

Sec. 3. Subsection (c) of section 22a-6b-8 of the Regulations of Connecticut State Agencies is amended by adding subdivision (4) as follows:

(NEW)

- (4) Violations related to Sources of Ionizing Radiation.
- (A) Each distinct violation of sections 22a-148 to 22a-162a, inclusive, and section 22a-6b of the Connecticut General Statutes, or of any regulation, order or permit administered or issued thereunder, or of an order administered or issued under section 16a-105, 22a-6 or 22a-7 of the Connecticut General Statutes to enforce any provision of section 16a-104 or sections 22a-148 to 22a-162a, inclusive, and section 22a-6b of the Connecticut General Statutes or a regulation or permit administered or issued thereunder, shall first be evaluated in terms of the actual or potential for harm to human health and welfare or the environment using each of the sub-factors listed in Tables 4A and 4B of this subdivision. The applicable category of harm for each sub-factor is the highest category that corresponds to the characteristics of the distinct violation. The actual or potential for harm of such violation shall be the highest category of harm identified in the sub-factor analysis.
- (B) The gravity-based penalty component for each distinct violation shall comprise the following:
- (i) A gravity-based penalty for the first day of violation, which is determined by first locating the penalty from the appropriate subcell in the penalty matrix in Table 4C,
 - (ii) A gravity-based penalty for each day the violation continued beyond the first day, up to a maximum of one-hundred-eighty days thereafter, which is equal to either: Twenty-five percent of the first day gravity-based penalty for each day such violation continued provided the violation commenced on or prior to one year prior to the date of issuance of the penalty notice; or, if the violation commenced within one year prior to the date of issuance of the penalty notice, one-hundred percent of the first day gravity-based penalty for each day such violation continued, up to a maximum of thirty days, and twenty-five percent of such first day penalty for each additional day thereafter. If the violation commenced prior to the effective date of these regulations, the first day of violation shall be the first day such violation continued after such effective date, and
 - (iii) At the sole discretion of the Commissioner, a gravity-based penalty for each day the violation continued for more than one-hundred-eighty-one (181) days, provided such violation has caused high or very high harm to public health and safety or the environment. The amount of such gravity-based penalty shall not exceed the number of days the violation continued beyond one-hundred-eighty-one (181) days multiplied by twenty-five percent (25%) of the first day gravity-based penalty.

Table 4A	
Actual or Potential for Harm for Radioactive Materials Security Violations	
Sub-factor: Theft, Diversion, or Sabotage of Radioactive Materials	
Category of Harm	Violations
Very High	1. The theft, diversion, or sabotage of a Category 1 quantity of radioactive material results from the failure to establish or implement one or more legal requirements.
High	1. The theft, diversion, or sabotage of a Category 2 quantity of radioactive material results from the failure to establish or implement one or more increased control legal requirements.
Moderate	1. A licensee fails to immediately respond (e.g., without undue delay in accordance with the licensee's prearranged plan) to an attempted theft, sabotage, or diversion of a Category 1 or Category 2 quantity of radioactive material, including a failure to request assistance from the local law enforcement agency, but the failure does not result in actual theft, sabotage, or diversion of radioactive material.
Sub-factor: Radioactive Materials Security Program Violations	
Category of Harm	Violations
Moderate	1. A licensee fails to establish or implement one or more increased control legal requirements.
Sub-factor: Information Security Violations	
Very High	1. A person who does not have authorization gains access to information requiring protection that may be useful to an adversary about technology or physical security plan of a facility, and both of the following are met: <ul style="list-style-type: none"> - Access to the information was not limited by other controls; and, - The number of days the information was not controlled properly in accordance with the respective handling and storage legal requirements is greater than or equal to 14 days from the date of infraction to discovery of the non-compliance.
High	1. A person who does not have authorization gains access to information requiring protection whose disclosure, taken by itself, would not aid an adversary in gaining information about a technology or physical security plan of a facility, and both of the following are met: <ul style="list-style-type: none"> - Access to the information was not limited by other controls; and, - The number of days the information was not controlled properly in accordance with the respective handling and storage legal requirements is greater than or equal to 14 days from the date of infraction to discovery of the non-compliance

Moderate	<p>1. A person who does not have authorization gains access to information requiring protection but either:</p> <ul style="list-style-type: none"> - Access to the information was limited by other controls: or, - The number of days the information was not controlled properly in accordance with the respective handling and storage legal requirements is less than 14 days from the date of infraction to discovery of the non-compliance. <p>2. Instances when information requiring protection has been secured, protected, or marked improperly but there is no evidence that anyone has accessed the information while it was improperly handled and either of the following conditions is met:</p> <ul style="list-style-type: none"> - The number of days the information was not controlled properly in accordance with the respective handling and storage legal requirements is greater than or equal to 14 days from the date of infraction to discovery of the non-compliance; or, - Access to the information was not limited by other controls
----------	--

Table 4B	
Actual or Potential for Harm for Other Violations Related to Sources of Ionizing Radiation	
Sub-factor: Operations	
Category of Harm	Violations
Very High	<p>1. The loss of control over licensed or regulated activities, including chemical processes that are integral to the licensed or regulated activity, results in serious injury or loss of life.</p> <p>2. A system designed to prevent or mitigate a serious safety event is inoperable when actually required to perform its design function, and this results in serious injury or loss of life.</p> <p>3. Failure to use a properly prepared medical written directive as required or failure to develop, implement, or maintain procedures for medical administrations requiring a written directive as required results in serious injury or loss of life.</p> <p>4. Failure to have or to follow required written operating and emergency procedures results in a serious injury or loss of life.</p>
High	<p>1. The loss of control over licensed or regulated activities, including chemical processes that are integral to the licensed or regulated activity, results in the substantial potential for a significant injury or loss of life, whether or not radioactive material is released.</p>

	<p>2. A system designed to prevent or mitigate a serious safety event is inoperable when actually required to perform its design function.</p> <p>3. A substantial programmatic failure to implement medical written directives or procedures for administrations requiring a written directive, such as a failure of the licensee’s procedures to address one or more of the essential elements, or a failure to train personnel in those procedures, results in a medical event.</p> <p>4. Failure to have or to follow required written operating procedures results in a substantial potential (e.g., an event did not occur, but no barriers, neither procedural nor system, including interlocks, would have prevented it, and the event was not highly unlikely to occur) for a serious injury or death.</p>
<p>Moderate</p>	<p>1. A system designed to prevent or mitigate a serious safety event has one of the following characteristics:</p> <p>(a) It is unable to perform its intended function under certain conditions (e.g., a safety system is not operable unless the required backup power is available); or,</p> <p>(b) It is outside design specifications to the extent that a detailed evaluation would be required to determine its operability.</p> <p>2. A programmatic failure occurs to implement written directives or procedures for administrations requiring a written directive.</p> <p>3. A licensee fails to secure a portable gauge as required by regulation.¹</p> <p>4. A significant failure to implement the legal requirements for radiation safety during radiographic operations.</p> <p>5. An unqualified person conducts licensed activities.</p> <p>6. Licensed radioactive material is used on humans where such use is not authorized.</p> <p>7. A licensee authorizes the release from its control of an individual who does not meet the release criteria for individuals containing unsealed byproduct material or implants containing byproduct material.</p> <p>8. An individual without supervision operates an irradiator when the individual has not been trained as required.</p>

¹ Civil penalty does not apply if a licensee fails to secure a portable gauge, whenever the gauge is not under the control and constant surveillance of the licensee, if one level of physical control existed and there was no actual loss of material, and that failure is not repetitive.

	<p>9. A programmatic failure occurs to have and follow required written operating procedures.</p> <p>10. A programmatic failure occurs to perform required irradiator inspection and maintenance checks.</p> <p>11. A licensee fails to seek required approval before the implementation of a significant change in licensed activities that has radiological or programmatic significance.</p> <p>12. A licensee fails to meet significant decommissioning legal requirements.</p>
Sub-Factor: Health Physics²	
Category of Harm	Violations
Very High	<p>1. An adult radiation worker receives a radiation exposure during any year in excess of 25 rem (0.25 sievert (Sv)) total effective dose equivalent; 75 rem (0.75 Sv) to the lens of the eye; or 250 rem (2.5 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue.</p> <p>2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus of 2.5 rem (0.025 Sv) total effective dose equivalent.</p> <p>3. A minor radiation worker (i.e., an individual less than 18 years of age) receives a radiation exposure during any year in excess of 2.5 rem (0.025 Sv) total effective dose equivalent; 7.5 rem (0.075 Sv) to the lens of the eye; or 25 rem (0.25 Sv) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue.</p> <p>4. A member of the public receives an annual exposure in excess of 1 rem (0.01 Sv) total effective dose equivalent.</p> <p>5. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of 50 times the limits for members of the public.</p> <p>6. Disposal of licensed radioactive material into sanitary sewerage occurs in quantities or concentrations in excess of 10 times the release limits.</p>
High	<p>1. An adult radiation worker receives a radiation exposure during any year in excess of 10 rem (0.1 Sv) total effective dose equivalent; 30 rem (0.3 Sv) to the lens of the eye; or 100 rem (1.0 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue.</p>

² Personnel overexposures and associated violations incurred during a lifesaving or other emergency response effort will be treated on a case-by-case basis.

	<p>2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus in excess of 1.0 rem (0.01 Sv) total effective dose equivalent.</p> <p>3. A minor radiation worker receives a radiation exposure during any year in excess of 1.0 rem (0.01 Sv) total effective dose equivalent; 3.0 rem (0.03 Sv) to the lens of the eye; or 10 rem (0.1 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue.</p> <p>4. A member of the public receives an annual exposure in excess of 0.5 rem (5 millisieverts (mSv)) total effective dose equivalent.</p> <p>5. Release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of 10 times the regulatory limits except when the Commissioner has approved operation up to 0.5 rem (5 mSv) per year.</p> <p>6. Disposal of licensed radioactive material into sanitary sewerage occurs in quantities or concentrations in excess of 5 times the release limits.</p>
Moderate	<p>1. An adult radiation worker receives a radiation exposure during any year in excess of 5 rem (0.05 Sv) total effective dose equivalent; 15 rem (0.15 Sv) to the lens of the eye; or 50 rem (0.5 Sv) to the skin of the whole body or to the feet, ankles, hands, or forearms, or to any other organ or tissue.</p> <p>2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus in excess of 0.5 rem (5 mSv) total effective dose equivalent.³</p> <p>3. A minor radiation worker receives a radiation exposure during any year in excess of 0.5 rem (5 mSv) total effective dose equivalent; 1.5 rem (0.015 Sv) to the lens of the eye; or 5 rem (0.05 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue.</p> <p>4. An annual exposure of a member of the public in excess of 0.1 rem (1 mSv) total effective dose equivalent except when operation up to 0.5 rem (5 mSv) per year is authorized by regulation.</p> <p>5. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of two times the effluent concentration regulatory limits except when the Commissioner has approved operation up to 0.5 rem (5 mSv) per year.</p> <p>6. A substantial potential exists for exposures or releases in excess of the applicable regulatory limits, whether or not an exposure or release occurs.</p>

³ Except when doses are in accordance with the provisions of 10 CFR 20.1208(d) which has been incorporated by reference in RCSA 22a-153-20.

	<p>7. Disposal of radioactive material occurs in quantities or concentrations in excess of the regulatory limits.</p> <p>8. A licensee releases, for unrestricted use, contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public exceeding the annual dose limits for members of the public.</p> <p>9. A technically unqualified person conducts licensee activities.</p> <p>10. A violation involves significant failure to secure, or maintain surveillance over, licensed radioactive material in any of the following situations:</p> <p>(a) involves licensed radioactive material in any aggregate quantity greater than 1,000 times the quantity of licensed radioactive material requiring labeling;</p> <p>(b) involves licensed radioactive material in any aggregate quantity greater than 10 times the quantity of licensed radioactive material requiring labeling, where the failure is accompanied by the absence of a functional program to detect and deter security violations that includes training, staff awareness, detection (including auditing), and corrective action (including disciplinary action); or</p> <p>(c) results in a substantial potential for exposures or releases in excess of the applicable regulatory limits.</p>
Sub-Factor: Transportation of Radioactive Materials⁴	
Category of Harm	Violations
Very High	<p>1. Failure to meet transportation legal requirements results in loss of control of radioactive material with a breach in package integrity such that the radioactive material causes a radiation exposure to a member of the public in excess of the regulatory limits.</p> <p>2. Surface contamination exceeds 50 times regulatory limits.</p> <p>3. External radiation levels exceed 10 times the regulatory limits.</p>
High	<p>1. Failure to meet transportation legal requirements results in loss of control of radioactive material with a breach in package integrity such that there is a clear potential for a member of the public to receive a radiation exposure in excess of the regulatory limits.</p>

⁴ Some transportation legal requirements apply to more than one licensee involved in the same activity (e.g., a shipper and a carrier). When such a violation occurs, the Commissioner will direct enforcement action against the responsible licensee or licensees.

	<p>2. Surface contamination exceeds 10 times, but not more than 50 times, regulatory limits.</p> <p>3. External radiation levels exceed 5 times, but not more than 10 times, regulatory limits.</p>
Moderate	<p>1. Surface contamination exceeds 5 times, but not more than 10 times, regulatory limits.</p> <p>2. External radiation exceeds 1 times, but not more than 5 times, regulatory limits.</p> <p>3. A violation involves labeling, placarding, shipping paper, packaging, loading, or other legal requirements that could reasonably result any of the following:</p> <p>(a) a significant failure to identify the type, quantity, or form of radioactive material;</p> <p>(b) a failure of the carrier or recipient to exercise adequate controls; or,</p> <p>(c) a substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of radioactive material.</p>
Sub-factor: Impacts the Commissioner's Ability to Perform a Regulatory Function	
Category of Harm	Violations
Very High	<p>1. A person provides or maintains information with careless disregard of its completeness or accuracy. If this information had been completely and accurately provided or maintained, it would likely have caused the Commissioner to issue an order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or the environment.</p> <p>2. A withholding of information or a failure to make a required report occurs, with careless disregard of the underlying legal requirement. If the information had been provided or the report been made, it would likely have caused the Commissioner to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or the environment.</p>
High	<p>1. A person provides or maintains information with careless disregard of its completeness or accuracy. If this information had been completely and accurately provided or maintained, it would likely have caused the Commissioner to reconsider a regulatory position or undertake a substantial further inquiry.</p>

	<p>2. A withholding of information or a failure to make a required report occurs with careless disregard of the underlying legal requirement. If the information had been provided or the report been made, it would likely have resulted in reconsideration of a regulatory position or substantial further inquiry.</p> <p>3. Inaccurate or incomplete information is provided or maintained, with careless disregard of the underlying legal requirement. If this information had been completely and accurately provided or maintained, it would likely have caused the Commissioner to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or the environment.</p> <p>4. A withholding of information or a failure to make a required report occurs, with careless disregard of the underlying legal requirement. If the information had been provided or the report been made, it would likely have caused the Commissioner to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or the environment.</p>
Moderate	<p>1. Inaccurate or incomplete information is provided or maintained, with careless disregard of the underlying legal requirement. If this information had been completely and accurately provided or maintained, it would likely have caused the Commissioner to reconsider a regulatory position or undertake a substantial further inquiry.</p> <p>2. A withholding of information or a failure to make a required report occurs, with careless disregard of the underlying legal requirement. If this information had been provided or the report been made, it would likely have caused the Commissioner to reconsider a regulatory position or undertake a substantial further inquiry including but not limited to failure to make a 24-hour report or notification when required.</p> <p>3. A programmatic failure to comply with reporting legal requirements for transactions involving Nationally Tracked Sources occurs, where a “nationally tracked source” has the same meaning as provided in 10 CFR 20.1003.</p>
Low	<p>1. Failure to register or renew a registration for a source of radiation requiring registration pursuant to Section 22a-148(b) or 22a-150 of Connecticut General Statutes.</p> <p>2. A licensee fails to make an immediate notification when required.</p>

Table 4C		
Penalty Matrix for Radioactive Material Violations		
Actual or Potential for	Gravity-Based Penalty for Radioactive Materials Security	Gravity-Based Penalty for Other Violations related to

Harm	Violations	Sources of Ionizing Radiation
Very High	\$25,000	\$16,000
High	\$20,000	\$12,000
Moderate	\$12,000	\$8,000
Low	Not Applicable	\$1,000

(d) Gravity-Based Penalty Adjustments.

For each distinct violation, gravity-based penalty adjustments shall be determined as follows:

(1) Good Faith Efforts to Comply.

A gravity-based penalty component may be adjusted downward by as much as 25% depending upon whether or not, in the sole judgment of the commissioner, the respondent had taken all steps or followed all procedures necessary or appropriate to comply or to correct the violation prior to the department's discovery of such violation. However, the commissioner need not adjust such gravity-based penalty in accordance with this provision if the respondent failed to take reasonable and prompt measures to fully comply upon respondent's discovery of such violation.

(2) History of Noncompliance.

A gravity-based penalty component may be adjusted upward by as much as 25% if the respondent has a history of a prior violation. In determining the amount of upward penalty adjustment, the commissioner shall consider all known violations, any prior violations by the respondent of statutes, regulations, orders, permits or licenses administered, adopted or issued by the commissioner, and any judgments or orders entered by the federal government or any state or municipality against the respondent.

(3) Ability to Pay.

The gravity-based penalty component, plus any gravity-based penalty adjustments under subdivisions (1) and (2) of this section, may be adjusted based on the economic and financial conditions of the violator. The commissioner may deem a respondent to be unable to pay a gravity-based penalty if payment of such penalty would interfere with the respondent's financial ability to come into compliance or force the respondent out of business. It shall be the respondent's sole burden to assert any claim of inability to pay and to submit all documents that the commissioner reasonably believes are necessary to evaluate such claim. Any penalty adjustment for a demonstrated inability to pay may be limited if the:

(1) Violation is chronic or repeat, or causes or has the potential to cause serious harm to the environment;

(2) Respondent refuses to correct a violation; or

(3) Respondent is a business entity that is no longer doing business.

Further, any of the following does not necessarily constitute an inability to pay: Potential reduction of manager or officer salaries or employee bonuses; potential reduction of shareholder dividends; limited cash flow, but respondent is able to raise money through borrowing, selling assets, or other steps without incurring extraordinary burdens.

(Adopted effective May 29, 2007)

Sec. 4. Sections 19-24-1 to 19-24-14, inclusive, and section 22a-6b sections 19-25a-1 through 19-25a-5, inclusive, and section 22a-6b and sections 19-25d-1 through 19-25d-11 of the Regulations of Connecticut State Agencies, inclusive, and section 22a-6b are repealed.

Statement of purpose.

Purpose of proposal.

This proposal takes the existing regulatory framework for users of radioactive material into the 21st century. The existing regulations have not been revised since their adoption in 1982, but our understanding of radiation and applicable federal regulations have changed considerably in the last four decades. The new regulations take into account changes in the science and understanding of radiation safety as set out in regulations of the Nuclear Regulatory Commission (NRC). The new regulations are consistent with the NRC's regulations, which will create a more uniform regulatory environment for the regulated sources. Consistency with the federal regulations is achieved by incorporation by reference of the NRC regulations.

The proposal also adds civil penalties for violations related to sources of ionizing radiation to the Department's existing administrative civil penalties.

Main provisions. Section 1 of this proposal is the adoption of new sections of the RCSA concerning users of radioactive material. While the Department currently regulates ionizing radiation through RCSA sections 19-24-1 through 19-24-14 (sources and materials), 19-25a-1 through 19-25a-5, and 19-25d-1 through 19-25d-11 (x-ray devices), those regulatory sections are proposed for repeal (Section 4). To the Department's existing administrative civil penalties, violations related to radioactive materials and other sources of ionizing radiation are added, and the approach to use in calculating the level of the penalty is set out. Definitions specific to violations related to sources of ionizing radiation are also added. (Sections 2-3)

Legal effects. In repealing and replacing the current regulations concerning radioactive material, the proposal does not change the number and types of entities regulated. Because current NRC license holders are now subject to these requirements, they will experience minimal change in the nature of the requirements but will experience improved efficiency by the transfer of the administration of the regulations to the Department. This more comprehensive and up-to-date state regulatory framework is a necessary step in creating the regulatory infrastructure to support the state's effort to become an Agreement State with the NRC. As an Agreement State, the NRC will transfer a portion of its authority to license and regulate ionizing regulation to DEEP.

The Department has used future incorporation by reference of the NRC's regulations to achieve compatibility and consistency with the NRC's requirements as required to attain and maintain agreement state status. Compatibility is required by sections 16a-100 and 22a-148 of the Connecticut General Statutes.

The new civil penalties are consistent with the authority provided in CGS section 22a-6b. The civil penalties that will be charged by the Department are essentially the same as those now imposed on violators by the NRC. A new standard of conduct, "careless disregard," is added consistent with this standard in the NRC Enforcement Policy. Civil penalties are assigned based

on the potential to harm human health and the environment.