COPY OF COMMENTS RECEIVED

REGARDING

PROPOSED AMENDMENT

32 ILL. ADM. CODE 322

COMMENTS

Commenter: Jaime Bregaudit
Organization: Chemring Energetic Devices
Comment: We need some clarification about the definition of " Operator"? Are you referring to the radiographer's personnel name or Name of the Facility or Company who own the Radiation Machines.

Response: "Operator" is defined in the Radiation Protection Act of 1990, 420 ILCS 40/4(d-7) and 32 Ill. Adm. Code 310 as an individual, group of individuals, partnership, firm, corporation, association, or other entity conducting the business or activities carried on within a radiation installation. For purposes of Part 320, the operator is the entity responsible for the conducting the business of the radiation installation. In most cases, this will be the name of the company as the operator and an individual who is an agent of the operator will register the radiation installation.

Commenter: Jim Jaglo
Organization: Patterson Companies
Comment: How will the state classify Dental CT type and will they require the dental facility with dental CT to follow the rule of having annual evaluations done and if that would be required to be done by a Physicist or supply company service technician. Would vet CT be classified as a medical CT?

Response: This issue is not covered by Part 320, but instead the operator requirements located in 32 Ill. Adm. Code 360. Currently, dental CT units, more precisely Cone Beam CT (CBCT) units, used in the practice of dentistry are considered dental radiographic units in Part 360. Therefore, for CBCT units used in the practice of dentistry, a physicist evaluation is not required.

Commenter: Elena Gamaliy-Snezhko, PhD
Organization: North Central College, Wentz Science Center
Comment:
Index 320.60: This section is missing in the further text

320.10(a) "minimal threat devices": definition of radiation machine is given further in the text, no need for it here; change "has occurred" to "can occur"; change location of analytical and cabinet radiation machines; change to...spectroscopic radiation machines (b/c we give examples of devices); change to...x-ray machines incorporated in lead boxes...(b/c minimal threat devices are machines, not facilities); delete "which are".

320.10(b)(4): This may conflict with the current wording of the Exemptions Section 320.40 subsection (c). I suggest to change wording in the Exemptions subsection to address this.

320.10(d)(2) Class C: Add Installations using radiation machines having radiation threat potential.

320.10(d)(2) Class D: I suggest to leave the original text for convenience of usage.

320.40(c): This may conflict with 320.10(4)(A). I suggest following changes:
...if notification is provided in accordance with subsection 320.10(b)(1)(B and C) and only if it does not conflict with subsection 320.10(4)(A).

320.40(c): Add…if notification is provided in accordance with subsection 320.10(b)(1)(B and C) and only if it does not conflict with subsection 320.10(4)(A).

Response:

Index 320.60: This section is not being amended and, therefore, was not included.

320.10(a):

The Agency does not agree with deleting "capable of generating or emitting fields of radiation that" as it provides clarity.

The Agency does agree to change "has occurred" to "can occur".

The Agency does not agree to make the change related to "analytical and cabinet radiation machines" as it is correct as written.

The Agency agrees to change "spectroscopy" to "spectroscopic radiation machines".

The Agency does not agree to change language regarding "x-ray machines in lead boxes" or with deleting "which are".

320.10(b)(4): The Agency disagrees with the commenter's suggestion. Each section (here and in the exemptions) explains different situations.

320.10(d)(2) Class C: The Agency disagrees with commenter's suggestion and will leave as is, defined clearly in 320.10(c)(3).

320.10(d)(2) Class D: The Agency disagrees with commenter's suggestion and will leave as is, defined clearly in 320.10(c)(4).

320.40(c): The Agency agrees to change this subsection to be clear about the difference between this subsection and 320.10(b)(4). The language will now state "Radiation machines provided for demonstration use or to replace out of service equipment during the out of service period. Notification in accordance with subsection 320.10(b)(1)(C) shall be provided to the Agency for the exemption."

Commenter: Jeffrey Stout
Organization: Stout Chiropractic Clinic, PC
Comment: I run a single doctor chiropractic facility. We use a digital (DR) system for spinal x-rays. I read through the new amendments, essentially what has changed for me? Is it mostly that my machine and facilities need to maintain safety and standards regardless of ownership, bankruptcy, etc? Also, it appears there is a written safety protocol to be reviewed by the agency, correct?

Response: The proposed amendments include application class changes for non-human use x-ray equipment. Changes affecting all radiation installations include the requirement to make all inventory changes (adding and/or removing x-ray machines) prior to December 31 of each year. See Section 320.10(d)(1). This will result in the registration fee billed in January of each year more accurate. Any inventory changes made after January 1 will be reflected on the fee notice for the following calendar year. Exemptions to registration were included for financial institutions that take possession of x-ray equipment due to bankruptcy or other legal proceedings and x-ray equipment operated for temporary use. There is not a requirement for a written safety protocol to be reviewed by the Agency under this rule for spinal x-ray units.

Commenter: L. Alan Shookman, CIH
Organization: Hydro-Gear
Comment: For Class 4 industrial lasers the fee change where by each device would be assessed a fee is NOT applicable to Class 4 Laser machines since these do not produce or emit ionizing radiation, correct ? Fees assessed for the Class 4 Lasers will continue to be by facility, a manufacturing plant operating one or more Class 4 Lasers ?

Response: Part 320 does not apply to laser installations (i.e., location or facility where laser systems are produced, stored, disposed of or used for any purpose). Fee information for laser installations is located in 32 Ill. Adm. Code 315, Standards for Protection Against Laser Radiation, specifically, Section 315.190.

Commenter: Leslye Smith
Organization: Harper College, Health Careers Division
Comment: Is there a classification of x-ray equipment used for educational purposes?

Response: X-ray units used for educational purposes are considered academic and are Class A.

Commenter: Hilda Pingo
Organization: Crusader Community Health
Comment: I am the Dental Unit Manager at Crusader Community Health. I received this email, and I am wondering if I need to do anything differently.

Response: The notification you received was to inform your radiation installation of the rulemaking process to amend 32 Ill. Adm. Code 320. Dental x-ray units are continuing to be classified, for registration purposes, as Class A with no change in fees. Changes affecting all radiation installations include the requirement to make all inventory changes (adding and/or

removing x-ray machines) prior to December 31 of each year. See Section 320.10(d)(1). This will result in the registration fee billed in January of each year more accurate. Any inventory changes made after January 1 will be reflected on the fee notice for the following calendar year.

Commenter: Indra Das, PhD, CSci, FIPEM, FAAPM, FACMP, FACR, FASTRO
Organization: Northwestern Memorial Hospital, Feinberg School of Medicine
Comment: I have read the document and agree with the revision.

Response: The Agency appreciates your support.

Commenter: Laura Paulius
Organization: Oak Park Animal Hospital
Comment: I am the Practice Manager at Oak Park Animal Hospital. We received a document in regard to Registration and Operator Requirements for Radiation Installations, 32 Ill. Adm. Code 320. Is there anything we need to do with this document? Are we being notified that the fee is increasing from $50 to $75?

Response: The notification you received was to inform your radiation installation of the rulemaking process to amend 32 Ill. Adm. Code 320. Veterinary facilities are classified, for registration purposes, as Class A and there is not a change in fees included in this amendment for Class A.

Commenter: Emily Sweeney
Organization: WellNow/Physicians Immediate Care
Comment: Upon review of the newer Section 320 Radiation equipment changes, I have a couple of questions:

1. "Quality control phantom analysis" - Does this need to be completed by the organization in addition to the phantom testing performed during annual calibration testing?
2. "Review of dose index values" - Do you have further information on this and what is the cadence of reviewing dose index values?

Response:

1. No time frames or specifics of a “quality control phantom analysis” have been specified in the Agency’s regulations. Ideally, quality control phantom analysis should be conducted at frequencies specified by the equipment manufacturer or by a medical physicist based on professionally published documents. In general quality control phantom analysis should provide for evaluation of digital x-ray image quality criteria, such as spatial resolution, high contrast, and low contrast.

2. The cadence for the “review of dose index values” (or other indices listed) can be done at any specified frequency established by the radiation installation under the direction of a diagnostic imaging specialist. During an inspection it would be noted what the frequency established is and the records reviewed to determine if the review was conducted done at

that frequency. Inspection findings have determined that radiation installations are conducting this monthly, quarterly and/or semi-annually. Factors to consider would include number of technologists and workload and should include an appropriate number of exams to indicate if clinical dose index values are within range of what is expected to provide good image quality.

Commenter: Tina Schwartz
Organization: Libertyville Dental Associates
Comment: We received an email showing some Draft Amendments for the "Registration & Operation Requirements for Radiation Installations, 32 Ill. Adm. Code 320". Is there something we need to be doing for you?

Response: The notification received was to inform your radiation installation of the rulemaking process to amend 32 Ill. Adm. Code 320. (The Agency already responded to Ms. Schwarz to relay this response to her.)

Commenter: James Ward, M.S.
Organization: Northwestern Medicine
Comment: I would like to recommend the revision or removal of the following requirement:

A. Review of exposure index, deviation index, s-number or dose index values from clinically acquired radiographic images.

The idea behind this requirement is fundamentally good. It would likely raise the minimum standard of care in Illinois by providing the end user with data based on a (proprietary) quantitative value that can be used for clinical practice improvement and/or potentially identify equipment malfunction prior to failure, which in turn could lead to shorter downtime and therefore increased patient access to medical care.

However, in its current form the rule would be little more than an additional checkbox for compliance and therefore provides little to no benefit. The reasons for that are severalfold:

1. This rule provides no requirement as to:
a. Who should review the images
b. Required credentials of the reviewer
c. Frequency the review should take place
d. Which clinical exam(s) should be reviewed
e. How many exams should be reviewed (or how many of each type, if applicable)
f. Criteria for patient selection/exclusion
g. If data need to be stratified by end user, i.e., technologist
h. What to do if the required exams are not performed on a given machine
i. Pass/fail criteria for the results
j. What corrective action, if any, should be taken based on the results
k. Necessary documentation of the review

2. By reviewing clinical images, the fundamental variable of the patient is being introduced. This will create an inherent uncertainty in the results beyond natural variability of the exams themselves, e.g., changes in hardware or software of the system, a different technologist, etc. Therefore, any action limits set, whether by revision to the rule or by the medical physicist, must be relaxed to prevent false identification of potential issues.

B. Another proposed rule change in the same section:

Quality control phantom analysis including but not limited to low contrast detectability, spatial resolution, and artifacts;

This requirement could be easily expanded to include a constancy measurement of the same or analogous clinically relevant quantities using the phantom already being used during physicist equipment evaluation.

In 2021, the International Atomic Energy Agency published IAEA Human Health Series No. 39 (978-92-0-102621-7) detailing an inexpensive, automated quality control methodology for radiography (and mammography) systems. The software includes automated quantitative evaluation of everything necessary to meet the requirements of the rule listed immediately above. It also provides a quantity referred to as the "detectability index", which is a newer metric relating contrast, noise, and resolution to a model of human eye response to relate changes in fundamental physics quantities to clinical fitness of the machine. The phantom required by this methodology is simple to make, use, and was specifically designed to be low-cost. The automated analysis software is provided at no cost and can be used for both local and remote monitoring. There is a summary document of this methodology, including validation, which was published in the Journal of Applied Clinical Medical Physics in the November 2021 issue (link: https://aapm.onlinelibrary.wiley.com/doi/10.1002/acm2.13431).

The benefits of using this method include a user-independent automated analysis, low implementation cost, remote monitoring capability, and pre-built software while removing patient-to-patient variability and reliance on proprietary manufacturer-specific quantities.

Response: The Agency disagrees with modifying or removing the current language.

A. The "review of exposure index, deviation index, s-number or dose index values from clinical acquired radiographic images" is not a new requirement, but rather just expanded to include other metrics (i.e., exposure index, s-number) that may be incorporated into various manufacturers' software as well as newer indexes that are or will be available (e.g., deviation index) as manufacturers move to a uniform metric. The list of items indicated by the commenter are not included in the rule, but are all points that should be considered and included in the Quality Assurance program established by any registrant. Inclusion of specific parameters to address each of the items could be included in the rule, however, that could also inadvertently cause additional issues as situations vary from registrant to registrant. This could result in being more burdensome to some registrants. The Agency has developed a guidance document that can be provided upon request to registrants, that provides additional information on what should be considered.

B. As long as the IAEA quality control methodology is substantially the same as the amended regulation, the IAEA methodology could be used.