

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 201, 225, and 3502 of the Public Health Law, Parts 16 and 89 of Title 10 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:

New section 16.70 is added to Part 16 to read as follows:

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 μ Sv (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 § 16.50 of this Part; and

(ii) 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 § 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, 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 § 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 and 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 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.

Section 89.30 is amended by adding a new subdivision (c) to read as follows:

(c) A person employed at a local correctional facility, as defined by Correction Law section 2(16), is exempt from licensure as a radiologic technologist when operating body imaging scanning equipment that applies ionizing radiation to humans for purposes of screening inmates committed to such facility, in connection with the implementation of such facility's security program.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The Department of Health (Department) is required by Public Health Law (PHL) § 201(1)(r) to supervise and regulate the public health aspects of ionizing radiation. PHL § 225(4) authorizes the Public Health and Health Planning Council (PHHPC) 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) and (q) and 201(1)(r) authorize PHHPC to establish regulations in the SSC to protect the public from the adverse effects of ionizing radiation.

PHL § 3502 authorizes personnel employed at local correctional facilities to utilize body imaging scanning equipment that applies ionizing radiation to humans for purposes of screening inmates as part of the facilities' screening program, provided that the use of such equipment is in accordance with regulations promulgated by the Department.

Legislative Objectives:

The legislative intent of PHL §§ 201(1)(r) and 225(5)(p) and (q) is to protect the public from the adverse effects of ionizing radiation. Establishing regulations to ensure safe and effective use of radiation producing equipment is consistent with this legislative objective.

The legislative intent of Article 35 of the PHL is to ensure that when radiation is applied to a human being it is being done appropriately and by a qualified individual. Although in general radiation should only be applied to humans for medical reasons, PHL § 3502 allows correctional facilities to utilize very low dose x-ray equipment for security screening of inmates, while protecting the health of screened inmates.

Needs and Benefits:

Effective January 30, 2019, PHL § 3502(6) permits unlicensed personnel working at local correctional facilities to utilize body imaging scanning equipment that applies ionizing radiation to humans, for purposes of screening inmates committed to such facilities, in connection with the implementation of a facility's security program. Such equipment can be an efficient method of detecting contraband, such as knives, other weapons, and illegal drugs including heroin and opioids, and will enhance the safety of both inmates and correction officers.

These regulations provide protections to the inmates and staff by establishing requirements and controls to ensure appropriate operation of the body scanning imaging equipment. These include testing of the equipment by a licensed medical physicist prior to use and annually thereafter; annual training for equipment operators to ensure proper operation and application; establishment of policies and procedures for use of the equipment; and documentation and inspection requirements to monitor and ensure that inmates are not overexposed to radiation based on the dose limits set forth in the law. The regulations will permit local correctional facilities to take advantage of the enhanced security that body imaging scanning equipment can provide, while minimizing the risk to inmates posed by exposure to ionizing radiation.

Costs:**Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:**

The regulations will impose little or no cost to regulated entities. The regulations would only apply to local correctional facilities that voluntarily choose to use body imaging scanning

equipment as part of the facility's security program. Local correctional facilities that choose to utilize body imaging scanning equipment will be subject to equipment purchase costs; costs to hire a licensed medical physicist to test the body scanning imaging equipment annually, at a cost of approximately \$500 per test; administrative costs associated with maintaining records of the use of the equipment; and annual staff training costs. County facilities must register their new x-ray equipment, but they are fee-exempt and will not be charged by the Department for registration or inspections.

Costs to State and Local Governments:

These regulations apply only to local correctional facilities operated by county governments that voluntarily choose to use body imaging scanning equipment as part of the facility's security program. Such facilities will be subject to the costs described above.

Costs to the Department of Health:

This regulation will require an increase in inspections of no more than 60 additional facilities out of a total of approximately 11,000 currently registered facilities that are inspected by the Department's Bureau of Environmental Radiation Protection. The Department will incur costs through preparing and disseminating guidance to the New York State Commission of Correction (NYSCOC) and the NYS Sheriffs Association as well as any local correctional facilities that wish to utilize body imaging scanning equipment. Staff time for registering, inspecting and providing guidance is expected to be handled using existing resources and staff.

Local Government Mandates:

The regulation does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district. The regulations apply only to local correctional facilities that voluntarily choose to use body imaging scanning equipment as part of the facility's security program. Such facilities will be subject to the costs described above.

Paperwork:

Local correctional facilities that voluntarily choose to use body imaging scanning equipment as part of the facility's security program will be required to register the equipment and maintain records related to the policies, procedures and utilization of the equipment.

Duplication:

The regulations do not duplicate, overlap or conflict with any existing federal or state rules or regulations.

Alternatives:

There are no suitable alternatives to the regulations that would meet the requirements of PHL § 3502 while adequately protecting the health of inmates.

Federal Standards:

Not applicable. The operation of radiation producing equipment is regulated by the State only.

Compliance Schedule:

There is no compliance schedule imposed by these regulations, which shall be effective upon publication of a Notice of Adoption in the New York State Register.

Contact Person:

Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

**REGULATORY FLEXIBILITY ANALYSIS FOR
SMALL BUSINESSES AND LOCAL GOVERNMENTS**

Effect of Rule:

The regulation will only apply to local correctional facilities, operated by county governments, that voluntarily choose to use body imaging scanning equipment as part of the facility's security program. This regulation will not impact local governments unless they operate such facilities. The regulation will have no impact on small businesses.

Compliance Requirements:

A local correctional facility that chooses to use body imaging scanning equipment as part of the facility's security program will need to ensure that equipment is installed properly and is operating as designed through licensed medical physicist verification. In addition, the local correctional facility must develop and maintain policies and a procedure manual; provide all personnel who will utilize the equipment with required training; and maintain records of the utilization.

Professional Services:

A local correctional facility that chooses to use body imaging scanning equipment as part of the facility's security program will be required to have equipment installed by qualified installers for the specific brand of body imaging scanning equipment being used. At facilities with female inmates, the jail physician will be required to develop policies regarding the determination of pregnancy and to update those policies over time as needed. Body scanning

imaging equipment will require annual testing by a licensed medical physicist with an estimated cost of approximately \$500; such testing is also required prior to use of the equipment.

Compliance Costs:

A local correctional facility that chooses to use body imaging scanning equipment as part of the facility's security program will acquire the equipment based on their own requirements. Annual compliance costs are expected to be minimal, and will consist of the costs of refresher training, annual testing by a licensed medical physicist, and record keeping of the inmates scanned.

Economic and Technology Feasibility

This regulation is economically and technically feasible, as these regulations only impose requirements on local correctional facilities that choose to use body imaging scanning equipment as part of the facility's security program. Such facilities will acquire equipment based on their own requirements and, as described above, ongoing compliance costs are minimal.

Minimizing Adverse Impact:

The impact of this regulation is expected to be minimal as these regulations only impose requirements on local correctional facility that choose to use body imaging scanning equipment as part of the facility's security program. To assist such facilities in minimizing any adverse impact, the Department will provide guidance to NYSCOC and the NYS Sheriffs Association as well as any local correctional facilities that wish to utilize body imaging scanning equipment.

Small Business and Local Government Participation:

The Department has consulted with the NYS Sheriffs' Association and the New York City Department of Health and Mental Hygiene during the development of the regulations.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement under the proposed regulation. This regulatory amendment governing the utilization of body imaging scanning equipment by local correctional facilities does not mandate that local correctional facilities use such equipment. Hence, no cure period is necessary.

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 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<http://quickfacts.census.gov>).

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates 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 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

Every county in NYS operates a local corrections facility, except Greene and Schoharie counties where the local corrections facilities are currently out of commission. They anticipate

eventually being back in operational status. Approximately 77% of local correctional facilities are in rural areas.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

A local correctional facility that chooses to use body imaging scanning equipment as part of the facility's security program will need to ensure that equipment is installed properly and is operating as designed through licensed medical physicist verification. In addition, the local correctional facility must develop and maintain policies and a procedure manual; provide all personnel who will utilize the equipment with required training; and maintain records of the utilization.

Costs:

A local correctional facility that chooses to use body imaging scanning equipment as part of the facility's security program will acquire the equipment based on their own requirements. Annual compliance costs are expected to be minimal, and will consist of the costs of refresher training and record keeping of the inmates scanned.

Minimizing Adverse Impact:

The impact of this regulation is expected to be minimal as these regulations only impose requirements on local correctional facility that choose to use body imaging scanning equipment as part of the facility's security program. To assist such facilities in minimizing any adverse

impact, the Department will provide guidance to NYSCOC and the NYS Sheriffs association as well as any local correctional facilities that wish to utilize body imaging scanning equipment.

Rural Area Participation:

The Department consulted with the NYS Sheriffs' Association during the development of the regulation. Sheriff's operate all the local correctional facilities in NYS except for Westchester County and New York City. They indicated that there were no specific issues in this rule that would impact the use body scanning equipment at rural facilities.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (“Department”) received two public comments in response to the proposed rulemaking amending Sections 16.70 and Part 89 of Title 10 of the New York State Code of Rules and Regulations. The comments and the Departments responses are summarized below.

Comment: A commenter requested that the Legislature and Department consider shifting resources away from surveillance through body scanning imaging equipment and toward providing adequate mental healthcare.

Response: This request is outside the scope of this proposed rulemaking, which implements legislation specifically permitting the use of body scanning equipment for purposes of implementing security screening programs at local correctional facilities. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter requested that the Department require facilities to provide inmates with more information concerning the risks of body scanning imaging equipment and access to their personal dose information.

Response: The maximum allowed annual exposure for inmates is low and does not represent a level of risk that is distinguishable from background levels of exposure. The rulemaking requires the reporting of exposure information to inmates upon release or transfer. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter suggested that local correctional facilities should only routinely scan those inmates that have a recorded history of contraband use, and that inmates should be provided with an opt-out option to avoid a scan and instead have a body search.

Response: Exposure levels permitted by the proposed regulations are low and do not represent a level of risk that is distinguishable from background levels of exposure. Provided that the use of body scanning equipment is in compliance with the proposed regulations, decisions concerning overall security and inmate supervision are appropriately the responsibility of the local correctional facility. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter suggested that local corrections facilities develop policies to only permit female corrections officers to scan female inmates and provide for confidential handling of scanned images, to require immediate destruction of images if no contraband is identified, and to impose penalties on any corrections officer identified misusing the images generated by the equipment.

Response: This suggestion is outside the scope of this proposed rulemaking. Decisions related to inmate supervision are the responsibility of the local correctional facility. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter requested that local correctional facilities maintain records of body scanner use upon intake, after visits, and upon the suspicion of contraband, but not upon “any other event that triggers the use of such equipment,” as required by Section 16.70(c)(6)(i).

Response: This requirement to maintain records of the use of body scanners upon “any other event that triggers the use of such equipment” ensures that all uses of the scanner are documented, regardless of the reason, so that records and documentation are complete. This requirement does not place an unreasonable burden on the facility. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter requested clarification that exposure limits established by the regulation were intended to be an annual sum.

Response: The exposure limits established by this regulation are expressly “annual exposure limits,” a term that is consistently used throughout Public Health Law (PHL) Article 35 and 10 NYCRR Part 16. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter requested Section 16.70(d)(3) be amended to read “incidents, including any complaint by inmates of misuse or abuse of equipment, or any injuries...”

Response: The proposed regulation requires the reporting of any “incidents” resulting from the use of body scanning imaging equipment or reported by persons scanned by the equipment. Further qualification of this requirement is not necessary. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter suggested promoting increased training and professionalism among those who operate the body scanning imaging equipment, and a requirement for operators to

obtain a license, to ensure that such equipment is not used excessively or without appropriate cause.

Response: These regulations address training requirements for operators and documentation of such training. Imposing a licensing requirement on operators would require an amendment of PHL § 3502(6), which specifically permits unlicensed personnel working at local correctional facilities to utilize body imaging scanning equipment. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter suggested that the Department require additional reporting mechanisms to enable greater long-term effectiveness of the equipment.

Response: PHL § 3502(6) already requires that “any local government agency that utilizes body imaging scanning equipment in a local correctional facility under its jurisdiction shall submit an annual report to the department, the speaker of the assembly, and the temporary president of the senate. Such report shall be submitted within eighteen months after the initial date of registration of such equipment with the department, and annually thereafter.” The statute further specifies the content of such report. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter requested clarification of the term “image usefulness.”

Response: The regulations require that body scanning imaging equipment must not be operated unless they produce images that can be used for satisfactory security screening purposes. Local correctional facilities, in consultation with a licensed medical physicist, are responsible for

determining whether their equipment can produce images of sufficient quality to meet this requirement.

Comment: A commenter suggested that radiation protection surveys required upon installation or major repair of body scanning imaging equipment could be conducted by a “certified health physicist” rather than a “licensed medical physicist,” as currently required, and further commented that the costs associated with licensed medical physicists exceeded the Department’s estimates.

Response: Article 166 of the Education Law requires that a licensed medical physicist oversee the quality assurance of diagnostic imaging. A Certified Health Physicist may be able to perform certain other radiation protection functions, but a licensed medical physicist is the best qualified to make determinations of image quality.

The cost estimate provided by the Department was based on the initial radiation protection survey, the shielding evaluation, the verification of image usefulness for detecting foreign objects, and the annual testing to assure proper operation of equipment. While facilities may employ licensed medical physicists for other related radiation safety and training activities, the tasks explicitly requiring a licensed medical physicist in these regulations are limited. Rates charged by licensed medical physicist rates in New York City were not included in the estimate, as the proposed regulations only apply to correctional facilities outside of New York City.