance for decommissioning has been provided.

(h) Emergency plans for responding to a release of radioactive material.

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR30.72, schedule C, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," as revised and implemented in full on October 1, 2007, must contain either:

(i) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent or 5 rems (50 mSv) to the thyroid; or

(ii) an emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under subparagraph (1)(i) of this subdivision:

(i) the radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) the release fraction in the respirable size range would be lower than the release fraction shown 10 CFR30.72 as revised and implemented in full on October 1, 2007, due to the chemical or physical form of the material;

(iv) the solubility of the radioactive material would reduce the dose received;

(v) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 10 CFR30.72 as revised and implemented in full on October 1, 2007;

(vi) operating restrictions or procedures would prevent a release fraction as large as that shown in 10 CFR30.72 as revised and implemented in full on October 1, 2007; or

(vii) other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under subparagraph (1)(ii) of this subdivision must include the following information:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the commissioner; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment, and a brief description of the means, to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established and the notification and coordination must be planned so that

unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the commissioner immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the commissioner.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide to workers on how to respond to an emergency; including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most

exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected

(xiii) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the commissioner. The licensee shall provide any comments received within 60 days to the commissioner with the emergency plan.

(5) Prior to the commencement of the on-site biannual emergency exercises required by paragraph (3) of this subdivision, at least 72 hours' notice must be provided to the New York State Department of Health, Bureau of Environmental Radiation Protection.

(i) An application from a medical facility, education institution, or federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licenses in its consortium authorized for medical use under section 16.123 of this Part shall include:

(*a*) A request for authorization for the production of PET radionuclides or evidence of existing license issued under this part for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(*b*) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 10 CFR32.72(a)(2) as revised and implemented on August 24, 2023.

(*c*) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized medical physicist as specified in 10 CFR32.72(b)(2) as revised and implemented in full on August 24, 2023.

(*d*) Information identified in 10 CFR 32.72(a)(3) as revised and implemented in full on August 24, 2023, on the PET drugs to be noncommercially transferred to members of its consortium.

16.103 Licensing requirements for radioactive materials.

(a) The department may approve an application for, and issue in response thereto, a specific license to transfer, receive, possess and use any radioactive material, if the department determines that the following requirements have been met:

(1) the applicant's proposed use, equipment, facilities and procedures will protect public health and safety, and will minimize danger to life and property, from radiation hazards;

(2) the applicant's radiation detection and measuring instrumentation is appropriate for the uses of radioactive materials requested in the application;

(3) the applicant, (or the applicant's personnel if the applicant is not an individual), is qualified by training and experience to use such radioactive material for each purpose covered by the application so as to protect public health and safety and to minimize danger to life and property from radiation hazards; and

(4) the applicant submits sufficient information to support a determination that the requirements of this section are satisfied.

(b) Any person issued a specific license to manufacture, transfer, receive, possess or use any radioactive material shall comply with the provisions of the following federal regulations, which

are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 30, Rules of General Applicability to Domestic Licensing of Byproduct Material as revised and implemented in full on October 16, 2020; Part 40, Domestic Licensing of Source Material as revised and implemented in full on August 24, 2023: and Part 70, Domestic licensing of Special Nuclear Material, as revised and implemented in full on August 24, 2023, except as follows:

(1) Sections 30.2, 30.3, 30.4 definitions of "Utilization facility", "Commencement of construction" and "construction", 30.5, 30.7, 30.8, 30.9, 30.21(c), 30.31, 30.32(a)-(f), 30.32(h), 30.33, 30.34(d), 30.34(e)(1)-(4), 30.37, 30.38, 30.39, 30.41 (b)(6), 30.50(c)(3), 30.51(c), 30.52, 30.53, 30.55, 30.61, 30.62, 30.63, 30.64, 40.2a, 40.4 definitions of "Commencement of Construction", "Construction", "Foreign obligations", "Reconciliation", "Residual radioactive material", and "Uranium milling", 40.5 – 40.9, 40.12(b), 40.13(c)(5)(iv), 40.14, 40.20 40.23, 40.26, 40.27, 40.28, 40.31(a)-h) and (j)-(m), 40.32 (d) with respect to "common defense and security", 40.32, (e) and (g), 40.33, 40.35 (d)-(f), 40.38, 40.41(d), (e), (g) and (h), 40.43, 40.44, 40.45, 40.51(b)(6), 40.52, 40.53, 40.56, 40.64 – 40.82, criterion 11A. through F of appendix A to Part 40, 70.1, 70.2, 70.10(b), 70.13, 70.14, 70.17, 70.20a, 70.20b, 70.21, 70.22, 70.24, 70.25(a)(1), (c), (d), f), and (h), 70.31 are excluded.

(2) Any reference to the "commission", "NRC", "US NRC", "NRC regional office", "United States nuclear regulatory commission", "administrator of the appropriate regional office", "Director of the Office of Nuclear Material Safety and Safeguards", "NRC Operations Center" or any other office or person thereof, shall be deemed to be a reference to the New York State Department of Health, except for when used in: sections 30.12, 30.21(c), 30.34(h)(1), 30.50(c)(1), 40.11. 70.11, 70.19(a)(1) and (2), 70.39(b), 70.40(b)-(d).

(3) Any reference to “Department” in 10 CFR40.11 means the United States Department of Energy.

(4) Any reference to “Parts 19, 20, and 21 of this Chapter” shall be deemed to be a reference to Title 10 of the CFR.

(5) Any reference to “an appropriate method listed in 10 CFR 30.6(a), 40.5(a) and 70.5(a)” shall be deemed to be a reference to “a means specified in section 16.1(c) of this Part”.

(6) Any reference to an “NRC Form” shall been deemed to reference “a form prescribed by the Department.”

16.104 Conditions of specific licenses.

(a) It is hereby made a condition of each specific license:

(1) that the licensee thereunder shall comply with all applicable provisions of the Public Health Law, of all other laws now or hereafter in effect, and with all applicable rules, regulations, codes and orders now or hereafter in effect of the department and of all appropriate regulatory agencies;

(2) that neither such license, nor any right, title or interest in, of or to such license, shall be disposed of by assignment, transfer or otherwise, either voluntarily or involuntarily, either directly or indirectly, unless the department shall, after securing complete and accurate pertinent information, have approved in writing of such disposal;

(3) that the licensee shall confine their possession and use of licensed radioactive material to such location or locations and for such purpose or purposes as the license may authorize; provided, however, that except as otherwise provided in such license or this Part, such license shall be deemed to authorize the licensee to transfer the material covered by such license to any

other person authorized to receive it by the department, the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission or any Agreement State; and

(4) that the licensee shall notify the department by letter within 30 days if an authorized user, radiation safety officer or radiation therapy physicist permanently discontinues performance of duties under the license; and

(5)(i) that each licensee shall notify the department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(*a*) the licensee;

(*b*) an entity (as that term is defined in 11 U.S.C. 101(15) (see section 16.200 of this Part) controlling the licensee or listing the license or licensee as property of the estate; or

(*c*) an affiliate (as that term is defined in 11 U.S.C. 101(2)) (see section 16.200 of this Part) of the licensee.

(ii) This notification must indicate:

(*a*) the bankruptcy court in which the petition for bankruptcy was filed; and

(*b*) the date of the filing of the petition.

(6) that any license covering the use of special nuclear material in the course of which licensed use additional special nuclear material is produced, shall be deemed to cover any such special nuclear material so produced; provided, however, that the total quantity of special nuclear material possessed by the licensee is not sufficient to form a critical mass.

(7) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall

test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 10 CFR35.204, as revised and implemented in full on July 16, 2018. The licensee shall record the results of each test and retain each record for three years after the record is made.

(8) Security requirements for portable gauges, excluding X-ray Fluorescence devices.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(9) Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR 35.

(i) Authorization under 10 CFR 30.32(j) as revised and implemented in full on September 30, 2014, to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and State requirements governing radioactive drugs.

(ii) Each licensee authorized under 10 CFR 30.32(j) as revised and implemented in full on September 30, 2014, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(*a*) Satisfy the labeling requirements in 10 CFR 32.72(a)(4), as revised and implemented in full on August 24, 2023,for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(*b*) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural,

radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 10 CFR 30.32(j) as revised and implemented on September 30, 2014, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(*1*) an authorized nuclear pharmacist that meets the requirements in 10 CFR 32.72(b)(2) as revised and implemented on August 24, 2023, or

(*2*) an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR35.27, as revised and implemented in full on November 14, 2022.

(iii) A pharmacy, authorized under 10 CFR 30.32(j) as revised and implemented on September 30, 2014, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 10 CFR 32.72(b)(5) as revised and implemented on August 24, 2023.

(b) The department may at any time set forth in any license or incorporate by reference therein, additional conditions, restrictions or requirements applicable to the licensee's transfer, receipt, possession or use of the radioactive material covered by such license in order to protect the public health and safety and to minimize danger to life and property from radiation hazards.

16.105 Duration, expiration and termination of specific licenses.

(a) Except as otherwise provided in this subdivision, each specific license will expire at the end of the expiration date stated in such license. If any licensee duly files with the department not less than 30 days prior to such expiration date, an application in accordance with section 16.102 of this Part for the renewal of his license or for a new and superseding license, such license shall not be deemed to have expired until the department has finally determined such application.

(b) The department may terminate any specific license upon the written request of the licensee

(c) Each specific license continues in effort, beyond the expiration date if necessary, with respect to possession of radioactive material until the commissioner notified the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) limit actions involving radioactive material to those related to decommissioning; and

(2) continue to control entry to restricted areas until they are suitable for release in accordance with department requirements.

16.106 Renewal or amendment of specific licenses.

Any application by a licensee for the renewal or amendment of the license shall be considered as an application for a license and shall be filed in accordance with section 16.102 of this Part; and any such application for amendment shall set forth the reasons for such requested amendment. In considering any such application for renewal or amendment, the department will apply the requirements set forth in section 16.103 of this Part as appropriate. Corrective amendments to a license may be issued by the department at any time upon its initiative.

16.107 Amendment, suspension or revocation of licenses.

(a) Specific and general licenses may be subject to amendment, suspension or revocation by reason of amendment of the Public Health Law, enactment or amendment of any other applicable law, amendment of this Part or amendment or promulgation of any other applicable rule, regulation, or order.

(b) The department may amend, revoke or suspend any license in whole or in part, for:

(1) any material misstatement in the application therefor or in any supplementary statement thereto;

(2) any condition revealed by such application, supplementary statement, report, record, inspection or other means, which would warrant the department to refuse to grant a license on an original application; or

(3) any violation or failure to observe any of the applicable terms or provisions of such license, the Public Health Law, this Part, or any other applicable rule, regulation, code or order now or hereafter in effect.

16.108 Recognition of Agreement State and U.S. NRC Licenses.

(a) The holder of a specific license or permit issued by the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission, and any Agreement State, or any licensing nonagreement state, may bring, possess or use radioactive material covered by such license or permit within the commissioner's jurisdiction for a period not in excess of 180 days in any calendar year without obtaining a specific license from the commissioner, and is granted a general license to conduct the same activity within areas of exclusive State jurisdiction within New York State, provided that:

(1) such license or permit does not limit the holder's possession or use of such material to a specific installation or installations;

(2) such holder shall, at least 3 days before engaging in each activity for the first time in a calendar year, file a submittal containing a completed form specified by the department, a copy of its U.S. Nuclear Regulatory Commission or Agreement State specific license, and the appropriate fee as prescribed in sections 16.40 and 16.41 of this Part with the New York State

Department of Health. If a submittal cannot be filed 3 days before engaging in activities under reciprocity, because of an emergency or other reason, the department may waive the 3-day time requirement provided the licensee:

(i) informs the department by telephone, facsimile, a completed form specified by the department, or a letter of initial activities or revisions to the information submitted on the initial form specified by the department;

(ii) receives oral or written authorization for the activity from the department; and

(iii) within 3 days after the notification, files a completed form specified by the department, a copy of the U.S. Nuclear Regulatory Commission or Agreement State license, and the fee payment;

(3) such holder, at least three days prior to engaging in such activities within the commissioner's jurisdiction, files with the commissioner a notice indicating the period, type and location of proposed possession and use within the commissioner's jurisdiction and a copy of the license or permit. At the discretion of the commissioner, oral notification of the commissioner or notification of the commissioner less than three days prior to engaging in such activities may be accepted in lieu of the filing requirement under this paragraph;

(4) such holder supplies such additional information as the commissioner may reasonably request;

(5) such holder, during the period of his possession and use of such material within the commissioner's jurisdiction, complies with all relevant provisions of this Part, and any additional requirements which the commissioner may impose, and which are reasonable under the circumstances;

(6) such holder, is engaged in licensable activities exclusive to the use, possession, or temporary storage of x-ray fluorescence devices, portable gauges, industrial radiography, well logging, decontamination and decommissioning services, waste brokerage, packaging of radioactive materials for transport, possession of radioactive material for training purposes, installation, manufacture, or service radioactive devices or equipment unless stated otherwise under subdivision (b) of this section, or other uses as deemed applicable by the department.

(b) Any holder of a license or permit issued by the State Department of Health, the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission, any Agreement State, or any licensing nonagreement state which authorizes the holder to manufacture, install or service a device of the type which is generally licensed and specified in section 16.101 of this Part may install or service such device without obtaining a license from the department, provided that:

(1) such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed within the department's jurisdiction. Such report shall contain the name and address of each person receiving such a device, shall identify the type of device or devices so transferred, and shall state the quantity and type of radioactive material contained in such device or devices;

(2) any such device is installed and serviced in accordance with the terms of the license or permit issued to such person;

(3) such person shall assure that any labels required to be affixed to any such device shall bear a statement that reads "Removal of this label is prohibited"; and

(4) the person to whom such holder transfers any such device or on whose premises such holder installs or services any such device has a copy of the general license requirements or equivalent requirements outlined in section 16.103 of this Part.

16.109 Licensees and contractors of the United States Nuclear Regulatory Commission and the United States Department of Energy within the State.

(a) Each person who holds a license from the United States Nuclear Regulatory Commission authorizing activities within the State shall be exempt from the requirements of this Part with respect to such activities during the period that such license is valid, provided, however, that such person:

(1) shall afford the department and health officer having jurisdiction access to all records which such person is required to maintain pursuant to the United States Nuclear Regulatory Commission's rules and regulations or pursuant to the provisions of the United States Nuclear Regulatory Commission license,

(2) shall afford the department and health officer having jurisdiction opportunity to sample effluents, and to conduct such measurement or survey of levels of radiation and radioactive contamination as will not substantially interfere with or interrupt any activities licensed by the United States Nuclear Regulatory Commission, and

(3) shall afford the department and health officer having jurisdiction access to the facilities of such person in order to accomplish the foregoing review of records, sampling of effluents and conduct of measurements or surveys.

(b) Each United States Nuclear Regulatory Commission contractor or subcontractor and each United States Department of Energy contractor and subcontractor of the following categories

operating within the State shall be exempt from the requirements of this Part to the extent that such contractor or subcontractor under such contract transfers, receives, possesses, or uses sources of radiation:

(1) prime contractors performing work for the United States Department of Energy at United States government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) prime contractors performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(3) prime contractors using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

(4) any other prime contractor or subcontractor when the State and the United States Nuclear Regulatory Commission or the United States Department of Energy jointly determine that:

(i) under the terms of the contract or subcontract there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; and

(ii) the exemption of such contractor or subcontractor is otherwise appropriate.

16.110 Licensure and inspection of radioactive materials; fees authorized. Provided that a written schedule of the licensing and inspection fees to be charged has been submitted to and approved by the State Commissioner of Health, any county, part-county or city health district having a population of more than 2,000,000 which has established substitute licensure requirements acceptable to the State Department of Health pursuant to the provisions of paragraph (2) of subdivision (b) of section 16.1 of this Part is authorized to charge adequate and

reasonable fees for the licensing and inspection of radioactive materials not exceeding the estimated cost of such services except that, with the approval of the State Commissioner of Health, one or more of such services may be rendered without charge.

16.111 Transfer of radioactive material.

(a) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of subdivisions (c) and (d) of this section, any licensee may transfer radioactive material:

(1) to the department, only after receiving prior approval from the department;

(2) to the United States Nuclear Regulatory Commission;

(3) to any person exempt from the regulations in this Part to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the United States Nuclear Regulatory Commission, or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department of Energy, or any Agreement State; or

(5) as otherwise authorized by the department in writing.

(c) Before transferring radioactive material to a specific licensee of the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State, or to a general licensee who is required to register with the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State prior to receipt of the

radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(d) The following methods for the verification required by subdivision (c) of this section are acceptable:

(1) the transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) the transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(3) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

(5) when none of the methods of verification described in paragraphs (1) through (4) of this subdivision are readily available, or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the department, the United States Nuclear Regulatory Commission or the

licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of section 16.17 of this Part.

16.112 Physical protection of category 1 and category 2 quantities of radioactive material, fingerprinting and criminal background check requirements.

(a) This section contains the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material, which provide reasonable assurance of the security of such material from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included.

(b) The licensee shall comply with 10 CFR 71.97, July 1, 2018, version.

(c)The licensee shall comply with the 10 CFR 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” August 9, 2021, version, except as follows:

(1) Sections 37.1, 37.3, 37.7, 37.9, 37.11(a-b), 37.13, 37.105, 37.107, and 37.109 are excluded.

(2) Any reference to the Commission or NRC shall be deemed to be a reference to the New York State Department of Health, except:

(i) section 37.5 Definitions: “Agreement State”, “Byproduct material”, “Commission”, “Fingerprint orders”, “Person”;

(ii) section 37.25(b);

(iii) section 37.27(a) and (c);

(iv) section 37.29(a);

(v) section 37.71 referring to NRC's license verification system.

(3) License required reports of events or notifications in sections 37.41, 37.45, 37.57, 37.77(a)-(d), 37.81, shall be reported to the department by means specified in section 16.1(c) of this Part instead of to the NRC.

16.113 Decommissioning.

(a) Decommissioning Plan.

(1) A licensee must submit a decommissioning plan: if otherwise required by this Part; if required by license condition; or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during the operation for which the license was issued;

(iii) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or,

(iv) procedures could result in significantly greater releases of radioactive material to the environment than those associated with the operation for which the license was issued.

(2) Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(3) The proposed decommissioning plan for the facility or site (or separate building or outdoor area) must include:

(i) a description of the conditions of the facility or site sufficient to evaluate the acceptability of the plan;

(ii) a description of planned decommissioning activities;

(iii) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) a description of the radiation survey planned to demonstrate compliance with paragraphs (f)(4) and (g)(1) of this section; and,

(v) an updated detailed cost estimate for decommissioning, comparison of that estimate with existing funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(4) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay. The proposed decommissioning plan may be approved by the department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(5) DFP (Decommissioning Funding Plan) Reviewed and Revised at least on a three (3) year basis

(b) Timeliness of Decommissioning.

(1) Each licensee or person in possession of a non-exempt source of radioactive material who decides to terminate all activities involving that source of radiation shall notify the department immediately in writing.

(2) Each licensee or person responsible for a facility or site which includes a non-exempt source of radioactive material or which may be contaminated by residual radioactivity shall, no less than 30 days before vacating or relinquishing possession or control of a restricted area, the facility or site, notify the department, in writing, of the intent to vacate.

(3) The licensee shall notify the department in writing within 60 days of the occurrence of any of the following:

(i) the licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with this Part; or,

(ii) no principal activities under the license have been conducted for a period of 24 months; or,

(iii) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with this Part.

(c) From the date of notification of the department required in subdivision (a) of this section, the licensee shall either:

(1) begin decommissioning activities; or

(2) within 12 months of notification submit a decommissioning plan, if required by subdivision (a) of this section, and begin decommissioning upon department approval of that plan.

(d) Coincident with the notification of the department required in subdivision (b) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee in conjunction with a license issuance or renewal or as required by this Part. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to

cover the detailed cost estimate for decommissioning established pursuant to section 16.113(a)(3)(v) of this Part.

(e) The department may approve an alternate schedule for the submission of plans and for the completion of decommissioning as required pursuant to subdivisions (a) and (c) of this section if the department determines that the alternate schedule:

(1) is necessary to effectively conduct decommissioning;

(2) presents no undue risks to public health and safety; and

(3) is otherwise in the public interest.

The request must be submitted no later than 30 days before notification pursuant to subdivision (b) of this section. The schedule for decommissioning may not commence until the department has made a determination on the request.

(f) Completion of Decommissioning.

(1) The licensee shall complete decommissioning of the facility or site as soon as practicable but no later than 24 months following the initiation of decommissioning, unless an alternate schedule addressing the factors in paragraph (3) of this subdivision is requested with written justification and approved by the department.

(2) When decommissioning involves the entire site, the licensee shall request license termination upon completion of decommissioning activities.

(3) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the decommissioning schedule warranted by consideration of the following:

(i) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(ii) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(iii) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(iv) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and,

(v) other site-specific factors which the department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(4) As the final step in decommissioning, the licensee shall:

(i) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

(*a*) report levels of gamma radiation in units of millisieverts (or microroentgens) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (or disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (or microcuries) per milliliter for water, and becquerels (or picocuries) per gram for solids such as soils or concrete; and,

(*b*) specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(ii) Certify the disposition of all licensed material including accumulated wastes, by submitting a form approved by the department.

(g) Termination of a License and Release of a Site Without Restriction.

(1) A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 0.25 millisievert (25 mrem) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning. Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

(2) Specific licenses, including expired licenses, will be terminated upon written notice to the licensee when the department determines that:

(i) radioactive material has been properly disposed;

(ii) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(iii) documentation is provided to the department that:

(*a*) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with department requirements; or

(*b*) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with department requirements.

(iv) The licensee has complied with applicable sections of the New York State Environmental Conservation Law regarding radiological decommissioning.

(h) Applicability of Decommissioning Criteria Following License Termination. After a site has been decommissioned and the license terminated in accordance with the criteria in this Part, the department will require additional cleanup only if, based on new information, it determines that the criteria of this Part were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

16.114 Financial assurance and record keeping for decommissioning.

(a) Any person issued a specific license to possess and use radioactive material shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 30, Rules of General Applicability to Domestic Licensing of Byproduct Material, Section 35, Financial Assurance and Recordkeeping for Decommissioning, December 19, 2014, version. Any reference to the "Commission" or "NRC" shall be deemed to be a reference to the New York State Department of Health.

16.115 RESERVED.

16.116 RESERVED.

16.117 RESERVED.

16.118 RESERVED.

16.119 RESERVED.

16.120 Specific licenses for the use of radioactive materials on human beings.

An application seeking a specific license for use of radioactive materials on human beings shall be

approved if all of the following criteria are satisfied:

(a) The application is completed, signed by an appropriate individual, and submitted to the department.

(b) The applicant is an individual, corporation, partnership or other entity that is legally authorized to do business in New York State. If the applicant is seeking a specific license pursuant to section 16.123 of this Part, the applicant shall be legally authorized to practice medicine in New York State or operate a hospital as defined in section 2801 of the Public Health Law.

(c) The applicant satisfies the requirements set forth in section 16.103 of this Part.

(d) The applicant demonstrates to the satisfaction of the department that it has adequate facilities for clinical care of patients.

(e) The applicant demonstrates to the satisfaction of the department that its facilities will be appropriately equipped and staffed and will be operated as required by this Part.

(f) The applicant provides additional information as requested by the department.

16.121 RESERVED.

16.122 RESERVED.

16.123 Specific licenses for certain medical uses of byproduct materials.

(a) Purpose and scope. This section contains requirements for the medical uses of byproduct materials that are subject to specific licenses. These requirements are in addition to, and not a substitute for, other requirements in this Part. Any license issued prior to the effective date of this section that references subdivisions (b) or (c) shall be deemed to reference the equivalent medical use category in 10 CFR 35 as follows:

Previous designation(s)	10 CFR 35 equivalent
16.123(b)(1) or 16.123(c)(1)……	35.100
16.123(b)(2) or 16.123(c)(2)……	35.200
16.123(b)(3) or 16.123(c)(3)……	35.300
16.123(b)(4) or 16.123(c)(4)…….	35.400
16.123(b)(5) or 16.123(c)(5)…….	35.500
16.123(c)(6)……	35.600
16.123(c)(7)……..	35.1000

(b) Definitions. Whenever used in this section, or in federal regulations incorporated herein, the following terms shall have the following meanings:

(1) “Associate Radiation Safety Officer”

(i) meets the requirements of 10 CFR 35.50 and 35.59, as revised and implemented in full on November 14, 2022;

(ii) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(*a*) a specific medical use license issued by the Commission or an Agreement State; or

(*b*) a medical use permit issued by a Commission master material license.

(2) "Authorized medical physicist" means an individual who is authorized to practice medical physics pursuant to article 166 of the Education Law and:

(i) meets the requirements for an authorized medical physicist set forth in 10 CFR 35.51, 35.57 and 35.59, as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized medical physicist or teletherapy physicist on:

(*a*) a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State;

(*b*) a medical use permit issued by a Nuclear Regulatory Commission master material licensee;

(*c*) a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

(*d*) a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee.

(3) "Authorized nuclear pharmacist" means an individual who is authorized to practice pharmacy pursuant to article 137 of the Education Law and:

(i) meets the requirements for an authorized nuclear pharmacist set forth in 10 CFR 35.55 and 35.59, as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized nuclear pharmacist on:

(*a*) a specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(*b*) a permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(*c*) a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(*d*) a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(iii) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(iv) was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a federal government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission.

(4) "Authorized user" means an individual who is authorized to practice medicine pursuant to article 131 of the Education Law and:

(i) meets the applicable requirements for an authorized user set forth in 10 CFR 35.59 and 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, or 35.690 as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized user on:

(*a*) a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of byproduct material;

(*b*) a permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of byproduct material;

(*c*) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(*d*) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(5) "Medical use" means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

(6) “Ophthalmic physicist”

(i) meets the requirements in 10 CFR 35.433(a)(2) and 35.59 as revised and implemented in full on November 14, 2022; and

(ii) is identified as an ophthalmic physicist on a:

(*a*) specific medical use license issued by the Commission or an Agreement State; or

(*b*) permit issued by a Commission or Agreement State broad scope medical use license; or

(*c*) medical use permit issued by a Commission master material licensee; or

(*d*) permit issued by a Commission master material licensee board scope medical use permittee.

(7) "Positron emission tomography facility" is a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(8) "Prescribed dosage" means the specified activity or range of activity of unsealed byproduct material as documented in a written directive, or in accordance with the directions of the authorized user for procedures performed pursuant to 10 CFR 35.100 and 35.200 as revised and implemented in full on November 14, 2022. Further details concerning this referenced code are contained in subdivision (c) of this section.

(9) "Prescribed dose" means:

(i) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(ii) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(iii) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(iv) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(10) "Radiation safety officer" means an individual who:

(i) meets the requirements for a radiation safety officer set forth in 10 CFR 35.50 and 35.59 as revised and implemented in full on November 14, 2022; or

(ii) is identified as a radiation safety officer on:

(*a*) a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or

(*b*) a medical use permit issued by a Nuclear Regulatory Commission master material licensee.

(11) "Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

(12) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(c) Approved medical uses of byproduct materials. A licensee may use byproduct materials on human beings for the particular uses set forth below, provided that the licensee meets all applicable requirements of this Part:

(1) use of unsealed byproduct material for uptake, dilution and excretion studies;

(2) use of unsealed byproduct material for imaging and localization studies;

(3) use of unsealed byproduct material for which a written directive is required;

(4) use of sources for manual brachytherapy;

(5) use of sealed sources for diagnosis;

(6) use of sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit; or

(7) other specific medical uses of byproduct material or radiation from byproduct material, as licensed by the department.

(d) Federal Standards. All licensees shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference in paragraphs (e)(1)-(4) and subdivisions (f)-(m) of this section, with the same force and effect as if fully set forth at length. All referenced provisions are found within 10 CFR 35, Medical Use of Byproduct Material, as revised and implemented in full on November 14, 2022. This code is published by the Office of the Federal Register National Archives and Records Administration. Copies may be obtained from the Superintendent of Documents, United States Government Printing Office, Washington D.C. 20402. This code is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237. Notwithstanding any provision herein to the contrary, if a conflict occurs between the above referenced CFR and other provisions in this Part, compliance with the more restrictive regulation is required.

(e) General requirements applicable to all licensees authorized to use byproduct materials for medical purposes.

(1) Record Keeping Requirements. A licensee shall comply with all record keeping requirements set forth in 10 CFR 35 subpart L (Records), as revised and implemented in full on November 14, 2022. Further details concerning this referenced code are contained in subdivision (c) of this section.

(2) Reporting requirements: A licensee shall comply with all reporting requirements set forth in 10 CFR 35 subpart M (Reports), as revised and implemented in full on November 14, 2022 as revised herein as follows: (i) in 35.3045(c)35.3047(c), and35.3204(a) replace phrase "NRC Operations Center" with "Department"; (ii) in35.3045(d), 35.3047(d),35.3067 and35.3204(b) replace “By an appropriate method listed in 30.6(a) of this chapter, the licensee shall submit a

written report to the appropriate NRC Regional Office listed in 30.6 of this chapter” with “shall submit a written report to the Department"; (iii) in 35.3045(g)(1) and 35.3047(f)(1), replace the term "NRC" with "Department"; and, (iv) in 35.3067 replace "The report must be filed with the appropriate NRC Regional Office listed in 30.6 of this chapter, by an appropriate method listed in 30.6(a) of this chapter, with a copy to the Director, Office of Federal and State Materials and Environmental Management Programs." with "The report shall be filed with the Department".

(3) Training and experience requirements. A licensee shall ensure that all staff who are involved in the use of byproduct material pursuant to a specific license have the training and experience required by this Part.

(4) Other General Requirements. A licensee shall comply with requirements set forth in 10 CFR 35.5,35.6, 35.11(a) and (b),35.24(b), (e), (f) and (g),35.27,35.40,35.41,35.49,35.60,35.61,35.63,35.65,35.67,35.69,35.70,35.75,35.80,35.92 as modified herein as follows: in 35.27(a)(1) and (b)(1), replace "19.12 of this chapter" with "16.13(c) of this Part".

(f) Requirements for the use of unsealed byproduct material for uptake, dilution and excretion studies. A licensee shall use unsealed byproduct material for uptake dilution and excretion studies only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35.100 and 35.190 as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(g) Requirements for the use of unsealed byproduct material for imaging and localization studies. A licensee shall use unsealed byproduct material for imaging and localization studies only if authorized to do so by a specific license issued by the department and provided that the licensee

complies with 10 CFR 35.200, 35.204 and 35.290 as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(h) Requirements for the use of unsealed byproduct material for which a written directive is required. A licensee shall use unsealed byproduct material for which a written directive is required only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart E (Unsealed Byproduct Material-Written Directive Required), as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(i) Requirements for the use of sources for manual brachytherapy. A licensee may use sources for manual brachytherapy only if authorized to so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart F (Manual Brachytherapy), as revised and implemented in full on November 14, 2022.

(j) Requirements for the use of sealed sources for diagnosis. A licensee may use sealed sources for diagnosis only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart G (Sealed Sources for Diagnosis) , as revised and implemented in full on November 14, 2022, and other applicable provision of this Part.

(k) Requirements for the use of sealed sources in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit. A licensee may use a sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit only if authorized to so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart H (Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma

Stereotactic Radiosurgery Units), as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(l) Requirements for the use of other medical uses of byproduct material or radiation from byproduct material. A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subdivisions (f) through (k) of this section if the licensee submits to the department information required by 10 CFR 35.12(b) through (d) as revised and implemented in full on November 14, 2022, and the licensee has received written approval from the department in a specific license or license amendment and uses the material in accordance with specific conditions that the department deems necessary or desirable for the safest medical use of the material.

(m) Notwithstanding the requirements of this Part, physically present for the use of high dose rate afterloader units, teletherapy units, and gamma stereotactic radiosurgery units means that the authorized medical physicist and physician is located at the console, unobstructed from visually viewing and communicating with the patient and able to provide face-to-face services immediately in the event of an emergency requiring immediate medical intervention.

(n) General Use License. Any licensee who is licensed for one or more of the types of medical uses specified in subdivisions (f) through (k) of this section also is authorized to use radioactive material under the general license in paragraph 16.101(a)(1) of this Part for the specified "in vitro" uses without registering with the department, provided, however, that the licensee is subject to the other provisions of 10 CFR 31.11 as revised and implemented on November 14, 1968.

16.124 Licenses to manufacture or transfer certain items containing radioactive material.

(a)(1) This section contains requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive material for sale or distribution to:

(i) persons exempted from the licensing requirements of this Part, or equivalent regulations of an Agreement State, the NRC; or

(ii) persons generally licensed under this Part or equivalent regulations of an Agreement State or the NRC; or

(iii) persons licensed under section 16.123 of this Part.

(2) This section prescribes requirements for the issuance of specific licenses to persons who introduce radioactive material into a product or material owned by or in the possession of a licensee or another, and regulations governing holders of such licenses.

(3) This section prescribes certain requirements governing holders of licenses to manufacture or distribute items containing byproduct material.

(4) This section describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources.

(b) The provisions and requirements of this section are in addition to, and not in substitution for, other requirements of this Part.

(c) Any person who manufactures or transfers items containing radioactive material shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10CFR 32, Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material as revised and implemented in full on August 24, 2023, except as follows:

(1) Sections 32.1, 32.11, 32.12, 32.14 through 32.23, 32.25 through 32.32, 32.301, and 32.303 are excluded.

(2) Any reference to the “Commission”, “NRC”, or “NRC Regional Office” or any other office thereof shall be deemed to be a reference to the New York State Department of Health, except for when used in 10 CFR 32.51(a)(3)(iii), 32.54(a), 32.58, 32.71(d), 32.72(b)(5), and 32.74(a)(3).

(3) Reporting required in 10 CFR32.56(a) shall be submitted to the department by means specified in section 16.1(c) of this Part, instead of to the NRC.

16.125 Additional Requirements for the Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under 10 CFR 35 or the equivalent regulations of any state.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 10 CFR 35 or the equivalent regulations of any state may be approved if:

(1) the applicant satisfies the general requirements specified in section 16.103 of this Part.

(2) the applicant submits evidence that the applicant is registered or licensed by the New York State Board of Pharmacy as a drug manufacturer or a pharmacy, as appropriate to their practice;

(3) the applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) the applicant satisfies the following labeling requirements:

(i) a label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “Caution, Radioactive Material” or “Danger, Radioactive Material”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

(ii) a label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “Caution, Radioactive Material” or “Danger, Radioactive Material” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary;

(2) check each instrument for constancy and proper operation at the beginning of each day of use; and

(3) use differing activity concentrations in preparing different radiopharmaceuticals and ensure that any discrepancy between the calculated volume of a dosage and the volume found to be

required by measurement to achieve the prescribed activity, is resolved before the dosage is dispensed. Records of actions taken to resolve any such discrepancy shall be maintained for three years.

(c) A licensee shall possess and use instrumentation for performing surveys and analyses for radioactive contamination, and for making such measurements of radiation levels and radiation dose as may be necessary to demonstrate compliance with all requirements of this Part. In addition, the licensee shall:

(1) provide appropriate instrumentation for each application. This must include but is not limited to: a microrem or microR meter for surveying non-radioactive trash before disposal, and for surveying workers' skin and clothing for contamination; a thyroid uptake system with a reproducible geometry and an adequate lower limit of detection; and analytical instruments for identifying and quantifying radioactive contamination; and

(2) calibrate all instruments in accordance with the manufacturer's specifications and calibrate all meters at least every 12 months.

(d) (1) A licensee shall provide a radiation safety officer who is a health physicist with qualifications listed in paragraph (3) of this subdivision.

(2) a licensee shall only allow persons who are certified by the New York State Board of Pharmacy as nuclear pharmacists to act as pharmacists in a facility licensed pursuant to this section. A licensee may also propose such a certified nuclear pharmacist as radiation safety officer provided that the nuclear pharmacist will be assisted in the administration of the radiation protection program by a health physicist with the qualifications listed in subparagraph (iii) of this paragraph, and who will be present at the licensee's facility for the equivalent of one working day per month at a minimum, and who will provide the following services:

(i) provide classroom instruction to non-professional personnel who will perform work under the license;

(ii) review personnel monitoring reports and recommend methods to reduce exposures exceeding ALARA levels;

(iii) review survey records and make confirmatory measurements;

(iv) review air monitoring and emission levels and ensure compliance with limits;

(v) assist in thyroid bioassays and review absorbed dose calculations;

(vi) observe operations and make recommendations for improvements;

(vii) assist in response to, and in the evaluation of root causes and impacts of, incidents and accidents in order to minimize their impact and prevent their recurrence; and

(vii) generally consult with the RSO and provide health physics support as needed. The services to be provided must be documented in a contractual agreement between the licensee and the health physicist, and the department must be given a minimum of thirty days advance notice of the licensee's intent to retain a different health physicist.

(3) A health physicist who will act as radiation safety officer, or who will provide the services described in paragraph (2) of this subdivision, must have the following qualifications:

(i) experience in performing radiation protection services, or the duties of a radiation safety officer for programs of similar type, size and scope as the licensee's program; and

(ii) a bachelor's degree in health physics or radiological health and four years of the experience as described in clause (a) of this subparagraph; or certification by the American Board of Health Physics (Comprehensive), the American Board of Radiology in Medical Nuclear Physics, the American Board of Science in Nuclear Medicine in Radiation Protection or the American Board

of Medical Physics in Medical Health Physics, and two years of the experience as described in clause (a) of this subparagraph.

(e) (1) A licensee shall only locate a nuclear pharmacy in a building that is zoned for commercial use, and which is not in a heavy public traffic area such as a large shopping center.

(2) A licensee who proposes to locate within a multi-tenant building must demonstrate that:

(i) there are no areas above or below the proposed facility which are not under the licensee's control, and to which the licensee does not have the authority to restrict access; and

(ii) there are no neighboring tenants on the same level with walls contiguous to the proposed radioactive materials use and storage areas. There must be a buffer zone of unrestricted area within the licensee's proposed facility along any walls that are common walls with a neighboring tenant.

16.126 Sealed source and device registration.

(a) Purpose. The requirements of this section apply to any manufacturer or initial distributor of a sealed source or device containing a sealed source to submit a request to the New York State Department of Health for evaluation of radiation safety information about its product and for its registration.

(b) Specific requirements. Each manufacturer or initial distributer of a sealed source or device shall comply with the provisions of 10 CFR 32, "Subpart D- Sealed Source and Device Information," Sections 32.210 and 32.211, December 19, 2014 edition.

16.127 Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations.

(a) This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials for persons using these sealed sources in industrial radiography, and for depleted uranium shielding in a radiographic exposure device. This section also contains radiation safety requirements for industrial radiography. The requirements of this section are in addition to other requirements of this Part.

(b) Any person that possesses or uses sealed sources for industrial radiography shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 34, Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations as revised and implemented in full on October 16, 2020, except as follows:

(1) Sections 34.1, 34.5, 34.8, 34.11, 34.43(a)(2), 34.45(a)(9), 34.111, 34.121 and 34.123 are excluded.

(2) Any reference to the "Commission", "NRC", "NRC Regional Office" or any office or individual thereof shall be deemed to be a reference to the New York State Department of Health, except for 34.20(a)(1), 34.27 (a)-(c) and (e), 34.41(c) and 34.43(a)(1).

(3) Reports and notifications required by 34.27(d) and 34.101 shall be reported to the Department by a means specified in 16.1(c) of this Part instead of to the NRC Director, Office of Nuclear Material Safety and Safeguards.

(4) In section 34.20 "10 CFR part 71" is replaced with "section 16.17".

(5) In section 34.25 "10 CFR 20" is replaced with "this Part".

(6) In section 34.33 (a)(1) "20.1601(a)(1) of this chapter" is replaced with "16.12(d)(1)(i) of this Part".

(7) In section 34.42 (c)(1) “current 10 CFR part 20 of this chapter” and “10 CFR part 20” are replaced with “this Part”.

(8) In section 34.42 (c)(4) “20.2203 of this chapter” is replaced with “16.15(c) of this Part”.

(9) In section 34.43 (b)(1) and (c)(1) “10 CFR parts 19 and 20, of this chapter” is replaced with “this Part”.

(10) In section 34.43 (g)(4) is replaced to read: “The requirements of pertinent State and Federal regulations; and”.

(11) In section 34.45 (a)(1), “10 CFR part 20 of this chapter ‘Standards for Protection Against Radiation’” is replaced with “this Part”, and the word “person” is replaced with “individual”.

(12) In section 34.53, “20.1902 of this chapter” is replaced with “16.12(b)(1) of this Part” and “20.1903 of this chapter” is replaced with “16.12(b)(2) of this Part”.

(13) In section 34.89(a)(2) “10 CFR parts 19 and 20” is replaced with “this Part”.

(14) In section 34.101(b) “10 CFR 20.2203” is replaced with “section 16.15(c) of this Part”.

16.128 Well-Logging.

(a) Any person conducting well-logging operations shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 39, Licenses and Radiation Safety Requirements for Well Logging as revised and implemented in full on March 18, 2020, except as follows:

(1) Sections 39.1, 39.5, 39.8, 39.11, 39.45, 39.91, 39.101, and 37.103 are excluded.

(2) Any reference to the “Commission” or “NRC” shall be deemed to be a reference to the New York State Department of Health, except in sections:

(i) 39.35 (b) and (d);

(ii) 39.41(f);

(iii) 39.43 (c) - (e); and

(iv) 39.51.

(3) Any reference to parts 19 and 20 shall be deemed to be a reference to this Part.

(4) Any reference to section 20.1901(a) shall be deemed to be a reference to section 16.12(a) of this Part.

(5) Section 39.63(h) “20.1906 of this chapter” is replaced with “16.16 of this Part”.

(6) Section 39.71(b) “20.1003 of this chapter” is replaced with “16.2 of this Part”.

(7) Section 39.75(d) “71.5 of this chapter” is replaced with “16.17 of this Part”.

(8) Section 39.77(b) “20.2201-20.2202, 20.2203” is replaced with “16.15 of this Part”.

(9) Reports of events or notifications in sections 39.35(d)(2), 39.63(l), and 39.77 shall be reported to the department by means specified in section 16.1(c) of this Part instead of to the NRC.

(b) The requirements in this section do not relieve any person from the requirements in New York State Department of Environmental Conservation (NYSDEC) regulations (6 NYCRR Part 380) for the use of unsealed radioactive material for tracer studies in the environment.

16.129 Specific requirements for irradiators.

(a) This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This section also contains radiation safety requirements for operating irradiators. These requirements are in addition to other requirements of this Part. Nothing in this

section relieves the licensee from complying with other applicable federal, State, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) This section applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Part.

(c) This section does not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

(d) Any person conducting irradiator operations shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10CFR 36, Licenses and Radiation Safety Requirements for Irradiators, as revised and implemented in full on March 18, 2020, except as follows:

(1) Section 36.2 definitions of “commencement of construction” and “construction”, sections 36.5. 36.8. 36.11, 36.15, 36.17, 36.19, 36.91 and 36.93 are excluded.

(2) Section 36.21 (a)(1) is amended to add “or equivalent Agreement State Regulations” following “10 CFR 32.210”.

(3) Section 36.23(g) is amended to replace “10 CFR 20.1902” with “this Part”.

(4) Section 36.51(a)(2) is amended to replace" Parts 19 and 36 of NRC regulations" with "this Part".

(5) Section 36.83(b) is amended to read: "The report must include a telephone report within 24 hours as described in 10 CFR 30.50(c)(1), and a written report within 30 days as described in 10 CFR 30.50(c)(2), except that such reports shall be made to the Department by means specified in section 16.1(c) of this Part instead of to the NRC Operation Center."

(6) Any reference to the "Commission", "NRC", or "NRC Regional Office" shall be deemed to be a reference to the New York State Department of Health, except for 10 CFR 36.59(a) and (c).

16.140 Radon testing and reporting.

(a) Definitions. As used in this Part:

(1) "Radon" means the radioactive noble gas radon-222.

(2) "Radon testing firm" means a commercial business which uses equipment or provides detectors for testing for radon or radon decay products, or analyzes radon measurement devices, including continuous radon monitors, and which provides the results of such tests to customers.

(3) "Radon mitigation firm" means a commercial business which evaluates buildings for the purpose of developing plans for reducing indoor air radon levels, and/or implements measures designed to reduce such levels within existing buildings. This includes contractors who install passive mitigation systems in new construction.

(b) General requirements.

(1) A radon testing firm shall report to the department in writing, within 30 days following the end of a reporting period, a summary of all indoor air radon screening and long-term radon tests performed in the State during that reporting period. Reporting periods shall be from January 1st

to June 30th and July 1st to December 31st of each year. The report shall include the dates for which the report is made and the number of such measurements performed for the reporting period in each county or ZIP code area in the State.

(2) When any radon screening or long-term testing result exceeds 20 pCi/l or 0.1 working level as defined in section 16.2 of this Part, the radon testing firm shall advise the customer, if a resident of this State, in writing to contact the New York State Department of Health, Bureau of Environmental Radiation Protection, for further technical advice and assistance.

(3) When any radon screening or long-term testing result exceeds 100 pCi/l or 0.5 working level as defined in section 16.2 of this Part, the radon testing firm shall provide telephone and written notification of measured radon concentrations to the department within two working days.

(4) Pursuant to Public Health Law Section 502 and Subpart 55-2 of this Title, no environmental laboratory may perform any examination on samples collected in the State of New York for which the commissioner issues a certificate of approval for such examination unless the laboratory has been issued such certificate of approval. Approval must be obtained through the department's Environmental Laboratory Approval Program.

(5) A radon mitigation firm shall report to the department in writing, within 30 days following the end of a reporting period, a summary of the number of homes mitigated in the State during that reporting period. Reporting periods shall be from January 1st to June 30th and July 1st to December 31st of each year. The report shall include the dates for which the report is made and the number of buildings for which mitigation was performed for the reporting period in each county or ZIP code area in the State.

16.200 Material incorporated by reference.

(a) Documents. The following documents, referenced in this Part, are available for review and copying through the Records Access Officer, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237:

(1) Except as set forth in paragraph (2) of this subdivision, Title 10 of the Code of Federal Regulations, Chapter I (Nuclear Regulatory Commission) Parts 19 (as revised and implemented in full on October 16, 2020), 20 (as revised and implemented in full on March 14, 2023), 30 (as revised and implemented in full on October 16, 2020), 31 (as revised and implemented in full on July 23, 2008), 33 (as revised and implemented in full on March 19, 2013), 35 (as revised and implemented in full on November 14, 2022), 37 (as revised and implemented in full on November 30, 2021), 71 (as revised and implemented in full on November 30, 2021) and 40.13 (revised as of May 29, 2013), 40.21 (revised as of October 3, 1980) and 40.22 (revised as of November 30, 2021) are hereby incorporated by reference with the same force and effect as if fully set forth in this Part. The CFR provisions incorporated by reference herein may be obtained from the department at the address provided above, or from the following:

(i) The United States Government Publishing Office (GPO), 710 North Capitol Street, N.W., Washington, DC 20401 (866) 512-1800, or GPO online at http://www.gpo.gov/fdsys, or

(ii) The U.S. Nuclear Regulatory Commission online at http://www.nrc.gov/reading-rm/doc-collections/cfr/.

(2) The following sections from Title 10 Chapter I of the CFR are not incorporated:

(i) Part 19: 19.1, 19.2, 19.4, 19.5, 19.8, 19.18, 19.30, 19.31, 19.32, and 19.40.

(ii) Part 20: 20.1001, 20.1002, 20.1006 through 20.1009, 20.1405, 20.1406(b), 20.1905(g), 20.2203(c), 20.2401, 20.2402, part 20 appendix D.

(iii) Part 30: 30.1, 30.2, 30.5 through 30.8, 30.21(c), 30.37 through 30.39, 30.41(b)(6), 30.53, 30.55, 30.62, 30.63, 30.64.

(iv) Part 31: 31.1, 31.2, 31.4, 31.22, and 31.23.

(v) Part 33: 33.1, 33.8, 33.11(b-c), 33.14, 33.15, 33.16, 33.21, 33.23, 33.100 Schedule A.

(vi) Part 35: 35.1, 35.8, 35.4001, and 35.4002.

(vii) Part 37: 37.1, 37.3, 37.7, 37.9, 37.11(a-b), 37.13, 37.105, 37.107, and 37.109.

(viii) Part 71: 71.2, 71.6, 71.11, 71.14(b), 71.19, 71.31 through 71.45, 71.51 through 71.77, 71.99, 71.100, 71.101(c)(2), 71.101(d)-(f), 71.107 through 71.125.

(3) To reconcile differences between this Part and the incorporated sections of the CFR, the following meanings shall be substituted for certain terms in the incorporated language of the CFR:

(i) Any reference to ‘‘NRC’’ or ‘‘Commission’’ in the incorporated CFR regulations means the department, unless the context clearly indicates otherwise. Notifications and correspondence indicated in the incorporated sections of the CFR should be sent to the department, except as required by 10 CFR37.27 (relating to requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material), which should be sent to the NRC.

(ii) References to forms in the incorporated CFR regulations mean the appropriate forms prescribed by the department.

(iii) Any reference to ‘‘NRC or Agreement State’’ in the incorporated CFR regulations means this department, NRC, or Agreement State.

(iv) Any reference to “Type A specific license of broad scope” in the incorporated CFR regulations means “specific license of broad scope” as defined in this Part

(v) Any reference to “byproduct material” in sections 30.31 through 30.62, and 31.9 of the incorporated CFR regulations means “radioactive material” as defined in this Part.

(4) Title 21 of the Code of Federal Regulations, Food and Drugs Parts 900 (as revised and implemented in full on July 14, 2023) and 1020 (as revised and implemented in full on January 20, 2023) are hereby incorporated by reference with the same force and effect as if fully set forth in this Part. The CFR provisions incorporated by reference herein may be obtained from the department at the address provided in paragraph (1) of this subdivision, or from the following:

(i) The United States Government Publishing Office (GPO), 710 North Capitol Street, N.W., Washington, DC 20401 (866) 512-1800, or GPO online at http://www.gpo.gov or https://www.ecfr.gov/current/title-10.

(5) The National Fire Protection Association (NFPA) 70, National Electrical Code - International Electrical Code Series, 2023 Edition, as incorporated by reference herein may be obtained from the department at the address provided in paragraph (1) of this subdivision, or online at https://www.nfpa.org/product/nfpa-70-code/p0070code.

(b) All persons subject to the requirements of this Part are required to comply with the specific regulations of Title 10 of the Code of Federal Regulations (CFR) as incorporated into this Part pursuant to subdivision (a) of this section.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 7 of Part B of Chapter 58 of the Laws of 2006 sets forth the authority for the Commissioner of Health to modify or abrogate the regulations found in Part 38 of Title 12 (Labor) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) pertaining to the radiation control program.

The Public Health and Health Planning Council is authorized by § 225(4) of the Public Health Law (PHL) to establish, amend, and repeal provisions of the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. PHL §§ 225(5)(p) & (q) and 201(1)(r) authorize SSC regulations to protect the public from the adverse effects of ionizing radiation. Pursuant to such statutory authority and as set forth in 10 NYCRR Part 16, the Department of Health (Department), licenses or registers health care providers to use radioactive materials or ionizing radiation emitting equipment on patients.

The federal Atomic Energy Act of 1954 (the Act), codified at 42 USC §§ 2021, et. seq., authorizes the United States Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. The Act also authorizes "Agreement States," to regulate the use of radioactive materials in lieu of the NRC, provided that the "Agreement State" promulgates regulations that are comparable to or exceed NRC's regulatory standards. New York State is an "Agreement State" within the meaning of the Act. New York's regulatory standards for the use of radioactive materials in 10 NYCRR Part 16 must therefore meet or exceed comparable NRC regulatory standards. The Act governs only the use of radioactive materials: it does not apply to x-rays or radiation therapy equipment that emit only x-rays.

Legislative Objectives:

Chapter 58 of the Laws of 2006 transferred the radiation control program from the Department of Labor (DOL) to the Department of Health, effective July 1, 2006. The law specifically sets forth that the regulations (12 NYCRR Part 38) would remain in effect until "duly modified or abrogated by the Commissioner of Health." The amendments being made by this regulation to 10 NYCRR Part 16 will incorporate and update the regulatory provisions currently found in 12 NYCRR Part 38. It is therefore appropriate to repeal 12 NYCRR Part 38 in its entirety.

The legislative intent of PHL §§ 225(5) and 201(1)(p) and (q) are to protect the public from the adverse effects of ionizing radiation. Promulgating regulations to ensure safe and effective uses of radioactive material and radiation producing equipment is consistent with this legislative objective. Section 225(5)(q) of the Public Health law also authorized the Department to recover the cost of the programs by charging adequate and reasonable fees for its regulatory activities. Such fees enable the program to maintain the staffing level required to meet the legislative mandate. By establishing the Special Revenue Operating fund in 1999 the Legislature intended the program to be funded through fees.

Needs and Benefits:

The US Nuclear Regulatory Commission (NRC) has relinquished its authority to regulate the use of radioactive materials in New York State to the State. The Atomic Energy Act of 1954 (the Act) (codified at 42 USC § 2021 et. seq.) requires New York to adopt and enforce regulatory standards for the use of radioactive materials that are comparable to or exceed federal regulatory standards that apply to the use of radioactive materials. The Department regulates approximately 1,100 facilities that use radioactive material and approximately 10,000 facilities that use x-ray

equipment. The proposed regulations incorporate by reference many of the NRC regulatory standards that govern the use of radioactive materials in medical and commercial settings. In recent years the technology and equipment used to deliver radiation therapy to cancer patients, including systems used to plan and execute radiation therapy treatment, have become significantly more complex. Recently developed radiation therapy systems more effectively deliver high-dose rate treatments to precisely defined three-dimensional tumor volumes while sparing doses to healthy tissue. Patients benefit significantly when, as is the case in most of such radiation treatments, the dose is delivered as intended.

Schedules for licensing and registration fees currently being assessed by the Bureau of Environmental Radiation Protection (BERP) are published under two separate Titles of the NYCRR. Title 12 NYCRR section 82.8 contains the fee schedule for radioactive materials licenses and radiation equipment registrations issued to industrial and commercial facilities formerly regulated by DOL under Industrial Code Rule number 38 (12 NYCRR 38). Title 10 NYCRR section 16.41 contains the corresponding schedule for radioactive sources regulated by the Department under 10 NYCRR Part 16. The current proposal combines these into one fee schedule to be published in 10 NYCRR § 16.41. Regulated parties would benefit from having a single fee schedule in one location for all radiation sources regulated by the Department.

The current fee schedules were established in 2001 (for the Department) and 2005 (for DOL). The costs of the Department's program have increased due to increased salary, equipment, and travel costs. In addition to these cost increases, increased security measures have been adopted requiring closer tracking and more frequent inspection by the Department of certain radiation sources that are of concern for national security reasons. The increased costs from these additional measures must be recovered through fees.

Finally, the proposed rule establishes an annual fee for reciprocity. Reciprocity is required under federal rules as it allows an entity licensed in another state to operate temporarily in New York based on their radioactive materials license in their home state. New York is currently one of only two states that does not charge a reciprocity fee (the other is Alabama). Other states' fees (including 48 other state programs) range from $100 to $1,400 with an average fee of about $900 per year.

The NRC audited New York State in August 2022 to review the overall status of the agreement state program. A significant finding of the last two such audits was that the New York State program is failing to meet compatibility standards. Since this is the third audit where NYS was deemed not compatible with NRC regulations, NRC placed NYS on heightened oversight. This status will be maintained until these regulations are updated and NRC completes another audit.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

This regulation updates the fees charged to facilities that use radioactive materials or x-ray equipment. On average the fee increases are 68% over existing fees. These fees are still significantly less than the corresponding fees charges by the NRC which, depending on facility type range from $12,300 to over $53,800, or two to six times higher than the proposed fees. Geographically adjacent states (PA, NJ, and MA) have different fee structures that are more variable, but in general their fees are slightly higher than what the Department is proposing in this rule.

Fee Category	Current fee	Proposed fee	Count
Radiation Equipment Category I (i.e., Hospital)	$1,420	$2,600	75
Radiation Equipment Category II (i.e., Clinic)	$1,080	$1,800	200
Radiation Equipment Category III (i.e., Large Private practice)	$740	$1,250	200
Radiation Equipment Category IV (i.e., Small Practice)	$325	$550	600
Radiation Equipment Category V (i.e., Small Practice Low Volume)	$190	$325	1,400
Radiation Equipment Category VI (i.e., Dental/Vet/Podiatry)	$65	$100	7,400
Radioactive Materials Category I (i.e., Medical Broadscope)	$5,265	$9,600	6
Radioactive Materials Category II (i.e., Academic Broadscope)	$3,510	$6,200	9
Radioactive Materials Category III (i.e., Nuc Pharm, Brachytherapy)	$1,400	$2,400	37
Radioactive Materials Category IV (i.e., Nuclear Medicine, LINAC)	$880	$1,500	502
Radioactive Materials Category V (i.e., Clinical Labs, XRF)	$350	$600	78
Radioactive Materials Category VI (i.e., Gas Chromatograph)	$50	$120	2
Radioactive Materials Commercial 1 (i.e., Industrial Radiography)	$2,500	$3,600	52
Radioactive Materials Commercial 2 (i.e., Manufacturing)	$1,833	$3,000	23
Radioactive Materials Commercial 3 (i.e., R&D, Irradiators)	$1,333	$2,400	148
Radioactive Materials Commercial 4 (i.e., Gauges)	$1,000	$1,800	182

Radioactive Materials Commercial 5 (i.e., GC, analytic Equipment)	$500	$600	5
Radioactive Materials General (i.e., General License)	$33	$120	146
Totals (count x fee)	$2,555,458	$4,291,760	11,065

Additionally, these regulations will impose new costs on Cone-Beam CT units (CBCTs). These units, like all other CT units, will have to be accredited within 18 months of the adoption of this rule. They will also be subject to annual quality assurance testing. Accreditation costs are approximately $3,000 every three years, and the annual Quality Assurance (QA) testing will be $800 to $1,200 per year.

Costs to State and Local Governments:

Government agencies are exempt from the fees in these regulations, except for government operated hospitals and higher education institutions. This will include about 30 hospitals (including Nassau County Medical Center, Westchester County Medical Center, and Erie County Medical Center) and State University of New York (SUNY) colleges who will have an approximately 60% to 75% increase in fees.

The cost increase to the three county run health care facilities are listed below:

County	Current Fees	Proposed Fees	Net increase
Nassau	2300	4100	+1800
Westchester	3635	5875	+2240
Erie	1960	3300	+1340

There are approximately 25 SUNY facilities that have X-ray equipment or a radioactive materials license. The sum of all SUNY fees will increase from approximately $36,000 currently to a total of $63,000 spread over the 25 regulated facilities. These fee increases are incidental costs for programs of this size.

Costs to the Department of Health:

These regulations make numerous technical changes and updates to the radiation safety rules. These changes will require the Department to update guidance, forms, and Standard Operating Procedures. These activities are done periodically and will not incur significant extra costs for the Department.

Local Government Mandates:

These proposed regulations apply to hospitals operated by public benefit corporations including Nassau, Erie and Westchester Medical centers. The increased annual fees will apply to these facilities. Registrants and licensees, including the hospitals operated by state and local governments, are currently required to retain all quality assurance documents for review by the Department. As such, no other additional costs or mandates are associated with implementation of these regulations.

Paperwork:

Department regulations (10 NYCRR Part 16) require registrants and licensees to maintain a variety of records relating to the use of ionizing radiation for review by the Department. The

Department estimates that licensees and registrants may have a small amount of additional documentation to create, maintain, or file these records. These regulations change the content of those records (ex. different quality assurance requirements) but do not significantly increase any required documentation over the current standards.

Duplication:

There is no duplication of the proposed regulatory requirements by any federal, state, or local agency for licensees, registrants, or authorized users subject to 10 NYCRR Part 16. New York State entered into an agreement with the federal government on October 15, 1962, by which the federal government discontinued its regulatory authority over the use of radioactive materials and New York assumed such authority.

Alternatives:

Many of the regulatory changes are required to meet federal standards. The alternative to the present fee proposal is to leave the current fees unchanged. This would require a proportional reduction in the scope of the Department's regulatory program to offset the effects of inflation and increased security measures. Failure to implement these changes would jeopardize the agreement state status and could also jeopardize public health.

Federal Standards:

New York State’s agreement with the NRC requires it to promulgate regulations consistent with the NRC’s rules, either by incorporation by reference or by developing state rules that are

nearly identical. These regulations incorporate by reference many federal standards developed by the U.S. NRC.

Compliance Schedule:

Except for the Cone-Beam CT accreditation requirements, there is no compliance schedule imposed by these regulations, which shall be effective upon publication of the Notice of Adoption in the State Register. The Cone-Beam accreditation rule requires that facilities apply to an accrediting body within 90 days of the regulations going into effect and that they complete the process with 18 months.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

These regulations will apply to two State University hospitals, one county hospital and three hospitals operating as a public benefit corporation. There are approximately 200 other facilities operated by local government agencies, mostly jails and community clinics that will be affected by these regulations but that are exempt from the fees set forth in regulation.

Of the roughly 11,000 licenses and registrations currently issued under 10 NYCRR Part 16, it is estimated that approximately two-thirds constitute small business, or roughly 6,400 throughout the state. This figure does not include any hospitals, educational facilities or government operated entities.

Compliance Requirements:

This rule change will affect small businesses and local government facilities that use ionizing radiation, including healthcare facilities, colleges, and commercial services. This is a repeal and replace of the entire existing regulation. Significant changes and updates include the following:

- Radioactive material licensing is updated to incorporate federal standards by reference and to include NYS Department of Labor regulations that were previously turned over to the Department of Health.
- Radioactive materials license and x-ray equipment registration fees are increased an average of 68%, fees for reciprocity are added, and late fees are removed. Commercial

license fees were converted to annual fees from triannual which will reduce the initial burden on applicants.

- The proposed rules include a requirement for accreditation and quality assurance (QA) testing on Cone-Beam CT units used on people, most of which are used in dentistry.
- QA requirements for diagnostic imaging have been updated to reflect the current technologies, in particular the replacement of film with digital imaging modalities. The regulations have been developed based on American College of Radiology (ACR) and American Association of Physicists in Medicine (AAPM) guidance documents that the Department of Health (Department) has used as a standard for facilities for the past decade.
- Definitions have been added for compatibility and clarity purposes. Other sections of the regulations have had out of date language or unclear phrasing reworded based on discussions with regulated entities and NRC staff.
- Updates require recording of high patient doses from fluoroscopy and notification of referring physician and instructions to patient.

Regulated facilities will need to become familiar with the updated rules and may need to modify their radiation safety program and quality assurance policies and procedures accordingly. Those facilities with Cone Beam CT units that are not accredited will need to do so within 18 months of the effective date of the rule.

Professional Services:

Many large facilities have in-house staff that perform quality assurance testing and operate radiation emitting technology. Smaller offices and private practices employ consultants

to provide QA services and assistance in the development of policies and procedures relating to radiation safety. The QA related changes will not require significant time and the Department will provide updated guidance and references to current professional and national standards as applicable.

The Department does not expect that it will be necessary for licensees to use additional professional services for completion of applications for accreditation or to implement the quality assurance requirements other than the operators of Cone-Beam equipment who will have to develop QA plans and become accredited.

Compliance Costs:

The Cone-Beam CT accreditation will cost the registrant about $3,000 dollars for a three-year period and the Cone Beam CT QA testing will cost approximately $800 to 1,200 per year. In addition, radioactive materials license and x-ray equipment registration fees are increased an average of 68%, fees for reciprocity are added, and late fees are removed. This fee increase is needed to cover program cost as the fees have not increased since 2001. Program used the US Bureau of Labor Statistics Consumer Price Index Calculator to determine average increases from 2002 to 2023. This program is a partial cost recovery program and staff salaries, and other program operation expenses are covered through the fees. Commercial license fees were converted to annual fees from triannual which will reduce the initial burden on applicants.

Economic and Technology Feasibility

There are no capital costs or new technology required to comply with the proposed rule. Most of the facilities affected will be dental, veterinary, and podiatric facilities and they will

have a $35 increase in registration fee which is still a low-cost relative to many other states annual fees. Large hospitals, universities and other large corporate entities will see larger amounts proportional to the cost to inspect and regulate these facilities. Therefore, the proposal should be economically and technologically feasible for regulated entities.

Minimizing Adverse Impact:

Most facilities will not need a substantial amount of time to comply with these updates. Mitigating the fee increase for commercial licensees will be the fact that they only pay a 1-year fee instead of a 3-year fee. Late fees for all regulated facilities are dropped. Facilities will have 90 days to apply for accreditation and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application, and budget funds for the accreditation fee. Most users of Cone Beam CT equipment already charge patients a fee for the images made by this equipment and will be able to recoup the increased cost associated with the increased QA requirements.

Small Business and Local Government Participation:

The diagnostic quality assurance testing changes were reviewed by NYS medical and health physics societies for technical content during the past several years. The therapy regulation updates have been developed with input from radiation oncology facilities, based on current professional standards and practices. The Department of Health will provide notice of rulemaking to organizations that represent the interested parties including the dental, veterinary, podiatry, medical (MSSNY) and healthcare (HANYS) and other interested parties. In addition, the proposed regulations will be published in the State Register to provide Small Business and

Local Government a review and comment period, which is an opportunity for comment and to participate in the regulatory process. Some sections of the regulations have had out of date language or unclear phrasing reworded based on discussions with regulated entities and NRC staff and many of their suggestions have been included.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation

Violations that had previously been cited by 12 NCYRR Part 38 may now be cited under 10 NYCRR Part 16 as the NYS Department of Labor regulations are transcribed into Title 10 NYCRR Part 16. There are no changes to any violations or penalties, however late fees have been removed from the fee schedule and will no longer be charged.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 44 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2020 (https://www.census.gov/quickfacts/). Approximately 17% of small health care facilities are located in rural areas.

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County	Oswego County	Washington County
Essex County	Otsego County	Wayne County
Franklin County	Putnam County	Wyoming County
Fulton County	Rensselaer County	Yates County
Genesee County	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2020.

Albany County	Niagara County	Orange County
Dutchess County	Oneida County	Saratoga County
Erie County	Onondaga County	Suffolk County
Monroe County		

There are just over 11,000 regulated facilities that possess and use x-ray equipment or radioactive materials. Approximately 20% are in the 44 counties defined as rural based on population and an additional 46% are in those counties defined as rural by population density. As of January 1, 2022, there are just under 7,200 facilities in rural areas. Approximately 50% of the regulated facilities are dental, 10% are veterinarians, 9% are physician's office, 8% are non-human use (academic, commercial, or industrial), 7% are hospitals, clinics or imaging centers, and the rest are a mix of podiatrists, chiropractors, and other specialty providers.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

There are no new reporting requirements to the State contained in the proposed regulations for most regulated facilities. However, certain medical users of fluoroscopy will have to report to the patient and maintain records of high patient exposure. This will affect hospitals and ambulatory surgery sites that perform interventional fluoroscopic procedures. No additional professional service costs are anticipated. Facilities are currently required to maintain records of quality assurance test results and accreditation documents for review by the Department's inspectors. The content of these tests is specified in sections 16.23 and 16.24 of these regulations. Compliance with the recordkeeping requirements will require only a minor incremental amount of time and effort for affected facilities.

Cost:

Fees are increased an average of 68% for all license and registration categories. Specifically, operators of Cone-Beam CT units will also have to get accredited which will cost them $3,000 for a three-year period. These units will now be subject to quality assurance testing

requirements that will cost an additional $800-1,200 per year. This will affect approximately 10% of the dental practices in the state, principally oral surgeons, and other specialty practices.

Schedules for licensing and registration fees currently being assessed by the Bureau of Environmental Radiation Protection (BERP) are published under two separate Titles of the NYCRR. Title 12 NYCRR section 82.8 contains the fee schedule for radioactive materials licenses and radiation equipment registrations issued to industrial and commercial facilities formerly regulated by DOL under Industrial Code Rule number 38 (12 NYCRR 38). Title 10 NYCRR section 16.41 contains the corresponding schedule for radioactive sources regulated by the Department under 10 NYCRR Part 16. The current proposal combines these into one fee schedule to be published in 10 NYCRR § 16.41. Regulated parties would benefit from having a single fee schedule in one location for all radiation sources regulated by the Department.

The current fee schedules were established in 2001 (for the Department) and 2005 (for DOL). The costs of the Department's program have increased due to increased salary, equipment, and travel costs. In addition to these cost increases, increased security measures have been adopted requiring closer tracking and more frequent inspection by the Department of certain radiation sources that are of concern for national security reasons. The increased costs from these additional measures must be recovered through fees.

Finally, the proposed rule establishes an annual fee for reciprocity. Reciprocity is required under federal rules as it allows an entity licensed in another state to operate temporarily in New York based on their radioactive materials license in their home state. New York is currently one of only two states that does not charge a reciprocity fee (the other is Alabama). Other states' fees (including 48 other state programs) range from $100 to $1,400 with an average fee of about $900 per year.

Minimizing Adverse Impact:

Most facilities will not need to take a substantial amount of time to comply with these updates. Mitigating the fee increase for commercial licensees is the fact that they will now only pay a 1-year fee instead of a 3-year fee. In addition, late fees for all regulated facilities are dropped. Cone Beam CT facilities will have 90 days to apply for accreditation and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application and budget funds for the accreditation fee. Most users of Cone Beam CT equipment already charge patients a fee for the images made by this equipment and therefore should be able to recoup the increased costs associated with the new regulatory requirements.

Rural Area Participation:

Regulated facilities are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council and as part of the formal public comment process. The diagnostic quality assurance testing changes were reviewed by NYS medical physics and health physics societies for technical content during the past several years. The therapy regulation updates have been developed with input from radiation oncology facilities, based on current professional standards and practices. The majority of the changes are based on existing guidance, published federal regulations, merge DOL regulations into DOH regulations, or were clarifications and modernizations of language. DOH has communicated the nature of these updates with interested professional organizations over the past few years.

JOB IMPACT STATEMENT

Nature of Impact:

It is anticipated that no jobs will be adversely affected by this rule. Medical providers of diagnostic imaging and radiation therapy will need to become familiar with the new quality assurance requirements.

Categories and Numbers Affected:

There are approximately 10,000 facilities registered to use radiation producing equipment (x-ray machines), and more than 1,100 facilities authorized by license to use radioactive material. Approximately 5,500 of the x-ray facilities are dental practices.

Regions of Adverse Impact:

No areas will be adversely affected.

Minimizing Adverse Impact:

There are no alternatives to the proposed regulations. Many of these changes are required for the State to maintain compatibility with federal regulations. Non-compatibility updates reflect technological change, especially the change from film-based imaging to digital x-ray systems. The Department will revise guidance to assist all licensees, including those in rural areas, with implementation of the proposed regulations.

Self-Employment Opportunities:

The rule may have impact on some dental practices. It imposes an additional cost and a quality assurance requirement on facilities that have Cone-Beam CT units (CBCT). The Department estimates that there are between 500 and 600 practices that have CBCT units.

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 241042-C
St. James Hospital

Program: **Hospital**
Purpose: **Construction**

County: **Steuben**
Acknowledged: **February 2, 2024**

Executive Summary

Description
St. James Hospital, an existing 15-bed acute care not-for-profit hospital at 7329 Seneca Road North, Hornell, NY (Steuben County), requests approval to convert two (2) Medical/Surgical beds to Intensive Care "Step Up" beds and certify a four (4) "Swing" bed program with no change in total bed count.

The proposal will create flexibility to switch from the inpatient to skilled care status or for an inpatient to Step-Up for care when applicable for patient care in the medical/surgical unit.

OPCHSM Recommendation
Contingent Approval

Need Summary
The applicant projects 91 inpatient visits in Year One and 183 in Year Three. Medicare is the primary payor source, with 89% in Year One and 87.4% in Year Three. Medicaid is projected to be 6.6% in Year One and 7.7% in Year Three.

Program Summary
Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary
The total project cost of $40,264 will be met with equity from hospital operations.

Budget:	Year One (2025)	Year Three (2027)
Revenues	$301,125	$608,753
Expenses	77,018	96,672
Excess Revenues	$224,107	$512,081

Health Equity Impact Assessment
Based on the information and analysis presented in the Health Equity Impact Assessment and the applicant's mitigation plan, the proposed project will not result in any significant adverse health equity impacts.

Recommendations

Health Systems Agency

The HSA recommends approval of this project.

Office of Primary Care and Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
3. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0 [AER]

Approval conditional upon:

1. This project must be completed by **April 1, 2026**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **January 1, 2025,** and construction must be completed by **January 1, 2026**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. Submission and approval of a Form CMS-855 to the Fiscal Intermediary prior to onsite inspection [HSP]

Council Action Date

April 11, 2024

Need Analysis

Background and Analysis

This project will treat patients in Steuben County. St. James Hospital is in a Health Professional Shortage Area for Dental Health, Mental Health, and Primary Care. The population of Steuben County is projected to increase from 93,584 to 114,226 by 2029. The 65+ population is expected to increase from 18,690 to 21,077 for the same period, per the Cornell Program on Applied Demographics. Demographics for the primary service area are noted below, including a comparison with New York State.

Demographics	Steuben County	New York State
Total Population	93,584	19,994,379
65+ Population	20%	17%
Hispanic or Latino (of any race)	1.8%	19.50%
White (non-Hispanic)	92.4%	53.8%
Black or African American (non-Hispanic)	1.4%	13.8%
Asian (non-Hispanic)	1.6%	8.8%
Other (non-Hispanic)	2.8%	4.1%

Source: 2022 American Community Survey (5-Year Estimates Data Profiles)

In 2021, 94.5% of the population in Steuben County had health coverage as follows.

Employer Plans	44.6%
Medicaid	21.8%
Medicare	13.8%
Non-Group Plans	12.6%
Military or VA	1.8%

Source: Data USA

The table below shows the projected payor mix. The facility sees a large population of elderly patients which is shown through their high Medicare payor mix.

Applicant Projected Payor Mix			
Payor	**Current**	**Year One**	**Year Three**
Commercial	4.35%	4.40%	4.92%
Medicare	91.30%	89.01%	87.43%
Medicaid	4.35%	6.59%	7.65%
Total Visits	23	91	183

Current and Projected Beds at St. James Hospital, Source HFIS/Applicant			
Bed Type	**Current Beds**	**Bed Change**	**Beds Upon Completion**
Intensive Care	0	2	2
Medical / Surgical	15	-2	13
Total	15	0	15

St. James Hospital Inpatient Occupancy, Source SPARCS				
Historical/Current				
	2019	**2020**	**2021**	**2022**
Medical/Surgical	47%	47%	80%	87.20%

Medical/Surgical occupancy has grown significantly from 2020 to 2022, with further growth anticipated. St. James also notes experiencing spikes in utilization, often reaching 100%.

Creating the ICU and Swing Bed Unit will allow more flexibility for the facility. They will be able to accommodate patients in need of higher acuity care, while patients who are on ventilators will be able to transition to the swing bed unit and receive extended care. There will be no change in the total bed count for the hospital.

Conclusion

The conversion of these beds will give the facility the ability to treat a greater range of patients and provide necessary care for the people located in this rural area.

Program Analysis

Project Proposal

St. James Hospital, an existing 15-bed Acute Care General Hospital located at 7329 Seneca Road North, Hornell, New York (Steuben County), seeks approval to convert two (2) beds for ICU ("Step-up") beds and to utilize four (4) beds for skilled nursing "Swing" beds. There will be no change in the total hospital number of bed capacity. The intent is to accommodate patients in need of ICU care, keeping patients on mechanical ventilation for up to 36 hours but no more than 96 hours. The proposal would address complex care with the certification of 2 medical/surgical beds as ICU beds. The proposed rooms would be used as medical/surgical beds when there are no complex care patients for admission.

The proposal will use the existing patient room 2140A and patient room 2120U for the skilled nursing "Swing" beds, and patient rooms 2120J and 2021H will be utilized as the "Step-Up" beds/ICU beds. This will create flexibility to switch from the in-patient to skilled care status or for an in-patient to "Step-Up" for care when applicable for patient care on the medical/surgical unit.

St. James Hospital will remain a 15-bed safety-net hospital. Medical/Surgical beds will decrease from 15 beds to 13 beds, and Intensive Care beds will increase from 0 beds to 2 beds.

There will be minor renovations to meet the higher level of care for the ICU ("Step-Up") beds. The proposed renovation will occur in the 2nd floor Medical/Surgical unit to improve visibility and opening access. The door will be changed to a sliding telescopic glass door, and headwall gases and electrical will be upgraded within the rooms. No building systems upgrades are proposed.

No construction work is proposed for the skilled nursing swing beds. These two medical/surgical inpatient sleeping rooms will be utilized as swing space for long-term care patients and remain as single occupancy 1-bed rooms.

Respiratory therapy will be available at the facility 24 hours/7 days a week, and nursing staff will be trained in ventilator management. One (1) RN will be assigned to every two (2) ICU patients. Staffing will include one (1) RN, who will be ICU-level trained and a 24/7 hospitalist. Additional staffing for the unit includes two (2) RNs, 2 LPNs, and one (1) PCT with an additional PCT from 9 am - 9 pm.

Staffing is expected to grow by 0.5 FTEs in Year One and 0.5 FTEs in Year Three of the completed project.

Prevention Agenda

St. James Hospital in Steuben County is seeking approval to convert existing patient rooms to Intensive Care Beds to accommodate patients who are in need of Step-Up care. They are also seeking approval for the certification of a 4-bed Swing Bed Program with no change in total bed count. Through this, the hospital aims to create the flexibility to switch from inpatient to skilled care status or inpatient to Step-Up care when applicable for patient care on the medical/surgical unit. This new addition is needed to cope with the rising demand for outpatient procedures.

St. James Hospital is implementing multiple interventions to support priorities of the 2019-2024 New York State Prevention Agenda, including:

- Prevent Chronic Diseases
- Promote Wellbeing and Prevent Mental and Substance Use Disorders

The proposed project, however, does not explicitly advance the local Prevention Agenda priorities that were identified in the most recently completed Community Service Plan (CSP), but it does improve access to care for patients that require Step-Up care in an outpatient setting.

In 2021, St. James Hospital spent $33,415 on community health improvement services, representing 0.06 % of total operating expenses.

Conclusion

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Analysis

Total Project Cost and Financing

Renovation and Demolition	$20,000
Moveable Equipment	18,150
CON Fees	2,000
Additional Processing Fees	210
Total Project Cost	$40,360

St. James Hospital will provide equity to meet the total project cost.

Operating Budget

The applicant has submitted an incremental operating budget, in 2024 dollars, for the first and third years, summarized below:

	Year One (2025)		Year Three (2027)	
	Per Discharge	Total	Per Discharge	Total
Revenues:				
Commercial FFS	$3,998	$15,993	$4,101	$36,913
Medicare FFS	$3,372	$131,508	$3,399	$254,925
Medicare MC	$3,372	$141,624	$3,399	$288,915
Medicaid FFS	$2,000	$2,000	$2,000	$6,000
Medicaid MC	$2,000	$10,000	$2,000	$22,000
Total		$301,125		$608,753
Expenses:				
Operating	$798.36	$72,651	$504.40	$92,305
Capital	$47.99	4,367	$23.86	4,367
Total Expenses	$846.35	$77,018	$528.26	$96,672
Excess Revenues		$224,107		$512,081
Utilization: (Discharges)		91		183

The following is noted with respect to the submitted operating budget:

- Expense and utilization assumptions are based on the historical experience of the hospital.
- Revenue assumptions are based on the current reimbursement methodologies for intensive care beds and swing beds.

Capability and Feasibility

The total project cost of $40,264 will be met with equity from hospital operations. Presented as BFA Attachment A is the June 30, 2023 Certified Financial Statements of St. James Hospital, which indicates the availability of sufficient funds to meet the total project cost. The submitted budget projects excess revenues of $284,107 and $512,081 during the first and third years, respectively. Revenues are based on current reimbursement methodologies. The submitted budget appears reasonable.

As shown in BFA Attachment A, the hospital had a positive working capital position, positive net asset position, and an operating loss of $8,490,689 for the period ending June 30, 2023. The applicant indicated the loss is a result of $6.5M in depreciation expense due to the construction of the new hospital. Currently, the hospital receives Direct Payment Template (DPT) funding and has a three (3) year Vital Access Provider (VAP) award supporting their surgical initiative to grow urology, primary care, and staff retention and recruitment. In addition to State support, St. James has been working to increase their outpatient growth in ED, urgent care, imaging, and specialty services, and develop physician recruitment. The facility is working with The University of Rochester Medical Center on payor contracts and revenue integrity to ensure payor contracts and billed services are paid at appropriate rates. St. James has identified over $1M in opportunities that are implemented or underway.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Health Equity Impact Assessment

Health Equity Impact Assessment Summary

The Applicant's service area includes portions of Allegany and Steuben counties. Notably, Allegany County is one of the poorest counties in New York. Due to the limited availability of medical services in the area, many patients must travel to Rochester or Buffalo, an up to 2-hour commute, to receive treatment. Long-distance travel creates barriers for many medically underserved groups, such as those who are low-income, aging, and/or who live with disabilities, due to the costs and time involved in travel, limitations in vehicle ownership, and inability to travel independently. Allegany and Steuben counties also include an Amish community for whom the impact of long-distance travel is compounded.

The independent entity was able to engage with multiple stakeholders for input on the project, including the Allegany and Steuben County health departments. Interviewed stakeholders strongly support the project, which is expected to not only improve availability and access to services but also improve the quality of life for patients and their loved ones. Since there are significant disparities in the availability of ICU beds between wealthier urban and lower-income rural communities in the United States, which impact mortality rates, increasing ICU beds may also reduce mortality rates for the service area. Finally, the proposed project will increase opportunities for staffing which will improve the "career pipeline" for hospital staff.

Conclusion

Based on the information and analysis presented in the Health Equity Impact Assessment and the applicant's mitigation plan, the proposed project will not result in any significant adverse health equity impacts.

Attachments

BFA Attachment A	June 30, 2023, Certified Financial Statements of St. James Hospital
OHEHR Attachment	Health Equity Impact Assessment Report
HSA Attachment	Common Grounds HSA Recommendation Report

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 232182-C
White Plains Hospital Center

Program: **Hospital**
Purpose: **Construction**

County: **Westchester**
Acknowledged: **November 27, 2023**

Executive Summary

Description
White Plains Hospital Center (WPH), a 292-bed acute care hospital and member of Montefiore Health System, at 41 East Post Road, White Plains (Westchester County), requests approval to certify 24 intensive care beds and 120 medical/surgical beds.

WPH plans to construct a 10-story addition to the existing hospital that will be connected to the hospital on the first three (3) floors of the new building. The new addition will include an emergency department expansion, the addition of three (3) new operating rooms, and 144 additional private, acuity adaptable inpatient beds.

OPCHSM Recommendation
Contingent Approval

Need Summary
The applicant projects 29,372 inpatient visits and 626,963 outpatient visits in Year Three with an 18% Medicaid payor mix.

Program Summary
Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary
Total project cost of $747,928,910, will be met with $147,928,910 in equity from WPH, fundraising of $100,000,000, and $500,000,000 tax-exempt bonds at an interest rate of 6.50% for a 30-year term.

	Year One 2029	Year Three 2031
Budget:		
Revenues	$1,632,300,000	$1,779,099,998
Expenses	1,629,300,000	1,775,400,000
Excess Revenues	$3,000,000	$3,699,998

Health Equity Impact Assessment
Based on the information and analysis presented in the Health Equity Impact Assessment and the applicant's mitigation plan, the proposed project will not result in any significant adverse health equity impacts.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Satisfactory responses to DASNY triage review commentary dated 1/17/24, triage closure, and re-submission of minimum required/revised Schedule 6 application review materials to NYSECON for DOH record and formal Schematic Design review. [DAS]
3. The submission of Design Development and State Hospital Code (SHC) Drawings, as described in NYSDOH BAER Drawing Submission Guidelines DSG-1.0 Required Schematic Design (SD) and Design Development (DD) Drawings, and 2.18 LSC Chapter 18 Healthcare Facilities Public Use, for review and approval. [DAS]
4. Submission of documentation of the receipt of fundraising that is acceptable to the Department of Health. [BFA]
5. Submission of bond financing that is acceptable to the Department of Health. [BFA]

Approval conditional upon:

1. This project must be completed by **March 15, 2028**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **October 1, 2024,** and construction must be completed by **December 15, 2027**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a) if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. (DAS)
4. Per 710.9 the applicant shall notify the appropriate Regional Office at least two months in advance of the anticipated completion of construction date to schedule any required pre-opening survey. Failure to provide such notice may result in delays affecting both the pre-opening survey and authorization by the Department to commence occupancy and/or operations. (DAS)
5. Compliance with all applicable sections of the NFPA 101 Life Safety Code (2012 Edition), and the State Hospital Code during the construction period is mandatory. This is to ensure the health and safety of all building occupants are not compromised by the construction project. This may require the separation of residents, patients and other building occupants, essential resident/patient support services and the required means of egress from the actual construction site. The applicant shall develop an acceptable plan for maintaining the above objectives prior to the actual start of construction and maintain a copy of same on site for review by Department staff upon request. (DAS)
6. This approval in no way obviates the applicant of the responsibility of complying with all applicable codes, rules, and regulations. Should violations be noted upon review of documents or found at time of on-site inspections, or surveys, such violations shall be corrected prior to occupancy without additional costs allowed for reimbursement beyond the total project cost listed above. (DAS)

Council Action Date

April 11, 2024

Need Analysis

Background and Analysis

The total population of Westchester County was 997,904 in 2022 and is estimated to increase to 1,033,438 by 2029 per projection data from the Cornell Program on Applied Demographics, an increase of 3.6%. Demographics for the primary service area are noted below including a comparison with New York State.

Demographics	Westchester County	New York State
Total Population – 2022 Estimate	997,904	19,994,379
Hispanic or Latino (of any race)	25.8%	19.50%
White (non-Hispanic)	51.2%	53.8%
Black or African American (non-Hispanic)	13.3%	13.8%
Asian (non-Hispanic)	0.1%	8.8%
Other (non-Hispanic)	9.6%	4.1%

Source: American Community Survey (5-Year Estimates Data Profiles)

In 2021 94.9% of the population in Westchester County had health coverage as follows.

Employer Plans	56.2%
Medicaid	14.2%
Medicare	12.7%
Non-Group Plans	11.5%
Military or VA	0.291%

Source: Data USA

The table below provides current and projected payor mix data for inpatient and outpatient services.

Applicant Projected Payor Mix						
Payor	Inpatient			Outpatient		
	Current	Year One	Year Three	Current	Year One	Year Three
Commercial	34.74%	31.51%	30.42%	43.76%	42.31%	41.61%
Medicare	48.61%	49.89%	50.29%	37.63%	37.93%	38.13%
Medicaid	15.02%	17.13%	17.82%	16.29%	17.49%	17.99%
Charity Care	0.99%	1.13%	1.23%	1.58%	1.68%	1.78%
Other	0.64%	0.34%	0.24%	0.74%	0.59%	0.49%
Total Visits	22,326	27,527	29,372	437,484	591,266	626,963

The applicant proposes adding 144 private inpatient beds to address current and future capacity issues. According to the applicant, many of the existing rooms are undersized and require updates in size and amenities. These rooms will also be able to be converted into critical care rooms if needed as future demands may dictate.

Current and Projected Bed Utilization (Based on Current Bed Numbers)									
Service	**Beds**		**Historical**					***Projected**	
	Current Beds	**Proposed Change**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2027**
Coronary Care	8	8	71%	67%	71%	77%	76%	85%	86%
Intensive Care	20	20	29%	38%	30%	33%	38%	49%	86%
Maternity	28	28	66%	60%	69%	61%	74%	73%	74%
Medical / Surgical	206	350	106%	102%	106%	109%	119%	119%	124%
Neonatal Intensive Care	15	15	61%	59%	66%	70%	66%	68%	70%
Pediatrics	15	15	3%	2%	6%	5%	5%	5%	5%
Total Beds	292	436							
Pediatric Rooms are often utilized for adult patients as census dictates. Source: Applicant									

WPH is projecting to expand the ED by an additional 22,650 square feet to help mitigate ED throughput and overcrowding issues and to facilitate the inpatient admission process. The expanded ED will utilize a split flow model where low acuity patients can be cared for in chairs and not utilize stretchers to enhance efficiency. The existing ED has 27 semi-private ED positions and 31 private bays for a total of 58 care spaces. The new ED will have 67 private bays. Changes in projected ED volume are below.

Current and Projected Emergency Department Volume

	Historical					**Projected**	
	2019	**2020**	**2021**	**2022**	**2023**	**2029**	**2031**
Bays	31	31	31	31	31	67	67
Visits	65,959	58,613	64,734	72,608	77,832	86,070	90,478
Visits: per Bay	2,128	1,891	2,088	2,342	2,511	1,285	1,350

Source: Applicant

With this application, WPH will add three ORs to help address the increasing volume and acuity of surgical cases. The table below outlines the growth seen at WPH over the past few years. Inpatient volume in the medical surgical beds has exceeded 100% often overflowing into other areas. The ORs are seeing higher acuity cases leading to extended surgical times.

Historical Surgical Volume					
	2019	**2020**	**2021**	**2022**	**2023**
Total Rooms in Operation	12.0	12.7	16.1	17.4	18.5
Total Surgical Cases	10,984	10,057	11,131	13,047	14,806
Total Operating Minutes	1,216,973	1,138,254	1,221,571	1,466,644	1,659,376
Average of all cases per room (except Cardiac)	915	792	700	790	843
Average minutes per room (except Cardiac)	101,414	89,626	76,460	87,365	92,663

Source: Applicant

WPH has transformed from a community hospital to a Tertiary Hub, providing high-acuity care to the community that is expanding to include its hospital partners and affiliates in the system. WPH now supports communities ranging from Newburgh in Orange County, Nyack in Rockland County, through the Hudson Valley to southern Westchester County, including Mount Vernon, New Rochelle, and Yonkers.

WPH joined Montefiore in 2015 and has since become the Hudson Valley Tertiary Hub for Montefiore. They currently provide advanced care that is not currently offered at St. Luke's Hospital, Nyack Hospital, New Rochelle Hospital, and Mount Vernon Hospital. The project enables the Montefiore system hospitals to continue to transfer secondary and tertiary level patients to WPH, instead of those patients having to travel to New York City or New Jersey.

Conclusion

This project will prepare White Plains Hospital for increasing demand and help relieve current overcrowding in the ED, inpatient units, and surgical suite.

Program Analysis

Project Proposal

White Plains Hospital Center (WPH or Hospital), a 292-bed acute care hospital and member of Montefiore Health System, Inc. (Montefiore), located at 41 East Post Road, White Plains (Westchester County), New York 10601, is submitting this Full Review Certificate of Need Application seeking approval for a major expansion project.

WPH plans to construct a 10-story addition to the existing hospital that will be connected to the hospital on the first three (3) floors of the new building. The new addition will include the following key components that are needed to meet current and projected patient demand: emergency department expansion; the addition of three (3) new operating rooms; and 144 additional private, acuity-adaptable inpatient beds.

Two (2) hospital-owned freestanding buildings - 192 Maple Avenue (vacated retail building) and 201 South Lexington Avenue (vacated retail and business office building), as well as a four-(4)-level parking structure adjacent to the existing hospital, will be demolished before this major expansion project is constructed.

The applicant reports that WPH's Emergency Department (ED) was on track to treat approximately 78,000 patient visits in 2023. The ED has increased 61% in visit volume between 2010 and projected 2023. The ED will expand by 22,650 square feet (from 16,950 square feet to 39,600 square feet) to help mitigate ED throughput and overcrowding issues and to facilitate the inpatient admission process.

WPH's surgical volume has grown 84% between 2010 and projected 2023. Not only has surgical volume increased, but the complexity and length of surgical cases continues to increase, generating a necessity for additional, appropriately sized operating rooms. Three (3) additional ORs with a new, private Pre/Post Unit, and an expanded sterile core are essential components of this major expansion which will address the increasing volume and acuity of surgical cases at WPH.

WPH's inpatient volume has grown by 50% between 2010 and projected 2023. WPH's market share within Westchester County (excluding normal newborns) has increased from 11% in 2010 to 17% in 2021. WPH is certified to operate 292 beds, of which only 41% are private. WPH plans to add 144 additional private inpatient beds to address current and future capacity issues throughout the organization. Twenty-four (24) of the additional beds will open as intensive care beds, bringing White Plains Hospital to a total of fifty-two (52) critical care beds.

The following table shows the Hospital's current and future services and programs impacted by this project.

	Current	+/-	Total	Difference
ED Bays	31	36	67	+36
Operating Room Beds	11	3	14	+3
ICU Beds	20	24	44	+24
CCU Beds	8	0	8	0
Maternity Beds	28	0	28	0
Med/Surg Beds	206	120	326	+120
NICU Beds	15	0	15	0
Pediatric Beds	15	0	15	0
Total Beds	**292**	**144**	**436**	**144**

NOTE: The current ED has 27 semi-private ED positions in addition to 31 private bays for a total of 58 care spaces. The project will upgrade the semi-private positions as well as add more bays for the new total of 67.

Staffing:

Staffing Categories	Current Year FTE (2022)	First Year FTE Budget	Third Year FTE Budget
Management & Supervision	355.6	467.4	487.6
Technician & Specialist	730.3	959.9	1001.3
Registered Nurses	752.0	988.3	1030.9
Licensed Practical Nurses	0.4	0.5	0.5
Physicians	283.1	372.0	388.1
Physicians' Assistants	64.8	85.1	88.8
Nurse Practitioners	56.9	74.8	78.0
Nurse Midwife	1.0	1.3	1.4
Social Workers and Psychologist**	18.8	24.7	25.8
Physical Therapist and PT Assistants	24.5	32.2	33.6
Occupational Therapist and OT Assistants	3.0	4.0	4.1
Speech Therapist and Speech Assistants	4.0	5.3	5.5
Other Therapist and Assistants	44.0	57.8	60.3
Laundry, Environment, Food Service and Other	290.9	382.3	398.8
Clerical and Other Administrative	1029.7	1353.3	1411.7
Total Full Time Equivalents (FTEs)	3659.1	4809.0	5016.4

Compliance with Applicable Codes, Rules, and Regulations

The medical staff will continue to ensure that the procedures performed at the facility conform to generally accepted standards of practice and that privileges granted are within the physician's scope of practice and expertise. The Facility's admissions policy includes anti-discrimination provisions regarding age, race, creed, color, national origin, marital status, sex, sexual orientation, religion, disability, or source of payment. All procedures are performed in accordance with all applicable federal and state codes, rules, and regulations.

This facility has no outstanding Article 28 surveillance or enforcement actions and based on the most recent surveillance information, is deemed to be currently operating in substantial compliance with all applicable State and Federal codes, rules, and regulations. This determination was made based on a review of the files of the Department of Health, including all pertinent records and reports regarding the facility's enforcement history and the results of routine Article 28 surveys as well as investigations of reported incidents and complaints.

Prevention Agenda

White Plains Hospital Center in Westchester County seeks approval to build a 10-story addition connected to the existing hospital's first three floors. This expansion, addressing current and future patient demand, will include an expanded emergency department, three new operating rooms, and 144 extra private, acuity-adaptable inpatient beds.

White Plains Hospital Center is implementing multiple interventions to support priorities of the 2019-2024 New York State Prevention Agenda, including:

- Promote a Healthy and Safe Environment
- Promote Healthy Women, Infants and Children

The proposed project does not directly advance the priorities outlined in the most recent Community Service Plan (CSP) for the local Prevention Agenda. However, it does enhance access to care for patients requiring radiation oncology.

In 2021, White Plains Hospital Center had $93,361,106 in Community Benefits Spending (0.92% of total operating expenses) with $116,264 in Community Health Improvement Services (0.02% of total operating expenses).

Conclusion

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Analysis

Total Project Cost and Financing

Total project cost, which is for new construction and the acquisition of moveable equipment, is estimated at $747,929,910, further broken down as follows:

New Construction	$466,219,094
Temporary Utilities	1,666,560
Asbestos Abatement or Removal	50,000
Design Contingency	46,621,909
Construction Contingency	23,310,955
Planning Consultant Fees	12,993,750
Architect/Engineering Fees	36,975,108
Construction Manager Fees	2,495,507
Other Fees (Consultant)	10,889,333
Moveable Equipment	38,021,382
Telecommunications	10,792,215
Financing Costs	6,000,000
Interim Interest Expense	87,800,000
CON Fee	2,000
Additional Processing Fee	4,091,097
Total Project Cost	$747,928,910

The applicant's financing plan appears as follows:

Equity	$147,928,910
Fundraising	$100,000,000
Tax exempt bonds (6.50% for a 30-year term)	500,000,000

The applicant has stated that to date they have received $5,900,000 in fundraising proceeds. They have indicated that if fundraising proceeds are not met, they will contribute additional equity from operations offset the shortfall. The applicant has indicated that they intend to pursue DASNY financing.

Operating Budget

The applicant has submitted an operating budget, in 2024 dollars, for the first and third years, summarized below:

	Current Year (2022)		Year One (2029)		Year Three (2031)	
Rev: (Inpatient)	Per Disch.	Total	Per Disch.	Total	Per Disch.	Total
Commercial FFS	$24,204	$6,849,872	$29,975	$8,243,090	$30,716	$8,108,983
Commercial MC	$30,548	$228,288,206	$38,129	$320,210,952	$39,059	$338,679,210
Medicare FFS	$15,350	$111,240,158	$17,553	$149,723,921	$17,980	$162,069,102
Medicare MC	$14,258	$51,412,855	$16,302	$84,817,674	$17,693	$101,860,977
Medicaid FFS	$11,502	$8,706,950	$13,157	$12,275,344	$13,471	$13,417,373
Medicaid MC	$9,049	$23,501,352	$10,347	$39,132,399	$11,889	$50,372,519
Charity Care	$1,994	$438,666	$2,280	$711,213	$2,337	$845,981
Other	$87,568	$12,522,246	$99,845	$9,385,407	$102,054	$7,245,854
Total Revenues		$442,960,305		$624,500,000		$682,599,999
Exp: (Inpatient)						
Operating	$17,525	$391,263,798	$21,917	$603,317,500	$22,580	$663,210,000
Capital	$1,811	40,421,587	$3,232	88,979,961	$3,079	90,445,700
Inpatient Expenses	$19,336	$431,685,385	$25,150	$692,297,461	$25,659	$753,655,700
Inpatient Excess Rev		$11,274,920		($67,797,461)		($71,055,701)
Discharges		22,326		27,527		29,372

	Per Visit	Total	Per Visit	Total	Per Visit	Total
Rev (Outpatient)						
Commercial FFS	$1,861.54	$18,604,272	$2,165.54	$26,690,295	$2,295.29	$27,118,813
Commercial MC	$1,551.98	$281,597,592	$1,736.98	$413,113,990	$1,768.24	$440,392,383
Medicare FFS	$682.41	$80,414,896	$747.45	$118,155,934	$755.44	$126,155,027
Medicare MC	$627.43	$29,347,351	$671.16	$44,411,912	$667.72	$48,107,775
Medicaid FFS	$324.75	$2,901,311	$353.07	$4,262,981	$355.51	$4,551,582
Medicaid MC	$377.54	$23,540,140	$385.64	$35,233,708	$389.91	$38,997,411
Charity Care	$70.33	$484,718	$71.90	$712,211	$68.32	$760,427
Other	$745.29	$2,425,916	$831.14	$2,918,969	$1,006	$3,116,581
Total Revenues		$439,316,196		$645,500,000		$689,199,999
Exp (Outpatient)						
Operating	$1,344.21	$588,070,946	$1,496.93	$885,082,500	$1,543.78	$967,890,000
Capital	62.02	27,132,521	87.81	51,920,039	85.90	53,854,300
Outpatient Expenses	$1,406.23	$615,203,467	$1,584.74	$937,002,539	$1,629.67	$1,021,744,300
Other Op Revenues		$26,296,586		$29,900,000		$32,000,000
Ancillary Services		$188,881,985		$332,400,000		$375,300,000
Total Revenues		$1,097,455,072		$1,632,300,000		$1,779,099,998
Total Expenses		$1,046,888,852		$1,629,300,000		$1,775,400,000
Excess Revenues		$50,566,220		$3,000,000		$3,699,998
(Visits)		437,484		591,266		626,963

The following is noted with respect to the submitted operating budget:

- The above budget is based on the current experience of the applicant and inclusive of the additional 24 intensive care beds and 120 medical/surgical beds.
- The existing ED is currently designed to accommodate approximately 46,000 visits. In 2023, WPH is projected to accommodate an estimated 78,000 visits with continuous annual growth anticipated. The ED will expand by 22,650 square feet (from 16,950 square feet to 39,600 square feet) to help mitigate ED throughput and overcrowding issues and to facilitate the inpatient admission process.
- WPH plans to add 144 additional private inpatient beds to address current and future capacity issues throughout the organization. The additional beds will be acuity adaptable. These rooms will all be able to be converted into critical care rooms as future demands may dictate, as inpatient care trends move toward high-acuity patients and for potential future pandemic surges.
- The increase in capital expenses from the current year to the 1st and 3rd is a result in increasing interest and depreciation.

Utilization is broken down by payor source for inpatient and outpatient services by current year, first and third years:

Inpatient:	Current Year (2022)	Year One (2029)	Year Three (2031)
Commercial FFS	1.27%	1.00%	0.90%
Commercial MC	33.47%	30.51%	29.52%
Medicare FFS	32.46%	30.99%	30.69%
Medicare MC	16.15%	18.90%	19.60%
Medicaid FFS	3.39%	3.39%	3.39%
Medicaid MC	11.63%	13.74%	14.43%
Charity Care	0.99%	1.13%	1.23%
Other	0.64%	0.34%	0.24%
Total	100.00%	100.00%	100.00%

Outpatient:			
Commercial FFS	2.28%	2.08%	1.88%
Commercial MC	41.47%	40.22%	39.72%
Medicare FFS	26.94%	26.74%	26.64%
Medicare MC	10.69%	11.19%	11.49%
Medicaid FFS	2.04%	2.04%	2.04%
Medicaid MC	14.25%	15.45%	15.95%
Charity Care	1.58%	1.68%	1.78%
Other	0.74%	0.59%	0.49%
Total	100.00%	100.00%	100.00%

Capability and Feasibility

Total project cost of $747,928,910 will be met with $147,928,910 in equity from hospital operations, $100,000,000 in fundraising, and a $500,000,000 tax-exempt bond at an interest rate of 6.50% for a thirty-year term. The applicant has indicated that they intend to pursue DASNY financing. As of this date, WPH has received $5,900,000 in fundraising proceeds. If fundraising proceeds are not met, WPH will contribute additional equity from operations to offset the shortfall. BFA Attachment A, 2021-2022 Certified Financial Statements of White Plains Hospital Center, indicates the availability of sufficient funds for the required equity contribution.

As shown on BFA Attachment A, WPH had an average positive working capital position and an average positive net asset position in 2021 and 2022. The hospital incurred an excess of operating revenues over expenses of $43,049,000 and $50,567,000 in 2021 and 2022, respectively. The submitted budget indicates excess revenues of $3,000,000 and $3,699,998 in the first and third years after the project completion. Revenues are based on current reimbursement methodologies. The submitted budget appears reasonable.

Presented as BFA Attachment B are the 2022 Certified Financial Statements and November 30, 2023 Internal Financial Statements of White Plains Hospital Center. As shown, WPH had an average positive working capital position, average positive net asset position for the period. WPH achieved an operating excess revenues of $55,527,000 through November 30, 2023.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Health Equity Impact Assessment

Health Equity Impact Summary

The Independent Entity evaluated data from several sources to understand the health equity impacts of the proposed project. Most engaged stakeholders (92%) indicated full support of the new building. At White Plains Hospital Center (WPH), 60% of all emergency room discharges are patients with Medicare or Medicaid as the primary payer. Discharge data also supports that Hispanic and non-White patients have a higher percentage of emergency department visits and higher readmission rates. The project will expand access to emergency services and therefore will positively impact several medically underserved groups. WPH will also construct three more operating rooms, ADA compliant public entrances, and private rooms and waiting areas. Potential negative impacts to the community were identified as language and communication barriers, architectural concerns for the elderly and disabled, inadequate parking, and increased traffic. WPH submitted a detailed mitigation plan to address these concerns.

Conclusion

Based on the information and analysis presented in the Health Equity Impact Assessment and the applicant's mitigation plan, the proposed project will not result in any significant adverse health equity impacts.

Attachments

BFA Attachment A	2021-2022 Certified Financial Statement – White Plains Hospital Center
BFA Attachment B	2022 Certified Financial Statements and the November 30, 2023, Internal Financial Statements of White Plains Hospital Center
OHEHR Attachment	Health Equity Impact Assessment

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 231323-C
St. Mary's Hospital for Children

Program: **Residential Health Care Facility** ***County:*** **Queens**
Purpose: **Construction** ***Acknowledged:*** **July 17, 2023**

Executive Summary

Description
St. Mary's Hospital for Children, Inc. (St. Mary's), an existing, pediatric residential health care facility (RHCF), requests approval to increase the certified bed capacity from 124 pediatric RHCF beds to 142 pediatric RHCF beds, an increase of 18 beds. St. Mary's will renovate existing space on the 4th floor and construct a new building, which will be attached to the existing facility. St. Mary's is at 29-01 216th Street, Bayside, New York (Queens County).

St. Mary's is one of three RHCFs in New York City serving the general pediatric population. The applicant reported that in May 2023, the facility had a waiting list of 91 children and from May 1, 2022 to April 30, 2023, there were 333 patients referred to St. Mary's, and only 121 patients could be admitted due to a lack of bed capacity.

St. Mary's Healthcare System for Children, Inc. (St. Mary's Healthcare System) is the sole corporate member of St. Mary's Hospital for Children, Inc.

OALTC Recommendation
Contingent Approval

Need Summary
Based upon weekly census data, current occupancy, as of February 7, 2024, was 100% for the facility.

Program Summary
Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary
The total project cost of $23,202,700 will be met with equity of $5,802,700 from St Mary's Healthcare System for Children, Inc., and a $17,400,000 bank loan with a 7-year term at a fixed rate of 5.3%. The proposed budget is as follows:

Budget	Year One	Year Three
Revenues	$124,098,986	$126,549,853
Expenses	118,627,349	118,976,672
Net Income (Loss)	$5,471,637	$7,573,181

Health Equity Impact Assessment
The was no Health Equity Impact Assessment required for this project under New York State Public Health Law §2802-B, as it was received by the Department on June 16, 2023.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR].
3. Submission of an executed loan commitment acceptable to the Department. [BFA]

Approval conditional upon

1. This project must be completed by **September 15, 2026**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **October 15, 2024,** and construction must be completed by **June 15, 2026**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a) if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [LTC]

Council Action Date

April 11, 2024

Need Analysis

Background and Analysis

St. Mary's Hospital for Children, Inc. (St. Mary's) is requesting approval to increase the certified bed capacity by 18 beds, from 124 pediatric RHCF beds to 142 pediatric RHCF beds. The primary service area is Queens County, which has a population projected to increase to 2,554,994 by 2029 based on Cornell Program of Applied Demographic estimates. Demographics for the primary service area are noted below including a comparison with New York State.

Demographics	Queens County	New York State
Total Population (2022 Estimate)	2,360,826	19,994,379
Hispanic or Latino (of any race)	28.0%	19.5%
White (non-Hispanic)	23.8%	53.8%
Black or African American (non-Hispanic)	16.7%	13.8%
Asian (non-Hispanic)	25.9%	8.8%
Other (non-Hispanic)	5.6%	4.1%

Source: American Community Survey (5-year estimates data profiles)

The table below shows the CMS Rating and the utilization of the closest RCHFs to St Mary's Hospital that have pediatric beds onsite in New York State.

Facility Name	CMS Overall Rating	Number of Beds	Distance from other RHCFs	Occupancy			
	As of 1/2024		Miles/Time	2019	2020	2021	2022
St Mary's Hospital	5	124	0 miles/0 mins	93.5%	97.8%	99.8%	98.2%
Rutland Nursing (Kings)	3	32	16.0 miles/42 mins	45.2%	77.4%	83.4%	N/A
Ditmas Park (Kings)	4	20	18.2 miles/57 mins	N/A	N/A	25.1%	70.7%
Elizabeth Seton (Westchester)	5	169	20.1 miles/51 mins	99.9%	99.7%	99.9%	99.9%
The Steven & Alexandra Cohen Pediatric (Westchester)	5	24	26.5 miles/52 mins	98.0%	99.5%	99.4%	99.5%
Brookside Multicare (Suffolk)	2	36	36.2 miles/58 mins	83.2%	97.4%	94.1%	90.1%
Sunshine Children's (Westchester)	5	54	36.6 miles/62 mins	99.7%	98.5%	100.9%	100.0%

St. Mary's is the only New York City-based, free-standing pediatric nursing facility serving the general pediatric population. Two facilities in Kings County (Rutland Nursing and Ditmas Park) primarily serve the adult population; with Rutland having 446 beds, of which 32 are pediatric beds, and Ditmas Park having 220 beds, of which 20 are pediatric beds. The closest free-standing facilities to only serve the pediatric population are in Westchester County and all three of those facilities show occupancy rates above 98% for the past few years.

With this project, St Mary's is seeking to add 18 new pediatric beds to help address the need for additional pediatric RHCF beds in the New York City area. The implementation of this project will help St. Mary's improve pediatric patient care in the region, and to help reduce the waiting list for pediatric RHCF services. The applicant reported that in May 2023, the facility had a waiting list of 91 children and from May 1, 2022 to April 30, 2023, there were 333 patients referred to St. Mary's, and only 121 patients could be admitted due to a lack of bed capacity

Medicaid Access

To ensure that the residential health care facility needs of the Medicaid population are met, 10 NYCRR §670.3 requires applicants to accept and admit a reasonable percentage of Medicaid residents in their service area. The benchmark is 75% of the annual percentage of residential healthcare facility admissions that are Medicaid-eligible individuals in their planning area. This benchmark may be increased or decreased based on the following factors:

- The number of individuals within the planning area currently awaiting placement to a residential health care facility and the proportion of total individuals awaiting such placement that are Medicaid patients and/or alternate level of care patients in general hospitals.
- The proportion of the facility's total patient days that are Medicaid patient days and the length of time that the facility's patients who are admitted as private paying patients remain such before becoming Medicaid eligible.
- The proportion of the facility's admissions who are Medicare patients or patients whose services are paid for under provisions of the federal Veterans' Benefits Law.
- The facility's patient case mix is based on the intensity of care required by the facility's patients or the extent to which the facility provides services to patients with unique or specialized needs.
- The financial impact on the facility due to an increase in Medicaid patient admissions.

An applicant will be required to make appropriate adjustments in its admission policies and practices to meet the resultant percentage.

Per the applicant and DOH staff verification, the original data on Medicaid admissions in the table below was reported inaccurately by the applicant through the RHCF cost report. According to the applicant, 86% of patients were covered by Medicaid or Medicaid Managed Care upon admission.

The facility's Medicaid admissions rate was below the threshold of 75% of the Queens County rate for the years 2020 through 2022.

Medicaid Access	**2020**	**2021**	**2022**
Queens County Total	39.8%	42.1%	44.0%
Queens County Threshold Value	29.8%	31.5%	33.0%
St. Mary's Hospital for Children	17.0%	12.2%	6.3%

Conclusion

The facility is seeking to add 18 new pediatric beds to address the need for additional pediatric beds in the New York City region. Based upon weekly census data, current occupancy as of February 7, 2024, was 100% for the facility.

Program Analysis

Program Description

	Existing	Proposed
Facility Name	St. Mary's Hospital for Children	Same
Address	29-01 216th Street, Bayside, NY 11360	Same
Pediatric Bed Capacity	124 beds	142 beds
ADHCP Capacity	50	Same
Type of Operator	Voluntary	Same
Class of Operator	Not-for-Profit Corporation	Same
Operator	St. Mary's Hospital for Children, Inc.	Same

Physical Environment

St. Mary's Hospital for Children, Inc. is seeking approval to increase the certified bed capacity from 124 pediatric beds to 142 pediatric beds. The facility will renovate the existing fourth floor and construct an addition to accommodate the new pediatric beds. Construction at the facility will be done in a single phase and take approximately a year and nine months to complete.

The fourth floor will be configured as a double-loaded corridor consisting of eight semi-private rooms and two private rooms. The semi-private resident rooms will feature a shared shower room located between two semi-private rooms. The shared shower room will be accessible from the resident bathroom in each room and will be sized to accommodate a shower trolley. The two private resident rooms on the floor will feature a private shower located in the resident bathroom that is able to accommodate a shower trolley.

The resident communal space is centralized on the fourth floor and consists of a large open recreation area, balcony, treatment room, and multipurpose room. Educational instruction for school-aged children ages 3 to 21 years old on the fourth floor will be provided through the Committee on Preschool Special Education early education program and the Committee on Special Education PS23Q on-site program. Educational instruction will take place in the facility classroom or at the bedside based on the resident's medical needs, developmental abilities, and individualized education plan.

The fourth floor will feature both centralized and decentralized staff work areas and facility support rooms. The communications center for staff documentation and oversight is centrally located on the floor and is adjacent to the medication room and the staff bathroom. In addition to the communications center, two additional staff workstations are provided on the corridor outside of resident rooms. Facility support rooms consisting of the formula room, utility rooms, storage rooms, IT closet, and janitor's closet are decentralized along the corridor outside of resident rooms.

Quality Review

Facility	*Ownership Since*	*Overall*	*Health Inspection*	*Quality Measure*	*Staffing*
St. Mary's Hospital for Children	Current	*****	*****	*****	*****
	CMS ratings started 1/2009	*****	***	*****	*****

Data date: 02/2024

Enforcement History

A review of the operations of St. Mary's Hospital for Children for the past ten years reveals no enforcements.

Conclusion

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Analysis

Total Project Cost and Financing

The total project cost for renovations and movable equipment in 2024 dollars is estimated at $23,202,700 and is distributed as follows:

New Construction	$6,453,593
Renovation & Demolition	8,651,617
Asbestos Abatement	450,000
Design Contingency	1,510,522
Construction Contingency	1,187,842
Planning Consulting Fees	78,125
Architect/Engineering Fees	1,600,000
Other Fees	255,657
Movable Equipment	1,933,532
Financing Costs Points	200,000
*Interim Interest Expense	752,906
Total Project Costs w/o fees	23,073,794
Application Fee	2,000
Additional Processing Fee	126,796
Total Project Cost	$23,202,700

Project costs of $23,202,700 will be met with equity of $5,802,700 from St. Mary's Healthcare System for Children, Inc., and a bank loan of $17,400,000 with a 7-year term at an estimated fixed rate of 5.3%. A letter of interest has been provided by M&T Bank for the loan.

Operating Budget

The applicant has submitted an operating budget, in 2024 dollars, for years one and three, summarized below:

	Current Year		**Year One**		**Year Three**	
Inpatient Revenues	Per Day	Total	Per Day	Total	Per Day	Total
Commercial FFS	$2,024.31	$2,005,913	$2,094.22	$2,903,924	$2,094.22	$2,364,374
Medicaid FFS	$2,052.89	71,305,252	$2,047.01	79,114,769	$2,047.01	81,026,673
Medicaid MC	$2,067.60	18,039,796	$2,061.76	20,015,556	$2,062.76	20,500,069
All Other/Feeding		2,032,719		2,032,719		2,032,719
Total Inpatient Rev		$93,383,680		$103,472,968		$105,923,835
Outpatient Revenues	Per Visit	Total	Per Visit	Total	Per Visit	Total
Medicaid FFS	$228.51	$7,906,900	$228.51	$7,906,900	$228.51	$7,906,900
Other Operating Rev.*	$237.42	$8,036,866	$237.42	$8,036,866	$237.42	$8,036,866
Bad Debt Expense		($378,680)		($378,680)		($378,680)
Total Outpatient Rev.		$15,565,086		$15,565,086		$15,565,086
Other Operating Rev.		$4,837,902		$4,837,902		$4,037,902
Non-Operating Rev.		223,030		223,030		223,030
Total Proj. Revenue		$114,009,698		$124,098,986		$126,549,853

	Current Year		Year One		Year Three	
Inpatient Exp.	Per Day	Total	Per Day	Total	Per Day	Total
Operating	1864.63	$82,882,974	1849.77	$91,489,615	1817.58	$92,069,356
Capital	189.51	$8,423,888	214.37	$10,602,899	204.77	$10,372,480
Total Inpatient Exp.	2054.15	$91,306,862	2064.14	$102,092,514	2022.34	$102,441,836
Outpatient Exp.	Per Day	Total	Per Day	Total	Per Day	Total
Operating	236.45	$16,185,504	236.45	$16,185,504	236.45	$16,185,504
Capital	5.10	$349,331	5.10	$349,331	5.10	$349,331
Total Outpatient	241.55	$16,534,835	241.55	$16,534,835	241.55	$16,534,835
Total Expenses		$107,841,697		$118,627,349		$118,976,671
Net Income		$6,168,001		$5,471,637		$7,573,182

** Represents operating preschool day health program, spinal cord therapy, behavioral health, and contribution made to the facility.*

Utilization broken down by payor is as follows:

Outpatient	Current Year	Years One and Three
Medicaid FFS	50.55%	50.55%
Other/Private Pay	49.45%	49.45%
Total	100%	100%
Inpatient		
Commercial FFS	2.23%	2.23%
Medicaid FFS	78.14%	78.14%
Medicaid MC	19.63%	19.63%
Total	100%	100%

The following is noted for the submitted budget:

- Commercial rates are based on the organization's current average reimbursement rates.
- Private pay visits for the proposed site are based on actual visit payer mix data and services currently offered and utilized at this location.
- Medicaid is based on the current rates received for the same currently offered services.
- Expenses are increased based predominantly on the current labor for the project costs and inpatient side.
- Visits are not changing since this project impacts inpatient beds only. However, inpatient days increase due to high occupancy and the need to increase beds.
- Utilization is based on average current visits and increased inpatients is based on the organization's historical and current experience and added beds it needs.
- As noted, the RHCF Hospital has a waiting list for more beds and had to turn away patients due to the lack of inpatient beds at this site.

Capability and Feasibility

The total project costs of $23,202,700 will be met with equity from St Mary's Healthcare System for Children Inc. of $5,802,700 and a bank loan of $17,400,000 with a 7-year term at approximately 5.3% fixed interest rate. A letter of interest has been provided by M&T Bank for the loan.

Working capital requirements are estimated at $19,829,445 based on two months of third-year expenses, and will be funded through the ongoing operations of St. Mary's Healthcare System for Children, Inc. The submitted budget projects a net income of $5,471,637 and $7,573,181 during Years One and Three, respectively. The budget appears reasonable based on current reimbursement and experience.

BFA Attachment B, 2021-2022 Consolidated Certified Financial Statement of St. Mary's Healthcare System for Children, Inc., shows an average positive working capital, average net asset position, and net income of $2,493,085 and $4,745,871 in 2021 and 2022, respectively.

Attachment C, St. Mary's Healthcare System for Children, Inc. Internal Financial Statements for the period ending November 30, 2023, shows positive working capital and net asset positions. As of November 30, 2023, St. Mary's Healthcare System for Children has a net income of $9,589,897.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BHFP Attachment	Map
BFA Attachment A	St. Mary's Healthcare System for Children, Inc. Organizational Chart
BFA Attachment B	2021-2022 Consolidated Certified Financial Statement for St. Mary's Healthcare System for Children, Inc.
BFA Attachment C	St. Mary's Healthcare System for Children, Inc. January 1, 2023 through November 30, 2023 Internal Financial Statement

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 232173-E
Long Island Center for Digestive Health, LLC

Program: **Diagnostic and Treatment Center** ***County:*** **Nassau**
Purpose: **Establishment** ***Acknowledged:*** **November 13, 2023**

Executive Summary

Description
Long Island Digestive Health, LLC (LICDH or The Center), an existing single-specialty freestanding ambulatory surgery center (FASC) specializing in gastroenterology at 106 Charles Lindbergh Boulevard, Suite B, Uniondale (Nassau County), is requesting approval to transfer 19.88% membership interest from three (3) existing members to a new member, PE Health Care Associates, LLC (PEHA). In addition, PEHA will add Katharine Losavio as an outside manager to serve on the current Board of LICDH Managers.

The current membership for LICDH consists of five (5) physician owners totaling 25.71% membership interest, three (3) non-physician owners with 19.88% membership interest, and Northwell LICDH Ventures, LLC with 51.00% membership interest. 3.43% membership interest is unissued and held by the Center for future allocation.

The Center is not proposing to add or change any services provided. The facility will continue to operate under the original lease, which ends October 31, 2041. Leonard B. Stein, M.D., will continue to serve as Medical Director. The facility will continue its transfer and affiliation agreement with North Shore University Hospital and remain unchanged on approval of this application. Additionally, the facility has a previously executed Administrative Service Agreement for general services in place between Physicians Endoscopy, LLC, and LICDH.

OPCHSM Recommendation
Approval

Need Summary
There will be no need review per Public Health Law §2801-a (4).

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary
There are no project costs or a purchase price associated with this application. There is no budget presented in this review since this application is a change of ownership, there are no changes to services provided, and the facility is in satisfactory financial standing.

Health Equity Impact Assessment
This project does not meet the requirements for a Health Equity Impact Assessment under Section 2802-B of the PHL.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

April 11, 2024

Program Analysis

Project Proposal

Long Island Center for Digestive Health, LLC (LICDH), also known as "the Center", operates a single-specialty (gastroenterology) freestanding ambulatory surgery center (FASC) at 106 Charles Lindbergh Boulevard, Suite B, Uniondale, New York 11553 in Nassau County.

LICDH submitted a Full Review Certificate of Need (C.O.N.) Application to transfer 19.88% membership interest in the Center from three (3) existing individual members to a new member, PE Healthcare Associates, LLC (PEHA). Also, in accordance with the terms of the Center's Operating Agreement, PEHA proposes to appoint Katharine Losavio as an outside manager to serve on the Center's Board of Managers.

The Center will continue to hold 3.43% for future syndication. PEHA's five (5) members will have indirect membership interest in the Center.

There are no programmatic changes because of this request; staffing will remain the same at 18.9 FTE with no change expected from Year 1 or Year 3.

The table below details the proposed change in ownership (totals are rounded):

	Current	**Proposed**
The Center	3.43%	3.43%
Perry C. Gould, M.D.	2.70%	2.70%
Leonard B. Stein, M.D.	3.00%	3.00%
Andrew B. Rosenberg, M.D.	9.02%	9.02%
Felice Mirsky-Bergman, M.D.	6.49%	6.49%
Eugene M. Sullivan, D.O.	4.50%	4.50%
Barry Tanner	9.29%	0.00%
Christina Morrison	5.29%	0.00%
David Young	5.29%	0.00%
PE Healthcare Associates, LLC	0.00%	19.88%
Barry Tanner 9.54% David Young 9.74% Ann Sariego 0.20% Rafael Axen, M.D. 0.20% Matthew Jenkins 0.20%		
Northwell LICDH Ventures, LLC	51.00%	51.00%
Total	100.00%	100.00%

Leonard B. Stein, M.D., will continue to serve as the Center's Medical Director.

Character and Competence

Katherine W. Losavio - Outside Manager. She earned a MPA from Baruch College in 2018 and a BBA from Hofstra University in 2011. She was employed with Northwell Health Women-in-Healthcare Business Employee Resource Group from May 2017 to September 2023 and with Healthcare Leaders of New York (HLNY) until January 2015. She is currently employed with SCA Health as the Vice President of Operations since September 2023. Katherine had various roles as the Assistant Vice President of Operations, Senior Director, Administrative Director of Business Development, and Director of Practice Transitions with Northwell Health from September 2013 to September 2023. She was also the Program Manager with the World Trade Center Health Program from September 2015 to April 2017 and a Financial Analyst with CareConnect (Northwell Health) from January 2013 to September 2015.

William "Barry" Tanner - Member: Approved as a new member through CON # 161079. He earned a BS in Accounting in June 1972 from Boston College. He was licensed (#3336) as an accountant in the state of Connecticut until 1983. His current professional experience includes acting as the non-executive Chairman and CEO/President of PE GI Solutions from June 1999 to the present. His current Board Memberships include PE GI Solutions, IPM MSO Holdings, Hero DVO, Smile Partners, Becker's Healthcare, Integrated Oncology Network, Vision Innovation Partners, Monadnock Freedom to Learn Coalition, and Lionheart Classical Academy. He is an executive with Integrated Oncology Network, located in Nashville, TN.

David W. Young - Member: Approved as a new member through CON # 201206. He earned a BA in Accounting from the University of Strathclyde in June 1990 and an MBA from the University of Strathclyde. He has two licenses in the state of Texas (#084685 and #0880948) as a CPA and as a Chartered Financial Analyst. He is employed as President and Chief Executive Officer (CEO) with Physicians Endoscopy from June 2018 to present, Chief Operations Officer (COO) with Privia Health Inc. in Arlington, VA, from June to present, and COO and Interim President for Smile Brands Inc., in Irvin, CA from June 2012 to May 2015.

Ann Sariego - Member: Approved as a new member through CON # 161079. She earned a BS in Healthcare Administration from Warren University in 2005 and an AAS from Pace University in 1979. She is licensed as a Registered Nurse in NJ (26NR12684500). Her license is active until May 2024. She is also licensed as a Registered Nurse in New York (317434). Her license is active until May 2025. She is a Board Member on the ASCAPAC, NYS ASC Association Governmental Affairs Committee, C5 Committee, and a member of the NYSAASC Association/Gov't Affairs. She is currently employed as a Market President with Physicians Endoscopy since August 2019 and as the Senior Vice President of Operations from November 2011 until August 2019.

Matthew A. Jenkins - Member. He earned an MBA from Northwestern University in August 2019 and a BS in Finance from Auburn University in May 2008. He is employed with SCA Health in Deerfield, IL, as the Group Vice President/Development from 2021 to present, Vice President from 2019 to 2021, Senior Director of Development from 2015 to 2019, and Director of Development from 2011 to 2015.

Rafael Z. Axen, M.D. - Member: Approved as a new member through CON # 221206. He received an M.D. from Rutgers New Jersey Medical School in June 2001 and a BA from the University of Rochester in June 1997. He is licensed (#22630) in New York until July 2024 and was licensed (#A91681) in California until August 2006. The California license was canceled due to working in New York, and there was no need to continue paying the cost of the fees to keep it active. He is currently the Senior Medical Director at Optum Medical Group, and Chair of the Anesthesiology and Perioperative Medicine Department; Chairperson of the Department of Anesthesiology and Perioperative Medicine since 2017 for CareMount Medical, P.C., Chappaqua, NY; Chief of Anesthesiology with Bedford Anesthesia, PLLC., Mount Kisco, NY from 2016 to 2017; and provided Anesthesia Care with Bedford Anesthesia, PLLC., Mount Kisco, NY from 2006 to 2017.

PE Healthcare Associates, LLC (PEHA) - Per a review on March 1, 2024, the following listed facilities are compliant. PEHA currently has an ownership interest in the following freestanding ambulatory surgery centers (FASC) in New York State:

- Liberty Endoscopy Center, LLC
- Manhattan Endoscopy Center, LLC
- Queens Endoscopy ASC, LLC
- Yorkville Endoscopy, LLC d/b/a The Endoscopy Center of New York
- Digestive Diseases Diagnostic and Treatment Center, LLC d/b/a South Brooklyn Endoscopy Center
- Putnam GI, LLC d/b/a Putnam Gastroenterology
- Great South Bay Endoscopy Center, LLC
- Long Island Digestive Endoscopy Center, LLC d/b/a Advanced Surgery Center of Long Island
- Advanced Endoscopy Center, LLC
- Carnegie Hill Endoscopy, LLC
- Mid-Bronx Endoscopy Center, LLC

- Island Digestive Health Center, LLC
- Eastside Endoscopy Center, LLC
- Endoscopy Center of Western New York, LLC
- Endoscopy Center of Niagara, LLC

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases, as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicants' character and competence or standing in the community.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Outside Manager Agreement

The applicant has submitted an executed Outside Manager to be effective upon PHHPC approval of the change in ownership. The terms of the agreement are summarized below.

Date:	October 13, 2023
Consultant:	P.E. Health Care Associates, LLC (Katharine Losavio, Proxy Mgr.)
Licensed Operator:	Long Island Digestive Health, LLC
Services Provided:	Regulatory compliance, regulations; direct independent authority to dismiss employees; approve capital budgets; control over policies and procedures; and control over the operations and management of the facility; control over health care delivery; authority to incur debts; procession of medical records and database; approve settlements as needed.
*Term:	Three (3) years with an automatic three (3) year renewal.
Fee:	Consideration for further development, education, and growth is offered for this position. No Direct or Indirect payment to the PE Manager on the Company's Board of Managers. Out-of-pocket expenses, as authorized, may be reimbursable to the Consultant. No referrals or Kickback monies are acceptable per this agreement. (As a Proxy-filled position and provider further, the PE Manager shall not receive fees of any kind for serving as Proxy to the PE Manager.)
Authority:	Direct independent authority over appointments or dismissals of all staff; control over records, books, and policies and procedures; control of operations and management of facility; approve contracts, settlements, patient records, database, or debt service payments.

** Termination may be discontinued for cause or any material terms that violate the contract. If there is any disagreement between the parties regarding control between the PE Manager and the Company, then the Operating Agreement shall control. Katharine Losavio, as V.P. of Operations, has executed an attestation certifying her responsibilities, functions, objectives, and commitments to the Center.*

Administrative Service Agreement

The applicant has submitted an executed Administrative Service Agreement. The terms of the agreement are submitted below.

Date:	November 10, 2021
Operator:	LICDH, LLC
Consultant:	Physicians Endoscopy, LLC
Services Provided:	Financial Management Services, Strategic Planning and Development, contracting services, personnel, supplies, utilities, policies and procedures, waste management, operating licenses, and banking.
Term:	Every (1) One year will automatically renew and continue to renew in (1) one-year successive terms unless 90-day notice is given by either party.
Fee:	$306,141 annually paid in monthly installments.

The administrative service agreement provides that the licensed operator retains ultimate authority, responsibility, and control in all final decisions associated with the services, acknowledges the reserve powers that must not be delegated, and the conflicts clause provisions that ensure compliance with governmental agencies, statutes, and regulations.

Capability and Feasibility

There are no project costs or a purchase price associated with this application. There is no budget presented in this review since this application is a change of ownership, there are no changes to services provided, and the facility is in satisfactory financial standing.

Presented as BFA Attachment B are LICDH's 2021-2022 Certified Financial Statements, which show LICDH experienced a positive working capital and positive members' equity position in both years and achieved a net income of $4,707,050 and $2,782,367 in 2021 and 2022, respectively. Presented as BFA Attachment C is the Internal Financial Statement for LICDH from 1/1/2023 through 12/31/2023, showing a

positive working capital and net asset position. Also, the LICDH achieved a net income of $3,758,541 through December 31, 2023.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BFA Attachment A	LICDH, LLC - Membership Interests (Current and Proposed)
BFA Attachment B	LICDH, LLC - Certified Financial Statements 2021-2022
BFA Attachment C	LICDH, LLC (Full Year) - Internal Financial Statement 1/1/2023 thru 12/31/2023

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer 19.88% ownership interest from three withdrawing members to one new member LLC, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
232173 E	Long Island Center for Digestive Health, LLC

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 222105-E
Alliance For Health, Inc.

Program: **LHCSA**
Purpose: **Establishment**
County: **Kings**
Acknowledged: **October 25, 2022**

Executive Summary

Description
Alliance For Health, Inc. d/b/a AccentCare Personal Care Services of New York, which operates a Licensed Home Care Services (LHCSA) agency, is requesting a change of indirect ownership transferring 100% ownership interest above the grandparent entity.

The applicant reports this transaction will not result in any changes to the name, location, or services provided.

OALTC Recommendation
Approval

Need Summary
In accordance with 10 NYCRR §765- 1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Program Summary
The individual background review indicates the proposed member has met the standard for approval as set forth in Public Health Law §3605.

Financial Summary
In accordance with 10 NYCRR §765-1(b)3, the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

April 11, 2024

Program Analysis

Program Description

Alliance For Health, Inc. d/b/a AccentCare Personal Care Services of New York, which operates a licensed home care services agency is requesting a change of indirect ownership transferring 100% ownership interest above the grandparent entity.

An affidavit of no control has been implemented above the parent entity, AccentCare, Inc., whereby Pluto Acquisition I, Inc. and all organizations above this entity will refrain from exercising control over the licensed home care services agency by directing or causing the direction of the actions, management or policies of the agency, whether through voting securities or voting rights thereunder, electing or appointing directors, the direct or indirect determination of policies, or otherwise. (Please refer to Attachment A for the organizational chart).

The applicant proposes to serve the residents of the following counties from an office located at 105 Court Street, Brooklyn, NY 11201.

- Bronx
- Kings
- New York
- Queens
- Westchester
- Richmond

The applicant intends to continue to provide the following healthcare services:

- Home Health Aide
- Nursing
- Personal Care

Character and Competence Review

Alliance For Health, Inc., is comprised of the following individual:

Joanna Ciampaglione, **Vice President, Director – Alliance for Health, Inc.**

Employment

Accentcare, Inc., Senior Vice President (May 2004 - Present)

Affiliations

- AccentCare of New York, Inc.; (January 2, 2015 – Present)
- AccentCare Personal Care Services of New York; (January 2, 2015 – Present)

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

A search of the individual named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement

The information provided by the Division of Home and Community Based Service's Bureau of Quality and Surveillance has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety, and welfare of patients and to prevent recurrent code violations.

Need Review

In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Financial Review

In accordance with 10 NYCRR §765-1.2(b)3 the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating financial feasibility of the agency.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed. Attachment B provides the Workforce Summary.

Conclusion

The individual background review indicates the proposed member has met the standard for approval as set forth in Public Health Law §3605.

Attachments

OALTC Attachment A	Post Organizational Chart
OALTC Attachment B	Workforce Summary

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer 100% ownership interest above the grandparent level, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
222105 E	Alliance For Health, Inc.

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in th*e Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 222106-E
AccentCare Of New York, Inc.

Program: **LHCSA**
Purpose: **Establishment**
County: **Westchester**
Acknowledged: **October 25, 2022**

Executive Summary

Description
Accentcare of New York, Inc., which operates two Licensed Home Care Services Agencies (LHCSA), is requesting a change of indirect ownership to transfer 100% ownership interest above the grandparent entity.

The applicant reports that this transaction will not result in any change of the name, location, or services provided.

OALTC Recommendation
Approval

Need Summary
In accordance with 10 NYCRR §765- 1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Program Summary
The individual background review indicates the proposed member has met the standard for approval as set forth in Public Health Law §3605.

Financial Summary
In accordance with 10 NYCRR §765-1(b)3, the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

April 11, 2024

Program Analysis

Program Description

Accentcare of New York, Inc., is requesting a change of indirect ownership to transfer 100% ownership interest above the grandparent entity.

An affidavit of no control has been implemented above the parent entity, AccentCare, Inc., whereby Pluto Acquisition I Inc.., and all organizations above this entity will refrain from exercising control over the licensed home care services agency by directing or causing the direction of the actions, management or policies of the agency, whether through voting securities or voting rights thereunder, electing or appointing directors, the direct or indirect determination of policies, or otherwise (please refer to Attachment A for the organizational chart).

The applicant will continue to serve the residents of the following counties from an office located at 27 Main Street, Yonkers, New York 10701:

- Bronx
- Dutchess
- Nassau
- Orange
- Putnam
- Rockland
- Suffolk
- Ulster
- Westchester

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Medical Social Services
- Nursing
- Personal Care

The applicant will also continue to serve the residents of the following counties from an office located at 659 Dutchess Turnpike, Suite 201, Poughkeepsie, New York 12603:

- Dutchess
- Orange
- Putnam
- Sullivan
- Ulster
- Westchester

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Homemaker
- Housekeeping
- Nursing
- Personal Care

Character and Competence Review

Accentcare of New York, Inc. is comprised of the following individual:

Joanna Ciampaglione, Vice President, Director – AccentCare of New York, Inc.

Employment

Accentcare, Inc., Senior Vice President (May 2004 - Present)

Affiliations

- AccentCare of New York, Inc.; (January 2, 2015 – Present)
- AccentCare Personal Care Services of New York; (January 2, 2015 – Present)

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

A search of the individual named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement

The information provided by the Division of Home and Community Based Services Bureau of Quality and Surveillance has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety, and welfare of patients and to prevent recurrent code violations.

Need Review

In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Financial Review

In accordance with 10 NYCRR §765-1.2(b)3 the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating financial feasibility of the agency.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed. See Attachment B for the Workforce Summary.

Conclusion

The individual background review indicates the proposed member has met the standard for approval as set forth in Public Health Law §3605.

Attachments

OALTC Attachment A	Organizational Chart
OALTC Attachment B	Workforce Summary

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer 100% ownership interest above the grandparent level, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
222106 E	AccentCare Of New York, Inc.

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 222108-E
All Metro Home Care Services of New York, Inc. d/b/a All Metro Health Care

Program: **LHCSA** ***County:*** **Nassau**
Purpose: **Establishment** ***Acknowledged:*** **November 4, 2022**

Executive Summary

Description
All Metro Home Care Services of New York, Inc. d/b/a All Metro Health Care, which operates a Licensed Home Care Services Agency (LHCSA), requests approval to effectuate a change of control under 10 NYCRR §765-1.14 with a transfer of indirect ownership interest above the great, great grandparent level.

The applicant is not proposing any changes to the LHCSA's service area, branch offices, or licensed services.

OALTC Recommendation
Approval

Need Summary
In accordance with 10 NYCRR §765- 1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Financial Summary
In accordance with 10 NYCRR §765-1(b)3, the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. All Metro Home Care Services of New York, Inc. will resume payments back to the Office of Medicaid Inspector General if they are unsuccessful in their challenge to the Final Audit Report. [CHA]

Council Action Date

April 11, 2024

Program Analysis

Program Description

All Metro Home Care Services of New York, Inc. d/b/a All Metro Health Care requests approval to transfer indirect ownership interest above the great, great grandparent level (please refer to Attachment A for the post-closing organizational chart).

An affidavit of no control has been implemented above the great, great, great grandparent level, whereby Modivcare Inc. and all its members will refrain from exercising control over the LHCSA by directing or causing the direction of the actions, management or policies of the agency, whether through voting securities or voting rights thereunder, electing or appointing directors, the direct or indirect determination of policies, or otherwise.

The applicant will continue to serve the residents of the following counties from an office at 170 Earle Ave., Lynbrook, NY. 11563:

- Nassau
- Queens
- Suffolk

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Homemaker
- Housekeeper
- Nursing
- Personal Care
- Specialty -Nursing Home Transition Diversion
- Specialty -Traumatic Brain Injury
- Therapy- Occupational
- Therapy- Physical

The applicant will continue to serve the residents of the following counties from an office at 6 Gramatan Ave., Suite 300, Mount Vernon, NY. 10550:

- Bronx
- Dutchess
- Orange
- Putnam
- Rockland
- Westchester

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Medical Social Services
- Nursing
- Personal Care
- Specialty- Traumatic Brain Injury
- Therapy- Occupational
- Therapy - Physical
- Therapy - Speech Language Pathology

The applicant will continue to serve the residents of the following counties from an office at 5225 Nesconset Highway, Bldg. 6, Suite 30-32, Port Jefferson Station, NY 11776

- Nassau
- Suffolk

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Medical Social Services
- Nursing
- Personal Care
- Therapy -Occupational
- Therapy - Physical
- Therapy - Speech Language Pathology

The applicant will continue to serve the residents of the following counties from an office at 350 Northern Blvd., Suite 206, Albany, NY. 12204

- Albany
- Clinton
- Columbia
- Delaware
- Essex
- Franklin
- Fulton
- Greene
- Hamilton
- Montgomery
- Otsego
- Rensselaer
- Saratoga
- Schenectady
- Schoharie
- Warren
- Washington

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Homemaker
- Housekeeper
- Nursing
- Personal Care
- Specialty - Nursing Home Transition Diversion
- Specialty - Traumatic Brain Injury
- Therapy - Occupational
- Therapy - Physical

The applicant will continue to serve the residents of the following counties from an office at 181 West Main Street, Babylon, NY. 11702

- Nassau
- Queens
- Suffolk

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Homemaker
- Housekeeper
- Nursing
- Personal Care
- Specialty - Nursing Home Transition Diversion
- Specialty - Traumatic Brain Injury
- Therapy- Occupational
- Therapy- Physical

The applicant will continue to serve the residents of the following counties from an office at 80 Broad Street, 14th Floor, NY, NY. 10004

- Bronx
- Kings
- New York
- Queens
- Richmond

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Medical Social Services
- Medical Supplies Equipment and Appliances
- Nursing
- Nutritional
- Personal Care
- Specialty - Traumatic Brain Injury
- Therapy - Occupational
- Therapy - Physical
- Therapy - Speech Language Pathology

The applicant will continue to serve the residents of the following counties from an office at 170 Franklin Street, Suite 501, Buffalo, NY. 14202

- Allegany
- Cattaraugus
- Chautauqua
- Erie
- Genesee
- Niagara
- Orleans
- Wyoming

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Nursing
- Nutritional
- Personal Care
- Specialty - Nursing Home Transition Diversion (NHT)
- Specialty - Traumatic Brain Injury (TBI)

The applicant will continue to serve the residents of the following counties from an office at 1344 University Avenue, Suite 100, Rochester, NY. 14607

- Chemung
- Livingston
- Monroe
- Ontario
- Schuyler
- Seneca
- Steuben
- Wayne
- Yates

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Nursing
- Personal Care
- Specialty - Traumatic Brain Injury

The applicant proposes to serve the residents of the following counties from an office at 1020 7th North Street, Suite 230, Liverpool, NY. 13088

- Broome
- Cayuga
- Chenango
- Cortland
- Herkimer
- Jefferson
- Lewis
- Madison
- Oneida
- Onondaga
- Oswego
- Saint Lawrence
- Tioga
- Tompkins

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Homemaker
- Nursing
- Personal Care
- Specialty - Nursing Home Transition Diversion
- Specialty - Traumatic Brain Injury

The applicant will continue to serve the residents of the following counties from an office at 650 Franklin Street, Suite 102, Schenectady, NY. 12305

- Albany
- Fulton
- Montgomery
- Rensselaer
- Saratoga
- Schenectady
- Schoharie
- Warren

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Nursing
- Personal Care
- Specialty - Nursing Home Transition Diversion
- Specialty - Traumatic Brain Injury

The applicant will continue to serve the residents of the following counties from an office at 4 East William Street, Suite 101, Corning, NY. 14830

- Allegany
- Chemung
- Livingston
- Ontario
- Schuyler
- Seneca
- Steuben
- Wayne
- Yates

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Nursing
- Personal Care

The applicant will continue to serve the residents of the following counties from an office at 65 Pennsylvania Ave., Suite 220, Binghamton, NY. 13903

- Broome
- Chemung
- Chenango
- Cortland
- Tioga
- Tompkins

The applicant will continue to provide the following healthcare services at the above-referenced location:

- Home Health Aide
- Nursing
- Personal Care

Character and Competence Review

The proposed new members in this application have ownership interest in healthcare facilities in several states. The applicant provided affidavits in lieu of out-of-state compliance reviews for facilities located in states that did not respond to compliance requests.

Seth J. Shapiro, Director – All Metro Home Care Services of New York, Inc.

Employment

Vice President, All Metro Home Care Services, Inc. and All Metro Health Care (1994 – Present)

Affiliations

- All Metro Home Care Services of New York (Lynbrook) (December 2005 – Present)
- All Metro Home Care Services of New York (Mount Vernon) (December 2005 – Present)
- All Metro Home Care Services of New York (Port Jefferson) (December 2005 – Present)
- All Metro Home Care Services of New York (Albany) (December 2005 – Present)
- All Metro Home Care Services of New York (Babylon) (December 2005 – Present)
- All Metro Home Care Services of New York (NYC) (December 2005 – Present)
- All Metro Home Care Services of New York (Buffalo) (December 2005 – Present)
- All Metro Home Care Services of New York (Rochester) (December 2005 – Present)
- All Metro Home Care Services of New York (Liverpool) (December 2005 – Present)
- All Metro Home Care Services of New York (Schenectady) (December 2005 – Present)
- All Metro Home Care Services of New York (Corning) (December 2005 – Present)
- All Metro Home Care Services of New York (Binghamton) (December 2005 – Present)
- All Metro Home Care Services of Florida (West Palm Beach) (December 2005 – Present)
- All Metro Home Care Services of Florida (Fort Lauderdale) (December 2005 – Present)
- All Metro Home Care Services of New Jersey (Hackensack) (December 2005 – Present)
- All Metro Home Care Services of New Jersey (Pennsauken) (December 2005 – Present)
- CareGivers America, LLC (Allentown, PA) (April 2015 – Present)
- CareGivers America, (Berwick, PA) (April 2015 – Present)
- CareGivers America, (Clarks Summit, PA) (April 2015 – Present)
- CareGivers America, (Plains, PA) (April 2015 – Present)
- CareGivers America, (Tannersville, PA) (April 2015 – Present)
- CareGivers America, (Pottsville, PA) (April 2015 – Present)
- CareGivers America, (Honesdale, PA) (April 2015 – Present)
- CareGivers America, (Lehighton, PA) (April 2015 – Present)
- CareGivers America, (Milford, PA) (April 2015 – Present)
- CareGivers America, (Montrose, PA) (April 2015 – Present)
- CareGivers America, (Sayre, PA) (April 2015 – Present)
- CareGivers America, (Selinsgrove, PA) (April 2015 – Present)
- CareGivers America, (Williamsport, PA) (April 2015 – Present)
- CareGivers America, (York, PA) (April 2015 – Present)
- CareGivers America, (Reading, PA) (April 2015 – Present)
- CareGivers America, (State College, PA) (April 2015 – Present)
- CareGivers America, (Lancaster, PA) (April 2015 – Present)
- CareGivers America, (Harrisburg, PA) (April 2015 – Present)
- CareGivers America, (Johnstown, PA) (April 2015 – Present)
- CareGivers America, (Pittsburgh, PA) (April 2015 – Present)
- Helping Hand Home Health Care Agency, Inc., (Jenkintown, PA) (April 2015 – Present)
- Helping Hand Home Health Care Agency, Inc., (Jenkintown, PA)
- Arsens Home Care, Inc., (Jenkintown, PA) (April 2015 – Present) (April 2015 – Present)
- Aruba, Inc. (Jenkintown, PA) (April 2015 – Present)
- CareGivers America Medical Supply, LLC (Clarks Summit, PA) (April 2015 – Present)
- Multicultural Home Care, Inc. (Lynn, MA) (December 2016 – Present)
- Multicultural Home Care, Inc. (Brighton, MA) (December 2016 – Present)
- Multicultural Home Care, Inc. (Lawrence, MA) (December 2016 – Present)
- All Metro Home Care Services of New York (Corning) (December 2005 – Present)

- All Metro Home Care Services of New York (Binghamton) (December 2005 – Present)
- All Metro Home Care Services of New York (Binghamton) (December 2005 – Present)
- All Metro Home Care Services of Florida (West Palm Beach) (December 2005 – Present)
- All Metro Home Care Services of Florida (Fort Lauderdale) (December 2005 – Present)
- All Metro Home Care Services of New Jersey (Hackensack) (December 2005 – Present)
- All Metro Home Care Services of New Jersey (Pennsauken) (December 2005 –Present)

Larry Heath Sampson, Director – OEP AM, Inc.

Employment
- Modivcare Solutions; Chief Financial Officer and Interim Chief Executive Officer (February 2021 – Present)
- Advanced Emissions Solutions; CEO (2014 - 2020)

Affiliations
None

Jennifer Jaskolka, Esq., Director – OEP AM, Inc.

Employment
- Modivcare, Vice President/Deputy General (April 2021 to Present)
- Xcel Energy, Assistant General Counsel & Corporate Safety Manager (March 2008 – April 2021)

Affiliations
None

A review of the Personal Qualifying information indicates that the above applicants have the required character and competence to operate a licensed home care services agency.

A search of the individuals and entities named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance and Enforcement

For the time period between January 2014 through December 2016, the Office of Medicaid Inspector General performed an audit of traumatic brain injury (TBI) claims paid to All Metro Home Care Services, Inc. A final audit report was released in November 2023 requesting a repayment of $6.6 million for the matter to be settled.

In November 2023, All Metro exercised its rights to request a hearing to challenge the Office of Medicaid Inspector General's Final Audit Report. An affidavit has been submitted by Socrates Health Holdings, LLC stating that All Metro agrees to resume payments back to the Office of Medicaid Inspector General if they are unsuccessful in its challenge to the Final Audit Report. Depending on the outcome of the hearing, All Metro may elect to avail itself of additional legal rights. Hearings are expected to commence by June 2024.

The information provided by the Division of Home and Community Based Services Bureau of Quality and Surveillance has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety, and welfare of patients and to prevent recurrent code violations.

Need Review

In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Financial Review

In accordance with 10 NYCRR §765-1.2(b)3 the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating financial feasibility of the agency.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed. Attachment B provides the Workforce Summary.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in New York State Public Health Law §3605.

Attachments

OALTC Attachment A	Organizational Chart
OALTC Attachment B	Workforce Summary

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer indirect ownership interest above the parent level, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
222108 E	All Metro Home Care Services of New York, Inc. d/b/a All Metro Health Care

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. All Metro Home Care Services of New York, Inc. will resume payments back to the Office of Medicaid Inspector General if they are unsuccessful in their challenge to the Final Audit Report. [CHA]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 222111-E
Allen Health Care Services d/b/a Elara Caring

Program: **LHCSA**
Purpose: **Establishment**
County: **Suffolk**
Acknowledged: **October 25, 2022**

Executive Summary

Description
Health Acquisition Corporation d/b/a Allen Health Care Services and d/b/a Elara Caring is a for-profit corporation Licensed Home Care Service Agency (LHCSA) seeking approval of a transfer of ownership interest above the great, great grandparent level.

The applicant does not propose any changes to the LHCSA's service area, branch offices, or licensed services.

OALTC Recommendation
Approved

Need Summary
In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Financial Summary
In accordance with 10 NYCRR §765-1(b)3 the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

April 11, 2024

Program Analysis

Program Description

Health Acquisition Corporation d//b/a Allen Health Care Services and d/b/a Elara Caring is seeking approval of a transfer ownership interest above the great, great grandparent level.

An affidavit of no control has been implemented above the great, great grandparent entity, Elara Holdings, LLC whereby all entities and persons above Elara Holdings, LLC (KIA IX (HH) Investor, L.P, BW III Homecare Holdings, LLC and BW NHHC Co-Invest, L.P. will refrain from exercising control over the licensed home care services agency by directing or causing the direction of the actions, management or policies of the agency, whether through voting securities or voting rights thereunder, electing or appointing directors, the direct and indirect determination of policies, or otherwise (please refer to Attachment A for the organizational chart).

The applicant operates from a main location (Hempstead, NY) and 4 branch offices (Forest Hills, Bronx, Brooklyn, and Medford), and each location has more than 25 patients.

For the Hempstead location at 175 Fulton Avenue, Suite 101, Hempstead, NY. 11550, the applicant will continue to serve the residents of the following counties:

- Dutchess
- Nassau
- Orange
- Putnam
- Queens
- Rockland
- Suffolk
- Sullivan
- Ulster
- Westchester

The location referenced above will continue to provide the following healthcare services:

- Home Health Aide
- Homemaker
- Housekeeper
- Nursing
- Personal Care

For the Forest Hills branch at 70-00 Austin Street, Suite 201, Forest Hills, NY 11375, the applicant will continue to serve the residents of the following counties:

- Bronx
- Kings
- New York
- Queens
- Richmond
- Westchester

The location referenced above will continue to provide the following healthcare services:

- Home Health Aide
- Homemaker
- Housekeeper
- Medical Social Services
- Nursing
- Personal Care

For the Bronx branch at 2432 Grand Concourse, Suite B, 2nd Floor, Bronx, NY 10458, the applicant will continue to serve the residents of the following counties:

- Bronx
- Kings
- New York
- Queens
- Richmond
- Westchester

The above-referenced location will continue to provide the following healthcare services:

- Home Health Aide
- Homemaker
- Housekeeper
- Medical Social Services
- Nursing
- Personal Care

For the Brooklyn branch at 1819 East 13th Street, Brooklyn, NY 11229, the applicant will continue to serve the residents of the following counties:

- Bronx
- Kings
- New York
- Queens
- Richmond
- Westchester

The above-referenced location will continue to provide the following healthcare services:

- Home Health Aide
- Homemaker
- Housekeeper
- Medical Social Services
- Nursing
- Personal Care

For the Medford branch at 3237 Route 112, Building 6, Suite 3, Medford, NY 11763, the applicant will continue to serve the residents of the following counties:

- Nassau
- Queens
- Suffolk

The location referenced above will continue to provide the following healthcare services:

- Home Health Aide
- Homemaker
- Housekeeper
- Nursing
- Personal Care

Character and Competence Review

Health Acquisition Corp. d/b/a Allen Health Care Services and d/b/a Elara Caring is comprised of the following individuals:

Tina Blasi – Board of Managers – Elara Holdings, LLC and BW Homecare Holdings, LLC

Employment
Retired since June 2015

Affiliations
Please refer to Attachment B for a list of healthcare affiliations.

Adam Blumenthal – Board of Managers – Elara Holdings, LLC and BW Homecare Holdings, LLC

Employment
Blue Wolf Capital Partners LLC – Managing Partner (2005 - Present)

Affiliations
No offices held or ownership interests in Health Facilities.

Scott Powers – Board of Managers – Elara Holdings, LLC and BW Homecare Holdings, LLC Board of Directors – BW NHHC Holdco, Inc., National Home Health Care Corp., and Health Acquisition Corp. d/b/a Allen Health Care/Elara Caring

Employment
- BW NHHC Holdco, Inc – Chief Executive Officer (9/2019 - Present)
- Alignment Healthcare - Chief Executive Officer (4/2018 - 9/2019)
- Cambia Health Solutions – President of Healthcare Operations (7/2010 - 4/2018)

Affiliations
Please refer to Attachment B for a list of healthcare affiliations.

Jeremy Kogler – Board of Managers – Elara Holdings, LLC and BW Homecare Holdings, LLC Board of Directors – BW NHHC Holdco, Inc., National Home Health Care Corp., and Health Acquisition Corp. d/b/a Allen Health Care/Elara Caring

Employment
- Blue Wolf Capital Partners LLC – Principal (5/2010 - Present)
- EnTrust Capital – Analyst (1/2004 - 1/2009)

Affiliations
Please refer to Attachment B for a list of healthcare affiliations.

Henry Mannix III – Board of Managers – Elara Holdings, LLC and BW Homecare Holdings, LLC Board of Directors – BW NHHC Holdco, Inc., National Home Health Care Corp., and Health Acquisition Corp. d/b/a Allen Health Care/Elara Caring

Employment
Kelso & Company – Managing Director (8/2004 - Present)

Affiliations
Please refer to Attachment B for a list of healthcare affiliations.

Hugh Mcbride – Board of Managers – Elara Holdings, LLC and BW Homecare Holdings, LLC

Employment
- Kelso & Company – Principal (8/2012 - Present)
- Lazard Freres – Analyst (6/2010 - 8/2012)

Affiliations
Please refer to Attachment B for a list of healthcare affiliations.

Church Moore – Board of Managers – Elara Holdings, LLC and BW Homecare Holdings, LLC

Employment
Kelso & Company – Managing Director (7/1998 - Present)

Affiliations
Please refer to Attachment B for a list of healthcare affiliations.

Mark Pacala – Board of Managers – Elara Holdings, LLC and BW Homecare Holdings, LLC

Employment
Self-employed (2010 - Present)

Affiliations
Please refer to Attachment B for a list of healthcare affiliations.

Anath Mohan – Board of Directors – Health Acquisition Corp. d/b/a Allen Health Care/Elara Caring

Employment

- BW NHHC Holdco, Inc. (Elara Caring) – Chief Operating Officer (8/2021 - Present)
- Cancer Treatment Centers of America – President, Enterprise Operations (5/2017 - 8/2021)
- McKinsey & Company – Associate Partner (6/2011 - 5/2017)

Affiliations
Please refer to Attachment B for a list of healthcare affiliations.

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

A search of the individual named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement

The information provided by the Division of Home and Community Based Services, Bureau of Quality and Surveillance has indicated that the applicant has provided sufficient supervision to prevent harm to the health, safety, and welfare of patients and to prevent recurrent code violations.

The following state agencies have indicated no issues with the licensure of the health affiliations of the applicant:

- Minnesota Department of Health
- Mississippi State Department of Health
- Nebraska Dept. of Health and Human Services
- New Hampshire Dept. of Health and Human Svcs.
- Oregon Health Authority
- Pennsylvania Department of Health
- Rhode Island Department of Health
- Tennessee Department of Health
- Vermont Disabilities, Aging, and Independent Living
- Georgia Department of Community Health
- Illinois Department of Public Health
- Indiana State Department of Health
- State of Louisiana Department of Health
- Massachusetts Dept. of Public Health
- Michigan Dept. of Licensing and Reg. Affairs
- Maine Department of Health and Human Services
- Missouri Dept. of Health and Senior Svcs.
- Arizona Department of Health Services
- Ohio Department of Health
- Oklahoma State Department of Health
- Arkansas Department of Health
- Connecticut Department of Public Health
- State of Florida Agency for HCA
- State of Wisconsin Dept. of Health
- Kansas Dept. of Health
- New Mexico Dept. of Health
- Colorado Dept. of Public Health & Environment
- Maryland Department of Health
- New Jersey Office of the Attorney General Division of Consumer Affairs

Need Review

In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Financial Review

In accordance with 10 NYCRR §765-1.2(b)3 the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating financial feasibility of the agency.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed. Please refer to Attachment C for the Workforce Summary.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Attachments

OALTC Attachment A	Organizational Chart
OALTC Attachment B	Health Care Affiliations
OALTC Attachment C	Workforce Summary

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer indirect ownership interest above the parent level, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
222111 E	Allen Health Care Services d/b/a Elara Caring

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 231047-E
SIAL Acquisition d/b/a The Veranda Assisted Living

Program: **LHCSA**
Purpose: **Establishment**
County: **Richmond**
Acknowledged: **February 17, 2023**

Executive Summary

Description
SIAL Acquisition LLC d/b/a The Veranda Assisted Living, a New York limited liability company is requesting approval to become the new operator of Plan and Partner Home Healthcare, an existing Licensed Home Care Services Agency (LHSCA).

The applicant does not propose any changes to the LHCSA's service area or licensed services.

OALTC Recommendation
Approval

Need Summary
In accordance with 10 NYCRR §765-1.16(c)3, this application is exempt from Public Need review as the agency is affiliated with an Assisted Living Program (ALP).

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in New York State Public Health Law §3605.

Financial Summary
In accordance with 10 NYCRR §765-1(b)3, the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

April 11, 2024

Program Analysis

Program Description

SIAL Acquisition LLC d/b/a The Veranda Assisted Living is requesting approval to become the new operator of Plan and Partner Home Healthcare, an existing LHSCA.

The applicant intends to continue to serve the residents of the following counties from an office at 110 Henderson Street, Staten Island, New York 10301:

- Kings
- New York
- Queens
- Richmond

The applicant intends to continue to provide the following healthcare services:

- Nursing
- Home Health Aide
- Medical Social Services
- Medical Supplies Equipment and Appliances
- Nutritional
- Personal Care
- Therapy- Occupational
- Therapy- Physical
- Therapy- Respiratory
- Therapy- Speech Language Pathology

Character and Competence Review

SIAL Acquisition LLC d/b/a The Veranda Assisted Living is comprised of the following individuals:

Lazer Strulovitch- **85%**
Managing Member, SIAL Acquisition LLC d/b/a The Veranda Assisted Living

Affiliations

- Sprain Brook Manor Rehab, LLC (September 2012 - Present)
- Newco Alp, Inc. d/b/a Island Assisted Living (Adult Home) (April 2014 - Present)
- L&A Operations, LLC d/b/a Adira at Riverside Rehabilitation and Nursing (September 2015 - Present)
- Baywood, LLC d/b/a Harbor Terrace Adult Home and Assisted Living (January 2020 - Present)
- Newco Alp, Inc. d/b/a Island Assisted Living (LHCSA) (June 2014 - Present)
- Baywood, LLC d/b/a Plan and Partner Home Healthcare (January 2020 - Present)
- Spring Hill Wellness NY, LLC (May 2021 - Present)
- Spring Hill Wellness, LLC (July 2017 - Present)

Shia Rosenbaum – **15%**
Managing Member, SIAL Acquisition LLC d/b/a The Veranda Assisted Living

Affiliations

- Baywood, LLC d/b/a Harbor Terrace Adult Home and Assisted Living (January 2020 - Present)
- Baywood, LLC d/b/a Plan and Partner Home Healthcare (January 2020 - Present)
- Spring Hill Wellness, LLC (July 2017 - Present)

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

A search of the individual named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement

The Division of Adult Care Facilities and Assisted Living Surveillance reviewed the compliance history of the above-mentioned adult care facilities and reports as follows:

- Newco ALP, Inc. d/b/a Island Assisted Living was fined Eight hundred twenty-five dollars ($825) pursuant to a stipulation and order dated February 7, 2017, and July 24, 2017, for violations of Article 7 of the Social Services Law and 18 NYCRR Part 487.
- Baywood, LLC d/b/a Harbor Terrace Adult Home and Assisted Living was fined one hundred dollars ($100) pursuant to a stipulation and order dated December 13, 2020, and January 13, 2021, for violations of 18 NYCRR Part 485.

Need Review

In accordance with 10 NYCRR §765-1.16(c)3, this application is exempt from Public Need review as the agency is affiliated with an Assisted Living Program (ALP).

Financial Review

In accordance with 10 NYCRR §765-1.2(b)3 the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating financial feasibility of the agency.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed. Attachment A outlines their workforce goals.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Attachments

OALTC Attachment A	Workforce Review

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish SIAL Acquisition LLC as the new operator of a Licensed Home Care Services Agency currently operated by Baywood LLC at 110 Henderson Street, Staten Island, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
231047 E	SIAL Acquisition d/b/a The Veranda Assisted Living

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON.*

Public Health and Health Planning Council

Project # 231232

Jewish Senior Life LHCSA, Inc., d/b/a Jewish Home of Rochester Licensed Home Care

Program: **LHCSA** ***County:*** **Monroe**
Purpose: **Establishment** ***Acknowledged:*** **June 13, 2023**

Executive Summary

Description

Jewish Senior Life LHCSA, Inc., d/b/a Jewish Home of Rochester Licensed Home Care, is requesting to be established as the new operator of Embrace Care LLC, a Licensed Home Care Services Agency (LHCSA) serving Monroe and Orleans counties.

An Asset Purchase Agreement was executed by Jewish Senior Life LHCSA, Inc. and Embrace Care LLC on February 28, 2023.

In conjunction with this application, Jewish Senior Life LHCSA, Inc. seeks to expand the service area to include Wayne and Livingston counties, which have been identified by the Department of Health as counties with an existing need for LHCSA services.

OALTC Recommendation

Approval

Need Summary

In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in New York State Public Health Law §3605.

Financial Summary

In accordance with 10 NYCRR §765-1(b)3, the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

April 11, 2024

Program Analysis

Program Description

This CON application seeks Department of Health approval to establish Jewish Senior Life LHCSA, Inc., d/b/a Jewish Home of Rochester Licensed Home Care, as the new operator of Embrace Care LLC. In conjunction with this CON application, Jewish Senior Life LHCSA, Inc. seeks to expand the service area to include Wayne and Livingston counties, which have been identified by the Department of Health as counties with an existing need for LHCSA services.

The applicant intends to serve the residents of the following counties from an office located at 2021 South Winton Road, Rochester, NY 14618:

- Monroe
- Orleans
- Wayne
- Livingston

The applicant proposes to provide the following healthcare services:

- Nursing
- Home Health Aide
- Personal Care

An Asset Purchase Agreement was executed by Jewish Senior Life LHCSA, Inc. and Embrace Care LLC on February 28, 2023.

Character and Competence Review

Jewish Senior Life LHCSA Inc. d/b/a Jewish Home of Rochester Licensed Home Care will be comprised of the following individuals:

Valerie D. Alhart, Board Member - Jewish Senior Life LHCSA/Jewish Senior Life Community Services, Inc./Jewish Senior Life

Employment

- Freelance Marketing and Communications (August 2023 - Present)

Affiliations

- Jewish Home of Rochester Senior Housing, Inc. (September 2021 - Present)
- Jewish Senior Life (September 2021 - Present)
- Jewish Home of Rochester (September 2021 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (September 2021 - Present)

Adam P. Anolik, Board Member - Jewish Senior Life

Employment

- University of Rochester – CFO, University of Rochester Medical Center; (January 1999 - Present)

Affiliations

- Jewish Home of Rochester Senior Housing, Inc.; (May 2016 - Present)
- Jewish Senior Life; (May 2016 - Present)
- Jewish Home of Rochester; (May 2016 - Present)
- Jewish Home of Rochester Enriched Housing, Inc.; (May 2016 - Present)

Robert Baker, Chair - Chair - Board of Directors - Jewish Senior Life

Employment
- Coldwell Manufacturing Company – CFO (November 2015 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (November 2015 - Present)
- Jewish Senior Life (November 2015 - Present)
- Jewish Home of Rochester (November 2015 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (November 2015 - Present)

Irena P. Boyce, Ph.D., Board Member - Jewish Senior Life

Employment
- University of Rochester Medical Center – Senior Director of UR Medicine Quality Institute (September 2007 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2015 - Present)
- Jewish Senior Life (May 2015 - Present)
- Jewish Home of Rochester (May 2015 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2015 - Present)

Betsy Brugg, Esq., Board Member – Jewish Senior Life

Employment
- Woods, Oviatt, Gilman, LLP – Attorney, Partner – Practice Law (2011 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2019 - Present)
- Jewish Senior Life (May 2019 - Present)
- Jewish Home of Rochester (May 2019 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2019 - Present)

Jill Eisenstein, Board Member – Jewish Senior Life

Employment
- Greater Rochester Regional Health Information Organization (January 2007 - August 2021)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2016 - Present)
- Jewish Senior Life (May 2016 - Present)
- Jewish Home of Rochester (May 2016 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2016 - Present)

Hon. Jonathan W. Feldman, Board Member – Jewish Senior Life

Employment
- United States Courts – Federal Judge – Part Time; (2021 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2016 - Present)
- Jewish Senior Life (May 2016 - Present)
- Jewish Home of Rochester (May 2016 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2016 - Present)

Kenneth Glazer, Board Member – Jewish Senior Life

Employment
- Buckingham Properties – CEO/Owner (June 2009 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2018 - Present)
- Jewish Senior Life (May 2018 - Present)
- Jewish Home of Rochester (May 2018 - Present)
- Jewish Home of Rochester Enriched House, Inc. (May 2018 - Present)

Helena M. Kaptein-Shrier. RN, BSN, Board Member – Jewish Senior Life

Employment
- BCSD – Provided care and record-keeping in the school setting (2005 - 2019)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc.; (May 2018 - Present)
- Jewish Senior Life (May 2018 - Present)
- Jewish Home of Rochester (May 2018 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2018 - Present)

Alan Kinel, Board Member – Jewish Senior Life LHCSA/Jewish Senior Life Community Services, Inc./Jewish Senior Life

Employment
- Strategic Interests, LLC (December 2009 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2015 - Present)
- Jewish Senior Life (May 2015 - Present)
- Jewish Home of Rochester (May 2015 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2015 - Present)

Michael S. King, President/CEO, – Jewish Senior Life LHCSA/Jewish Senior Life Community Services, Inc./Jewish Senior Life

Employment
- Jewish Senior Life – President/CEO (March 2005 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2015 - Present)
- Jewish Senior Life (May 2015 - Present)
- Jewish Home of Rochester (May 2015 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2015 - Present)

Emily A. Krohn, LCSW-R, Board Member – Jewish Senior Life

Employment
- Private Practice Psychotherapist (December 2013 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2018 - Present)
- Jewish Senior Life (May 2018 - Present)
- Jewish Home of Rochester (May 2018 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2018 - Present)

Marc Reich, Board Member – Jewish Senior Life LHCSA/Jewish Senior Life Community Services, Inc./Jewish Senior Life

Employment
- Stark Tech – Director of Applications and Data (January 2022 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2017 - Present)
- Jewish Senior Life (May 2017 - Present)
- Jewish Home of Rochester (May 2017 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2017 - Present)

Michele J. Ruda, Board Member – Jewish Senior Life

Employment
- Jewish Community Center – Director of the Resource Place (1999 - April 2019)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2016 - Present)
- Jewish Senior Life (May 2016 - Present)
- Jewish Home of Rochester (May 2016 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2016 - Present)

Joy Ryen Plotnik, Esq., Board Member – Jewish Senior Life

Employment
- Canandaigua National Bank and Trust Company – Senior Trust Officer, Senior Vice President (March 2018 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2023 - Present)
- Jewish Senior Life (May 2023 - Present)
- Jewish Home of Rochester (May 2023 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2023 - Present)

Wendy A. Silverman, RN, BSN, Board Member – Jewish Senior Life

Employment
- Acute Kids Pediatric Urgent Care – RN (2020 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2018 - Present)
- Jewish Senior Life (May 2018 - Present)
- Jewish Home of Rochester (May 2018 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2018 - Present)

Eric Stonehill, Esq., Board Member – Jewish Senior Life

Employment
- Retired 2013

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (October 2022 - Present)
- Jewish Senior Life (October 2022 - Present)
- Jewish Home of Rochester (October 2022 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (October 2022 - Present)

Maurice E. Varon, M.D., Board Member – Jewish Senior Life

Employment
- Rochester Regional Health – SCHI VP Administrator (January 2015 - Present)

Affiliations
- Jewish Home of Rochester Senior Housing (May 2017 - Present)
- Jewish Senior Life (May 2017 - Present)
- Jewish Home of Rochester (May 2017 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2017 - Present)

Marsha N. Wittink, M.D., M.B.E., Board Member – Jewish Senior Life

Employment
- University of Rochester School of Medicine – Academic Chief, Division of Medicine in Psychiatry

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2023 - Present)
- Jewish Senior Life (May 2023 - Present)
- Jewish Home of Rochester (May 2023 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2023 - Present)

Marvin L. Wolk, Board Member – Jewish Senior Life

Employment
- Retired 1998

Affiliations
- Jewish Home of Rochester Senior Housing, Inc. (May 2019 - Present)
- Jewish Senior Life (May 2019 - Present)
- Jewish Home of Rochester (May 2019 - Present)
- Jewish Home of Rochester Enriched Housing, Inc. (May 2019 - Present)

Carly A. Zecher, Board Member - Jewish Senior Life LHCSA/Jewish Senior Life Community Services, Inc./Jewish Senior Life

Employment
- Jewish Home of Rochester – Director of Finance (January 2016 - Present)

Affiliations
- No offices held or ownership interests in Health Facilities.

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

A search of the individuals named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

The Office of the Professions of the State Education Department, the New York State Physician Profile, and the Office of Professional Medical Conduct, where appropriate, indicate no issues with the licensure of the health professionals associated with this application.

Facility Compliance/Enforcement

The Division of Adult Care Facilities and Assisted Living Surveillance reviewed the compliance history of the above-mentioned adult care facilities and reports that there are no enforcement actions against the operator for the period reviewed.

The Division of Nursing Homes and ICD/IID Surveillance reviewed the compliance history of the above-mentioned nursing home and reports as follows:

- Jewish Home of Rochester was fined $2,000 pursuant to a Stipulation and Order for inspection findings on October 14, 2021, for violations of 10 NYCRR Part 415.19(a)(1-3). This facility was also fined a Civil Monetary Penalty in the amount of $3,250 on October 14, 2021, for violations of F880-D. The CMP has been paid and closed.

Need Review

In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review, as the agency is actively serving over 25 patients as attested to by the current operator. This application seeks to expand the service area to include Wayne and Livingston counties, which have been identified by the Department of Health as counties with an existing need for LHCSA services.

Financial Review

In accordance with 10 NYCRR §765-1.2(b)3, the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed. Refer to Attachment B for the Workforce Summary.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Attachments

OALTC Attachment A	Organizational Chart
OALTC Attachment B	Workforce Summary

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish Jewish Senior Life LHCSA, Inc. as the new operator of a Licensed Home Care Services Agency currently operated by Embrace Care LLC at 2021 South Winton Road, Rochester, and add Wayne and Livingston counties to its service area, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
231232 E	Jewish Senior Life LHCSA, Inc., d/b/a Jewish Home of Rochester Licensed Home Care

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 231300-E
Community Health And Home Care, Inc.

Program: **LHCSA**
Purpose: **Establishment**
County: **Tompkins**
Acknowledged: **July 26, 2023**

Executive Summary

Description
Community Health and Home Care, Inc., a New York not-for-profit corporation, is requesting to transfer 100% ownership interest of the Licensed Home Care Services Agency (LHCSA) to Cayuga Health System, Inc. Cayuga Health System, Inc. will become the sole member of Community Health and Home Care, Inc.

The applicant does not propose any changes to the LHCSA's service area or licensed services.

OALTC Recommendation
Approval

Need Summary
In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Financial Summary
In accordance with 10 NYCRR §765-1(b)3, the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

April 11, 2024

Program Analysis

Program Description

Community Health and Home Care, Inc. is requesting to transfer 100% ownership interest of the LHCSA to Cayuga Health System, Inc., who will become the sole member of Community Health and Home Care, Inc.

The applicant intends to continue to serve the residents of the following counties from an office located at 138 Cecil A Malone Drive, Ithaca, New York 14850:

- Broome
- Cayuga
- Cortland
- Schuyler
- Tioga
- Tompkins

The applicant intends to continue to provide the following healthcare services:

- Nursing
- Home Health Aide
- Personal Care
- Therapy-Physical
- Medical Social Services

Character and Competence Review

Cayuga Health Systems, Inc. is comprised of the following individuals:

Tom LiVigne
Chair, Board of Directors, Cayuga Health Systems, Inc.

Affiliations

- Cayuga Medical Center at Itaca, Inc. (January 2013 - Present)
- Schuyler Hospital, Inc. (January 2016 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2016 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Paula E.F. Younger
Vice Chair, Board of Directors, Cayuga Health Systems, Inc.

Affiliations

- Cayuga Medical Center at Itaca, Inc. (January 2013 - Present)
- Schuyler Hospital, Inc. (January 2016 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2016 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Gregory J Hartz
Treasurer, Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2013 - Present)
- Schuyler Hospital, Inc. (January 2016 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2016 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Suzanne Blowers
Secretary, Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2016 - Present)
- Schuyler Hospital, Inc. (January 2013 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2013 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

James Brown
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2013 - Present)
- Schuyler Hospital, Inc. (January 2016 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2016 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Kenneth I Clarke Sr.
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2014 - Present)
- Schuyler Hospital, Inc. (January 2016 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2016 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Yvette N Conyers
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2023- Present)
- Schuyler Hospital, Inc. (January 2023- Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2023- Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023- Present)

La Jerne Cornish
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2022 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Cristine Donovan
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2022 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Robert Brook Hollis
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2022 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Gary Koretzky
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2023 - Present)
- Schuyler Hospital, Inc. (January 2023 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2023 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Joel Malina
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2017 - Present)
- Schuyler Hospital, Inc. (January 2017 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2017 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Laurie Mante
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2022 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

John Paul Mead, MD
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2022 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Eunice Nayo, MD
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2016 - Present)
- Schuyler Hospital, Inc. (January 2013 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2013 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Paul Streeter
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2023 - Present)
- Schuyler Hospital, Inc. (January 2023 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2023 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Fred Wickham
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2022 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Jennifer Whitaker
Board of Directors, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. (January 2022 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2022 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

Martin Stallone, MD
Ex-Officio, Cayuga Health Systems, Inc.

Affiliations
- Cayuga Medical Center at Itaca, Inc. (January 2019 - Present)
- Schuyler Hospital, Inc. (January 2019 - Present)
- Schuyler Hospital, Inc. and Long-Term Care Unit (January 2019 - Present)
- Ithaca Alpha House Center, Inc. d/b/a Cayuga Addiction Recovery Services (January 2023 - Present)

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a licensed home care services agency.

A search of the individual named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement
The Bureau of Quality and Surveillance reviewed the compliance history for Schuyler Hospital Inc. and Long Term Care Unit and reported that the facility was fined a civil monetary penalty of $2,275 pursuant to a survey dated July 5, 2021, $1,950 pursuant to a survey dated June 21, 2021, $1,625 pursuant to a survey dated May 31, 2021, $1,300 pursuant to a survey dated May 17, 2021, $975 pursuant to a survey dated May 10, 2021, and $650 pursuant to a survey dated April 26, 2021. All violations were associated with F884-F (reporting COVID-19 vaccination rates).

Need Review
In accordance with 10 NYCRR § 765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Financial Review
In accordance with 10 NYCRR 765-1.2(b)3, the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Workforce Review
The applicant's response regarding the recruitment and retention of the workforce was adequately addressed. Attachment A outlines their workforce goals.

Conclusion
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Attachments

OALTC	Workforce Review

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer 100% ownership interest to one new not-for-profit corporate member, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
231300 E	Community Health And Home Care, Inc.

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 232143-E
Saratoga-Schenectady Endoscopy Center, LLC

Program: **Diagnostic and Treatment Center** ***County:*** **Saratoga**
Purpose: **Establishment** ***Acknowledged:*** **November 7, 2023**

Executive Summary

Description
Saratoga Schenectady Endoscopy Center, LLC, an existing single-specialty Ambulatory Surgery Center (ASC) specializing in gastroenterology, requests approval to transfer 8.33% membership interest to one new member. The Center is submitting this application for a change in membership as the change will exceed the 25% threshold limit for the past five years. There will be no changes in services offered.

Currently, there are 11 equal members with an ownership interest of 9.09%. Through this application, Dr. Christopher Brown would be added as an 8.33% owner, and the existing member's ownership percentage would decrease to 8.33% per member.

Presented as BFA Attachment A is the current and proposed ownership of Saratoga Schenectady Endoscopy Center.

OPCHSM Recommendation
Contingent Approval

Need Summary
There will be no need review per Public Health Law §2801-a (4).

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary
The purchase price for the 8.33% membership interest is $443,946 and will be funded with a loan at an interest rate of 7.11% for a five-year term.

There is no budget presented in this review since this application is a change of ownership and there are no changes to current operations.

Health Equity Impact Assessment
This project does not meet the requirements for a Health Equity Impact Assessment under Section 2802-B of the PHL.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval contingent upon:

1. Submission of a bank loan commitment that is acceptable to the Department of Health. [BFA]

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

April 11, 2024

Program Analysis

Project Proposal

Saratoga-Schenectady Endoscopy Center LLC (SSEC) is licensed as a single-specialty Ambulatory Surgery Center specializing in gastroenterology, and it has been in operation since August 2004. The Center is submitting this application for a change in membership as the change will exceed the 25% threshold limit for the past five years. During the past five years, the appropriate notices were filed for membership changes.

Currently, there are 11 equal members with an ownership interest of 9.09%. This application, to add Dr. Christopher Brown, would decrease membership interest to 8.33% per member.

The table below details the proposed change in ownership:

Member	Current	Proposed
George Boyar	9.09%	8.33%
Howard Malamood	9.09%	8.33%
John DeFrancisco	9.09%	8.33%
William Gusten	9.09%	8.33%
David Goetz	9.09%	8.33%
Natalya Belova	9.09%	8.33%
Mark Metwally	9.09%	8.33%
Justin Provost	9.09%	8.33%
Chad Cornish	9.09%	8.33%
Vinay Sood	9.09%	8.33%
Zachary Feinberg	9.09%	8.33%
*Christopher Brown	0.00%	8.33%
Total	**100.00%**	**100.00%**

**Member subject to Character and Competence*

Character and Competence

Dr. Christopher Brown is a current licensed physician in the state of New York. Dr. Brown completed a degree in medicine at St. George's University in the nation of Grenada in 2012. In 2018, Dr. Brown completed a residency and internship at Yale University - Norwalk Hospital. Additionally, Dr. Brown became employed in New York State in 2022 at Saratoga-Schenectady Gastroenterology Associates, PC after completing a four-year tenure at Tidelands Health Department of Gastroenterology and Hepatology in South Carolina. Dr. Brown is currently employed at Saratoga-Schenectady Gastroenterology Associates, PC. Dr. Brown is Board Certified in Gastroenterology, since 2018.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Membership Interest Agreement

The applicant has submitted an executed membership interest purchase agreement, which is summarized below:

Date	October 13, 2023
Purpose	To purchase 8.33% membership interest in Saratoga Schenectady Endoscopy Center, LLC
Seller	Saratoga Schenectady Endoscopy Center, LLC
Purchaser	Christopher Brown, MD.
Purchase Price	$443,946.59

Capability and Feasibility

The purchase price for 8.33% in membership interest is $443,946, which the purchaser will finance with a loan at an interest rate of the Federal Home Loan of NY advance rate (5.11%) plus 2% (equivalent to 7.11% as of 2/12/2024) for a five-year term.

Presented as BFA Attachment B are the 2021-2022 Certified Financial Statements of Saratoga-Schenectady Endoscopy Center, LLC. As shown, the entity had an average positive working capital position and an average positive net asset position. Also, the entity achieved an average operating income of $4,702,833 in 2021 and 2022.

Presented as BFA Attachment C is the December 31, 2023, internal financial statement of Saratoga Schenectady-Endoscopy Center. As shown, the entity had a positive working capital position and a positive net asset position through December 31, 2023. Also, the entity achieved a net income of $5,531,030 through December 31, 2023.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BFA Attachment A	Current and Proposed Ownership Interest of Saratoga-Schenectady Endoscopy Center, LLC
BFA Attachment B	2021-2022 Certified Financial Statements of Saratoga-Schenectady Endoscopy Center, LLC
BFA Attachment C	December 31, 2023, Internal Financial Statements of Saratoga Schenectady-Endoscopy Center, LLC

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer 8.33% ownership interest to one new member, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
232143 E	Saratoga-Schenectady Endoscopy Center, LLC

APPROVAL CONTINGENT UPON:

1. Submission of a bank loan commitment that is acceptable to the Department of Health. [BFA]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in th*e Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 232201-B
FJ Community Health Center

Program: **Diagnostic and Treatment Center** ***County:*** **Queens**
Purpose: **Establishment and Construction** ***Acknowledged:*** **January 22, 2024**

Executive Summary

Description
FJ Community Family Corp (FJCFC), an existing proprietary business corporation, is seeking approval to establish and construct an Article 28 diagnostic and treatment center (D&TC) at 54-08 74th Street, Unit #3A, in Elmhurst (Queens County). FJCFC will provide primary care, other medical specialty services, physical therapy, and behavioral health services up to the 30% threshold of patient visits.

Grand Holdings Real Estate LLC, the landlord, and FJ Community Family Corp., the tenant, have entered into a proposed lease agreement for site control of the facility.

The proposed owner of FJ Community Family Corp. is (Fei) Kevin Guo. Abdalla Adam, M.D., who is Board-Certified in Physical Medicine and Rehabilitation, will serve as FJCFC's Medical Director. The applicant will seek a transfer and affiliation agreement with Elmhurst Hospital Center, 2.0 miles (6-minute travel time) from the proposed D&TC location.

OPCHSM Recommendation
Contingent Approval

Need Summary
The applicant projects 4,497 visits in Year One and 7,931 in Year Three, with Medicaid at 60% and Charity Care at 2.0%.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary
Total project cost of $578,242 will be met with $57,824 in equity and a $520,417 10-year term loan at an interest rate of 6% from Hudsonshine Capital.

Budget:	Year One (2025)	Year Three (2027)
Revenues:	$764,640	$1,347,475
Expenses:	$715,289	$1,091,021
Net Income:	$49,351	$256,454

Health Equity Impact Assessment
This project does not meet the requirements for a Health Equity Impact Assessment under Section 2802-B of the PHL.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of an executed lease agreement, acceptable to the Department of Health. [BFA]
3. Submission of an executed loan commitment, acceptable to the Department of Health. [BFA]
4. Submission of an executed working capital loan commitment, acceptable to the Department of Health. [BFA]
5. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
6. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
7. Submission of a photocopy of an amended and executed Certificate of Incorporation, acceptable to the Department. [CSL]
8. Submission of a photocopy of an amended and executed Lease, acceptable to the Department.[CSL]
9. Submission of an executed Transfer and Affiliation Agreement acceptable to the department. [HSP]

Approval conditional upon:

1. This project must be completed by **August 1, 2025**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **January 1, 2025,** and construction must be completed by **May 1, 2025**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]

Council Action Date

April 11, 2024

Need Analysis

Background and Analysis

The primary service area is Queens County. The facility is in a Health Professional Shortage Area for Mental Health and Primary Care. The county's overall population is estimated to increase to 2,554,994 or 8.2% by 2029 per projection data from the Cornell Program on Applied Demographics. Demographics for the primary service area are noted below including a comparison with the county and New York State.

Demographics	Queens County	New York State
Total Population	2,360,826	19,994,379
Hispanic or Latino (of any race)	28.0%	19.5%
White (non-Hispanic)	23.8%	53.8%
Black or African American (non-Hispanic)	16.7%	13.8%
Asian (non-Hispanic)	25.9%	8.8%
Other (non-Hispanic)	5.6%	4.1%

Source: 2022 American Community Survey (5-Year Estimates Data Profiles)

In 2021 91.1% of the population in Queens County had health coverage as follows.

Employer Plans
Medicaid
Medicare
Non-Group Plans
Military or VA

Source: Data USA

Applicant Projected Payor Mix		
Payor	Year One	Year Three
	Outpatient	
Commercial	13.23%	13.92%
Medicare	21.01%	20.99%
Medicaid	60.75%	60.08%
Private Pay	3.00%	3.00%
Charity Care	2.00%	2.00%
Total Visits	4,497	7,931

The applicant seeks to be certified for primary care, podiatry, physical therapy, and other medical services including behavioral and mental health services. The Hours of operation will be Monday - Friday, 9:00 AM to 8:00 PM, and Saturday 10:00 am to 2:00 pm.

Prevention Quality Indicators (PQIs) are hospital admission rates for conditions that good outpatient care and early intervention can potentially prevent. The table below provides information on the PQI rates for the overall PQI condition.

Hospital Admissions per 100,000 Adults		
Observed PQI Rates: 2020	**Queens County**	**New York State**
Prevention Quality Overall Composite	866	994

Conclusion

The applicant plans to provide primary care along with education to the community to enhance access, improve patient outcomes, and reduce re-hospitalizations in the Queens County area.

Program Analysis

Project Proposal

FJ Community Family Corp (FJCFC), an existing proprietary business corporation, requests approval to establish and construct an Article 28 diagnostic and treatment center (D&TC) at 54-08 74th Street, Unit #3A, in Elmhurst (Queens County). FJCFC will provide primary care, other medical specialty services, physical therapy, and behavioral health services under the 30% threshold of patient visits in a known Primary Care Health Professional Shortage Area as well as in a Mental Health Professional Shortage Area.

Renovations proposed will include modifying 1817 square feet of an existing tenant space located on the 3rd floor in Unit #3B. This will include renovations to add an outpatient and exam rooms and a physical therapy area. There will be upgrades to the HVAC, electrical, and plumbing systems. The existing plumbing, sprinkler, fire alarm, and electrical base building systems will be re-utilized, and new annunciating and notification devices will be added and monitored by a dedicated panel connected to the main building fire alarm system.

The proposed owner of FJ Community Family Corp. is (Fei) Kevin Guo. Abdalla Adam, M.D. will serve as the Medical Director and is registered in New York State through December 31, 2025.

The Center will be open Monday - Friday 9:00 AM to 8:00 PM, and Saturday 10:00 AM to 2:00 PM.

The applicant anticipates entering into a Transfer and Affiliation Agreement with Elmhurst Hospital Center, 79-01 Broadway, Elmhurst, NY 11373, 2.0 miles (6-minute travel time) from the proposed Diagnostic and Treatment Center.

Staffing is expected to increase by 5.32 FTEs from Year One to Year Three. There will be 7.34 FTEs in Year One and 12.66 FTEs by Year Three.

The table below shows the expected staffing complement in Year One and Year Three:

Staffing Categories	Year One FTE Budget	Year Three FTE Budget
Management & Supervision	.70	.70
Registered Nurses	.50	1.00
Aides, Orderlies & Attendants	2.00	3.00
Physicians	.96	1.70
Nurse Practitioners	.50	1.00
Social Workers and Psychologist**	.25	.50
Physical Therapist and PT Assistants	.43	.76
Infection Control	1.00	2.00
Clerical and Other Administrative	1.00	2.00
Total Full-Time Equivalents (FTEs)	7.34	12.65

Character and Competence:

Abdalla Ishag Adam is the proposed Medical Director (MD) for FJ Community Health Center and is currently registered as an MD in New York, license #241981-01 until January 31, 2025, and New Jersey, license #MA09545200 until June 6, 2025.

Dr. Adam received a PMR degree (Physical Medicine & Rehabilitation) in 2003 from SUNY at Stony Brook, Stony Brook, NY; completed an internship in 1999 at Howard University Hospital, Washington DC; and received an MD M.B.B.S. (Medicine/Surgery) in 1986 from Khartoum University, Khartoum Sudan.

Current employment history includes the following: MD/President at Empire Medical & Rehabilitation, NY, from 2008 to present and Staff Physiatrist at Citi Medical, NY from 4/2016 to present. Dr. Adam was previously employed at Sentara Virginia Beach General Hospital working in inpatient rehabilitation from 4/2019 to 12/2019, as a Staff Physiatrist at Metro working with pain specialists in NY and in NJ from 1/2017 to 1/2018 and as Director of Relief and Development for Darfur Peace and Development Organization, VA from 2003 to 2009.

(Fei) Kevin Guo / Owner is the proposed owner/member (100%) of FJ Community Family Corp (FJCFC) and does not currently list any licenses. Employment history indicates several years of being self-employed. Kevin Gou was the Owner and President of Happiness Adult Day Care Center, Inc., at 49-03 69th St, Queens, NY 11377 from December 2015 to 2022, Contractor and President for Futan Construction Inc. from 2013 to 2015, Owner and President of Futan Realty, Inc. from 2013 to present, and as the President of Grand Centurion Construction, Inc. from 2008 to December 2013.

Kevin Guo currently owns Bright Horizon Prime Care Inc., a Licensed Home Care Service Agency (LHCSA), license number # 2571L001, at 4125 Kissena Boulevard, Unit 127, Flushing, New York 11355 in Queens County. This LHCSA was licensed on March 12, 2021.

The following legal actions were disclosed for Kevin Guo:

Conviction for one (1) DUI and required classes completed and one (1) open legal case which involves a slip and fall lawsuit, which is pending.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Cost and Financing

The total project cost for renovations and movable equipment is estimated at $578,242 and is distributed as follows:

Renovation and Demolition	$242,991
Design Contingency	24,299
Construction Contingency	24,299
Planning Consultant Fees	15,000
Architect/Engineering Fees	18,514
Other Fees	50,000
Movable Equipment	177,356
Financing Costs	15,004
Interim Interest Expense	5,627
Application Fee	2,000
Additional Processing Fee	3,152
Total Project Cost	$578,242

The financing for this project will be as follows:

Cash	$57,824
Loan (10 years, 6% interest)	520,417
Total	$578,241

Operating Budget

The applicant has submitted an operating budget, in 2024 dollars, for Years One and Three, summarized below:

	Year One (2025)		Year Three (2027)	
	Per Proc.	Total	Per Proc.	Total
Revenues:				
Commercial FFS	$180.00	$81,000	$180.00	$142,740
Commercial MC	$153.00	22,185	$153.00	47,583
Medicare FFS	$180.00	137,700	$180.00	242,640
Medicare MC	$153.00	27,540	$153.00	48,501
Medicaid FFS	$200.30	18,227	$200.30	31,847
Medicaid MC	$170.25	449,638	$168.82	784,184
Private Pay	$210.00	28,350	$210.00	49,980
Total Revenue		$764,640		$1,347,475
Expenses:				
Operating	$121.72	$547,393	$116.95	$927,546
Capital	37.34	167,896	20.61	163,475
Total Expenses	$159.06	$715,289	$137.56	$1,091,021
Net Income/(Loss)		$49,351		$256,454
Procedures		4,497		7,931
Cost/Visit		$159.06		$137.56

Utilization by payor source during the first and third years is broken down as follows:

	Year One	Year Three
Commercial FFS	10.01%	9.99%
Commercial MC	3.23%	3.92%
Medicare FFS	17.01%	16.99%
Medicare MC	4.00%	4.00%
Medicaid FFS	2.02%	2.01%
Medicaid MC	58.73%	58.08%
Private Pay	3.00%	3.00%
Charity Care	2.00%	2.01%
Total	100.00%	100.00%

The following is noted with respect to the submitted budget:

- Medicaid Fee for Service is based on the base rate of $170.71 plus the capital component of $29.59.
- Medicaid Managed Care is 80% of the Medicaid APG Fee for Service rate.
- Commercial Fee for Service and Medicare Fee for Service rates are based on Medicare Part B Fee Schedule, and Commercial Managed Care and Medicare Managed Care rates are 80% of the Medicare Part B Fee Schedule.
- Utilization assumptions are based on the demographic needs of the proposed service area. Medicaid utilization is based on the current statistical analysis of the population and the patients to be served.
- Staffing mix is determined by operations of existing Article 28 D&TCs and a review of existing AHCF-1 Cost Reports.
- Expenses are based predominantly on labor costs for the staffing model

Draft Lease Agreement

The applicant has submitted a draft lease agreement, the terms of which are summarized below:

Premises:	Building located at 5408 74th Street in Elmhurst, NY 11373
Landlord:	Grand Holdings Real Estate LLC
Tenant:	FJ Community Family Corp.
Term:	10-year term following approval of the Department of Health with an option to renew for an additional five-year term.
Rent:	Base rent for total leased space is $72,453 per year ($6,037.75 per month) for the first year. Rent will increase by 3% of the base year rent for years 2 through 10.
Security Deposit:	Tenant shall pay a security deposit of $12,075.50
Provisions:	Tenant is responsible for, insurance, utilities, and maintenance.

The applicant submitted an affidavit stating the lease agreement between the property owner and the lessee is an arm's length arrangement. The applicant has submitted letters from two NYS licensed realtors attesting to the reasonableness of the per square footage rental.

Capability and Feasibility

Total project cost of $578,242 will be met with $57,824 in equity and a $520,417 loan from Hudsonshine Capital at a 10-year term and interest rate of 6%. The working capital requirement based on two months of third-year expenses is estimated at $181,837 and will be funded with a $90,918 equity contribution from the proposed member and a bank loan for $90,918 with a three-year term at 6% interest. Hudsonshine Capital has provided a letter of interest for the respective loans at the stated terms. BFA Attachment A presents the proposed member's Personal Net Worth Statement, which indicates sufficient resources overall to fund the equity requirements.

BFA Attachment B is the Pro-Forma Balance Sheet, which shows the operation will begin with $148,743 in equity as of the first day of operations. The submitted budget indicates a net income of $49,351 in Year One and $256,454, in Year Three. The budget appears reasonable.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BHFP Attachment	Map
BFA Attachment A	Net Worth Statement – (Fei) Kevin Guo
BFA Attachment B	Pro-Forma Balance Sheet

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a new Diagnostic and Treatment Center at 54-08 74th Street, #3A, Elmhurst, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
232201 B	FJ Community Family Corp. d/b/a FJ Community Health Center

APPROVAL CONTINGENT UPON:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of an executed lease agreement, acceptable to the Department of Health. [BFA]
3. Submission of an executed loan commitment, acceptable to the Department of Health. [BFA]
4. Submission of an executed working capital loan commitment, acceptable to the Department of Health. [BFA]
5. The submission of State Hospital Code (SHC) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
6. The submission of Engineering (MEP) Drawings for review and approval, as described in BAER Drawing Submission Guidelines DSG-1.0. [AER]
7. Submission of a photocopy of an amended and executed Certificate of Incorporation, acceptable to the Department. [CSL]
8. Submission of a photocopy of an amended and executed Lease, acceptable to the Department.[CSL]
9. Submission of an executed Transfer and Affiliation Agreement acceptable to the department. [HSP]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **August 1, 2025**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **January 1, 2025**, and construction must be completed by **May 1, 2025**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]

5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the *Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 232163-B
BSD Birthing Center of Rockland

Program: **Midwifery Birthing Center** ***County:*** **Rockland**
Purpose: **Establishment and Construction** ***Acknowledged:*** **November 13, 2023**

Executive Summary

Description
BSD Birthing Center of Rockland, LLC (the Center), a limited liability company, requests approval to establish and construct a Midwifery Birth Center in leased space at 84 Route 59, Suffern, New York. The new Center will convert an existing PC practice to an Article 28 Midwifery Birthing Center.

The Center will provide prenatal, childbirth, post-partum care, and primary reproductive healthcare to low-risk patients. Services are provided during pregnancy, labor, and delivery to those who require a stay of less than 24 hours after birth. As part of this application, the applicant will seek certification for birthing services and primary medical care. The Center will serve all women in Rockland County but anticipates that its primary patient base will be Orthodox Jewish women.

The proposed medical director will be Thomas Martin, MD., a licensed OB/GYN since 1999. The applicant has initiated conversations with Good Samaritan Hospital for a transfer and affiliation agreement.

The proposed members of BSD Birthing Center of Rockland, LLC are as follows:

Yutta Engel	60.00%
Jacob Engel	30.00%
Rivkah Friedman	5.00%
Chava Schwartz	5.00%

OPCHSM Recommendation
Contingent Approval

Need Summary
The applicant projects 180 procedures in Year One and 221 in Year Three with 95% Medicaid for both years.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary
The total project cost of $1,314,178 is funded with equity.

Health Equity Impact Assessment
Based on the information and analysis presented in the Health Equity Impact Assessment and the applicant's mitigation plan, the proposed project will not result in any significant adverse health equity impacts.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of executed Transfer and Affiliation Agreements acceptable to the Department, with a local acute care hospital(s). Transfer agreements for mother and/or infant should include a list of indicators necessitating transfer and a written procedure for automatic acceptance of such transfers by the transfer hospital. [HSP]
3. The NNP will provide proof of admitting privileges at the nearest hospital. [HSP]
4. BSD will provide a formal executed and approved collaborative agreement with a pediatric provider at Good Samaritan Hospital. [HSP]
5. Submission of proof of current licensure by the New York State Education Department, Office of the Professions, for Licensed Midwife Y. Engel. [BFH]
6. Upon mutual agreement, the applicant shall submit a dually signed Transfer Agreement between the Applicant and Good Samaritan Hospital. [BFH]
7. Submission of an executed lease rental agreement that is acceptable to the Department of Health. [BFA]

Approval conditional upon:

1. This project must be completed by **February 11, 2025**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **October 11, 2024,** and construction must be completed by **November 11, 2024**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a) if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. Provide formal arrangements for the provision of obstetrical care at the transfer hospital with a qualified physician for these services and for consultation and referral. [HSP]
4. Provide formal arrangements for the provision of pediatric care at the transfer hospital and for consultation and referral. [HSP]
5. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]

6. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https: www.health.ny.gov/facilites/hospitals/docs/hcs_access_forms_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]
7. The applicant shall submit the letter of decision and any findings as provided by the Commission; a decision by the Commission to not accredit the applicant will result in further considerations between the Department and the applicant before approval could be recommended. [BFH]
8. Upon receipt of findings of an accreditation site visit by the Commission for the Accreditation of Birth Centers, the applicant shall provide the Department with the findings of the site visit, including any documentation related to these findings, proof of the outcome of such findings. These documents will be reviewed by the Department to assess any exemptions or other findings from the Commission and will be considered prior to full approval. [BFH]
9. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]

Council Action Date
April 11, 2024

Need Analysis

Background and Analysis

The primary service area for this project is Rockland County. The population of Rockland County is estimated to increase to 354,877 by 2029 per projection data from the Cornell Program on Applied Demographics, an increase of 5.2%. Demographics for the primary service area are noted below including a comparison with New York State

Demographics	Rockland County	New York State
Total Population	337,326	19,994,379
Hispanic or Latino (of any race)	18.6%	19.5%
White (non-Hispanic)	61.9%	53.8%
Black or African American (non-Hispanic)	10.9%	13.8%
Asian (non-Hispanic)	6.0%	8.8%
Other (non-Hispanic)	2.6%	4.1%

Source: 2022 American Community Survey (5-Year Estimates Data Profiles)

In 2021, 95.7% of the population of Rockland County had health coverage as follows:

Employee plans	45.0%
Medicaid	27.7%
Medicare	11.7%
Non-group plans	11.1%
Military or VA plans	0.3%

Source: Data USA

Applicant Projected Payor Mix		
Payor	**Year One**	**Year Three**
Commercial	3.9%	4.1%
Medicare	0.0%	0.0%
Medicaid	95.0%	95.0%
Private Pay	1.1%	0.9%
Charity Care	0.0%	0.0%
Other	0.0%	0.0%

The applicant projects 180 procedures in Year One and 221 in Year Three. There are no other Midwifery Birthing Centers in Rockland County. Birthing options in the county include two hospitals with maternity beds and a diagnostic and treatment center birthing center.

Patients in need of services will be accepted regardless of age, sex, sexual orientation, race, creed, gender, religion, disability, source of payment, or any other personal characteristic.

The applicant is negotiating a Transfer and Affiliation Agreement with Good Samaritan Hospital of Suffern, NY, 0.8 miles (4 minutes away), for backup hospital services. The closest Regional Perinatal Center is Westchester Medical Center in Valhalla, NY, 22.9 miles (28 minutes away).

Conclusion

Approval of this project will allow for access to Article 28 Licensed midwifery birthing services for the residents of Rockland County.

Program Analysis

Project Proposal:

The facility will provide prenatal and childbirth services, postpartum care, and primary preventive reproductive health care to low-risk patients. There will be one (1) to two (2) midwives in the office holding office hours for consultation, prenatal, well-woman, contraception, etc. A separate midwife will be on call for births. The facility will also have two (2) nurses on staff who will assist with births as needed during regular business hours.

The Midwifery Birth Center will provide a homelike environment which will include three (3) Birthing Rooms with birth pools and soaking tubs, two (2) Ultrasound Rooms, two (2) Exam Rooms, one (1) Ultrasound /Exam Room, one (1) Ultrasound Consult Room, and one (1) Midwife Room. The scope of renovation work will involve upgrades to the HVAC, sprinkler, plumbing, and electrical systems. The proposed work area in the already existing one-story building will be approximately 5,520 square feet.

Proposed Operator	BSD Birthing Center of Rockland LLC
Doing Business As	BSD Birthing Center
Site Address	84 Route 59, Suffern, New York 10901
Shift/Hours/Schedule	9 am to 4 pm
Approved Services	Birthing Service O/P Medical Services - Primary Care
Staffing (1st Year/3rd Year)	8.75 FTEs for both the 1st and 3rd years
Medical Director(s)	Thomas W. Martin, M.D.
Emergency, In-Patient, and Backup Support Services Agreement and Distance	Good Samaritan Hospital (.8 mile / 4 minutes)

The applicant anticipates entering into a Transfer and Affiliation Agreement with Good Samaritan Hospital, located at 255 Lafayette Avenue, Route 59, Suffern, NY 10901

Staffing will remain the same throughout Year One and Year Three of operation at 8.75 FTEs, which will include Management and Supervision (1.75 FTEs), Registered Nurses (1.0 FTE), Physician Assistant (1.5 FTEs), Nurse Practitioners (.50 FTE), Nurse Midwife (1.5 FTEs), Other Therapist and Assistants (.50 FTE) and Clerical and Other Administrative (2.0) FTEs).

The applicant anticipates being credentialed for the Neonatal Nurse Practitioner to have admitting privileges at the nearest hospital.

BSD Birthing Center indicates there are Collaborative Practice Agreements between Montefiore Nyack Hospital (Dr. Maria Emerson/OB-GYN) and Kate Keller (CNM), Good Samaritan Hospital of Suffern (Dr. Vinick, the Director of OB/GYN) and Kate Keller, Montefiore Nyack Hospital (Dr. Maria Emerson, OB-GYN) and Rachel Siegel (CNM), and Good Samaritan Hospital of Suffern and Rachel Siege, and with Dr. Weiner at Pascack Valley Medical Center in Westwood, NJ.

Positions at the facility will be managed by Kate Keller and Rachel Siegel.

Character and Competence

The proposed membership of BSD Birthing Center of Rockland LLC is:

Member Name/Title	Membership Interest
Yutta Engel / Member	60%
Jacob Engel / Member-Manager	30%
Rivkah Friedman / Member	5%
Chava Schwartz / Member	5%
Total	**100%**

Thomas W. Martin / Medical Director -

Thomas Martin is the proposed Medical Director (MD) and is currently registered as an MD in New York State (license #325550) until July 31, 2025. Dr. Martin received an MD degree from Medical College of Virginia, Richmond, VA, in 05/1995, completed a residency at Vanderbilt University Medical Center, Nashville, TN in 06/1999, and received a B.S. from James Madison University, in Harrisonburg, VA in 05/1991. Past employment is reported as working as a staff physician in the OB/GYN Department at Simmonds, Martin & Helmbrecht, Chartered (a Division of Advantia Healthcare) in Damascus MD from 08/1999 to 09/2022, also as the leader of Quality Improvement Committee of Advantia Healthcare, Simmonds, Martin & Helmbrecht, as a Staff Physician and Chairperson in the OB/GYN Department at Shady Grove Medical Center, from 1999 to 2022, as a Staff Physician at Frederick Memorial Hospital, from 2004 to 2022, and as a staff physician at Washington Adventist Hospital, from 2015 to 2021.

Yutta Engel / Manager -

Yutta Engel received a BS Midwifery (LM, CM & BSM) degree from the National College of Midwifery, Taos, New Mexico, in 08/2010; and a Bachelor of Science degree in Midwifery in 2010. Licensure (license #001499) was received for Midwifery in New York state in August 2012 and has an ACNM Board certification (license #CM0137) which registration is until 12/31/2027. Current employment history includes acting as a community Doula and as a Midwife for the community in Monsey, New York since 2012 and in New Jersey since 2008.

Jacob M. Engel / Manager -

Jacob Engel completed his education at Rabbinical College in Jerusalem, Israel. Employment history includes being an entrepreneur, investor, author, and consultant for various community businesses such as Co-Founder and CEO of the proposed BSD Birthing Center of Rockland LLC, CEO at Yeda LLC in Monsey, NY, Consultant and Author of the book “The Prosperous Leader”, as the owner and Real Estate investor for industrial and multi-family properties in NY, NJ, TN, AL and in IA, COO of Family Enterprise (Food & Real Estate) in JC, and NJ, and the COO for Gel Spice Co., Inc in Bayonne, NJ.

Rivka Friedman / Member -

Rivka Friedman graduated high school from Bais Rochel, Airmont, NY in June 2008. Employment history includes customer service type of jobs such as a Medical Biller at Besad Midwifery from 2014 to 2018, and at DRF Services Inc. from 2018 to present.

Chava Shwartz / Member -

Chava Shwartz is the proposed office manager for BSD Midwifery. Chava completed undergraduate classes at Excelsior College in Albany, New York. Employment history includes working as an Art Instructor at Hamaspik, in Monsey, NY, at Advenium in Suffern, NY, and CEC Educational Services in Monsey, NY. Past employment also included office work at Her Secret LLC as a Buyer, in Spring Valley, NY, at Marino Ave Inc., as an Amazon Lister, in Suffern, NY, at ILH Sales Inc. as the Office Manager in Monsey, NY, and Caretech Group as a Customer Service Representative in Monsey, NY.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and disclosure of the applicant’s ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Cost and Financing

The total project cost, which is for renovations and the acquisition of moveable equipment, is estimated at $1,314,178 and will be met with equity.

Renovation and Demolition	$1,000,000
Design Contingency	50,000
Construction Contingency	50,000
Architect/Engineering Fees	80,000
Other Fees (Consultant)	75,000
Moveable Equipment	50,000
CON Fee	2,000
Additional Processing Fee	7,178
Total Project Cost	$1,314,178

Lease Rental Agreement

The applicant has submitted a draft lease rental agreement, summarized below:

Premises	5,520 square feet located at 84 Route 59, Suffern, New York.
Lessor	Route 59 Holdings, LLC
Lessee	BSD Birthing Center of Rockland, LLC
Term	Five (5) year term with four (4) additional five (5) year renewal terms.
Rental	$192,000 annually for the first five years ($34.78 per sq.ft.)
Provisions	The lessee shall be responsible for maintenance, real estate taxes and utilities.

The applicant has submitted an affidavit indicating that the lease agreement will be an arm's length lease arrangement. The applicant has submitted two (2) real estate letters in support of the reasonableness of the rent.

Capability and Feasibility

The total project cost of $1,314,178 will be met with equity. The applicant has indicated that this project is a conversion of an already existing PC practice to an Article 28 midwifery birthing center. BFA Attachment A, Personal Net Worth Statements - Proposed Members of BSD Birthing Center of Rockland, LLC, indicates sufficient resources to fund the total project costs. The proposed members provided an affidavit stating that the equity contributions would be disproportionate to ownership interests. BFA Attachment B, Pro Forma Balance Sheet of BSD Birthing Center of Rockland, LLC, indicates a positive net asset position of $1,314,178 as of the first day of operation.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Health Equity Impact Assessment

Health Equity Impact Assessment Summary

The independent entity evaluated data from several sources to understand the health equity impacts of the proposed midwifery birth center in Suffern, NY (Rockland County). Most engaged stakeholders (10 out of 11) indicated full support of the project. Themes of support highlight that the center will benefit people who prefer the midwifery model of care and an alternative delivery site instead of a traditional hospital setting. Stakeholders anticipate an enhanced patient experience and a culturally sensitive space for low-income residents, immigrants, and racial and ethnic minorities. The applicant estimates that most patients will be Orthodox Jewish and Medicaid recipients.

Rockland County has the highest maternal mortality rate in the Mid-Hudson region. Advancing the birth center and midwifery model of care could help reduce health disparities in this county by increasing access for vulnerable groups, like Black and Hispanic women, lowering cesarean rates, and reducing the number of medical interventions for low-risk pregnant women. Potential negative impacts were identified as language and communication barriers for women, racial and ethnic minorities, and people with disabilities. The applicant submitted a detailed mitigation plan to address these concerns.

Conclusion

Based on the information and analysis presented in the Health Equity Impact Assessment and the applicant's mitigation plan, the proposed project will not result in any significant adverse health equity impacts.

Attachments

BFA Attachment A	Personal Net Worth Statement- Proposed Members
BFA Attachment B	Pro forma Balance Sheet
OHEHR Attachment	Health Equity Impact Assessment

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 11th day of April 2024, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a Midwifery Birth Center at 84 Route 59, Suffern, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
232163 B	BSD Birthing Center of Rockland

APPROVAL CONTINGENT UPON:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of executed Transfer and Affiliation Agreements acceptable to the Department, with a local acute care hospital(s). Transfer agreements for mother and/or infant should include a list of indicators necessitating transfer and a written procedure for automatic acceptance of such transfers by the transfer hospital. [HSP]
3. The NNP will provide proof of admitting privileges at the nearest hospital. [HSP]
4. BSD will provide a formal executed and approved collaborative agreement with a pediatric provider at Good Samaritan Hospital. [HSP]
5. Submission of proof of current licensure by the New York State Education Department, Office of the Professions, for Licensed Midwife Y. Engel. [BFH]
6. Upon mutual agreement, the applicant shall submit a dually signed Transfer Agreement between the Applicant and Good Samaritan Hospital. [BFH]
7. Submission of an executed lease rental agreement that is acceptable to the Department of Health. [BFA]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by February 11, 2025, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before October 11, 2024, and construction must be completed by November 11, 2024, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a) if construction is not started on or before the approved start date this shall constitute abandonment of the approval. [PMU]
3. Provide formal arrangements for the provision of obstetrical care at the transfer hospital with a qualified physician for these services and for consultation and referral. [HSP]
4. Provide formal arrangements for the provision of pediatric care at the transfer hospital and for consultation and referral. [HSP]
5. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]

6. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https: www.health.ny.gov/facilites/hospitals/docs/hcs_access_forms_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]
7. The applicant shall submit the letter of decision and any findings as provided by the Commission; a decision by the Commission to not accredit the applicant will result in further considerations between the Department and the applicant before approval could be recommended. [BFH]
8. Upon receipt of findings of an accreditation site visit by the Commission for the Accreditation of Birth Centers, the applicant shall provide the Department with the findings of the site visit, including any documentation related to these findings, proof of the outcome of such findings. These documents will be reviewed by the Department to assess any exemptions or other findings from the Commission and will be considered prior to full approval. [BFH]
9. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in th*e Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

MEMORANDUM

To: Public Health and Health Planning Council (PHHPC)

From: Kathy Marks KSM
General Counsel

Date: March 19, 2024

Subject: Ezras Choilim Health Center, Inc. Proposed Corporate Name Change

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Attached is the proposed Certificate of Amendment of the Certificate of Incorporation of Ezras Choilim Health Center, Inc. This not-for-profit corporation is the operator of a Diagnostic and Treatment Center pursuant to Article 28 of the Public Health Law, with two extension clinics, and seeks approval to change its name to “Aizer Health, Inc.” for rebranding purposes. According to the applicant, the name change is sought “because the new name better reflects the Corporation's mission as a federally qualified health center to provide primary care services in underserved areas.”

The Certificate of Incorporation of the Corporation was filed with the Department of State on June 26, 1992, pursuant to the Not-for-Profit Corporation Law of the State of New York (the "NPCL"). A Certificate of Amendment of the Certificate of Incorporation was filed on October 13, 1995, which made technical changes to the Certificate of Incorporation. The current Operating Certificates of the entity/operator are attached.

Pursuant to 10 NYCRR § 600.11(a)(4) and NY NPCL § 804(a)(i), Public Health and Health Planning Council (PHHPC) approval is required for this change of corporate name because PHHPC (or its predecessor) previously approved the not-for-profit corporation's Certificate of Incorporation. The Corporation’s Board of Directors has approved of the name change by vote, and the Corporate Resolution/Board Minutes are attached.

Also attached is a letter dated July 21, 2023, from Jeffry Adest, attorney for the Corporation, which requests the name change and explains the intent and meaning of the proposed name change. In addition, the existing Certificate of Incorporation and amendments thereto, prior Certificate of Incorporation, proposed Certificate of Incorporation, and other associated corporate documents are attached.

The Department has no objection to the proposed name change and the proposed Certificate of Amendment is in legally acceptable form. Of note, Attorney General approval will need to be obtained after PHHPC approval.

Attachments

GARFUNKEL WILD, P.C.
ATTORNEYS AT LAW

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JEFFRY ADEST
Partner/Director
Licensed in NY, NJ, CT, PA
Email: Jadest@garfunkelwild.com
Direct Dial: (516) 393-2270

FILE NO.: 15137.0001

July 21, 2023

By FedEx

Ms. Colleen M. Leonard
Executive Secretary
NYS Department of Health
Public Health and Health Planning Council
Empire State Plaza, Corning Tower, Room 1805
Albany, New York 12237

Re: Approval of Amendment to Certificate of Incorporation
Ezras Choilim Health Center, Inc.

Dear Ms. Leonard:

Our firm is legal counsel to Ezras Choilim Health Center, Inc., (the "Corporation"), a New York not-for-profit corporation formed on June 26, 1996. The Corporation is a licensed diagnostic and treatment center under Article 28 of the Public Health Law and has been designated as a federally qualified health center.

Enclosed on behalf of the Corporation is an executed copy of the proposed Certificate of Amendment to Certificate of Incorporation of the Corporation. In addition, we enclose a complete copy of all the Corporation's Certificate of Incorporation and Certificate of Assumed Name which are on file with the New York State Secretary of State.

The Corporation wishes to change its name to "Aizer Health, Inc." because the new name better reflects the Corporation's mission as a federally qualified health center to provide primary care services in underserved areas.

Please review the enclosed proposed Certificate of Amendment to Certificate of Incorporation, and if acceptable, enclose the appropriate consent and return the original Certificate of Amendment to Certificate of Incorporation of the Corporation to us so that we may complete the filing process.

In addition, please acknowledge your receipt of the enclosed by providing your stamp or signature in the space provided below on the enclosed copy of this letter and by returning same to the undersigned in the enclosed, postage-paid, self-addressed envelope.

Very truly yours,

Jeffry Adest/eo

Jeffry Adest

Enclosures

ACKNOWLEDGMENT OF RECEIPT

I hereby acknowledge receipt of the proposed Certificate of Amendment to Certificate of Incorporation of Ezras Choilim Health Center, Inc.

_____

By: Colleen Leonard
Title: Executive Secretary
NYS Department of Health
Public Health and Health Planning Council

CERTIFICATE OF AMENDMENT

OF THE

CERTIFICATE OF INCORPORATION

OF

EZRAS CHOILIM HEALTH CENTER, INC.

(Under Section 803 of the Not-For-Profit Corporation Law)

The undersigned, being Secretary of the Board of Directors of EZRAS CHOILIM HEALTH CENTER, INC., hereby certifies:

1. The name of the corporation is EZRAS CHOILIM HEALTH CENTER, INC. (the "Corporation").

2. The Certificate of Incorporation of the Corporation was filed by the Department of State on June 26, 1992 pursuant to the Not-for-Profit Corporation Law of the State of New York (the "NPCL"). A Certificate of Amendment of the Certificate of Incorporation was filed on October 13, 1995.

3. The Corporation is a corporation as defined in subparagraph (a)(5) of Section 102 of the NPCL.

4. The Certificate of Incorporation is hereby amended to effect the following change as authorized under subparagraph (b)(1) of Section 801 of the NPCL: Paragraph FIRST of the Certificate of Incorporation, which provides the name of the Corporation as EZRAS CHOILIM HEALTH CENTER, INC. is hereby deleted in its entirety and replaced as follows:

"FIRST: The name of the Corporation is AIZER HEALTH, INC."

5. This Amendment of the Certificate of Incorporation of the Corporation was authorized by the vote of the Board of Directors.

Dated: July 21, 2023

Name: Chaim Wertzberger
Title: Secretary of the Board

CERTIFICATE OF AMENDMENT

OF THE

CERTIFICATE OF INCORPORATION

OF

EZRAS CHOILIM HEALTH CENTER, INC.

(Under Section 803 of the Not-for-Profit Corporation Law of the State of New York)

FILED BY:
KIMBERLY REDMOND, PARALEGAL
GARFUNKEL WILD, P.C.
ATTORNEYS AT LAW
350 BEDFORD STREET, STE 406A
STAMFORD, CONNECTICUT 06901

9206260007744

CERTIFICATE OF INCORPORATION

OF

EZRAS CHOILIM HEALTH CENTER, INC.

Under Section 402 of the Not-For-Profit Corporation Law

IT IS HEREBY CERTIFIED THAT

1. The name of the corporation is:

EZRAS CHOILIM HEALTH CENTER, INC.

2. The corporation is not formed for pecuniary profit or financial gain. The corporation is a corporation as defined in subparagraph (a)(5) of Section 102 (Definitions) of the Not-For-Profit Corporation Law. It shall be a Type B Corporation under Section 201 of the Not-For-Profit Corporation Law. The purposes for which said corporation are to be formed are developing policies for a comprehensive health program for those in medical need and other persons in need of comprehensive health services; receiving funds from governmental and non-governmental sources and applying same to the aforesaid purposes and to the purposes set forth and/or as payment to an appropriate licensed hospital or health agency for the delivery of comprehensive health services and the corporation shall itself have the power to establish and operate a treatment and diagnostic center within the definition of a hospital as defined in Article 28 of the Public Health Law.

For the purposes of the foregoing, in addition to and not in limitation of the powers, general or specific conferred on such corporation by the laws of the State of New York, the corporation shall have the power to receive, maintain and administer a fund or funds, and to apply the income therefrom to the purposes specified above voluntarily, to collect and distribute, directly or indirectly, funds and contributions of money, personal services and other property and other services appropriate or convenient to the effectuation of the aforesaid purposes; to acquire property for its corporate purposes by grant, gift, purchase, devise or bequest and to hold and dispose of same,subject to such limitations as may be prescribed by law.

Nothing herein contained shall authorize the doing of any act mentioned in the Not-For Profit Corporation Law, Section 404, (a-n), (p-s), (u-z).

3. This corporation shall be organized and operated exclusively for the purposes herein above stated, and the income therefore shall be derived from public and private solicitation and from governmental sources. No part of the earnings of the corporation shall inure to the benefit of any member, trustee, officer of the corporation, or any private individual (except that reasonable compensation may be paid for services rendered to or for the corporation affecting one or more of its purposes), and no members, trustee, officer of the corporation, or any private individual shall be entitled to share in the

distribution of the corporate assets or dissolution of the corporation.

4. The number of its directors shall be not less than three (3) nor more than twenty-five (25).

The names and residences of the initial directors are:

Pincus Strulovic
70 Acres Road
Monroe, New York 10950

Morris Steinberg
1 Carter Lane
Monroe, New York 10950

David Falkowitz
1 Taylor Court
Monroe, New York 10950

Alexa Indig
4 Wilson Road
Monroe, New York 10950

Max Glauber
24 Satmar Drive
Monroe, New York 10950

5. The meetings of the Board of Director shall be held only within the State of New York.

6. In furtherance of its corporate purposes, the corporation shall have all the general powers enumerated in Section 202 of the Not-For-Profit Law, together with the power to solicit grants and contributions for corporate purposes.

7. Nothing contained in the Certificate of Incorporation shall authorize the company:

(a) To carry on propaganda or otherwise attempt to influence legislation, or to participate in, or intervene in (including the publishing or distributing of statements), any political campaign on behalf of any candidate for public office;

(b) To undertake or carry on any of the activities specified in Section 404, (a-n), (p-s), (u-z),Not-For-Profit Corporation Law.

8. The office of the corporation is to be located in the County of **Orange.**

9. The Secretary of State is designated as agent of the corporation upon whom process against it may be served. The post office address to which the Secretary of State shall mail a copy of any process against the corporation served upon him is:

c/o Adrian W. Salinger, Esq.
118 West 79th Street
New York, New York 10024

10. The corporation shall be empowered to buy, own, sell, assign, mortgage or lease any interest in real estate and personal property, and to construct, maintain and operate improvements thereon necessary or incident to the accomplishment of the purposes of the Certificate and the corporation shall be empowered to borrow money and issue evidence of indebtedness in furtherance of any or all of the objects of its business, and to secure the same by mortgage, pledge or other lien on the Corporation's property and shall be empowered to do and perform all acts reasonably necessary to accomplish the purposes of the Corporation. In the event of the dissolution of the Corporation or the winding up of its affairs, or other liquidation of its assets, the Corporation's property shall not be conveyed to any organization created or operated for profit or to any individual for less than the fair market value of such property, and all assets remaining after the payment of the Corporation's debts shall be conveyed or distributed only to an organization or organizations created and operated for nonprofit purposes similar to those of the Corporation.

11. Notwithstanding any other provision of these articles, the Corporation is organized exclusively for religious,charitable or scientific purposes, as specified in Section 501 (c) (3) of the Internal Revenue Code of 1954, and shall not carry on any activities not permitted to be carried on by a corporation exempt from Federal Income Tax under Section 501 (2)(3) of the Internal Revenue Code of 1954.

IN WITNESS WHEREOF, the undersigned incorporator being at least eighteen years of age has executed and signed this certificate this 11th day of **March**, 1991.

Jean M. Sherett
c/o XL CORPORATE SERVICES, INC.
62 White Street
New York, New York 10013

STATE OF NEW YORK

COUNTY OF NEW YORK

On this 11th day of **March**, 1991, before me personally came **Jean M. Sherett** who executed the foregoing instrument, and she duly acknowledged to me that she executed the same.

Notary Public

ROSEMARIE ENGLE
Notary Public, State of New York
No. 4760542
Qualified in Nassau County
Commission Expires Dec. 31, 19 92

I, JOSEPH G. OWEN, the undersigned Acting Justice of the Supreme Court of the State of New York Ninth Judicial District, do hereby approve the foregoing Certificate of Incorporation of **EZRAS CHOILIM HEALTH CENTER INC.**

Dated: March 26, 1991
Goshen, NY

Hon. Joseph G. Owen
Acting Justice of the Supreme Court

STATE OF NEW YORK
DEPARTMENT OF LAW
ALBANY 12224

ROBERT ABRAMS
ATTORNEY GENERAL

JAMES G. MCSPARRON
DEPUTY FIRST ASSISTANT
ATTORNEY GENERAL

(518) 473-3683

March 19, 1991

Jean M. Sherett
XL Corporate Services, Inc.
62 White Street
New York, NY 10013

Dear Ms. Sherett:

RE: EZRAS CHOILIM HEALTH CENTER, INC.

Due and timely service of the notice of application for the approval of the proposed certificate of incorporation of the above-entitled organization is hereby admitted.

The Attorney General does not intend to appear at the time of application.

Very truly yours,

ROBERT ABRAMS
Attorney General

By:

RICHARD S. REDLO
Assistant Attorney General

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STATE OF NEW YORK
DEPARTMENT OF STATE
FILED JUN 26 1992
TAX $ NONE
BY: NB
ORANGE

CERTIFICATE OF INCORPORATION

OF

EZRAS CHOILIM HEALTH CENTER, INC.

Under Section 402 of the Not-For-Profit Corporation Law

RECEIVED
MAY 17 3 00 PM '91

Filed By:

Adrian William Salinger, Esq.
118 West 79th Street
New York, New York 10024

91 MAR 25 AM 10:25

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CERTIFICATE OF AMENDMENT OF THE CERTIFICATE OF INCORPORATION

OF F95101300 0 4//

EZRAS CHOILIM HEALTH CENTER, INC.

Under Section 803 of the Non For Profit Corporation Law

IT IS HEREBY CERTIFIED THAT:

1. The name of the corporation is:

EZRAS CHOILIM HEALTH CENTER, INC.

2. The Certificate of Incorporation was filed by the Department of State on the 26th day of June 1992 pursuant to Section 402 of the Not for Profit Corporation Law and is a corporation defined in subparagraph (a) (5) of Section 102-a Type B corporation under § 201.

3. The Certificate of Incorporation is hereby amended to effect the following change:

(a) to amend the typographical error in Paragraph 11 by deleting Paragraph 11 in its entirety and by replacing it with
"Notwithstanding any other provisions of these articles, the organization is organized exclusively for one or more of the purposes as specified in Section 501 (c) (3) of the Internal Revenue Code of 1986, and shall not carry on any activities not permitted to be carried on by an organization exempt from Federal income tax under IRC 501 (c) (3) or corresponding provisions of any subsequent law.

(b) to insert the following two paragraphs to be numbered Paragraphs 12 & 13,

12. In the event of dissolution, all of the remaining assets and property of the organization shall, after payment of all necessary expenses thereof, be distributed to organizations that qualify under Section 501 (c) (3) of the Internal Revenue Code of 1986, or corresponding provisions of any subsequent Federal tax laws, or to the Federal government or State or local government for a public purpose, subject to the approval of a Justice of the Supreme Court of the State of New York.

13. In any year in which the organization is a private foundation as described in Section 509 (a), the organization shall distribute its income for said period in such time and manner as not to subject it to tax under IRC 4942, and the organization shall not (a) engage in any act of selfdealing as defined in IRC 4941 (d), (b) retain an excess business holdings as defined in Section 4943 (c), (c) make any investments in such a manner as to subject the organization to tax under Section 4944, or (d) make any taxable expenditures as defined in IRC 4945 (d) or corresponding provision of any

(1)

subsequent Federal tax laws.

4. Paragraph 9 shall provide that the Secretary of State is designated as agent of the Corporation upon whom process against it may be served. Furthermore, the post office address to which the Secretary of State shall mail a copy of any process against the corporation served upon him is: 500 Forest Road, Suite 202, Monroe, New York 10950.

5. The amendment to the Certificate of Incorporation was authorized by the vote of the Board of Directors.

IN WITNESS WHEREOF, this Certificate has been subscribed September 14, 1995 by the undersigned who affirms that the statements made herein are true under the penalties of perjury.

WOLF SCHNITZER
50 Satmar Drive
Monroe, New York 10950
President and Director

SHLOMO KATZ
3 Wilson Road
Monroe, New York 10950
Secretary and Director

MARTIN SCHLESINGER
15 Satmar Drive
Monroe, New York 10950
Treasurer and Director

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951013000411

RECEIVED
OCT 12 1 08 PM '95

CERTIFICATE OF AMENDMENT TO CERTIFICATE OF INCORPORATION

OF

EZRAS CHOILIM HEALTH CENTER, INC.

RECEIVED
OCT 4 3 13 PM '95

ICC

JOSEPH A. SCHUBIN, ESQ.
Attorney(s) for
Office and Post Office Address
SCHUBIN & ISAACS
ATTORNEYS AT LAW
3054 BEDFORD AVENUE
BROOKLYN, NEW YORK 11210
(718) 377-4938
FAX (718) 692-4737

STATE OF NEW YORK
DEPARTMENT OF STATE
FILED OCT 13 1995
TAX $
BY:

To

Attorney(s) for

Service of a copy of the within **is hereby admitted.**

Dated,

Attorney(s) for .....

Sir: Please take notice

☐ *NOTICE OF ENTRY*
that the within is a (certified) true copy of a
duly entered in the office of the clerk of the within named court on 19

☐ *NOTICE OF SETTLEMENT*
that an order of which the within is a true copy will be presented for
settlement to the HON. one of the
judges

of the within named Court, at
on the day of 19 at M.
Dated,

951013000436

(3)

Yours, etc.
JOSEPH A. SCHUBIN, ESQ.
Attorney(s) for
Office and Post Office Address
SCHUBIN & ISAACS
ATTORNEYS AT LAW
3054 BEDFORD AVENUE
BROOKLYN, NEW YORK 11210
(718) 377-4938
FAX (718) 692-4737

To

Attorney(s) for

CERTIFICATE OF AMENDMENT OF THE CERTIFICATE OF INCORPORATION

OF F95101300 0 4//

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President and Director

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JOSEPH A. SCHUBIN, ESQ.
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BROOKLYN, NEW YORK 11210
(718) 377-4938
FAX (718) 692-4737

STATE OF NEW YORK
DEPARTMENT OF STATE
FILED OCT 13 1995
TAX $
BY:

To

Attorney(s) for

Service of a copy of the within **is hereby admitted.**

Dated,

Attorney(s) for .....

Sir: Please take notice

☐ *NOTICE OF ENTRY*
that the within is a (certified) true copy of a
duly entered in the office of the clerk of the within named court on 19

☐ *NOTICE OF SETTLEMENT*
that an order of which the within is a true copy will be presented for
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judges

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on the day of 19 at M.
Dated,

951013000436

(3)

Yours, etc.
JOSEPH A. SCHUBIN, ESQ.
Attorney(s) for
Office and Post Office Address
SCHUBIN & ISAACS
ATTORNEYS AT LAW
3054 BEDFORD AVENUE
BROOKLYN, NEW YORK 11210
(718) 377-4938
FAX (718) 692-4737

To

Attorney(s) for

EZRAS CHOILIM HEALTH CENTER, INC.
49 Forest Rd.
Monroe NY 10950

Minutes
Board of Directors Meeting
June 11, 2023

Present: Abraham Wieder, Chairman
Martin Schlesinger, Treasurer
Moses Goldstein, Board Member
Chaim N. Werczberger, Secretary
Nusen Weinstock, Board Member
Pinchas Kish, Board Member
Esther Srugo, Board Member
Esther Rubinstein, Board Member

Also present: Joel Mittelman, Executive Director

With a quorum present:

Chairman Wieder called the meeting to order at 10:35 AM

First item of business: review and approve the Minutes of the May 7, 2023 Board Meeting minutes.

The Chairman stated that a draft of the Minutes was distributed to the Board members prior to the meeting and asked for corrections, if any. There were none.

A motion to approve the May 7, 2023 Board Meeting minutes was made by the Chairman and was seconded by Board member Kish.

With all in favor, the resolution passed unanimously.

Seconded by Board member Goldstein, motion carried unanimously.

The next item was a review and discussion of a proposal to change the name of the center to AIZER Inc.

Chairman Wieder moved the following resolution:

Resolved: That the Center should change the name of the center to AIZER Inc. and, the Executive Director is hereby directed and authorized to submit a Certificate of Amendment to the certificate of incorporation to the New York State department of state, and to take all other necessary steps to affect the change of name.

Seconded by Board member Weiss, motion carried unanimously.

With no further business before the Board a motion to adjourn was made by the Chairman and was seconded by Board member Kish.

With all in favor, the resolution to adjourn passed unanimously.

The meeting was adjourned at 11:55 AM

Ezras Choilim
HEALTH CENTER

CERTIFICATION:

I, Chaim Wertzberger, Secretary of the Board of Ezras Choilim Health Center, Inc., hereby certify that the above minutes of the duly called meeting held on June 11, 2023 is true and accurate and that the resolutions were adopted by its Board of Directors at the same time with a quorum present.

Chaim Wertzberger, Secretary

CORPORATE BYLAWS

OF

EZRAS CHOILIM HEALTH CENTER, INC.

The name of the Corporation shall be **EZRAS CHOILIM HEALTH CENTER, INC.** (hereinafter, "the Corporation").

ARTICLE I.

PURPOSES AND POWERS

1. The purposes for which the Corporation is formed and the powers which may be exercised by the Corporation, in addition to the general powers set forth in Section 202 of the Not-for-Profit Corporation Law of the State of New York, are those set forth in its Certificate of Incorporation, to wit: developing policies for a comprehensive health program for those in medical need and other persons in need of comprehensive health services; receiving funds from governmental and non-governmental sources and applying the same to the aforesaid purposes and to the purposes set forth and/or as payment to an appropriate licensed hospital or health agency for the delivery of comprehensive health services and the Corporation shall itself have the power to establish and operate a diagnostic and treatment center (the "Center") within the definition of a hospital as defined in Article 28 of the Public Health Law. In furtherance of the foregoing corporate purposes, the Corporation shall have all of the general powers set forth in

Section 202 of the Not-for-Profit Corporation Law, together with the power to solicit and receive grants, bequests, and contributions for the corporate purposes.

2. The Corporation is not formed for pecuniary or financial gain, and no part of the assets, income or profit of the Corporation is distributable to, or inures to the benefit of, its directors or officers, except as to the extent permitted under the Not-for-Profit Corporation Law of the State of New York. No substantial part of the activities of the Corporation shall be the carrying on of propaganda, or otherwise attempting to influence legislation, and the Corporation shall not participate in, or intervene in (including the publishing or distribution of statements) any political campaign on behalf of any candidate for public office.

ARTICLE II.

NO MEMBERS

The Corporation shall have no members.

ARTICLE III.

GOVERNING AUTHORITY

1. **Board of Directors**. The governing authority and managing body of the Corporation is hereby designated as the Board of Directors (hereinafter "the Board"). It shall be the duty of the Board, and it shall have the power, to manage the property, affairs, business and concerns of the Corporation in a manner consistent with the applicable statutes and regulations of the State of New York, and the purposes and powers set forth in the Certificate of Incorporation and these Bylaws. Such duties shall include, but not be limited to responsibility for the Center's organization, operation and quality of care (including selection of the services to be provided and the locations and hours of operation); assuring compliance with federal, state and local laws;

adoption of the Center's operational, management, patient care, administrative, clinical, financial, and human resource policies; establishing personnel policies and procedures, employee grievance procedures, and equal opportunity practices; adopting policy for financial management practices, including a system to assure accountability for Center resources, budget approval, Center priorities, and long term financial planning; evaluating Center activities, including service utilization patterns, productivity, patient satisfaction, achievement of project objectives, and development of a process for hearing and resolving patient grievances; appointment, dismissal, and evaluation of the performance of the Executive Director; appointment of medical and dental staff, assignment of their clinical privileges and review of such appointments at least every two years; approval of the Center's annual budget and major resource decisions and control of all assets and funds, including making provision for annual audits; approval of written agreements and/or contracts entered into by the Center; establishment and oversight of the Center's quality assurance program; adoption of policies for the handling of patient emergencies within the Center; establishing a policy for quality-of-care audit procedures; maintenance of a properly equipped and staffed physical plant; and carrying out Board duties described elsewhere in these Bylaws. No assignment, referral or delegation of authority by the Board shall relieve the Board of any of its responsibilities nor limit any of the Board's powers.

2. **Membership and Qualifications**. Members of the Board must be at least 18 years of age and shall reflect a broad representation of the community served by the Center. More specifically:

A majority of the members of the Board must be active users of the Center's services and must reasonably represent (without imposing any quota) the individuals served by the Center in terms of such factors as race, ethnicity and gender;

No more than half of those members of the Board who are not users of the Center may be individuals who derive more than ten percent (10%) of their annual income from the health care industry;

An individual's leadership role in the community and functional expertise should be major criteria in selecting non-user members of the Board;

As a general rule, all members of the Board should live or work within the Center's service area; and no employee of the Center other than the Executive Director, and no immediate family member (i.e., spouse, child, parent, brother or sister by blood or marriage) of an employee of the Center, may be a voting or non-voting member of the Board.

The Executive Director may not serve as a voting member of the Board.

3. **Number of Directors.** The Board shall consist of not less than nine (9) and not more than fifteen (15) voting members; the exact number will be determined by a resolution of the Board. The Board may increase or decrease the number of directors of the Corporation by a vote of the majority of the entire Board, but the number of voting directors constituting the entire Board may not be less than nine (9). As used in these by-laws, the term "entire Board" means the total number of voting directors that the corporation would have if there were no vacancies. No decrease in the number of voting directors will shorten the term of any incumbent voting director.

4. **Election of Directors.** Board members shall be elected by the Board at the Annual Meeting of the Board from a proposed slate submitted to the Board by the Nominating Committee. Additional nominations may be made by sitting Board members.

5. **Classification of Voting Directors and Term of Office.** Voting Directors shall be divided into three (3) classes for the purpose of staggering their terms of office. The terms of office of the Directors initially classified shall be as follows: that of the first class shall expire at the first Annual Meeting of the Board, the second class at the second succeeding Annual Meeting, and the third class at the third succeeding Annual Meeting. After such initial classification, voting Directors elected to replace those whose terms expire at each Annual Meeting shall be elected at such meeting to hold office for a full three (3) year term in accordance with such classification. Voting Directors may be re-elected any number of times.

If the number of voting Directors is changed by action of the Board, any newly created directorships or any decrease in directorships shall be so apportioned among the classes as nearly equal in number as possible.

6. **Resignation of Directors.** Any Director may resign at any time by giving written notice thereof to the Chairman or the Secretary of the Corporation. A resignation will be effective upon delivery unless it specifies an effective date, in which case the resignation is effective at the time specified. Unless the resignation specifies otherwise, Board acceptance of the resignation is not necessary to make it effective.

7. **Removal of Directors.** Any Director may be removed as a Director at any time for cause by majority vote of the entire Board. "Cause" includes, but is not limited to, absence of a

Director from three (3) consecutive meetings of the Board without communicating to the Chairman of the Board his or her reason for so doing, or if his or her excuse should not be accepted.

8. **Vacancies.** Vacancies among the Directors may be filled by vote of a majority of the Directors then in office, even if less than a quorum exists. A Director appointed to fill a vacancy shall hold office until the expiration of the term that he or she was appointed to fill.

9. **Advisory Directors.** Former members of the Board and others having special expertise or insight that may prove helpful to the Board, may be appointed by the Board to serve as Advisory Directors. Advisory Directors may attend meetings of the Board at the invitation of the Board but may not vote or hold office and shall not be considered members of the Board for any purpose. Advisory Directors may serve as non-voting members on all committees, including committees of the Board and ad hoc committees, and may perform such other duties as may be requested by the Board.

10. **Conflict of Interest Policy.** The Board shall adopt and implement a policy that prohibits conflict of interest and the appearance of conflict of interest by Board members and officers.

11. **Compensation.** No Director will be compensated for serving as a director, except that the Corporation may reimburse Directors for expenses necessarily incurred in effecting one or more of the corporate purposes of the Corporation, provided that such expenses are approved by the Chairman or the Board.

ARTICLE IV.

MEETINGS OF THE BOARD

1. **Regular Meetings**. The Board shall meet on a monthly basis, at the Center or such other place as the Chairman may designate.

2. **Annual Meeting**. The Board shall hold an Annual Meeting of the Corporation. at a time and place fixed by the Chairman. Unless otherwise fixed, the Annual Meeting shall take place in January.

3. **Special Meetings.** Special meetings may be called by the Chairman or Executive Director. Special meetings shall be called by the Secretary after receipt in person or by mail of a request for such a meeting signed by at least three (3) members of the Board. Such a request shall specify the object of the meeting.

4. **Notice of Meetings.** Regular meetings of the Board may be held without notice if the time and place of such meetings are fixed by the Board by resolution. Notice of the date, time, place and purpose of special meetings shall be given by telephone, mail, electronic mail, or fax to all members of the Board at least three (3) days prior to the date of the special meeting. Notice of any change of the date, time or place of a regular or special meeting previously scheduled shall be given by telephone, mail, electronic mail or fax to all members of the Board at least three (3) days prior to the date of the meeting. Notice of a meeting need not be given to any Director who submits a signed waiver of notice whether before or after the meeting or who attends the meeting without protesting, prior to or at the commencement of the meeting, the lack of notice to him or her.

5. **Quorum.** A quorum shall consist of a majority of the entire Board

6. **Participating in a Meeting by Conference Telephone or Similar Means.** One (1) or more of the members of the Board or of any committee of the Board may participate in a meeting of the Board or of such committee by means of a conference telephone or other communications equipment, that allows all persons participating in the meeting to hear each other at the same time. Participation by such means shall constitute presence in person at a meeting.

7. **Majority Vote.** Except as otherwise provided in the Certificate of Incorporation, these Bylaws or the laws of the State of New York, the vote of a majority of the Directors present at a meeting of the Board, where a quorum is present, shall be the act of the Board.

8. **Action Without Meeting.** Any action which the Board or a committee thereof is required or permitted to take may be taken without a meeting if all members of the Board or the committee consent in writing to the adoption of a resolution authorizing the action. The written consents shall be filed with the minutes of the proceedings of the Board or the committee.

9. **Minutes.** A written record shall be kept of all proceedings and meetings of the Board, including findings, conclusions and recommendations. All minutes shall be approved by the Board.

ARTICLE V.

OFFICERS OF THE CORPORATION

1. **Officers.** The officers of the Corporation shall consist of a Chairman, Vice-Chairman, Secretary, Treasurer, and Executive Director, together with such other offices as may

be created by the Board. Each officer other than the Executive Director, shall be a voting member of the Board of Directors. Any two (2) or more offices may be held by the same person, except the offices of Chairman and Secretary shall be held by different persons.

2. **Election and Terms of Office.** The Chairman, Vice-Chairman, Secretary, and the Treasurer shall be elected for one (1) year terms at the Annual Meeting of the Board. Immediately after their election, those elected shall assume the responsibilities of their offices. The Executive Director shall be appointed by the Board to serve until removed or replaced by the Board. A vacancy in such offices shall be filled by the Board at its next regular meeting or at an earlier special meeting convened for that purpose.

3. **Removal.** Any officer may be removed or have his or her authority suspended by the Board at any time, with or without cause.

4. **Resignation.** Any officer may resign at any time by giving a resignation in writing to the Chairman or the Secretary. A resignation will be effective upon delivery unless it specifies an effective date, in which case the resignation is effective at the time specified. Unless the resignation specifies otherwise, Board acceptance of the resignation is not necessary to make it effective.

5. **Duties of Officers May Be Delegated.** If an officer is absent or unable to perform his or her duties, or for any other reason that the Board deems sufficient, the Board, except where otherwise provided by law, may delegate the powers or duties of any officer to any voting Director.

6. **Compensation.** No officer other than the Executive Director will be compensated

for serving as an officer, except that the Corporation may reimburse officers for expenses necessarily incurred in effecting one or more of the corporate purposes of the Corporation, provided that such expenses are approved by the Chairman or the Board.

7. **Duties of Officers.**

a. **Chairman.** The Chairman shall preside at all meetings of the Board and shall have such other duties and responsibilities as may be assigned by the Board, the Certificate of Incorporation, these Bylaws and the laws of the State of New York.

b. **Vice-Chairman.** In the event of the absence, death, removal or inability of the Chairman to discharge the responsibilities of the office, the Vice-Chairman shall assume all of the powers and responsibilities of the Chairman until a new Chair is selected by the Board. The Vice-Chairman shall have such other duties and responsibilities as may be assigned by the Board.

c. **Secretary.** The Secretary shall attend meetings of the Board, take or cause to be taken accurate minutes thereof, and distribute transcribed copies of the minutes to each member of the Board prior to the next meeting of the Board; give or cause to be given notice of all meetings of the Corporation in the manner provided in these Bylaws; keep in safe custody the Seal of the Corporation and affix it to any instrument when authorized by the Board; keep all records and minutes of meetings of the Corporation as required by law or otherwise in a proper and safe manner; have such other duties and responsibilities as shall be assigned by the Board. The Secretary shall preside at meetings of the Board in the absence of the Chairman, Vice-Chairman, and Treasurer.

d. **Treasurer.** The Treasurer shall serve on the Finance Committee and shall discharge such other duties and responsibilities as may be assigned by the Board. The Treasurer shall preside at meetings of the Board in the absence of the Chairman and Vice-Chairman.

e. **Executive Director.** The Executive Director shall be the Administrator of the Center and shall be responsible for the overall management, supervision, and operation of the Center, subject to the duties of the Board described in Article III, Section 1. The Executive Director shall provide liaison among the Board, the medical/dental staff and the Center administration; organize the administrative functions of the Center; implement policies and procedures adopted by the Board; report to the Board concerning the operation of the Center and developments that affect the operation of the Center; review and act promptly upon the reports of authorized inspecting agencies; hire and terminate Center staff; provide for the control and use of the physical and financial resources of the Center; and submit such business plans, budgets and reports to the Board as may be required by it. The Executive Director shall report to the Board at least annually or at such other times as the Board may direct, concerning the discharge of his or her duties as set forth in this Article. The Executive Director shall serve at the pleasure of the Board.

ARTICLE VI.

COMMITTEES OF THE BOARD

1. **Executive Committee.** The Board, by resolution adopted by a majority of the entire Board, may establish an Executive Committee consisting of the Chairman, Secretary, and at least one (1) other voting member of the Board appointed by the Board. In addition, the Executive

Director and the Medical Director shall be ex-officio, non-voting members of the Executive Committee. The Chairman shall serve as chairman of the Executive Committee. In the absence of the Chairman, the Secretary or such other person as the Secretary shall designate shall preside at meetings of the Executive Committee.

If appointed, the Executive Committee shall meet regularly, as authorized by the Board, and shall also meet at the call of the Chairman or Executive Director or on the personal or written request of two (2) members of the Committee to the Chairman.

Between regular meetings of the Board, the Executive Committee shall exercise the powers of the Board to the fullest extent permitted by the laws of the State of New York, except as limited by resolution of the Board.

2. **Finance Committee.** The Board, by resolution adopted by a majority of the entire Board, may establish a Finance Committee comprised of at least three (3) voting members of the Board, including the Treasurer. In addition, the Executive Director and the Fiscal Director of the Center shall be ex-officio, non-voting members of the Finance Committee. The Finance Committee shall meet at the call of the Chairman, the Treasurer, or the Executive Director.

The responsibilities of the Finance Committee shall include the following: (i) monitoring the financial operations of the Corporation and making recommendations to the Board regarding such operations, including but not limited to, the Corporation's policies and procedures regarding eligibility for services and sliding fee scale, the investment of operating and endowment funds, the financing of operating and capital needs, and long-range financial planning; (ii) assisting Center administration in developing the annual budget and any necessary amendments thereto;

(iii) reviewing financial reports and the annual financial audit prepared by the Corporation's certified public accountant; and (iv) exploring, reviewing and proposing possible sources of additional funding for the Corporation.

3. **Strategic Planning Committee.** The Board, by resolution adopted by a majority of the entire Board, may establish a Strategic Planning Committee organized for the purpose of considering and proposing to the Board short-term and long-range objectives for the growth and development of the Center. As part of this process, the Strategic Planning Committee shall examine the Center's mission, goals, policies and current programs. The Strategic Planning Committee shall meet periodically and shall be composed of voting members of the Board, the Executive Director and the Fiscal Director.

4. **Nominating Committee.** The Board, by resolution adopted by a majority of the entire Board, may establish a Nominating Committee, which shall consist of the Chairman and at least two (2) other voting directors appointed by the Board. It shall be the Nominating Committee's responsibility to submit nominations to the Board for the purpose of filling the vacant positions of members of the Board. Such nominations shall be transmitted to the Board before the Board's Annual Meeting or any other meeting at which a vacancy in the Board is to be filled.

5. **Bylaws Committee.** The Board, by resolution adopted by a majority of the entire Board, may establish a Bylaws Committee, which shall consist of at least three (3) voting directors appointed by the Board. It shall be the Bylaws Committee's responsibility to review these Bylaws for the purpose of determining and recommending to the Board any necessary or

desirable revisions. The Bylaws shall be dated to indicate the time they were last reviewed.

6. **Additional Standing Committees.** The Board may, from time to time, designate and appoint other standing committees, each consisting of at least three (3) voting directors, and define the duties and authority of such committees. The Board shall appoint a Quality Improvement/Assurance Committee in accordance with Article VII, Section 3.

7. **Advisory Committees.** In addition to standing committees, the Board may create advisory committees to serve at the pleasure of the Board and to perform tasks assigned by the Board. Persons other than directors may serve on such committees. Advisory committees have no authority to act on behalf of the Board.

8. **General Provisions.** The members and chairmen of committees shall be appointed by the Board, and each committee shall serve at the pleasure of the Board.

A majority of the voting members of a committee of the Board shall constitute a quorum. Action of a committee shall be taken by majority vote where a quorum is present.

Minutes shall be kept of all committee meetings. Such minutes shall reflect all business conducted at the meeting of the committee, including findings, conclusions and recommendations. Transcribed copies of the minutes shall be supplied to all members of the committee and to all members of the Board.

Should any member of any committee of the Board be absent unreasonably from three (3) consecutive meetings of the committee without sending a communication to the chairman of the committee stating his or her reason therefore, or if his or her excuse shall not be accepted by the

members of the committee, the chairman of the committee shall notify the Board, which may remove that committee member from the committee.

A committee shall meet at times and places determined by the chairman of the committee and specified in the notice of the meeting. Meetings of committees will be governed by the provisions of Sections 4, 6, 8 and 9 of Article IV of these by-laws, which govern meetings of the entire Board.

ARTICLE VII.

MEDICAL/DENTAL STAFF AND QUALITY IMPROVEMENT/ASSURANCE

1. **Medical/Dental Staff**. The Board shall ensure that medical and dental services are provided at the Center only by members of the medical/dental staff of the Center. The Board shall adopt and update as necessary medical and dental staff policies and procedures relating to the credentialing, appointment and reappointment (at least every two years) of members of the medical/dental staff, and obligations of the medical/dental staff. There shall be a Medical Director of the Center and a Dental Director of the dental service. The Medical Director and the Dental Director shall oversee the fitness, adequacy and quality for medical and dental care, respectively, rendered to patients in the Center by: establishing and maintaining professional standards and practice; coordinating the clinical departments of the Center; promoting the scientific and educational advancement of all members of the medical/dental staff through encouraging education; acting as a liaison whereby medico-administrative problems may be discussed and resolved among the members of the medical/dental staff and Center administration.

2. **Quality Improvement/ Assurance Program**. The Board shall ensure the development and implementation of a written quality improvement/ assurance program that includes a planned and systematic process for monitoring and assessing the quality and appropriateness of patient care and clinical performance on an ongoing basis. The program shall resolve identified problems and pursue opportunities to improve patient care. The quality improvement /assurance program shall be supervised by the Center's Medical Director in the case of medical services and the Center's Dental Director in the case of dental services, and shall include participation by administrative staff and health-care professionals representing each professional service provided.

3. **Quality Improvement/Assurance Committee.** There shall be a Quality Improvement/Assurance Committee of the Corporation, consisting of at least three (3) voting Directors. The Quality Improvement/Assurance Committee shall meet at least bi-annually and at such other times as may be requested by the Chairman for the purpose of reviewing the quality assurance plan and the activities of the medical and dental quality assurance committees created pursuant to such plan. The Quality Improvement/Assurance Committee shall make recommendations to the Board concerning the quality improvement/assurance program.

ARTICLE VIII.

INDEMNIFICATION OF DIRECTORS AND OFFICERS

1. **Indemnification**. The Corporation shall indemnify its present and former Directors and officers to the fullest extent permitted under the laws of the State of New York, against all liability, cost, and expense actually and personally incurred by or imposed upon them in connection with the defense of any action, suit or proceeding or other matter having to do with

their acts and conduct relative to the affairs of the Corporation.

2. **Insurance**. The Corporation may maintain insurance, at its expense, to protect itself and those persons entitled to indemnification under paragraph 1 of this Article against such liability, cost or expense to the extent permitted by law.

ARTICLE IX.

CORPORATE FINANCE

1. **Corporate Funds.** The funds of the Corporation will be deposited in its name with banks or other depositories designated by the Board. All checks, notes, drafts and other negotiable instruments of the Corporation will be signed only by those officers, agents or employees authorized by the Board to sign. No officers, agents or employees of the Corporation, alone or with others, have the power to make any checks, notes, drafts or other negotiable instruments in the name of the Corporation or to bind the Corporation thereby, except as provided in this section.

2. **Fiscal Year.** The fiscal year of the Corporation will be the 12-month period ending on December 31 unless otherwise determined by the Board.

3. **Loans to Directors and Officers.** No loans will be made by the Corporation to its Directors or Officers.

4. **Income from Corporate Activities.** All income from activities of the Corporation will be applied to the maintenance, expansion or operation of the lawful activities of the Corporation.

5. **Audit.** The books and financial records of the Corporation will be audited at least annually by a certified public accountant or firm of certified public accountants selected for that purpose by the Board.

ARTICLE X.
EXECUTION OF INSTRUMENTS

All corporate instruments and documents shall be signed and, where required, countersigned, and verified and acknowledged by the Chairman, Vice-Chairman, Secretary or Treasurer. The Board of Directors may also by resolution designate the Executive Director to sign instruments and documents on behalf of the Corporation

ARTICLE XI.
AMENDMENT OR REPEAL

Amendment or repeal of the Bylaws shall be by affirmative vote of two-thirds (2/3) of all of the entire Board. Notice shall be mailed to each member of the Board at least thirty (30) days prior to a meeting to consider such amendment or repeal of the Bylaws. Such notice shall fully present the current Bylaws and the proposed amendments thereof.

ARTICLE XII.

EFFECTIVE DATE

These Bylaws shall become effective the 1st day of November 2018, and replace any Bylaws previously adopted by the Corporation.

EZRAS CHOILIM HEALTH CENTER, INC.

By: _____
Abraham Wieder, Chairman

Date: 10/28/18

Facility Id. 5726
Certificate No. 3526201R

State of New York
Department of Health
Office of Primary Care and Health Systems

OPERATING CERTIFICATE

Effective Date: 01/12/2023
Expiration Date: NONE

Diagnostic and Treatment Center

Ezras Choilim Health Center Inc

49 Forest Road

Monroe, New York 10950

Operator: Ezras Choilim Health Center, Inc
Operator Class: Voluntary Not for Profit Corporation

Has been granted this Operating Certificate pursuant to Article 28 of the Public Health Law for the service(s) specified:

Clinic Part Time Services	Dental O/P	Medical Services - Other Medical Specialties	Medical Services - Primary Care	Optometry O/P
Podiatry O/P	Therapy - Occupational O/P	Therapy - Physical O/P	Therapy - Speech Language Pathology O/P	

Other Authorized Locations

Diagnostic and Treatment Center Extension Clinic

Ezras Choilim Health Center Mobile Van #1
Facility ID 15401
49 Forest Road
Monroe, New York 10950

Ezras Choilim Health Center Mobile Van #2
Facility ID 15402
49 Forest Road
Monroe, New York 10950

20230421

Deputy Commissioner, Office of Primary Care and Health Systems Management

This certificate must be conspicuously displayed on the premises.

Commissioner

Facility Id. 15401
Certificate No. 3526201R

State of New York
Department of Health
Office of Primary Care and Health Systems

OPERATING CERTIFICATE

Effective Date: 01/12/2023
Expiration Date: NONE

Diagnostic and Treatment Center Extension Clinic

Ezras Choilim Health Center Mobile Van #1

49 Forest Road

Monroe, New York 10950

Operator: Ezras Choilim Health Center, Inc
Operator Class: Voluntary Not for Profit Corporation

Has been granted this Operating Certificate pursuant to Article 28 of the Public Health Law to operate an Extension Clinic at the above site for the service(s) specified.

Medical Services - Other Medical Specialties

Medical Services - Primary Care

20230421

Deputy Commissioner, Office of Primary Care and Health Systems Management

This certificate must be conspicuously displayed on the premises.

Commissioner

Facility Id. 15402
Certificate No. 3526201R

State of New York
Department of Health
Office of Primary Care and Health Systems

OPERATING CERTIFICATE

Effective Date: 01/12/2023
Expiration Date: NONE

Diagnostic and Treatment Center Extension Clinic

Ezras Choilim Health Center Mobile Van #2

49 Forest Road

Monroe, New York 10950

Operator: Ezras Choilim Health Center, Inc
Operator Class: Voluntary Not for Profit Corporation

Has been granted this Operating Certificate pursuant to Article 28 of the Public Health Law to operate an Extension Clinic at the above site for the service(s) specified.

Medical Services - Other Medical Specialties

Medical Services - Primary Care

20230421

Deputy Commissioner, Office of Primary Care and Health Systems Management

This certificate must be conspicuously displayed on the premises.

Commissioner

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, on this 11th day of April 2024, approves the filing of the Certificate of Amendment of the Certificate of Incorporation of Ezras Choilim Health Center, Inc. dated July 21, 2023.