

HEARING REPORT

Prepared Pursuant to Section 4-168(d) of the Connecticut General Statutes and Section 22a-3a-3(d)(5) of the Department of Energy and Environmental Protection Rules of Practice

Regarding Notice of Intent to Repeal and Adopt Ionizing Radiation Regulations

Hearing Officer:
Denny Galloway

Date of Hearing: April 16, 2014

On March 13, 2014, the Commissioner of the Department of Energy and Environmental Protection (DEEP) published a notice of intent to repeal and adopt ionizing radiation regulations by repealing 19-24-1 to 19-24-14 inclusive, and 19-25a-1 to 19-25d-11 inclusive. DEEP is proposing to adopt new regulatory sections for the control of ionizing radiation, as RCSA sections 22a-153-1 to 22a-153-9, inclusive. Pursuant to such notice, a public hearing was held on April 16, 2014, with the public comment period closing on May 17, 2014.

I. Hearing Report Content

As required by section 4-168(d) of the Connecticut General Statutes (CGS), this report describes the proposal, identifies principal reasons in support of and in opposition to the proposal, and summarizes and responds to all comments on the proposal.

The proposal is included as Attachment 2 to this report. A final revised version of the proposal based on the recommendations in this report is included as Attachment 3. A statement in satisfaction of CGS section 22a-6(h) is included as Attachment 1.

II. Summary of Proposal

The proposed regulations will better protect the environment and public health from the dangers of radiological contamination while also improving and updating its regulations concerning sources of ionizing radiation. DEEP identified several areas of concern regarding its current regulations, including the need for a more efficient and effective program and the need to incorporate current practices to better protect public health, safety and the environment. The proposal is consistent with the Department's enforcement process and procedures, including the authority to issue and enforce orders to correct or abate any violations that could cause or lead to radiological contamination. Specifically, DEEP is proposing to repeal sections 19-24-1 to 19-24-14 inclusive, and 19-25a-1 to 19-25d-11 inclusive of the Regulations of Connecticut State Agencies (RCSA) and adopt RCSA sections 22a-153-1 to 22a-153-9.

III. Opposition to the Proposal

DEEP received comments opposing sections 22a-153-2, 22a-153-3 and 22a-153-9. DEEP responded to those concerns. See response to comment number 31.

IV. Summary of Comments

No oral comments were given at the hearing.

Written comments were received from the following persons:

1. James Fomenko
UConn Health Center
Farmington, CT
2. Chris Dodge
Regulatory Affairs Specialist
Aribex, Inc.
Orem, UT 84097
3. April Nunn, MS, DABR
The Harold Leever Cancer Center
1075 Chase Parkway
Waterbury, CT 06708
4. Brantley Buerger, P.E.
ISFSI Manager
CYAPCO.
Haddam Neck Plant
362 Injun Hollow Road
East Hampton, CT 06424-3099
5. Gene Cardarelli, Ph.D.
Director of Physics and Radiation Oncology
Hartford Healthcare Cancer Institute
6. CAMPS (CT Area Medical Physics Society)
CT Science Center
200 Columbus Blvd
Hartford, CT 06103
7. David Wishko, Ph.D.
Danbury Hospital
24 Hospital Ave
Danbury, CT 06810-6099

8. Kenneth Morse, CMD
Sensus Healthcare
851 Broken Sound Pkwy NW #215
Boca Raton, FL 33487
9. David Monz
Updike, Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
10. Tammy Stemen, CHP
Radiation Safety Officer
Yale University
New Haven, CT
11. Jerry Darling, Ph.D.
University of Saint Joseph
West Hartford, CT
12. Commenter #12
Unknown
13. Peter Hollenbeck
Radiation Safety & Control Services, Inc.
91 Portsmouth Ave.
Stratham, NH 03885
14. Office of the Attorney General
55 Elm Street
Hartford, CT 06106

All comments submitted are summarized below with DEEP's responses. Commenter's are associated with the individual comments below by the number assigned above. When changes to the proposed text are indicated in response to comment, new text is in bold font and deleted text is in strikethrough font.

Comment 1: The commenter identified that there are older dental diagnostic x-ray devices in Connecticut that may not comply with Section 22a-153-4(h)(3)(B)(i). Specifically some x-ray devices may have audible indicators, but may not have the visual indicator prescribed by the new regulation.

Commenter submitting this comment: 1

Response: DEEP concurs with the commenter's observation and did not intend for dental facilities to back fit older devices with visual indicators when they have audible indicators. Modern dental x-ray devices come with both visual and audible indicators.

Comment 2: The commenter's believe based upon empirical data occupational monitoring for exposure to ionizing radiation is not necessary for users of hand-held dental x-ray devices manufactured by Airbex.

Commenter submitting this comment: 1, 2

Response: If conditions of Section 22a-153-2(2)(A)(i) of the draft regulations are met (occupational exposure is less than 10 percent of the annual limit), then occupational exposure is not required to be monitored.

Comment 3: The commenter is concerned that the requirements of 22a-153-4a(c)(3) would prevent the holding of an un-anesthetized animal while taking diagnostic x-rays.

Commenter submitting this comment: 1

Response: The requirement of 22a-153-4a(c)(3) does not prevent someone other than the operator from holding an animal when necessary for diagnostic x-rays.

Comment 4: The commenter noted that in 2011 the designations Radiological Physics and Therapeutic Radiological Physics were changed to Medical Physics and Therapeutic Medical Physics respectively by the American Board of Radiology, and that Section 22a-153-7(d)(2)(b)(i) should be modified to reflect those changes.

Commenter submitting this comment: 3

Response: DEEP concurs with the commenter's observation.

Comment 5: The commenter request that a provision be added to section 22a-153-2(b) of the proposed regulations that recognize ongoing radiological decommissioning plans that were approved prior to the effective date of these regulations.

Commenter submitting this comment: 4

Response: DEEP's position is the terms of prior agreements, and authorizations regarding decommissioning plans, and site closure and remediation activities are still in place. DEEP doesn't see a conflict with the proposed new draft regulations.

Comment 6: The commenter request for clarity purposes, since therapy simulators are not routinely used for diagnostic purposes that an exemption be added for simulators for the entirety of Section 22a-153-4 recognizing that they would be covered by Section 22a-153-7.

Commenter(s) submitting this comment: 5, 6

Response: DEEP concurs with the commenter's observation.

Commenter(s) submitting this comment: 5, 6

Comment 7: To avoid burdensome paperwork the commenter request that 22a-153-6(c)(1)(A) be revised to indicate that reports be required only for those individuals that exceed 10% of the maximum permissible dose.

Response: DEEP's position the requirement found in 22a-153-6(c)(1)(A) are consistent with current federal standards.

Comment 8: The commenter request additional clarification in 22a-153-7 if references to "record of signature" doesn't include electronic signatures.

Commenter(s) submitting this comment: 5, 6

Response: DEEP will accept electronic signatures as meeting the requirements of a “record of signature”.

Comment 9: The commenter suggest that DEEP add the American Society for Radiation Oncology (ASTRO) to 22a-153-7(c)(7)(A).

Commenter(s) submitting this comment: 5, 6

Response: DEEP concurs with the commenters recommendation to add ASTRO to the list of accreditation bodies in 22a-153-7(c)(7)(A).

Comment 10: The commenter is interpreting 22a-153-7(c)(8)(D) to mean minor adjustments associated with monthly quality assurance and regular service doesn't constitute modifications capable of significantly affecting the characteristics of the radiation beam.

Commenter(s) submitting this comment: 5, 6

Response: DEEP concurs with the commenter's interpretation as long as there isn't a significant change in the radiation beam.

Comment 11: The commenter request that the full calibration interval in 22a-153-7(j)(19)(c) be modified from ...“intervals not exceeding twelve(12) calendar months” to intervals not exceeding fourteen(14)calendar months.

Commenter(s) submitting this comment: 5, 6

Response: DEEP's position is the requirement is consistent with recommendations from the American College of Radiology and the American Association of Physicist in Medicine, and doesn't need modification.

Comment 12: The commenter asks if in 22a-153-7(k)(2)(A) “Visual identification of the center of the x-ray field to within a 2 millimeter diameter” is the same as a graticule/cross hair congruence with the central axis?

Commenter(s) submitting this comment: 5, 6

Response: Yes, the visual identification of the center of the x-ray field to within a 2 millimeter diameter” is the same as a graticule/cross hair congruence with the central axis.

Comment 13: The commenter request that 22a-153-7(k)(2)(B) be modified to allow a wider tolerance than 2 mm for the SID due to difficulty in determining the true SID because of interfering protective covers.

Commenter(s) submitting this comment: 5, 6

Response: DEEP's position is this parameter is reasonable. The SID typically is done at first use or when major service is performed. During major service, the protective cover is removed from the imager allowing for more accurate SID measurements.

Comment 14: The commenter is looking for clarification in 22a-153-7(k)(2)(F). Specifically, what parameter is the coefficient of variation referring to, and how would they measure it.

Commenter(s) submitting this comment: 5, 6

Response: DEEP is looking for a quantifiable measure for the reproducibility of dose.

Comment 15: The commenter is looking for clarity 22a-153-7(k)(2)(G). Specifically, what parameter is linearity referencing in this section?

Commenter(s) submitting this comment: 5, 6

Response: The parameter referenced in this subsection is for dose linearity.

Comment 16: The commenter recommends DEEP modify 22a-153-7(l)(1)(C) by inserting an S in front of Imulation.

Commenter(s) submitting this comment: 5, 6

Response: DEEP concurs with the commenter's recommendation.

Comment 17: The commenter request that "treatment room" be removed from 22a-153-8(hh)(4)(A)(i) due to the fact that portable HDR units can be placed in locked storage in a different room. This allows the treatment room to be used for other purposes.

Commenter(s) submitting this comment: 5, 6

Response: DEEP concurs with the commenter's recommendation.

Comment 18/19: The commenter request that applicator and transfer tube testing be removed from the full calibration requirement done at each source change under 22a-153-8(hh)(8)(B)(vi).

Commenter(s) submitting this comment: 5, 6

Response: DEEP doesn't believe this rule needs to be modified. This rule is consistent with Nuclear Regulatory Commission rules for calibration measurements on remote afterloader units.

Comment 20: The commenter recommends that Section 22a-153-2 be modified to require occupationally exposed radiation workers be monitored monthly for exposure to ionizing radiation.

Commenter(s) submitting this comment: 7

Response: DEEP recognizes that there are situations that require occupationally exposed radiation workers to be monitored for exposure on a monthly basis. However, there are situations where occupationally exposed radiation worker dosimetry need only be read on a quarterly or biannual basis which the regulation allows for.

Comment 21: The commenter recommends social security numbers not be used on radiation exposure records as referenced in 22a-153-6(c)(1)(A)(ii).

Commenter(s) submitting this comment: 7

Response: DEEP doesn't concur with the commenter's recommendation. Many facilities use social security numbers for identification purposes, and are capable of protecting said information. Moreover, the regulatory reference to social security number in 22a-153-6(c)(1)(A)(ii) is optional.

Comment 22: The commenter believes taking ten exposures to determine compliance with 22a-153-4(g)(7)(c) is excessive.

Commenter(s) submitting this comment: 7

Response: DEEP believes the number of exposures required in this subsection isn't excessive. These standards come from nationally recognized standard setting bodies e.g., National Council on Radiation Protection and Measurements.

Comment 23: In 22a-153-4(g)(8)(A)(iii) the commenter asks what is meant by contrast ratio corrected for ambient light.

Commenter(s) submitting this comment: 7

Response: Contrast ration is the difference between light and dark (illuminance) from the light localizer. The ambient room light illuminance must be subtracted from the light field illuminance at each measurement point.

Comment 24: The commenter is not familiar with the term CTDI as found in 22a-153-4(i)(1)(F).

Commenter(s) submitting this comment: 7

Response: CTDI stands for computed tomography dose index. It's a standardized measure of radiation dose output of a CT scanner which allows the user to compare radiation output of different CT scanners. Definition added to 22a-153-4.

Comment 25: The commenter would like to know how you measure the dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum and midrange values of the nominal tomographic section thickness as found in 22a-153-4(i)(4)(F)

Commenter(s) submitting this comment: 7

Response: This test is performed using a CT dosimetry phantom using protocols from the Food and Drug Administration, American Association of Physicist in Medicine or other standard setting bodies.

Comment 26: The commenter would like to know what "CTN" is? CTN is found in 22a-153-4(i)(5)(B).

Commenter(s) submitting this comment: 7

Response: CTN is the abbreviation for Computed Tomography Noise. It's measured as the standard deviation of voxel values in a homogenous (typically water) phantom. Definition added to 22a-153-4.

Comment 27: The commenter believes that checking safety and warning devices including interlocks as found in 22a-153-5(g)(3) is excessive and could cause premature failure of components.

Commenter(s) submitting this comment: 7

Response: DEEP doesn't believe this test is excessive. The test protocol uses a CT dosimetry phantom and procedures developed by the Food and Drug Administration, American Association of Physicist in Medicine and other standard setting bodies.

Comment 28: The commenter believes the requirement in 22a-153-5-(h)(1) that requires checking portable monitoring equipment daily is excessive and it provides no proof that the instrument is operational when it is turned on.

Commenter(s) submitting this comment: 7

Response: DEEP doesn't believe this test is excessive. Performing functional checks of portable instrumentation used in support of particle accelerator operations isn't excessive. This requirement is consistent with recommendations, and procedures developed by the Food and Drug Administration, American Association of Physicist in Medicine and other standard setting bodies.

Comment 30: The commenter would like to know if the training program they provide to physicians for the use of their superficial radiation therapy device would meet the alternative equivalent qualification found in 22a-153-7(d)(1)(C), 22a-153-7(d)(1)(D) and 22a-153-7(d)(1)(E).

Commenter(s) submitting this comment: 8

Response: The information provided appears to be responsive to the requirements for alternative equivalent qualifications found in 22a-153-7(d)(1)(D), however the department full review, and evaluation cannot be done as part of the hearing officers report.

Comment 31: The commenter's believe that the state should repeal its regulations for sources of ionizing radiation for the reason they are preempted by and duplicative of the regulations promulgated by the Nuclear Regulatory Commission (NRC).

Commenter(s) submitting this comment: 9, 10, 11

Response: DEEP does not agree that the Atomic Energy Act preempts state regulation of radioactive materials and further notes that there is no conflict between the two sets of regulations. More importantly, the NRC is limited by law to regulating nuclear materials to protect human health and safety. The DEEP charge is much broader and requires the agency to regulate to protect not just human health and safety, but also natural resources within the state. CGS. 22a-1, -2d, -5, and -6.

Comment 32: The commenter asks if there will be a grandfather clause (or other exception) for meeting qualification under 22a-153-7(d)(2)(b) for those physicist who have been practicing for several years without certification who are not eligible to sit for a certification exam due to changes in eligibility rules and requirements put in place by the American Board of Radiology and other certifying bodies.

Commenter(s) submitting this comment: 12

Response: DEEP does not anticipate allowing a grandfather clause. The rule is intended to improve image quality and uniformity of medical physics training among other things for those that calculate radiation dose and beam shape in radiation therapy for tumor treatment.

Comment 33: The commenter asks if there will be a provision in 22a-153-7 for a non-certified physicist to work under the supervision of an "authorized medical physicist".

Commenter(s) submitting this comment: 12

Response: DEEP believes it's not necessary for a specific provision to be put in the regulation for a non-certified physicist to work under the supervision of a qualified medical physicist. General supervision by the qualified medical physicist of the non-qualified physicist would allow overall direction and control, but accountability would remain with the "qualified medical physicist"

Comment 34: The commenter asks if there will be an exception to 22a-153-7(d)(2) for those who are not certified, but are named as an “authorized medical physicist” on an existing Nuclear Regulatory Commission license.

Commenter(s) submitting this comment: 12

Response: Section 22a-153-7 applies to therapeutic radiation producing machines. The commenters question applies to 22a-153-8 for the use of by-product material used in the healing arts. Section 22a-153-8(m)(2)(A) has a provision that has an exception for training programs approved by the Nuclear Regulatory Commission.

Comment 35: The commenter states the requirements in 22a-153-9((d)(4)(A)(i) which in part requires gamma radiation measurements at one meter from the ground surface aren’t necessary since NUREG-1575, Multi-Agency Radiation Survey & Site Investigation Manual (MARSSIM) doesn’t require gamma radiation measurements for final status surveys.

Commenter(s) submitting this comment: 13

Response: DEEP concurs with the commenters observation, however the prescriptive requirements found in 22a-153-9((d)(4)(A)(i) aren’t exercised unless “ the licensee demonstrates that the premises are suitable for release in some other manner” which allows for other methodologies approved by DEEP e.g., MARSSIM.

Comment 36: The Attorney General’s Office suggest changing registrant to person in 22a-153-2(p) which requires in part that the Commissioner of DEEP be notified in writing 90 days before vacating a premise that may have been contaminated with radioactive material

Commenter(s) submitting this comment: 14

Response: DEEP concurs with the commenter’s recommendation.

Comment 37: The commenter recommends that DEEP modify 22a-153-8(kk)(2)(E) by removing physician discretion for reporting a dose to an embryo, fetus, or child that requires 24 hour reporting to the mother.

Commenter(s) submitting this comment: 14

Response: DEEP concurs with the commenter’s recommendation.

V. Comments of Hearing Officer

The hearing officer suggests the following additional revisions to the proposal. The suggested revisions are minor, noncontroversial and will make for a clearer final proposal.

- 1) To address concerns the about back-fitting older dental x-ray devices the statement “ Subclause (i) is applicable for all dental x-ray devices installed after the effective date of these regulations” should be added to proposed new RCSA section 22a-153-4h(3)(B)(i) and read as follows:
 - (3) Each registrant shall provide for the following radiation exposure controls:
 - (A) For exposure initiation:
 - (i) Initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch, and
 - (ii) Exposure shall not be possible when the timer is set to a "zero" or "off" position, if either position is provided;
 - (B) For exposure indication:
 - (i) A visual indicator of radiation exposure shall be observable at or from the operator's protected position whenever x-rays are produced. **Subclause (i) is applicable for dental x-ray devices installed after the effective date of these regulations,** and
 - (ii) A signal audible to the operator shall indicate that the exposure is occurring;
- 2) An incorrect reference to subsections (f) and (c) are made in section 22a-153-4a(c)(2) and (d) and should read as follows:

(2) For a system installed prior to the effective date of this section or any portable veterinary x-ray system, each registrant shall meet the beam limitation requirements of section 22a-153-4(g)(1)(D) of the Regulations of Connecticut State Agencies.

References to exemptions in section 22a-153-4a(d) of the Regulations of Connecticut State Agencies should be modified to read as follows:

- (d) Exemptions. Each registrant of a system subject to this section is exempt from the following requirements of section 22a-153-4 of the Regulations of Connecticut State Agencies:
 - (1) Subsection (c)(H)(i)(b)(9)(A);
 - (2) The restriction of subsection (c)(H)(iv)(b)(9)(D);

- (3) Subsection (g)(1)(A);
- (4) Subsection (g)(2)(F); and
- (5) Subsection (g)(3).

3) The reference to exemptions for therapy simulators in section 22a-153-4(f)(11) of the Regulations of Connecticut State Agencies should be modified because they are covered in section 22a-153-7, and should read as follows:

Radiation therapy simulation systems. Each registrant operating a radiation therapy simulation system shall be exempt from all the requirements of **22a-153-4. subdivision (3) of this section.** ~~A registrant operating such a system shall be exempt from:~~

- ~~(A) The requirements of subdivisions (1) and (5) of this subsection, provided such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and~~
- ~~(B) The requirements of subsection (8) of this subsection if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.~~

4) The American Society for Radiation Oncology performs organized reviews of radiation therapy management programs. 22a-153-7(c)(7)(A) should be modified as follows:

(7) Each registrant shall implement procedures for auditing the effectiveness of a radiation therapy quality management program, as follows:

(A) At intervals not to exceed four (4) years, audits must be conducted by an organized review program supervised by the American College of Radiology, **American College of Radiation Oncology** or a program found to be equivalent by the Commissioner based on the scope of the audit and the experience of the sponsoring organization in performing such audits;

5) 22a-153-7(d)(2)(b)(i) should be modified to reflect the new American College of Radiology designations for therapeutic radiological physics and radiological physics, and read as follows:

(2) Authorized medical physicist. The registrant for any therapeutic radiation machine subject to subsection (i) or (j) of this section shall obtain or utilize the services of an authorized medical physicist and shall require the authorized medical physicist to:

(A) Register with the Commissioner as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units;

(B) Hold one of the following certifications:

(i) By the American Board of Radiology in:

(I) Therapeutic radiological physics, **Therapeutic medical physics**

(II) Roentgen-ray and gamma-ray physics,

- (III) X-ray and radium physics, or
- (IV) Radiological physics; **Medical Physics**

6) There was a typographical error in 22a-153-7(l)(1)(C), and should be modified to read as follows:

(l) Treatment chart review.

(1) An authorized medical physicist shall develop a chart review protocol for reviewing the accuracy of treatment delivery, which shall require review of the following parameters, as applicable:

(A) New or modified treatment fields;

(B) Treatment prescriptions;

(C) ~~Si~~mulation instructions;

7) Because remote afterloader units can be placed in locked storage within a treatment room 22a-153-8(hh)(4)(A)(i) should be modified to read as follows:

(4) Safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

(A) A registrant or licensee shall:

(i) Secure the unit, the console, the console keys ~~and the treatment room~~ when not in use or unattended,

8) To address the concern about someone relinquishing possession or control of premises that may have been contaminated with radioactive material as a result of his activities, section 22a-153-2(p) should be modified as follows.

Each ~~registrant~~ **person** shall, no less than (90) days before vacating or relinquishing possession or control of premises that may have been contaminated with radioactive material as a result of his activities, notify the Commissioner in writing of intent to vacate.

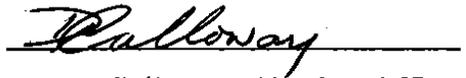
9) To address concerns about reporting radiation dose to an embryo, fetus, or child in 22a-153-8(kk)(2)(E) the following modification should be made.

(E) Notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than twenty four (24) hours after discovery of an event that would require reporting under subdivision (2)(A) or (2)(B) of this subsection, unless the referring physician personally informs the registrant or

licensee ~~either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful.~~

VI. Conclusion

Based upon the comments addressed in this Hearing Report, I recommend the proposal be revised as recommended herein and that the recommended final proposal, included as Attachment 3 to this report, be submitted by the Commissioner for approval by the Attorney General and the Legislative Regulations Review Committee.



Denny Galloway, Hearing Officer

11/4/2015

Date

Attachment 1
Federal Standards Analysis Pursuant to Section 22a-6(h) of the General Statutes
New Sections 22a-153-1 to 22a-153-9 of the
Regulations of Connecticut State Agencies

Pursuant to the provisions of section 22a-6(h) of the Connecticut General Statutes (CGS), the Commissioner of the Department of Energy and Environmental Protection (the Department) is authorized to adopt regulations pertaining to activities for which the federal government has adopted standards or procedures. At the time of public notice, the Commissioner must distinguish clearly all provisions of a proposed regulation that differ from federal standards or procedures.

In accordance with the requirements of CGS section 22a-6(h), in the matter of the adoption of sections 22a-153-1 to 22a-153-9, inclusive, of the Regulations of Connecticut State Agencies (RCSA), the Department has performed a comparison with applicable analogous federal provisions, which is set out below.

Regarding proposed RCSA section 22a-153-9: Proposed RCSA section 22a-153-9 will codify a radiological decommissioning standard for effective dose equivalent from all exposure pathways, and treat risk from radiological exposure above background the same as risk from chemical carcinogen exposure. Federal regulatory agencies have conflicting radiological remediation standards. For example, the Nuclear Regulatory Commission standard of 25 millirem/yr codified in 10 CFR 20 Subpart E calculates risk over a 100 year period. The U.S. Environmental Protection Agency has issued a standard of 15 millirem/yr as guidance only. The 19 millirem/yr standard set forth in 22a-153-9 treats radioactive material the same as other carcinogens and is adjusted to reflect a 30-year exposure period. Additionally, this standard is technically achievable and within the risk range of other carcinogens.

Regarding proposed RCSA sections 22a-153-4, 22a-153-4a, 22a-153-5 and 22a-153-7: Diagnostic x-ray equipment manufactured for the US market must meet the Food and Drug Administration (FDA) performance requirements described in 21 CFR 1020.30 through 1020.33, which require manufacturers to provide users with operational and safety information as well as to meet standards for equipment performance. However, the federal requirements apply to the manufacturer, rather than the end-user. The proposed sections apply to the end-user and address areas not covered by the FDA requirements, such as shielding, performance, operations, labeling, radiation safety, qualifications, and testing.

Regarding proposed RCSA sections 22a-153-1, 22a-153-2, 22a-153-3, and 22a-153-6: Sections 22a-153-1 and 22a-153-2 of the RCSA establish standards for protection against ionizing radiation resulting from activities conducted pursuant to the use, possession, storage, transfer and disposal of licensed or registered radioactive material or devices. These standards are substantially the same as the standards of 10 CFR 19 and 20.

Section 22a-153-3 of the RCSA establishes standards for the use of ionizing radiation for industrial radiography. Radiography operations and general public safety is controlled by prescribing equipment performance standards, labeling and storage requirements, radiation safety requirements, and training requirements. The requirements of this section are substantially the same as 10 CFR 34.

Section 22a-153-6 of the RCSA establishes requirements for notices, instructions and Department reports for individuals engaged in activities under license or registration. Additionally, this section sets out requirements governing inspections to determine compliance with the Department's regulations concerning ionizing radiation. As the section is about the administration of the Department's licenses and registrations concerning ionizing radiation, there are no analogous federal standards.

