RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 218]

Fees

The Environmental Quality Board (Board) by this order amends Chapter 218 (relating to fees) to adjust existing fees for registration of X-ray machines for inflation since last revised; to establish fees for accelerator licensing; and to establish fees for radioactive material licenses now administered by the Nuclear Regulatory Commission (NRC) that will be transferred to the Department of Environmental Protection (Department) when the Commonwealth attains agreement state status from the NRC.

This order was adopted by the Board at its meeting of September 18, 2001.

A. *Effective Date*

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

B. *Contact Persons*

For further information, the contact persons are L. Ray Urciuolo, Chief, Licensing Section, Radiation Control Division, Bureau of Radiation Protection, 13th Floor, Rachel Carson State Office Building, P. O. Box 8469, Harrisburg, PA 17105-8469, (717) 787-3720; and Marylou Barton, Assistant Counsel, Bureau of Regulatory Counsel, Rachel Carson State Office Building, 9th Floor, 400 Market Street, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This final-form rulemaking is available electronically through the Department's website (http://www.dep.state.pa.us).

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 delegate to the Board the power to adopt the regulations of the Department to implement the act.

Section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20) authorizes and directs the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. *Background and Summary*

The act requires the Department to establish fees in amounts at least sufficient to cover the costs of the radiation protection program mandated by that act. The present fees were established in 1992 and have not been revised since that time, despite a substantial increase in inspector salaries and equipment costs. In the last fiscal year, receipts from registrations and licenses fell short of the costs to operate the program. Further, in 1998, Chapter 228 (relating to radiation safety requirements for particle accelerators) was amended to provide that accelerators be licensed, with review of the proposed installation, use and radiation safety program, rather than simply being registered like X-ray machines. In addition to the costs of license application review, experience in recent years has demonstrated that the cost to the Department of inspections and enforcement for accelerators is greater than for X-ray installations. Finally, before the Commonwealth can acquire the authority and responsibility for the radioactive materials licenses in this Commonwealth that are now administered by the NRC, the Department will have a fee structure in place to fund the effort. It is particularly important that the authority be established for "full cost" recovery for certain types of licenses, notably low-level radioactive waste and decommissioning licenses, where there is no reasonable way of establishing fixed fees.

Therefore, Chapter 218 is being amended for the purposes of:

(1) Increasing annual fees for registration of X-ray machines and for licenses to possess and use naturally occurring and accelerator-produced radioactive material (NARM) by an overall average of 40%, an amount sufficient to ensure income adequate to fund those programs.

(2) Establishing fees for licensing of particle accelerators.

(3) Establishing annual fees for radioactive material licenses located in this Commonwealth and now administered by the NRC. These fees will not be effective until the Commonwealth is granted agreement state authority by the NRC under section 274 of the Atomic Energy Act of 1954 (42 U.S.C.A. § 2021).

As required by section 301(c)(14) of the act, the Department provided the Radiation Protection Advisory Committee (Committee) with an opportunity to review the final amendments and to advise the Department prior to submittal to the Board. On May 17, 2001, the Committee met and reviewed the draft final rulemaking. The chairperson announced by letter dated May 17, 2001, the Committee's concurrence to send the final-form rulemaking to the Board.

E. *Summary of Regulatory Requirements*

A description of the amendments is provided as follows.

General

§ 218.1. Purpose and scope.

A new subsection (b)(3) is added to include holders of and applicants for accelerator licenses to the list of persons subject to this chapter.

Payment of Fees

§ 218.11. Registration, renewal of registration and license fees.

Subsection (a) is rewritten to remove accelerators from the category of radiation-producing machines and to revise the fee structure for X-ray machines. The existing fee structure contains a registration fee that includes the first tube, and a fee of $25 for each additional tube. Fees will now consist of the sum of an annual administrative fee for each registrant plus a $35 fee for each tube possessed. The fees are presented in a table. Overall, fees are increased by an average of 40% to compensate for increased staff salaries since 1992 when they were established.

Subsection (c) is revised to provide for fees for the NRC licenses that will be transferred to the Commonwealth upon achievement of agreement state status. Because there are many types of licenses recognized by the NRC for which the Commonwealth does not have separate categories, the fees are tabulated in a new Appendix A. The lead sentence is revised by deleting "this subsection" and adding "Appendix A." Existing paragraph (1) and subparagraphs (i)—(iii) have been deleted. A new paragraph (1) is added to specify that no refunds will be made if a license is terminated. New paragraph (2) provides for changes in license category to take place on the anniversary date of the license. Existing paragraph (2), pertaining to exceptions, is deleted as it is no longer needed.

Existing subsections (d)—(f) are renumbered as (e)—(g), respectively, and a new subsection (d) is added to institute license fees for several classes of accelerators. These fees are proportional to the complexity and potential for radiation safety problems of the accelerators.

Language was added to renumbered subsection (e) to include reciprocity as a license category requiring advance payment of fees, to include the fees instituted in new subsection (d), and to recognize the various fee schedules in revised Chapter 218.

Language was also added to renumbered subsection (f) to recognize the new fee schedules. Other than renumbering, no change was made to subsection (g).

§ 218.12. Failure by registrant or licensee to pay required fee.

Subsection (b) was revised to provide that failure to pay X-ray registration fees shall be cause for revocation of the registration. The subsection already provides for revocation of licenses for nonpayment of fees.

Appendix A

Appendix A is new and both replaces former language of § 218.11(c), which specified fees for NARM licenses, and establishes fees for licenses that will be transferred to the Commonwealth when regulatory authority for most types of radioactive material is transferred from the NRC.

F. Summary of Comments and Responses on the Proposed Rulemaking

The notice of proposed rulemaking was published at 31 Pa.B. 943 (February 17, 2001) and included a 30-day comment period that ended on March 19, 2001. The Board received no comments from the public, the Independent Regulatory Review Commission (IRRC) or the legislative committees concerning the proposed rulemaking. Therefore, no Comment/Response document was prepared.

G. *Benefits, Costs and Compliance*

Executive Order 1996-1 requires a cost/benefit analysis of the final-form rulemaking.

Benefits

Receipt of fees necessary to cover the costs of the radiation protection program will preserve the current program for the benefit of the people of this Commonwealth. Holders of radioactive materials licenses will benefit from simplification of compliance costs associated with the present dual regulation and by generally reduced fees as noted as follows.

Compliance Costs

The compliance costs under the proposed amendments will vary with the type of license or registration held, or both. X-ray registrants and NARM licensees will incur a fee increase on average of about 40%. License fees for former NRC radioactive materials licenses will decrease by about 30% from FY 2000 NRC fees, and somewhat more if they also hold a NARM license, which will be combined with the NRC license at the fee for the NRC license. These holders of both types of radioactive materials (RAM) licenses will also experience substantial savings by no longer being required to follow two sets of regulations and be inspected by two regulators.

Holders of accelerator registrations being converted to licenses will incur a significant increase in fees, the exact amount of which will be determined by the type and number of machines that they possess. The Board instituted the change to licensing because of the complexity and potential hazards associated with accelerator use. License review, facility inspection and enforcement activities require considerably more time than regulation of X-ray machines, and the proposed fees reflect that fact.

Compliance Assistance Plan

Compliance assistance requirements are expected to be negligible because, other than changes in the amount of fees and, for former NRC licensees, to whom they are paid, and the elimination of one set of inspectors, no changes in operating requirements are involved. Outreach and assistance will be provided by regional inspectors and technical staff in the Radiation Control Division.

Paperwork Requirements

No additional paperwork will be required under these amendments. Once agreement state authority is approved, which is anticipated in 2002, and the NRC licenses are converted to State licenses, over a period of a year, licensees will have significantly less paperwork.

H. *Sunset Review*

These final-form 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 February 6, 2001, the Department submitted a copy of the notice of proposed rulemaking, published at 31 Pa.B. 943, to IRRC and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment. There were no comments received from the public, IRRC or the Committees on the proposed rulemaking.

Under section 5.1(d) of the Regulatory Review Act (71 P. S. 745.5a(d)), on October 11, 2001, these final-form regulations were deemed approved by the House and Senate Committees. The regulations were deemed approved under section 5(g) of the Regulatory Review Act by IRRC, effective October 12, 2001.

J. *Findings*

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 no comments were received.

(3) These final-form regulations do not enlarge the purpose of the proposal published at 31 Pa.B. 943.

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

K. *Order*

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

(a) The regulations of the Department, 25 Pa. Code Chapter 218, are amended by amending §§ 218.1, 218.11 and 218.12; and by adding Appendix A to read as set forth at 31 Pa.B. 943.

(b) The Chairperson of the Board shall submit this order and 31 Pa.B. 943 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 31 Pa.B. 943 to IRRC and the Senate and House Environmental Resource and Energy Committees as required by law.

(d) The Chairperson of the Board shall certify this order and 31 Pa.B. 943 and deposit them with the Legislative Reference Bureau, as required by law.

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

DAVID E. HESS,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 31 Pa.B. 6120 (November 3, 2001).)

Fiscal Note: Fiscal Note 7-363 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 01-2051. Filed for public inspection November 16, 2001, 9:00 a.m.]

ENVIRONMENTAL QUALITY BOARD
[25 PA. CODE CHS. 221, 227 AND 228]
Radiological Health

The Environmental Quality Board (Board) by this order amends Chapters 221, 227 and 228 (relating to X-rays in the healing arts; radiation safety requirements for analytical X-ray equipment, X-ray gauging equipment, electron microscopes and X-ray calibration systems; and radiation safety requirements for particle accelerators). These final-form amendments to the standards for protection against radiation update and clarify the standards for the safe use of radiation-producing machines.

This order was adopted by the Board at its meeting of September 18, 2001.

A. *Effective Date.*

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

B. *Contact Persons.*

For further information, contact Edward M. Burtsavage, Chief, Regional Liaison Section, Radiation Control Division, Bureau of Radiation Protection, 13th Floor, Rachel Carson State Office Building, P. O. Box 8469, Harrisburg, PA 17105-8469, (717) 787-3720; or Marylou Barton, Assistant Counsel, Bureau of Regulatory Counsel, Rachel Carson State Office Building, 9th Floor, 400 Market Street, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060.

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 of Environmental Protection (Department) to develop and conduct comprehensive programs for the registration, licensing, control, management, regulation and inspection of radiation sources and radiation source users, and delegate to the Board the power to adopt the regulations of the Department to implement the act.

Section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20) authorizes and directs the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. *Background and Summary.*

The final-form rulemaking, for the most part, correct printing errors, clarify existing language or modify existing language to accommodate changes in equipment since these chapters were last amended.

The only major change is the addition of a new group of sections under the heading of "X-ray calibration systems" in Chapter 227 for the purpose of specifically extending X-ray protection requirements to this type of facility. Accompanying changes in the chapter title, contents, general provisions and definitions are also made.

Most of the revisions to § 221.11 (relating to registrant responsibilities) were made in the final-form rulemaking to eliminate separate requirements for dental X-ray operations and to make the requirements applicable to all types of medical X-ray uses.

Persons affected by the final-form rulemaking include many of the approximately 9,600 individuals, corporations, institutions, groups or agencies that possess and use X-ray machines for medical purposes, any of the approximately 250 entities using particle accelerators and fewer than five X-ray calibration facilities. Except for calibration facilities, the final-form amendments will either reduce the registrants' regulatory burden or have minimal practical effect on their operations.

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 draft final-form rulemaking and to advise the Department prior to submittal to the Board. On May 17, 2001, RPAC met and reviewed the draft final-form rulemaking. The RPAC chairperson announced by letter dated June 20, 2001, RPAC's concurrence to send the final-form rulemaking to the Board.

E. *Summary of Comments and Responses and Changes Made to the Proposed Rulemaking.*

Notice of proposed rulemaking was published at 31 Pa.B. 792 (February 10, 2001) and included a 30-day comment period that ended on March 12, 2001. The Board received one response during the comment period. The Independent Regulatory Review Commission (IRRC) also provided comments on the proposed rulemaking. The Department prepared a comment and response document that summarizes and responds to each of these comments. A copy of the comment and response document is available upon request from the contact persons listed in

Section B. A description of the final-form amendments and the comments and responses are provided.

Chapter 221

§ 221.11. Registrant responsibilities.

A new subsection (e)(4) is added that reads "No individual, other than the patient being examined, may be in the useful beam, unless required to conduct the procedure." This amendment is being made to consolidate requirements as suggested by IRRC.

The word "film" is replaced by the words "image receptor" in two places in § 221.11(h) in the final-form rulemaking because many modern X-ray machines use digital technology rather than film. The term "image receptor" includes any device used to transform incident X-ray photons into a visible image or into another form, which can then be transformed into a visible image.

The Pennsylvania Dental Hygienists' Association requested addition of the words "dental hygienist" in § 221.11(m). In the final-form rulemaking, the prohibition against holding patients or film was made generic to all X-ray procedures and placed in § 221.11(h)(3), which does not identify any specific type of person holding the patient.

Section 221.11(h)(4) is deleted and a generic prohibition against holding the tube housing or collimating device of an X-ray machine, applicable to all machines, is added as § 221.11(m) in the final-form rulemaking. As previously noted, this amendment is being made because other medical specialties, such as podiatrists, use the same type of machine, and there is no reason to limit the rule to dentists. Similar language existed in § 221.56 (relating to administrative controls), which is being deleted.

IRRC disagreed with replacing the word "shall" in § 221.11(k) with "should" because this term would not be a binding requirement. The Board agrees and is retaining the word "shall." Section 221.11(k) is significantly changed in the final-form rulemaking based on IRRC's concern and suggestions of RPAC that compatible films and screens need to be used. This subsection is split into § 221.11(j) and (k). Existing language in § 221.11(j) is deleted because similar language was added to Chapter 215 (relating to general provision) in a recent rulemaking.

In the proposed rulemaking, § 221.11(l) was modified to allow the Department to develop its own guidelines for quality assurance programs as opposed to relying on the guidelines of specific organizations. IRRC suggested that the source or content of those guidelines, as well as how registrants can obtain copies of the guidelines, be included in the final-form regulations. Section 221.1(l) is revised in the final-form rulemaking to also allow guidelines from organizations recognized by the Department. This amendment will make it easier for the Department to add and change guidelines as needed without a formal rulemaking whenever a medical specialty organization issues new quality assurance guidelines. The final-form rulemaking also indicates that the Department will maintain a list of approved guidelines and make them available on the Department website and on request.

IRRC noted that § 221.11(g), (m) and (n) contain rules designed to limit or prevent unnecessary exposure to X-rays and suggested that the requirements be combined into a concise set of rules or a general rule. The Board agrees that it is better to have rules that apply across the board whenever feasible. As a result, proposed § 221.11(m), (n) and (p) are deleted in the final-form rulemaking. Section 221.11(o) is renumbered as § 221.11(m) and the word "cone" replaced by "collimating device," which is a more generally applicable term. Section 221.11(p) is deleted in its entirety because this type of equipment is not presently used. In the event that the Federal Food and Drug Administration (FDA) authorizes equipment of this type, appropriate conditions of use would be specified.

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

Section 221.13(14) is modified to clarify that mammography facilities must comply with 21 CFR Part 900.

§ 221.29. Kilovoltage (kV) accuracy.

Section 221.29 is modified to clarify that the 10% variation permitted under the existing language applies only to the range of technique factors used.

§ 221.32a. Radiographic beam limitation.

Section 221.32a(d)(1) is modified to state that the requirement for an indicator only applies to machines having a variable angle between the X-ray beam axis and the image receptor plane and to exempt portable, mobile and dental X-ray units from the requirement. Typically, these units do not have this type of indicator. The section title has also been revised to add the term "radiographic."

Section 221.32a(i) was changed to clarify that intraoral dental X-ray systems are not limited to a source-to-skin distance of 30 centimeters.

§ 221.33a. Radiation from capacitor energy storage equipment in standby status.

Section 221.33a is being modified to correct a typographical error in the published text. The unit should be 0.516 μC/kg rather than 0.516 μmC/kg. The unit as currently published is a factor of 1,000 lower than intended. In addition, the words "a fully charged" are added to clarify that the system should be charged when measurements are made.

§ 221.36a. Limitation of useful beam of fluoroscopic equipment.

Section 221.36a(d) is modified to adopt the wording used by the FDA in 21 CFR 1020.32(b) (relating to fluoroscopic equipment). This eliminates confusion regarding the permissible size and shape of the useful beam.

§ 221.56. Administrative controls.

Section 221.56(a)—(c) is deleted as duplicative of requirements added in the final-form rulemaking to § 221.11(h)(3), (e)(4) and (m).

§ 221.61. Radiation therapy simulation systems.

This section was changed in the final-form rulemaking to correct an exemption erroneously identified as § 221.42a. The correct reference is § 221.41a (relating to fluoroscopic timer).

§ 221.202. Equipment requirements.

Section 221.202(c) is modified to delete paragraph (2) because many units do not have a feature which is not required by the FDA.

Chapter 227

This chapter is modified to add X-ray calibration systems. New §§ 227.101—227.104 were originally approved by RPAC in 1998 as part of an amendment to Chapter 225 (relating to radiation safety requirements for industrial uses and radiographic operations). The Board decided, however, that the content would be more appro-

priately placed in Chapter 227, which deals with miscellaneous X-ray equipment. These sections are needed to specifically extend X-ray protection requirements to this type of operation, which is becoming more common. The chapter title, contents, general provisions and definitions were also changed to reflect the new sections.

The language of § 227.101 (relating to scope) was modified in the final-form rulemaking to more accurately describe the function of these systems. Minor language changes were also made in §§ 227.102 and 227.103 (relating to area requirements; and operating requirements).

Chapter 228

Changes to §§ 228.22a and 228.36 are made for purposes of clarification.

§ 228.22a. Issuance of specific licenses.

Section 228.22a contains a minor revision recommended by RPAC. RPAC felt that, by definition, if an application met the requirements of the act and article, the operation would not be "inimical to the safety of the public," as indicated in § 228.22a(a). The Board concurs, and the phrase was removed from § 228.22a(a).

§ 228.36. Radiation monitoring requirements.

This section is modified to provide: (1) that an independent radiation monitoring system be provided so that the individuals entering or present become aware of the existence of the hazard; and (2) the system be tested for response, rather than calibrated, at least annually and after servicing or repair. The Board and RPAC agree that calibration, which implies that the response be accurate within a specified limit, is not necessary for this function. In the final-form rulemaking, the words "in a potential very high radiation area" were added to emphasize the hazard being warned against.

F. *Benefits Costs and Compliance.*

Executive Order 1996-1 requires a cost/benefit analysis of the final-form rulemaking.

Benefits

As set forth in these final-form amendments, users of X-ray machines and particle accelerators will benefit from the rulemaking being clarified to conform better to present equipment and installations and elimination of a 1,000-fold error in units in § 221.33a. The additions to Chapter 227 specifically extend the safety requirements set forth for other types of X-ray installation to X-ray calibration systems.

Compliance Costs

The compliance costs under the final-form amendments should not differ appreciably from the costs presently incurred.

Compliance Assistance Plan

Compliance assistance requirements are expected to be negligible. Outreach and assistance will be provided by regional inspectors and technical staff in the Radiation Control Division.

Paperwork Requirements

No additional paperwork will be required under these final-form amendments.

G. *Sunset Review.*

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

H. *Regulatory Review.*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on January 29, 2001, the Department submitted a copy of the notice of proposed rulemaking, published at 31 Pa.B. 792, to IRRC and the Chairpersons of the Senate and House Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, 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 these final-form regulations, the Department has considered the comments from IRRC, the Committees and the public.

Under section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), on October 11, 2001, these final-form amendments were deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 18, 2001, and approved the final-form amendments.

I. *Findings.*

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 at 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 amendments do not enlarge the purpose of the proposal published at 31 Pa.B. 792.

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

J. *Order.*

The Board orders that:

(a) The regulations of the Department, 25 Pa. Code Chapters 221, 227 and 228, are amended by amending §§ 221.13, 221.29, 221.36a, 221.202, 227.1, 227.2 and 228.22a, by deleting § 221.56 and by adding § 227.104 to read as set forth at 31 Pa.B. 792; and by amending §§ 221.11, 221.32a, 221.33a, 221.61 and 228.36 and adding §§ 227.101—227.103 to read as set forth in Annex A, with ellipses referring to the existing test of the regulations.

(b) The Chairperson of the Board shall submit this order, 31 Pa.B. 792 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, 31 Pa.B. 792 and Annex A to IRRC and the Senate and House Environmental Resource and Energy Committees as required by law.

(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 in the *Pennsylvania Bulletin*.

DAVID E. HESS,
Chairperson

Fiscal Note: Fiscal Note 7-360 remains valid for the final adoption of the subject regulations.

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 31 Pa.B. 6120 (November 3, 2001).)

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 221. X-RAYS IN THE HEALING ARTS

ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

* * * * *

(e) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. The following apply for individuals other than the patient being examined:

* * * * *

(4) No individual, other than the patient being examined, may be in the useful beam, unless required to conduct the procedure.

* * * * *

(h) If a patient or image receptor requires auxiliary support during a radiation exposure the following apply:

(1) Mechanical holding devices shall be used when the technique permits.

(2) The human holder shall be protected as required by subsection (e).

(3) An individual may not be used routinely to hold image receptors or patients.

(i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(j) The screen and film system used shall be spectrally compatible. Defective screens may not be used for diagnostic radiological imaging.

(k) With the exception of intraoral dental radiography, film may not be used without intensifying screens for routine diagnostic radiological imaging.

(l) The registrant shall have a quality assurance program. This quality assurance program shall be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request.

(m) Neither the X-ray tube housing nor the collimating device may be hand-held during the exposure.

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 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 radiographic 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.

§ 221.33a. Radiation from capacitor energy storage equipment in standby status.

Radiation emitted from an X-ray tube when the exposure switch or timer in not activated may not exceed a rate of 2 milliroentgens (0.516 μC/kg) per hour at 5 centimeters from an accessible surface of a fully charged diagnostic source assembly, with the beam-limiting device fully open.

OTHER SYSTEMS

§ 221.61. Radiation therapy simulation systems.

Radiation therapy simulation systems shall comply with §§ 221.35a—221.43a. Radiation therapy simulation systems are exempt from §§ 221.36a, 221.38a, 221.39a and 221.41a if the systems that do not meet the requirements in § 221.41a (relating to fluoroscopic timer) are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. In this case, procedures shall require that the timer be reset between examinations.

CHAPTER 227. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT, X-RAY GAUGING EQUIPMENT, ELECTRON MICROSCOPES AND X-RAY CALIBRATION SYSTEMS

X-RAY CALIBRATION SYSTEMS

§ 227.101. Scope.

This section and §§ 227.102—227.104 apply to registrants who use X-ray producing machines to calibrate or test radiation detection or measuring devices.

§ 227.102. Area requirements.

A room or enclosure used for testing or calibration shall be shielded so that every location on the exterior meets conditions for an unrestricted area, and the only access to the room or enclosure 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).

§ 227.103. Operating requirements.

(a) The operator shall conduct a physical radiation survey to determine that the radiation machine X-ray tube is de-energized prior to each entry of any body part into the X-ray exposure area.

(b) As an alternative to subsection (a), 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.

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

GENERAL RADIATION SAFETY REQUIREMENTS

§ 228.36. Radiation monitoring requirements.

An independent radiation monitoring system shall be provided so that the individuals entering or present in a potential very high radiation area become aware of the existence of the hazard. Independent radiation monitors shall be tested for response at least annually and after each servicing or repair.

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