

Municipal Public Health Services Plan - Radioactive Material and Radiation Equipment

Effective date: 12/28/11

Pursuant to the authority vested in the Commissioner of Health by article 6, sections 602, 603 of the Public Health Law, Part 40 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon filing with the Department of State, to read as follows:

Subpart 40-3 is REPEALED, in its entirety. Subpart 40-2 is amended and new subdivisions 40-2.240, 40-2.241, 40-2.250, and 40-2.251 are added to read as follows:

40-2.240. Radioactive materials licensing and inspection program; performance standard.

The municipal public health services plan shall include a radioactive materials licensing and inspection program containing those provisions set forth in section 40-2.241 of this Subpart, if the Department has authorized the municipality to conduct such a program.

40-2.241. Radioactive materials licensing and inspection program; authorization.

The department shall authorize a municipality's radioactive materials licensing and inspection program if such program includes, at a minimum, provisions for:

(a) regulating all facilities in the municipality's jurisdiction;

(b) ensuring the technical quality of licensing actions by the municipality;

(c) assessing licensee compliance with Part 16 of the State Sanitary Code and conditions of the license, and ensuring correction of violations; and

(d) inspecting regulated facilities at a frequency established by the department.

40-2.250. Radiation-producing equipment program; performance standard.

The municipal public health services plan shall include a radiation-producing equipment inspection program containing those provisions set forth in section 40-2.251 of this Subpart, if the department has certified such a program for the municipality.

40-2.251 Radiation-producing equipment program; authorization.

The department shall certify a municipality's radiation producing equipment inspection program if such program includes, at a minimum, provisions for:

(a) inspecting all facilities and equipment in the municipality's jurisdiction; and

(b) performing inspections and issuing reports in accordance with Part 16 of the State Sanitary Code and, in particular, reporting as described in section 16.10.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Article 6 of the Public Health Law (PHL) provides statutory authority to provide State aid to municipalities for general public health work (GPHW). PHL § 614(3) defines municipality to be a county or city. PHL § 602(3)(b)(5) provides that GPHW must include certain health services, including environmental health services. PHL § 602(3)(a) authorizes the Commissioner to adopt rules and regulations after consulting with the Public Health and Health Planning Council and county commissioners, boards, and the public health directors, to establish standards of performance for environmental health services delivered under the GPHW program.

Legislative Objectives:

The State Legislature recently amended PHL § 605 to eliminate “optional services” as a category of services eligible for State aid reimbursement. These optional services are still described in regulations of the Department of Health (Department) at 10 NYCRR subpart 40-3. Repealing subpart 40-3 will eliminate this superfluous language.

However, two of the optional services that are no longer eligible for State aid are regulation of radioactive materials and regulation of radiation producing equipment. The Department recognizes that radioactive materials and radiation producing equipment present significant environmental health hazards to the public. The Department should encourage counties to protect their citizens from the potentially harmful effects of

radioactive materials and radiation producing equipment by providing State aid to offset the cost of these services.

The Department further recognizes that not every county has the technical capability to regulate radioactive materials and radiation producing equipment. Counties without such technical capability should not be precluded from receiving State aid for public health work. Accordingly, the proposed regulation provides that a county that wishes to receive State aid must regulate radioactive materials and equipment only if its programs have the technical capability to do so, as authorized or certified by the Department.

Needs and Benefits:

Pursuant to a New York State agreement with the federal Nuclear Regulatory Commission (NRC), radioactive materials must be regulated throughout the State. Currently, the New York City Department of Health and Mental Hygiene (DOHMH) is the only municipality certified by the Department to regulate radioactive materials; the State provides this service in all other counties. DOHMH licenses and inspects approximately 350 radioactive material facilities in New York City. By protecting the public from the environmental health hazards from these radioactive materials, DOHMH provides a substantial benefit to the public health.

Additionally, pursuant to Part 16 of the State Sanitary Code, the Department has certified DOHMH and four additional counties (Suffolk, Westchester, Dutchess and Niagara) to inspect radiation producing equipment. DOHMH and these additional counties license

and inspect nearly 10,000 radiation equipment facilities. Like the radioactive materials program, these municipalities offer a substantial public health benefit by protecting their citizens from the environmental health hazards potentially created by radiation producing equipment.

Failure to conduct timely inspections of any of these facilities could result in equipment failure or technician errors going unnoticed and uncorrected for longer periods of time, resulting in radiation overexposure during diagnostic or therapeutic procedures or misadministration of nuclear medicine for patients who require these life-saving health services. Inspection of facilities that use radioactive materials ensures appropriate handling and minimizes exposure to workers, the public and the environment. A security check of high-risk radiation sources is also conducted during these inspections.

A recent series of New York Times articles indicate the public's concern over radiation medical events and malpractice has significantly and justifiably increased. Recent events in Japan further indicate that the public is highly concerned about radiation exposure.

During the week of March 14, 2011, the Department's Bureau of Environmental Radiation Protection received approximately 40 calls every day from concerned citizens with concerns about exposure. The public rightfully expects a robust regulatory program, which DOHMH and other counties currently provide, through their partnership with the Department.

Due to the public health threat presented by radiation, it is imperative that these local governments continue to operate their radiation protection programs. The proposed regulation ensures that municipalities have the resources to protect the public from the environmental health threat posed by radioactive materials and radiation producing equipment.

Costs to Regulated Parties for the Implementation of, and Continuing Compliance with, the Rule:

Because the regulated municipalities are currently performing these programs, there will be no increase in their costs. Rather, regulated municipalities that wish to continue these programs will save money by continuing to receive State aid. However, without this regulatory change, the costs to municipalities that wish to continue these programs will increase substantially.

Costs to the Agency, the State and Local Governments for the Implementation of the Rule:

The municipalities that operate these programs and receive funding have indicated they would discontinue the programs if State aid is not provided. By encouraging counties to continue these programs, the Department will save money. As noted, pursuant to the State's agreement with the federal Nuclear Regulatory Commission, if DOHMH ceases to regulate radioactive materials, the State must do so. This will cost substantially more than the \$370,000 in State aid that was paid to New York City in State aid in 2009, which represented only 26% of DOHMH's total costs for regulating radioactive materials.

Although the NRC could theoretically take over regulation of radioactive materials, the burden on local businesses to pay federal fees would be more than five (5) times higher

than the costs imposed by programs operated by State or local government. Similarly, and as a matter of sound public policy, if municipalities cease to regulate radiation producing equipment the Department would take over these programs.

In 2009, the cost to the State to fund the municipalities that conduct these programs was approximately \$560,000. Specifically, New York City was reimbursed \$370,000 for its radioactive materials inspection and licensing program and \$119,000 for the radiation producing equipment program, for a total of \$489,000. Two other counties were reimbursed approximately \$71,000 for their radiation producing equipment programs. The remaining two counties recovered enough in fees that year that they exceeded their expenses for their radiation producing equipment programs and did not receive State aid. These costs are not expected to change if the proposed regulations are adopted.

It would be fiscally inefficient for the State to take over programs that are already operational in these municipalities, considering the initial cost of transition and the continuous costs of travel for State employees. Thus, this regulation represents both good public health policy as well as sound fiscal policy.

The Information, Including the Source(s) of Such Information and the Methodology, upon Which the Cost Analysis is Based:

The cost analysis is based on calendar year 2009 State Aid claims provided by municipalities, as currently required by PHL § 618 and 10 NYCRR § 40-1.20(b). An annual summary of State aid is routinely prepared by the Department.

Local Government Mandates:

This proposed rule does not impose any program, service, duty or responsibility upon the municipalities that has not already been agreed to and certified by the Department.

Paperwork:

The requirements for reporting will remain unchanged.

Duplication:

There are no relevant rules and other legal requirements of the state and federal governments, that duplicate, overlap or conflict with the proposed rule.

Alternatives:

The alternative is for the Department to take over regulation of radioactive materials as well as regulation of radiation producing equipment in those municipalities that discontinue these programs because they are ineligible for State aid. It is estimated that this alternative would cost the State over \$3,000,000, based on the cost of funding the 22 FTEs currently employed by the municipalities to operate these programs. This number does not include clerical, administrative, and management positions that support the municipal programs.

Federal Standards:

There is no federal minimum standard that determines whether the State must supply State aid to municipalities that choose to provide these services. However, the federal government does require that these programs be provided throughout the State.

Compliance Schedule:

The regulations will take effect upon filing with the Department of State.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect on Small Business:

This rule will apply to county radiation programs that are certified or become certified in the future. Currently only Dutchess, Niagara, Westchester, Suffolk counties and New York City have such programs. The proposed regulatory change will result in no additional cost to these local governments.

However, without this change, the fees that registered facilities must pay are likely to increase. 10 NYCRR 16.41 (c) and (d) indicate the fees for State inspection programs and county inspection programs, respectively. In all cases, the State fees are higher. Thus, if the State is required to take over these programs, the fee costs will increase. This will result in an increase in costs to small businesses. Further, if the federal NRC were to take over regulation of radioactive materials, the cost to small business would be at least five (5) times higher than it is now.

Compliance Requirements:

The certified county programs already meet the requirements and comply with the regulations. Facilities inspected will still be required to meet the requirements of Part 16, regardless of whether they are inspected by county inspectors or State inspectors.

Professional Services:

Certified counties do not need professional services to establish or maintain certification.

Capital Costs and Annual Costs of Compliance:

There are no capital costs associated with this regulation.

Economic and Technology Feasibility:

The proposed regulatory change will result in no additional cost to local governments or impose any new technology requirements or costs.

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Thus, if the State is required to take over these programs, the fee costs will increase. This will result in an increase in costs to small businesses. Further, if the federal NRC were to take over regulation of radioactive materials, the economic cost to small business would be at least five (5) times higher than it is now.

Minimizing Adverse Impact:

No adverse impact of implementation has been identified. Failure to implement may result in some county programs dropping certification, which will then require the State DOH to implement these programs.

Small Business Input:

No small businesses were surveyed. The proposed changes do not have any direct effect on small business. Failure to implement these changes may result in fee increases for small business.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

No affected county programs are classified as rural areas (18 counties with less than 200,000 population and 9 counties with certain townships with a population density less than 150 persons/square mile).

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

There are no new reporting requirements contained in the proposed regulations. No additional professional service costs are anticipated.

Costs:

No rural counties affected.

Minimizing Adverse Impact:

No rural counties are affected by this regulation.

Rural Area Participation:

No communications were made with rural counties.

JOB IMPACT STATEMENT

Nature of Impact:

No jobs will be adversely affected by adoption of these regulations. The proposal does not change the regulatory requirements on regulated entities.

Categories and Numbers Affected:

The certified counties include Dutchess, Niagara, Westchester, Suffolk and New York City.

Regions of Adverse Impact:

No regions will be adversely impacted by the adoption of these regulations

Minimizing Adverse Impact:

As stated, no jobs will be adversely affected by the adoption of the proposed changes in the regulations.

EMERGENCY JUSTIFICATION

On July 1, 2011, state funding for municipal programs to conduct inspections of x-ray facilities and regulate and control radioactive material use in New York City ceased to be available because the Legislature repealed the enabling statute. This emergency regulation moves these programs under a new basic State aid environmental health program. See Public Health Law § 602(3)(b)(5). The Commissioner has authority to issue regulations for basic State aid programs under Public Health Law § 602(3)(b).

If the City discontinues its radioactive materials program, the State must take over this work pursuant to its agreement with the federal Nuclear Regulatory Commission. If municipalities discontinue their x-ray inspection programs, the State will be required to take over this work pursuant to the Public Health Law. The fiscal impact to the State of taking over these programs would be significant.

In 2009, the cost to the State to continue to fund the municipalities that are conducting these programs was approximately \$560,000. It is estimated that the cost to the Department to take over these programs would exceed \$3,000,000. It would be fiscally inefficient for the State to take over programs that are already operational in these municipalities, considering the initial cost of transition and the continuous costs of travel for State employees. Thus, this regulation represents both good public health policy as well as sound fiscal policy.

It is imperative that these local governments continue to operate their radiation protection programs. The proposed regulation ensures that municipalities have the resources to protect the public from the environmental health threat posed by radioactive materials and radiation producing equipment.