

RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 215, 221, 225, 230 AND 240]

Radiological Health

The Environmental Quality Board (Board) by this order amends Chapters 215, 221, 225, 230 and 240. These amendments update and correct Federal citations incorporated by reference from 10 CFR Part 71 (relating to packaging and transportation of radioactive material) concerning the transportation and packaging of radioactive material and remove references to obsolete regulatory provisions that were deleted in previous rulemakings. The amendments update references to guidance and standards for radon testing and mitigation, restore a written reporting requirement concerning Department of Environmental Protection (Department) notification of incidents involving the malfunction of shielded room radiography equipment and remove the requirement for notarization of radon service permit applications. Additional changes are also included to clarify requirements for X-ray use in the healing arts as well as the assessment of civil penalties to recover abatement costs incurred by the Department. The amendments also clarify the healing-arts screening requirements for facilities operating under the Federal Mammography Quality Act Standards.

This order was adopted by the Board at its meeting of December 18, 2007.

A. Effective Date

These amendments are effective upon publication in the *Pennsylvania Bulletin* as final-form rulemaking.

B. Contact Persons

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C. Statutory Authority

This final-form rulemaking is being made under the authority of sections 301 and 302 of the Radiation Protection Act (act) (35 P. S. §§ 7110.301 and 7110.302), which, respectively, direct the Department to develop and conduct comprehensive programs for the registration, licensing, control, management, regulation and inspection of radiation sources and radiation source users, and delegates to the Board the power to adopt the regulations of the Department to implement the act.

These amendments are also made under section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), which authorizes and directs the Board to adopt regulations necessary for the proper performance of the work of the Department and under the Radon Certification Act (63 P. S. §§ 2001—2014).

D. Background of the Amendments

In 2001, the Board updated chapters of its radiological health regulations to provide for compatibility with other states and to serve as a basis for the Commonwealth to assume authority from the United States Nuclear Regulatory Commission (NRC) for radioactive material licensees in this Commonwealth under the Agreement State program. These updates were published at 31 Pa.B. 5239 (September 15, 2001) and 31 Pa.B. 6280 and 6282 (November 17, 2001). Subsequently, in 2004, the Board published a final-form rulemaking at 34 Pa.B. 3823 (July 17, 2004) that corrected cross-references in the regulations for radiological health that were no longer accurate.

In the period following the 2004 amendments to the regulations for radiological health, there have been substantive changes to Federal regulations incorporated by reference, most notably 10 CFR Part 71. It is required that these references be corrected for the Commonwealth to have consistent regulations that are compatible with the NRC for submission as part of its application, which is currently under review by the NRC, to become an agreement state and assume authority over Federally-regulated radioactive materials. Under the Energy Policy Act of 2005 (Pub. L. No. 109-58, 119 Stat. 594), the Commonwealth may otherwise lose authority over accelerator-produced radioactive materials and discrete radium sources in 2009 if agreement state status is not attained. This final-form rulemaking also takes advantage of the opportunity to provide further clarification of the regulations in general regarding X-ray use and radon.

As required by section 301(c)(14) of the act, the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the proposed amendments and to advise the Department prior to submittal to the Board. On October 27, 2005, and December 26, 2005, the RPAC met and reviewed the proposed amendments. The RPAC accepted the regulations as proposed without issue and with minimal discussion. The RPAC, by letter dated December 29, 2005, from the chairperson, recommended that the amendments to the radiological health regulations be sent to the Board as proposed rulemaking. The unchanged proposed amendments were presented to the RPAC as final-form on July 19, 2007, and August 21, 2007. At the August 21, 2007, meeting, RPAC approved the final-form rulemaking and recommended the Department submit the final rulemaking to the Board for action.

No public meetings were held. The proposed regulations were published at 36 Pa.B. 7028 (November 18, 2006) with a 30 day comment period. No comments were received during the public comment period.

The regulations regarding transportation of radioactive material currently affect about 480 licensees of naturally occurring and accelerator produced isotopes. Approximately 720 licensees of the NRC in this Commonwealth are already subject to these regulations. Failure to enact the final-form rulemaking may delay or prevent the NRC approving the Commonwealth's application for agreement state. This could delay overall cost savings and efficiency under state rule for NRC licensees. Without agreement status, the Commonwealth will lose its authority to regulate all radioactive material in 2009, except diffuse naturally occurring radioactive material. The final-form rulemaking for radon reduces the regulatory burden and cost for about 600 certificate holders by removing the

requirement for notarization of permit applications. This also streamlines the application process. The remaining changes to the regulations for clarity and consistency are a general benefit to some 12,000 X-ray registrants and radon service certificate holders.

E. *Summary of Changes to the Proposed Rulemaking*

The final-form rulemaking is unchanged from the proposed version.

F. *Summary of Comments and Responses on the Proposed Rulemaking*

No comments were received regarding the proposed rulemaking.

G. *Benefits, Costs and Compliance*

Benefits

The primary benefits of this final-form rulemaking are to: (1) correct references that are no longer accurate as a result of changes in previous rulemakings and changes in the regulations of the NRC incorporated by reference to provide compatibility necessary to be an agreement state and to provide additional clarity and consistency; (2) restore shielded room radiography equipment malfunction report requirements so appropriate regulatory response can be considered and others in the regulated community potentially affected can be alerted; and (3) relieve radon services applicants of the unnecessary burden of attestation and to provide updated references to approved radon standards and protocols and reporting intervals. This is part of a comprehensive effort to provide additional clarity to the regulations for radiological health to make it easier for the regulated community to understand and comply. Compatible regulations are necessary for an agreement state that will eventually result in a net savings to the regulated community by eliminating duplicative State and NRC licenses, reducing the net burden on the regulated community for licensing fees, decreasing time lost to inspection and providing more responsive local regulation. Changes to the healing arts screening regulations will allow the Department to make more informed decisions regarding applications for approval to conduct screenings. The removal of notary requirements for radon service applications will speed up the application process and potentially save on application costs.

Compliance Costs

The majority of final-form amendments represent clarifications of requirements. Thus, the underlying requirements have not actually changed so there is no additional cost to comply. The failure of shielded room radiography equipment is not common and the additional cost to supply a written report should be negligible since a facility would investigate any serious failure anyway.

Compliance Assistance Plan

The majority of final-form amendments clarify references and definitions are self-explanatory. The updated guidance on radon measurement protocols and standards is freely available. There is a free radon hotline for additional assistance with radon guidance and applications.

Paperwork Requirements

Most of the final-form rulemaking is not associated with paperwork requirements. The time to report an equipment malfunction involving shielded room radiography of 30 days should not be a burden. The removal of notary requirements from radon services applications lessens the paperwork requirements for filing an application.

H. *Sunset Review*

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on November 2, 2006, the Department submitted a copy of the proposed rulemaking, published at 36 Pa.B. 7028 (November 18, 2008), to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department. A copy of this material is available to the public upon request.

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees are to be provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing these final-form regulations, the Department has received no comments to consider.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on March 19, 2008, this final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5(g) of the Regulatory Review Act, the final-form rulemaking was deemed approved by IRRC, effective March 19, 2008.

J. *Findings of the Board*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and regulations promulgated thereunder in 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law, and all comments were considered.

(3) These regulations do not enlarge the purpose of the proposal published at 36 Pa.B. 7028.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

K. *Order of the Board*

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 25 Pa. Code Chapters 215, 221, 225, 230 and 240, are amended by amending §§ 215.1, 215.2, 215.23, 221.2, 221.13, 221.30, 221.32a, 221.71, 221.201, 225.102, 230.3, 240.103, 240.113, 240.123, 240.133, 240.303 and 240.308; and by deleting § 221.3 to read as set forth in Annex A, with ellipses referring the existing text of the regulations.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of the Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson shall submit this order and Annex A to the IRRC and the Senate and House Environmental Resource and Energy Committees as required by the Regulatory Review Act.

(d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(e) This order shall take effect immediately upon publication.

KATHLEEN A. MCGINTY,
Chairperson

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 38 Pa.B. 1906 (April 19, 2008).)

Fiscal Note: Fiscal Note 7-402 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION
PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH
CHAPTER 215. GENERAL PROVISIONS

GENERAL PROVISIONS

§ 215.1. Purpose and scope.

* * * * *

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and §§ 150.1, 150.2, 150.3, 150.11 and 150.20 of the CFR are incorporated by reference with the exceptions set forth in paragraphs (1)–(13). Notwithstanding the requirements incorporated by reference, nothing in this article relieves or limits a person from complying with the laws of the Commonwealth, including the act and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101–7130.905).

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(13) Sections 71.2, 71.6, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, 71.100, 71.101(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125 are not incorporated.

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§ 215.2. Definitions.

The definitions in 10 CFR Chapter 1, Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and 150 are incorporated by reference in this article unless indicated otherwise. In addition, the following words and terms, when used in this article, have the following meanings, unless the context clearly indicates otherwise:

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Radiation source—An apparatus, device, equipment, radiation-producing machine or material, other than a nuclear power reactor and nuclear fuel located on a plant site, emitting or capable of emitting ionizing radiation.

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PROHIBITIONS AND RESTRICTIONS

§ 215.23. Penalties.

A person who violates this article is subject to the civil and criminal penalties in the act. At a minimum, civil penalties may be assessed in an amount sufficient to

recover the costs expended by the Department in the correction of the violation or abatement of the resulting radiological nuisance.

CHAPTER 221. X-RAYS IN THE HEALING ARTS

GENERAL PROVISIONS

§ 221.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

AAPM—American Association of Physicists in Medicine.

Aluminum equivalent—The thickness of type 1100 aluminum alloy—the nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, .12% copper—affording the same attenuation, under specified conditions, as the material in question.

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Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

Certified components—Components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 (42 U.S.C.A. §§ 263b–263n).

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Diagnostic X-ray system—An X-ray system designed for irradiation of a part of the human body for the purpose of diagnosis or visualization.

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Entrance exposure rate—The exposure in air per unit time at the point where the center of the useful beam enters the patient.

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Portable X-ray system—See X-ray equipment.

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Protective barrier—A barrier of radiation absorbing material used to reduce radiation exposure. The term includes the following types:

(i) Primary protective barrier—Material used to reduce radiation exposure from the useful beam.

(ii) Secondary protective barrier—Material used to reduce exposure from stray, leakage or scattered radiation.

Radiation therapy simulation system—A radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

* * * * *

Research—One of the following:

(i) Theoretical analysis, exploration or experimentation.

(ii) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental testing of models, devices, equipment, materials and processes. The term includes the external administration of X-ray radiation to human

beings for diagnostic or therapeutic purposes or in an equivalent manner as a diagnostic or therapeutic procedure.

SSD—The distance between the source and the skin of the patient.

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Useful beam—The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Visible area—The portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

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§ 221.3. (Reserved).

ADMINISTRATIVE CONTROLS

§ 221.13. Information to be submitted by persons requesting approval to conduct healing arts screening.

(a) The Department will consider efficacy as a factor in evaluating healing arts screening procedures. In its review, the Department will consider National medical organization consensus statements as well as peer reviewed scientific and medical literature that addresses the efficacy of the proposed screening procedures. The review may also consider relevant information from appropriate Federal agencies. For procedures that result in an individual organ dose or deep dose equivalent greater than 1 mSv (100 mrem) to a screened individual the Department will consult with the Department of Health (DOH) for assistance in reviewing the efficacy of the proposed procedures but the final decision will remain that of the Department. The DOH will have access to all relevant materials when rendering its review.

(b) A person requesting that the Department approve a healing arts screening program other than mammography shall submit in writing the following information for evaluation by the Department. If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

(1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.

(2) The diseases or conditions for which the X-ray examinations are to be used.

(3) The description in detail of the X-ray examinations proposed in the screening program.

(4) A description of the population to be examined in the screening program—age, sex, physical condition and other appropriate information.

(5) An evaluation of all known alternate methods that could achieve the goals of the screening program and why these methods are not used in preference to the proposed X-ray examinations.

(6) An evaluation by a qualified expert of the X-ray systems to be used in the screening program. The evaluation must show that the systems satisfy the requirements of this article. The evaluation must include a measurement of patient entrance exposures and calculation of the maximum shallow dose, deep dose equivalent and organ dose from the X-ray examinations to be performed.

(7) A description of the diagnostic X-ray quality control program.

(8) A copy of the technique chart for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.

(9) The qualifications of all individuals who will be operating the X-ray systems.

(10) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

(11) The name, address and qualifications of the individual who will interpret the screening procedure results.

(12) A description of the information and procedure for advising the individuals screened of the potential for false positive or negative results and the implications for the patient; the procedure for recording informed consent for the procedure following disclosure of this information; and the procedure for advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and further medical needs indicated.

(13) A description of the procedures for the retention or disposition of the diagnostic images, data and other records pertaining to the X-ray examination.

(14) An approximation of the frequency of screening activities and duration of the entire screening program.

(c) Mammography facilities shall comply with 21 CFR Part 900 (relating to mammography).

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.30. Exposure reproducibility for noncertified systems.

The coefficient of variation of exposure reproducibility may not exceed 0.10 when technique factors are held constant. This requirement shall be deemed to have been met when four exposures are made. This requirement applies when either manual techniques or automatic exposure control is used.

§ 221.32a. Radiographic beam limitation.

(a) The useful beam shall be limited to the area of clinical interest.

(b) The beam limiting device shall do one of the following:

(1) Indicate numerically the field size in the plane of the image receptor to which it is adjusted to within 2% of the SID.

(2) Provide for visually defining the perimeter of the X-ray field except for systems designed for one image receptor size. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field may not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

(c) A means shall be provided for stepless (continuous) adjustment of the size of the X-ray field except for systems which use removable fixed operation beam limiting devices.

(d) A means shall be provided to:

(1) Indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor if the angle between the axis of the X-ray beam and the plane of the

image receptor is variable. This paragraph does not apply to portable, mobile or intraoral dental units.

(2) Align the center of the X-ray field with respect to the center of the image receptor to within 2% of the SID.

(3) Indicate the SID to within 2%.

(e) Intraoral dental X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD to not less than either of the following:

(1) Eighteen centimeters if operable above 50 kVp.

(2) Ten centimeters if not operable above 50 kVp.

(f) Indication of field size dimensions and SIDs shall be specified so that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(g) Intraoral dental systems designed for use with an intraoral image receptor shall be provided with a means to limit the X-ray beam so that:

(1) Eighteen centimeters or more, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

(2) Less than 18 centimeters, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(h) When positive beam limitation is used, the following conditions shall be met:

(1) The radiation beam may not be larger than the linear dimensions of the image receptor being used.

(2) The positive beam limitation device shall allow the operator to further reduce the size of the radiation field.

(i) Mobile or portable X-ray systems, other than intraoral dental X-ray systems, shall be provided with a means to limit the source-to-skin distance to at least 30 centimeters.

(j) Radiographic equipment designed for one or more image receptor sizes at a fixed SID shall be provided with a means to accomplish one of the following:

(1) Limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and align the center of the X-ray field with the center of the image receptor to within 2% of the SID.

(2) The X-ray field shall be sized and aligned so that at the plane of the image receptor, it does not extend beyond the edge of the image receptor by more than 2% of the SID.

THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

§ 221.71. Equipment requirements.

(a) When the tube is operated at its leakage technique factors, the leakage radiation may not exceed:

(1) One hundred milliroentgens (25.8 μ C/kg) per hour at 5 centimeters from the surface of the tube housing assembly for contact therapy systems.

(2) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured or installed prior to December 19, 1987.

(3) One hundred milliroentgens (25.8 μ C/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured on or after December 19, 1987.

(4) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 151 to 500 kVp systems.

(5) One-tenth percent of the exposure rate of the useful beam 1 meter from the source for 501 to 999 kVp systems at 1 meter from the source.

(b) Fixed diaphragms or cones used for limiting the useful beam must provide at least the same protection as required by the tube housing assembly.

(c) Beam limiting devices may, for the portion of the useful beam blocked by these devices, transmit not more than 5% of the original X-ray beam intensity at the maximum voltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

(d) The filter system shall be designed so that:

(1) Filters cannot be accidentally displaced from the useful beam at any possible tube orientation.

(2) The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under operating conditions.

(3) A filter is marked as to its material of construction and its thickness. For wedge filters, the wedge factor and wedge angle shall appear on the wedge or wedge tray.

(4) On equipment purchased after January 1, 1971, a filter indication system shall be used on therapy machines using changeable filters. The system must indicate from the control panel the presence or absence of a filter and be designed to permit easy recognition of an added filter in place.

(5) An X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

(e) The tube housing assembly shall be immobilized during stationary treatments.

(f) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and the marking shall be readily accessible for use during calibration procedures.

(g) Contact therapy tube housing assemblies shall have a removable shield of at least .5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(h) Systems of greater than 150 kVp manufactured after December 19, 1987, must have a beam monitor system which meets the following requirements:

(1) Not allow irradiation until a preselected value of exposure has been made at the treatment control panel.

(2) Independently terminate irradiation when the preselected exposure has been reached.

(3) Be designed so that, in the event of a system malfunction or electrical power failure or other interruption, the dose administered to a patient prior to the interruption can be accurately determined.

(4) Have a control panel display which maintains the reading until intentionally reset to zero.

(5) Have a control panel display which does not have scale multiplying factors and utilizes a design so that increasing dose is displayed by increasing numbers.

(i) The following apply to timers on the equipment:

(1) A timer shall be provided which has a display at the control panel. The timer must be graduated in minutes and fractions of minutes. The timer must have a preset time selector and an elapsed time indicator.

(2) The timer must be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the timer to zero.

(3) The timer must terminate irradiation when a preselected time has elapsed if a dose monitoring system present has not previously terminated irradiation.

(4) The timer must permit accurate presetting and determination of exposure time as short as 1 second.

(5) The timer may not permit an exposure if set at zero.

(6) The timer may not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.

(j) The control panel, in addition to the displays required in this section, must have:

- (1) An indication of power status.
- (2) An indication of X-ray production.
- (3) The means of indicating X-ray tube current and voltage.
- (4) The means of terminating an exposure.

(k) When a control panel may energize more than one X-ray tube, the following requirements shall be met:

(1) It must be possible to activate only one X-ray tube at one time.

(2) There must be an indication at the control panel identifying which X-ray tube is energized.

(3) There must be an indication at the tube housing assembly when that tube is energized.

(l) There must be a means of determining the SSD to within 5 millimeters.

(m) Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

(1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

(2) An indication of shutter position must appear at the control panel.

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.201. Definitions.

In addition to the definitions of §§ 215.2 and 221.2 (relating to definitions), the following words and terms, when used in this section and §§ 221.202—221.205, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

CT conditions of operation—The selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration and the technique factors as defined in this chapter.

Detector—A device that provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Elemental area—The smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted.

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CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subchapter B. RADIATION-PRODUCING MACHINES

RADIATION-PRODUCING MACHINE REQUIREMENTS

§ 225.102. Shielded room X-ray radiography.

(a) A room used for shielded room X-ray radiography shall be shielded so that every location on the exterior meets conditions for an unrestricted area and the only access to the room is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

(b) The operator shall conduct a physical radiation survey to determine that the radiation source is deenergized prior to each entry into the radiographic exposure area.

(c) As an alternative to subsection (b), the registrant may use an independent radiation monitoring system that displays the radiation intensity or displays when radiation levels have returned to their pre-irradiation levels.

(d) With the exception of the provisions in §§ 225.4a, 225.76 and 225.84 (relating to radiation safety program; reporting requirements; and operating and emergency procedures), shielded room radiography is exempt from all other provisions of this chapter.

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE AND DEFINITIONS

§ 230.3. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 71.2, 71.6, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, 71.100, 71.101(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125 are not incorporated by reference.

CHAPTER 240. RADON CERTIFICATION

Subchapter B. CERTIFICATION

CERTIFICATION FOR RADON TESTING

§ 240.103. Radon testing application contents.

An application for radon testing certification, by both individual and firm, shall be submitted to the Department in writing on forms provided by the Department and must contain:

(1) Evidence that the applicant has the certification prerequisites in § 240.102 (relating to prerequisites for radon testing certification), including the services offered and experience in each. If the applicant is a firm, the application must also include the duties assigned to the certified individual.

(2) A nonrefundable fee of \$200 for individuals, \$500 for firms.

(3) The applicant's name, address and telephone number. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Copies of reporting forms, information distributed to potential clients and recent advertisements.

(6) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon testing.

(7) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief.

CERTIFICATION FOR RADON MITIGATION

§ 240.113. Radon mitigation application contents.

An application for mitigation certification, by both individual and firm, shall be submitted to the Department in writing on forms provided by the Department and must contain:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.112 (relating to prerequisites for radon mitigation certification), including the services offered and experience in each. If the applicant is a firm, the applicant shall also include the duties assigned to the certified individual.

(2) A nonrefundable fee of \$200 for individuals, \$500 for firms.

(3) The applicant's name, address and telephone number. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon mitigation.

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief.

CERTIFICATION FOR RADON LABORATORY

§ 240.123. Radon laboratory application contents.

An application for radon laboratory certification shall be submitted to the Department in writing on forms provided by the Department and must contain:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.122 (relating to prerequisites for radon laboratory certification), including the services offered and experience in each. If the applicant is a firm, the applicant shall also include the duties assigned to the certified individual.

(2) A nonrefundable fee of \$250 for individuals, \$500 for firms.

(3) The applicant's name, address and telephone number. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to laboratory analysis of radon samples.

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief.

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

§ 240.133. Certification application contents.

A person who has a certification from a state with which the Department has entered into a reciprocal agreement, and who intends to conduct the radon-related activity in this Commonwealth for at least 90 days a year, shall obtain certification from the Department. The application must be in writing and contain:

(1) A copy of the certification from foreign state.

(2) A nonrefundable fee of \$200.

(3) The applicant's name, address and telephone number. It must also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application must include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications, or technical or administrative information related to radon testing, mitigation of radon contamination or laboratory analysis of radon samples.

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief.

Subchapter D. OPERATION REQUIREMENTS**§ 240.303. Reporting of information.**

(a) Within 45 days after testing, mitigation or other radon-related service is provided, the person providing the service shall submit to the Department in a format approved by the Department the results of testing, including screening measurements, follow-up measurements, premitigation measurements, postmitigation measurements and the method used to mitigate against radon contamination. At a minimum, these results will be retained for 2 years. The information must include:

- (1) The name of the person providing the service.
- (2) The name and address of the owner or occupant of the building involved.
- (3) The address and location of the building involved, including street and number, post office, full zip code and county.
- (4) The date each measurement was taken, or the mitigation performed.
- (5) The type of house or building, the types of measurements, location within the building of specific measurements, and the results in picocuries per liter or in working levels.
- (6) The type and price of mitigation system installed.

(b) Within 45 days after testing, mitigation or other radon-related service is provided, the person providing radon-related services shall report in writing to the owner or occupier of the building the results in picocuries per liter and when appropriate in working levels of radon measurements taken in the building. If a person provides the service through a certified intermediary, it is the responsibility of the intermediary to report the results.

(c) For a person performing mitigation, each building shall be tested for radon levels before and after the mitigation is performed. Each test must be at least 48 hours in duration and follow EPA- or DEP-approved protocols. The postmitigation test shall be conducted no sooner than 24 hours after completion of the mitigation. The results of radon testing shall be reported in accordance with this section.

§ 240.308. Testing and mitigation protocols.

A person conducting radon testing or mitigation for radon contamination shall conduct the testing and mitigation in accordance with EPA- or DEP-approved protocols and shall comply with applicable statutes, regulations, ordinances and building codes. The following protocols, "Protocols for Radon and Radon Decay Product Measurements in Homes," "Indoor Radon and Radon Decay Product Measurement Device Protocols" and "Pennsylvania Radon Mitigation Standards" are available upon request from the following sources:

Environmental Protection Agency
Office of Radiation Programs
Washington, D.C. 20460

Department of Environmental Protection
Bureau of Radiation Protection
Rachel Carson State Office Building, 13th Floor
400 Market Street
Post Office Box 8469
Harrisburg, Pennsylvania 17105-8469

[Pa.B. Doc. No. 08-916. Filed for public inspection May 16, 2008, 9:00 a.m.]

Title 40—LIQUOR**LIQUOR CONTROL BOARD****[40 PA. CODE CHS. 3, 5, 7 AND 13]****License Applications and Management Contracts**

The Liquor Control Board (Board), under the authority of section 207(i) of the Liquor Code (47 P. S. § 2-207(i)) has amended Chapters 3, 5, 7 and 13.

Purpose

The Board has reviewed its regulations and determined that these revisions are necessary to conform to changes in the Liquor Code, update obsolete regulations and implement new procedures to improve service to the public.

Summary of Amendments

The regulatory amendments rescind regulations concerning the "Points System," the enabling legislation for which has expired. Other changes permit the Board to conduct tasting events in its stores. Finally, obsolete and repetitive regulations are updated and consolidated.

- The rulemaking rescinds regulations concerning the "Points System."
- It consolidates two separate regulations about the appointment of managers for licensed establishments.
- It corrects a regulation relating to license transfers upon death of a licensee.
- It amends regulations on the safekeeping of licenses to parallel recent changes in the Liquor Code.
- It permits the Board to conduct tasting events in its stores.

Affected Parties

The final-form rulemaking will affect licensees and customers of the Board's wine and spirits stores.

Paperwork Requirements

The final-form rulemaking will not significantly increase paperwork for the agency or the regulated community.

Fiscal Impact

No fiscal impact is expected.

Effective Date

This rulemaking shall become effective upon its publication as final-form in the *Pennsylvania Bulletin*.

Contact Person

Requests for information should be addressed to James F. Maher, Assistant Counsel, Office of Chief Counsel, Liquor Control Board, Room 401, Northwest Office Building, Harrisburg, PA 17124-0001.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (act) (71 P. S. § 745.5(a)), on December 6, 2007, the Board submitted a copy of the notice of proposed rulemaking, published at 37 Pa.B. 6932 (December 29, 2007), to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Liquor Control Committee on December 6, 2007, and Senate Committee on Law and Justice on December 6, 2007, for review and comment.

Under section 5(c) of the act, the Board is required to provide IRRC and the Committees with copies of the

comments received during the public comment period, as well as other documents when requested. No comments from IRRC, the Committees or the public were received.

Under section 5.1(j.2) of the act, on March 19, 2008, these final-form regulations were deemed approved by the House and Senate Committees. Under section 5(g) of the act, the final-form regulations were deemed approved by IRRC effective March 19, 2008.

Findings

The Commission finds that:

(1) Public notice of the intention to adopt the administrative amendments adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The amendments to the Board's regulations in the manner provided in this order is necessary and appropriate for the administration of the Liquor Code.

Order

The Board, acting under authorizing statute, orders that:

(a) The regulations of the Board, 40 Pa. Code Chapters 3, 5, 7 and 13 are amended by amending §§ 5.23, 7.5, 7.31, 7.32, 13.221 and 13.227; and by deleting §§ 3.121, 3.122 and 5.16 to read as set forth at 37 Pa.B. 6932.

(b) The Executive Director of the Board shall certify this order and 37 Pa.B. 6932 and deposit them with the Legislative Bureau as required by law.

(c) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

PATRICK J. STAPLETON, III,
Chairperson

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 38 Pa.B. 1905 (April 19, 2008).)

Fiscal Note: Fiscal Note 54-64 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 08-917. Filed for public inspection May 16, 2008, 9:00 a.m.]

Title 58—RECREATION
PENNSYLVANIA GAMING CONTROL BOARD
[58 PA. CODE CH. 437a]
Vendor Certification and Registration

The Pennsylvania Gaming Control Board (Board), under the general authority in 4 Pa.C.S. §§ 1202(b)(30) and 1321 (relating to general and specific powers; and additional licenses and permits and approval of agreements) amends Chapter 437a (relating to vendor certification and registration) to read as set forth in Annex A.

Purpose of the Proposed Rulemaking

These amendments modify provisions related to registration of vendors, clarify which individuals must obtain certification and update the names of several forms.

Explanation of Amendments to Chapter 437a

Currently, applications for certification or registration of vendors must be submitted by an applicant for or

holder of a slot machine license. These amendments give applicants for registration as a vendor the option to file their applications directly with the Board. This simplifies the application process and is expected to increase the number of registered vendors on the Board's approved vendor list. Because slot machine applicants and licensees may use any vendor on the Board's approved list, this will increase the vendors' opportunities to provide services and give slot machine applicants and licensees more vendors to choose from.

In § 437a.4 (relating to individual certifications and investigations), minor revisions clarify who will be required to file for certification.

Additionally several references to forms have been updated throughout the chapter to reflect the current names of the applicable forms.

Comment and Response Summary

Notice of proposed rulemaking was published at 37 Pa.B. 6420 (December 8, 2007).

The Board did not receive any comments during the public comment period. No comments were received from the Standing Committees and by letter dated February 6, 2008, the Independent Regulatory Review Commission (IRRC) notified the Board that IRRC had no objections, comments or recommendations to offer on these amendments.

No changes have been made to the proposed regulation in this final-form regulation.

Affected Parties

Applicants for vendor registration will benefit from having another option for applying for registration as a vendor. Slot machine applicants and licensees may benefit by having more vendors to choose from.

There are currently 11 slot machine licensees, 5 applicants for slot machine licenses and 244 registered vendors.

Fiscal Impact

Commonwealth

There will be no new costs to the Board or other Commonwealth agencies as a result of this regulation. Because the application for an unsponsored vendor registration does not require a Slot Machine Licensee/Applicant's Verification form, there will be some minor savings to the Board related to review of vendor registration applications submitted directly by vendors.

Political Subdivisions

This final-form rulemaking will have no fiscal impact on political subdivisions of the Commonwealth.

Private Sector

The Board anticipates that there may be some small direct savings to slot machine applicants and licensees and to applicants for vendor registrations as a result of having another option for applying for registration as a vendor.

Because the Board anticipates an increase in the number of vendors, slot machine applicants and licensees may benefit from increased competition for their business.

General Public

This final-form rulemaking will have no fiscal impact on the general public.

Paperwork requirements

These amendments eliminate the need for a Slot Machine Licensee/Applicant's Verification form as part of the vendor registration application when the vendor applies directly.

Effective Date

The rulemaking will become effective upon final-form publication in the *Pennsylvania Bulletin*.

Contact Person

The contact person for questions about this final-form rulemaking is Richard Sandusky, Director of Regulatory Review, at (717) 214-8111.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (act) (71 P. S. § 745.5(a)), on November 28, 2007, the Board submitted a copy of the proposed rulemaking, published at 37 Pa.B. 6420, and a copy of the Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Gaming Oversight Committee and the Senate Committee on Community, Economic and Recreational Development.

Under section 5(c) of the act (71 P. S. § 745.5(c)), IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments received from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the act (71 P. S. § 745.5a(j.2)), the final-form rulemaking was deemed approved by the House Gaming Oversight Committee and the Senate Committee on Community, Economic and Recreational

Development on April 2, 2008. Under section 5(g) of the act (71 P. S. § 745.5(g)), the final-form rulemaking was deemed approved by IRRC effective April 2, 2008.

Findings

The Board finds that:

(1) Public notice of intention to adopt these amendments was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The final-form rulemaking is necessary and appropriate for the administration and enforcement of 4 Pa.C.S. Part II (relating to gaming).

Order

The Board, acting under 4 Pa.C.S. Part II, orders that:

(a) The regulations of the Board, 58 Pa. Code Chapter 437a, are amended by amending §§ 437a.2—437a.5, 437a.9 and 437a.10 to read as set forth at 37 Pa.B. 6420.

(b) The Chairperson of the Board shall certify this order and 37 Pa.B. 6420 and deposit them with the Legislative Reference Bureau as required by law.

(c) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

MARY DIGIACOMO COLINS,
Chairperson

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 38 Pa.B. 1905 (April 19, 2008).)

Fiscal Note: Fiscal Note 125-74 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 08-918. Filed for public inspection May 16, 2008, 9:00 a.m.]