

NEW YORK STATE DEPARTMENT OF HEALTH  
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

RADIATION GUIDE 10.5 REV. 1  
GUIDE FOR THE PREPARATION OF APPLICATIONS  
FOR TYPE A BROAD SCOPE LICENSES

ATTACHMENTS: Licensing Guide(s) \_\_\_\_\_  
NRC Guides 8.20 and 8.23  
NYS DEC Part 381

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## 1. INTRODUCTION

### 1.1 PURPOSE OF GUIDE

This guide describes the additional information you need to provide when applying for a Type A license of broad scope (hereinafter called a broad license) for radioactive material. This information addresses administrative issues not covered in our guides for limited licenses.

### 1.2 CONCEPT AND CONDITIONS OF BROAD LICENSES

Broad licenses differ from all other types of materials licenses in that they are primarily based on the administrative procedures and organizational qualifications of the licensee to operate safely under the license rather than on a detailed review by the department of the qualifications, equipment, and procedures for each use and user. The applicant, through its radiation safety officer and radiation safety committee and based on past experience and performance under specific licenses, performs these detailed reviews in lieu of such reviews by the department. Persons licensed under broad licenses may not (1) conduct tracer studies in the environment involving direct release of radioactive material (field uses), (2) use 100,000 curies or more of radioactive material for irradiation of materials, (3) use radioactive material for medical research, diagnosis or therapy in humans unless specifically authorized in the license\*, (4) add or cause the addition of radioactive material to any food or other product designed for ingestion by or application to a human being, or (5) provide commercial services such as instrument calibration, leak-testing or radioactive waste disposal.

Broad licenses will be issued only to organizations that have:

1. Considerable experience in the use of radioactive materials under specific licenses of limited scope. Although not specified in the regulations, it is recommended that an applicant have had a limited specific license for at least a 5-year period.
2. A good performance record, including satisfactory understanding of and compliance with regulatory requirements and license conditions, based on department licensing and inspection of prior activities.
3. A radioactive materials utilization program of such scope that the organization needs a variety of radionuclides and operational flexibility to cover numerous use and users.

\* RADIATION GUIDE 10.1 is enclosed for medical-human use applicants. Other appropriate guides are enclosed for other portions of your radioactive materials program. You should submit responses to all items on the application form which apply to your program.

4. An administrative organization and procedures appropriate and adequate to ensure safe operations and to review and approve proposed uses, users, facilities, and procedures under the license.

Items 2, 3 and 4 will also determine whether licenses will be renewed as broad scope by the department, or converted to specific licenses upon renewal. The department may also act to convert a broad license to a specific license at other times when it becomes apparent that a program does not require or cannot adequately administer this type of license.

### 1.3 As Low As Reasonably Achievable (ALARA)

Item (a) of 10NYCRR 16.5 requires that persons who operate or permit the operation of radiation installations shall make every effort to maintain radiation exposures and releases of radioactive material as far below the limits of Part 16 as is reasonably achievable. License applicants should give consideration to the ALARA philosophy in the development of plans for work with radioactive materials and the ALARA concept should be incorporated into the radiation protection program.

### 1.4 RADIOLOGICAL CONTINGENCY PLANNING

NUREG-0767, "Criteria for Selection of Fuel Cycle and Major Materials Licenses Needing Radiological Contingency Plans"\* (July 1981) includes a schedule of possession limits above which contingency planning for emergency preparedness is required. A number of transuranic radionuclides have limits of less than 1 curie. The most restrictive limits for atomic numbers 1 to 83 are:

<u>Radionuclide</u>	<u>Curies</u>
I-129	1.0
I-131	3.3
I-125	8.0
P-32	15.0
Sr-90	25.0

You should submit a radiological contingency plan if (1) you request possession of radionuclides in forms other than as sealed sources and (2) the sum of the quotients of the requested quantities for individual radionuclides divided by the quantities of these radionuclides specified in the schedule of possession limits is greater than one.

You should consult NUREG-0767 for detailed calculations, but as an approximation, if the sum of the quotients for the above-listed nuclides with atomic numbers 1-83 is less than 0.9 and if no transuranic materials are required, a radiological contingency plan will probably not be required.

\* Copies may be obtained from the NRC/GOP Sales Program, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

## 1.5 PRELICENSING CONFERENCE

After an application has been reviewed by the department and found to be complete and responsive to GEN 307B and this licensing guide, a prelicensing conference may be scheduled by the department at your facility. The department licensing staff and perhaps a member of the inspection staff would participate in this visit. You should be represented by your radiation safety officer (RSO), the chairman and preferably other members of your radiation safety committee (RSC), and one or more representatives of institutional management. The management representatives may or may not be members of the RSC and may be present for the entire conference or only for the summary, as is frequently the case during licensee inspections.

Discussions during the conference provide the department staff with a better understanding of your program and qualifications that can be obtained from the review of the written application. The conference includes observation and discussion of your facilities and equipment as they exist and as they will be provided for new or expanded uses.

A prelicensing conference provides the department staff an opportunity to evaluate whether your program needs a broad license. It also provides the staff an opportunity to impress on your management, RSO, and RSC the importance of their responsibilities under a broad license and to discuss and agree upon additional information or commitments that may be needed. If a broad license is not warranted, the department staff may suggest and agree upon continuation of your program with an appropriate specific license.

## 2. FILING AN APPLICATION

You should apply for a license by completing GEN 307B. You should complete Items 1 through 4, and 26 on the form itself. For Items 5 through 25, submit the required information on supplementary sheets. You should identify and key each sheet or document submitted with the application to the item number on the application to which it refers. All typed pages, sketches, and if possible, drawings should be on 8 1/2 X 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8 1/2 X 11 inches.

You should complete all items in the application in enough detail for the department to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should not be submitted unless they are a part of an emergency response plan. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if requested by the department.

You should file your application in duplicate. Retain one copy for yourself, because the license will require that you possess and use licensed material in accordance with the statements and representations in your application and any supplements to it.

### 3. CONTENTS OF AN APPLICATION

The following comments apply to the indicated items of GEN 307B.

#### Item 1.a. - APPLICANT'S NAME AND MAILING ADDRESS

Applicants should be corporations or other institutional entities. Because a broad licensee must have a radiation safety committee, it is not appropriate for a private individual to apply for a broad license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used, as specified in Item 1.b.

#### Item 1.b. - LOCATIONS OF USE

You should specify each location of use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, State) to allow us to easily locate your facilities. A Post Office Box address is not acceptable. If radioactive material is to be used at more than one location, you must give the specific address of each location. In Items 6 through 11 of the application, describe the intended use and the facilities and equipment at each location.

If you plan to use radioactive material at temporary job sites, specify so and describe your procedures, including your procedures for transportation, storage, control of material against access by unauthorized users, and control of contamination.

#### Item 2 - PERSON TO BE CONTACTED ABOUT APPLICATION

You should name the individual who knows your proposed radioactive materials program and can answer questions about the application. Provide his or her telephone number. This individual, usually the radiation safety officer or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify his or her position and relationship to you. Notify the department if the person assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for a license amendment.

#### Item 3

Indicate whether this is an application for a new license, an amendment or a renewal.

Item 4 - RADIATION SAFETY OFFICER

State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program.

Item 5 - INDIVIDUAL USERS

The usual response should be "Radioactive materials are to be used by or under the supervision of individuals designated by the radiation safety committee." Medical-human use applicants should also state that the use of radioactive materials in or on human beings shall be by a physician who meets the training and experience criteria established in Appendix A-1 of New York State Department of Health Radiation Guide 10.1.

Item 6 - MATERIAL TO BE POSSESSED

Describe the radioactive material you wish to possess by isotope, chemical or physical form, and quantity in millicuries or microcuries. You should state the maximum quantity of each radioactive material you wish to possess at any one time. The usual entry is "\_\_\_\_\_ millicuries of each radionuclide with atomic numbers 1-83; total possession limit \_\_\_\_\_ millicuries or curies." The maximum quantities for individual nuclides and total possession should be commensurate with your needs, facilities, procedures, and personnel and should be consistent with your prior licensed activities. If a few nuclides will be needed in much larger quantities than others, they should be listed separately in Items 6a, 6b, and 6c, rather than increasing the quantity of all nuclides to include these larger quantities. If certain nuclides in the form of sealed sources will be needed in quantities larger than requested in Items 6a, 6b, and 6c in any form, these should be listed separately. Larger sealed sources should also be described by manufacturer and model number under Item 6b. Similarly, if certain relatively more hazardous nuclides (e.g., strontium-90) are not needed or are needed only in smaller quantities, they should be listed separately. The maximum quantities of nuclides with atomic numbers above 83 should be stated separately. Stored wastes should be included in establishing both individual nuclide and total maximum quantities. A typical entry for Items 6a, 6b, and 6c would be:

6a(1) Any radioactive material with atomic numbers 3-83 except as specified below.	6b(1) Any	6c(1) 50 millicuries of each radionuclide with atomic numbers 3 to 83, with a total possession limit of 2 curies except as specifically listed below.
(2) Hydrogen-3	(2) Any	(2) 1 curie
(3) Carbon-14	(3) Any	(3) 500 millicuries
(4) Iodine-125	(4) Any	(4) 300 millicuries
(5) Strontium-90	(5) Any	(5) 1 millicurie
(6) Cesium-137	(6) Sealed Source XYZ Co. Model 123	(6) 5 curies

Item 7 - PURPOSE FOR USE OF LICENSED MATERIAL

Describe in general terms the purposes for which you will use licensed material and explain why you need a broad license rather than amendments to a specific license. The uses should be consistent with your prior licensed activities. Examples of appropriate uses are "research and development" ("or research and development, including medical research, diagnosis and therapy in humans" for medical-human use applicants).

A broad license may include sealed sources for uses related to the basic purpose of the broad license (e.g., research and development or calibration of the licensee's instruments). If you desire to use an irradiator under a broad license, you should follow the guidance in separate regulatory guides that cover licenses for large sealed sources contained in irradiators. However, you may not use 100,000 curies or more of radioactive material in sealed sources for irradiation of material under a broad license.

A broad license does not authorize industrial radiography or human use of radioactive material unless these activities are specifically authorized. A broad license does not authorize the use of radionuclides in field studies that involve release of radioactive materials to the environment unless such studies are specifically authorized by a condition of the license. You should discuss proposals for such field uses with department licensing personnel before you submit an application for a license or license amendment.

Item 8.a) - INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY--THEIR TRAINING AND EXPERIENCE

8.a)1. Radiation Safety Officer

You are required to appoint a radiation safety officer (RSO) by paragraph 16.5(b) of 10NYCRR Part 16. The RSO should have an academic degree in physical or biological science or engineering and specific training in radiation health sciences and should have considerable professional experience (generally about 5 years) with radioactive materials. The RSO's professional experience should include the application of this training to the management and administration of a radiation safety program related to the types, quantities, and uses of the radioactive material to be used under this license. List and describe the training and experience of the RSO.

8.a)2. Radiation Safety Committee

You are required to establish a Radiation Safety Committee (RSC). The RSC should consist of such persons as the radiation safety officer, at least one representative of management, and technical persons representing the departments, groups, or activities that will use radioactive materials under the broad license. Each technical member of the RSC should have training and experience in the use of radioactive materials and radiation safety, but this background need not be as extensive as that of the RSO. The administrative member or members of the RSC should ensure management support of the radioactive materials program and due consideration of the financial, legal, and business interests of the organization. Administrative members of the RSC need not have a background in radiation safety.

You should identify the chairman and members of the RSC and their positions in your organization. Describe each member's formal training and work experience with radioactive materials and radiation safety. Either a resume for each individual or a generic description of the minimum requirements for these positions may serve to describe training and experience.

#### Item 8.b) - RADIATION SAFETY PROGRAM

Broad scope licenses will only be issued to organizations who have considerable experience in the use of radiological material and have established administrative controls and provisions related to organization and management, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations under the license. You should describe these organizational matters and internal procedures of your proposed program. Your description should be in narrative form and should include the elements identified below.

##### 8.b)1. Previous Licenses

List the present and previous radioactive materials licenses for which this application requests a continuation or expansion of activities.

##### 8.b)2. Radiation Safety Committee

Your RSC should establish policies and overall guidance for your radioactive materials program and should review, approve, and record safety evaluations of proposed uses of radioactive material before such use. The RSC should conduct a periodic audit of the safety program and review the activities of the RSO and the records that must be maintained to ensure compliance with conditions of the license and applicable parts of the department's regulations. The RSC should meet as often as necessary to conduct its business (but not less than quarterly) and should keep minutes of committee meetings and activities.

You should describe the responsibilities and duties assigned to the RSC, the authority delegated to the RSC, and the frequency and quorum required for RSC meetings.

##### 8.b)3. Radiation Safety Officer

The RSO should be responsible for the day-to-day coordination and management of the radiation safety program within your organization and should ensure compliance with the conditions of your license and New York State regulations. The RSO should report to top management in a staff capacity, should have ready access to all levels of the organization, and should have authority to immediately terminate a project that is found to be a threat to health, safety, or property. The RSO position for a broad-license program is usually a full-time assignment and is sometimes supported by a staff. You should indicate whether the RSO position is a full-time assignment and should state the size of the staff.



You should list the responsibilities and duties of the RSO in your application. The extent of these responsibilities and duties will depend on the scope of the proposed broad license; however, the following should be considered and included, if applicable:

1. Coordinating the RSC's review of safety evaluations of all proposed uses of radioactive material.
2. Generally overseeing all activities involving radioactive material, including conducting routine monitoring and special surveys of all areas in which radioactive material is used. The RSO generally conducts periodic surveys of work areas to supplement and audit routine monitoring by authorized users. You should indicate the types and frequencies of monitoring and surveys to be performed by the RSO.
3. Determining compliance with rules and regulations, license conditions, and the conditions of project approval specified by the RSC.
4. Receiving, opening, and delivering all shipments of radioactive material arriving at the institution and receiving, packaging, and shipping all radioactive material leaving the institution.
5. Maintaining an inventory of all radionuclides at the institution and limiting the quantities of radionuclides to the amounts authorized by the license. The inventory record should include the name of the person responsible for each quantity of radionuclide, where it will be used or stored, and the date the quantity was delivered to that person. When items are removed from the inventory, it should show how and when the radionuclide was disposed of.
6. Supervising and coordinating the radioactive waste disposal program, including keeping waste storage and disposal records and monitoring effluents.
7. Storing all radioactive materials not in current use, including wastes.
8. Distributing personnel monitoring devices and arranging for their processing, determining the need for and evaluating bioassays, keeping records of personnel exposures and bioassays, notifying individuals and their supervisors of exposures that are approaching maximum permissible amounts, and recommending and supervising appropriate remedial action.
9. Performing or arranging for calibration of instruments.
10. Performing leak tests on sealed sources.
11. Conducting training programs and otherwise instructing personnel in the proper procedures before they are allowed to use radioactive material and as required by changes in procedures, equipment,

regulations, etc. All individuals working in or frequenting a restricted area must receive instructions according to §16.13 of JONYCRR16. These individuals include not only radiation workers but also others such as clerical, custodial, and maintenance personnel.

12. Furnishing consulting services on all aspects of radiation safety to personnel at all levels of responsibility.
13. Monitoring and maintaining special filter systems associated with the use, storage, or disposal of radioactive material.
14. Supervising decontamination in case of contaminating accidents.
15. Maintaining other records not specifically designated above, e.g., records of surveys, radiation monitoring, and disposal, and records of receipts and transfers, of material.

#### 8.b)4. Administrative Procedures

You should establish administrative procedures to ensure control of procurement and the use of radioactive material and to ensure completion of safety evaluations of proposed uses of radioactive material. The safety evaluations should include a determination of the adequacy of facilities and equipment, training and experience of the users, and operating or handling procedures.

##### 8.b)4.1. Control of Procurement and Use

Your application should describe the administrative procedures you have established to ensure that all procurement, use, and users of radioactive material are properly authorized by the license and approved by the RSC. Licenses usually have a procedure that centralizes all purchases or other procurement through an authorized purchasing agent in order to verify that the procurement and use are authorized under the license. If you do not use such a centralized procedure, describe how your procedure prevents unauthorized procurement and use.

##### 8.b)4.2. Safety Evaluations of Proposed Uses

Your application should describe in detail the procedures and criteria for conducting the safety evaluations for approving uses and users. Some licensees with broad licenses use application forms and guidance adapted from department forms and radiation guides to do the equivalent of a licensing review of each proposed use. A copy of your request and approval forms, if available, would be helpful to the department in its review of your application. Your procedures and criteria should include the evaluation and approval of:

1. Training and experience requirements for project supervisors and individual users who will use material without direct supervision.

2. Facilities and equipment for each specific use. The following should be considered:
  - a. Shielding,
  - b. Containment (hoods, filters, gloveboxes),
  - c. Restricted area controls and posting,
  - d. Remote handling equipment, and
  - e. Survey and monitoring instruments.

You should also include a commitment to keep, for the duration of your license, records of proposed uses approved by the Radiation Safety Committee.

Items 9 and 10 - See Applicable Guide.

Item 11 - FACILITIES AND EQUIPMENT

Describe the facilities and equipment available in major areas of use including diagrams and locations. Include special considerations for iodination labs, hot cells, waste storage areas, hot labs, source storage areas, animal labs, etc. Your administrative procedures for internal control of uses under the broad license (discussed in Item 8.b) should include provisions for determination that your facilities and equipment are adequate for uses that may be approved by the Radiation Safety Committee.

Items 12 through 16 - See Applicable Guide.

Item 17 - WASTE MANAGEMENT

Describe your program for management of the institution's radioactive waste.

Appendix J of our licensing guides describes acceptable methods of disposal. You should state that your users will follow the model procedures and describe methods of ensuring compliance.

Describe your centralized waste management procedures (collection, processing, record keeping, quality assurance.)

Enclosed is a copy of the New York State Department of Environmental Conservation regulations on transport of low level radioactive waste. You should be familiar with their requirements and apply for a permit if applicable.

Items 18 through 25 - See Applicable Guide.

Item 26 - CERTIFICATION

The application should be dated and signed by the director or chief executive officer. Identify the title of the office held by the individual who signs the application.