Regulatory Analysis Form

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REVIEW COMMISSION

(1) Agency

Department of Environmental Protection
Bureau of Radiation Protection

(2) I.D. Number (Governor's Office Use)

7-360

IRRC Number: 2169

(3) Short Title

RADIOLOGICAL HEALTH (CHAPTERS 221, 227, AND 228)

(4) PA Code Cite

25 Pa. Code Chapters 221, 227, and 228.

(5) Agency Contacts & Telephone Numbers

Primary Contact: Sharon Freeman, 783-1303

Secondary Contact: Barbara Sexton, 783-1303

(6) Type of Rulemaking (Check One)

___Proposed Rulemaking
__X Final Order Adopting Regulation
____Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

__X No
___ Yes: By the Attorney General
___ Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

The amendments, for the most part, are to correct omissions and printing errors from the previous rulemaking, clarify existing wording, or to modify existing wording to accommodate changes in equipment since the last amendments in 1998.

The only major change is the addition of a new subchapter entitled "X-Ray Calibration Systems" to 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 recommended.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

Sections 301 and 302 of the Radiation Protection Act (35 P.S. Secs. 7110.301, 7110.302) which, respectively, direct the Department to develop and conduct comprehensive programs for the registration, licensing, control, regulation and inspection of radiation sources and radiation source users, and delegates to the Environmental Quality Board the power to adopt the regulations of the Department to implement the Act.

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No. The chapters being amended pertain to X-ray machines and particle accelerators which, except for machine design and use in mammography, are exclusively regulated by the states.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The amendments to Chapters 221 and 228 provide correction and clarification to existing regulations and will simplify compliance on the part of the regulated community and DEP staff performing inspections.

The addition to Chapter 227 extends radiation protection regulations, already applicable to other X-ray installations, specifically to X-ray calibration facilities.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.
The adoption of these amendments will reduce misunderstandings on the part of the regulated community and Department inspectors and, in comparison to the present regulations, should reduce the possibility of unnecessary exposure of patients or facility staff. Some slight decrease in regulatory burden should result.

The addition to Chapter 227 will ensure that exposure of staff and the public from calibration facilities meets the same standards applied to other X-ray facilities.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The amendments to Chapter 221 could potentially affect as many as 9600 registrants who use X-rays for medical purposes. The actual number affected will probably be substantially fewer. The effect may reduce their regulatory burden or have no real effect on their operations.

The amendments to Chapter 228 will affect about 250 registrants/licensees and will reduce the regulatory burden by several hundred dollars annually.

The new section in Chapter 227 will affect 1-5 registrants and will benefit the staff doing X-ray calibrations by formally defining safety requirements for that type of operation.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effect as completely as possible and approximate the number of people who will be adversely affected.)

In terms of risk, nobody is adversely affected by these amendments. The overall financial costs of regulation are slightly reduced with two possible exceptions. Registrants possessing very old equipment that does not meet current federal equipment standards on useful beam size will either have to modify or replace their equipment or obtain an exemption from the Department. Data maintained by the Department is not sufficiently detailed to determine how many such units currently exist.

The number of registrants affected by the changes to Chapter 227 is certainly less than 5 and there may be only one. The cost of compliance will depend whether or not the existing facility has adequate shielding, interlocks, and monitoring equipment and could range from zero to thousands of dollars.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Registrants using X-rays in the healing arts – about 7,600

Registrants using particle accelerators – about 250

Registrants operating an X-ray calibration facility – One known, possibly as many as 5.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who where involved, if applicable.

The amendments were developed with the assistance of the Radiation Protection Advisory Committee (RPAC), comprised of 15 expert representatives of various radiation protection and user groups. Groups represented include: (1) American Associations of Physicists in Medicine (AAPM), Delaware Valley Chapter; (2) AAPM, Penn-Ohio Chapter; (3) Appalachian Compact Users of Radioactive Isotopes (ACURI); (4) Health Physics Society (HPS), Delaware Valley Society for Radiation Safety; (5) HPS, Susquehanna Valley Chapter; (6) HPS, Western PA. Chapter; (7) PA Chiropractic Association; (8) PA College of Nuclear Medicine; (9) PA Dental Association; (10) PA Osteopathic Medical Society; (11) PA Podiatric Medicine Association; (12) PA Radiological Society; (13) PA Society of Radiological Technologists; (14) PA Veterinary Medicine Association; and (15) Independent consultant in industrial uses of radiation.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

The effects of these amendments on costs is expected to be trivial and, except for the addition to Chapter 227, will decrease costs to both the state and the regulated community. However, our X-ray and accelerator registration data are not sufficiently detailed to identify how many of the 13,000 registrants will be affected and thereby quantify the savings. Trying to quantify costs for the X-ray calibration facility is likewise hampered from not knowing how many there are and what the existing facilities are like.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

Not relevant. Local governments are not involved with anything addressed in these amendments.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting or consulting procedures which may be required.

The effects of these amendments on costs is expected to be trivial and, except for the addition to Chapter 227, will decrease costs to both the state and the regulated community. However, our X-ray and accelerator registration data are not sufficiently detailed to identify how many of the 13,000 registrants will be affected and thereby quantify the savings. Trying to quantify costs for the X-ray calibration facility is likewise hampered from not knowing how many there are and what the existing facilities are like.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and cost associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Local Government	0	0	0	0	0	0
State Government	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Total Savings	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
COSTS:						
Regulated Community	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Local Government	0	0	0	0	0	0
State Government	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Total Costs	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
REVENUE LOSSES:						
Regulated Community	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Local Government	0	0	0	0	0	0
State Government	See 20a	See 20a	See 20a	See 20a	See 20a	See 20a
Total Revenue Losses	See 20a	See 20a	See 20a*	See 20a	See 20a	See 20a

(20a) Explain how the cost estimates listed above were derived.

The effect of these amendments on costs is expected to be trivial and, except for the addition to Chapter 227, will decrease costs to both the state and the regulated community. However, our X-ray and accelerator registration data are not sufficiently detailed to identify how many of the 13,000 registrants will be affected and thereby quantify the savings. Trying to quantify costs for the X-ray calibration facility is likewise hampered from not knowing how many there are and what the existing facilities are like.

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY-3	FY-2	FY-1	Current FY
X-ray reg/testing	1,431,660	1,630,977	1,710,140	No data

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

These data reflect the total costs of the X-ray and accelerator registration and inspection programs. The effect of these amendments is expected to be trivial and probably result in a slight decrease in cost from the present regulations. There is no reasonable way to do a cost-benefit analysis when there are basically no adverse effects, costs are expected to be reduced, and where existing records do not allow identification of affected registrants.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

None considered. See (23)

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

The proposed amendments represent minor changes to existing regulations and were devised with the assistance of the RPAC, representing the regulated community. Any changes initially suggested by the Department and not acceptable to RPAC were modified or dropped.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

Yes. All state regulations regarding X-ray machines and accelerators are more stringent than federal regulations because the federal government (FDA), with the exception of mammography, only approves the design of such machines. All regulation of their use is done by the states. PA regulations conform in most respects to the Suggested State Regulations of the Conference of Radiation Program Directors (CRCPD).

The FDA has stringent requirements for the conduct of mammography, including the machines and staff qualifications, which are more stringent than PA regulations for X-ray facilities in general. The Department, on contract with the FDA, inspects about 450 such installations annually.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

These are minor amendments to existing DEP regulations only.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No. There may be some reduction in reported violations due to adjustment of regulations to fit the equipment on the market.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

None. See item (23).

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

When published in the PA Bulletin. No new permits, licenses, or approvals will be necessary.

(31) Provide the schedule for continual review of the regulation.

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.

DL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

2169

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General (DEPUTY ATTORNEY GENERAL) DATE OF APPROVAL Check if applicable. Copy not approved. Objections attached.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by: DEPARTMENT OF ENVIRONMENTAL PROTECTION ENVIRONMENTAL QUALITY BOARD (AGENCY) DOCUMENT/FISCAL NOTE NO. #7-360 DATE OF ADOPTION: 9-18-01 BY: David E. Hess TITLE: DAVID E. HESS, CHAIRMAN (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	Copy below is hereby approved as to form and legality. Executive or Independent Agencies. BY: K. Scott Ray 9/20/01 DATE OF APPROVAL (Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (Strike inapplicable title) ☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

ORDER ADOPTING REGULATIONS

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Radiological Health Amendments

25 Pa. Code, Chapters 221, 227 & 228

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, SHALL BE IN THE USEFUL BEAM, UNLESS REQUIRED TO CONDUCT THE PROCEDURE.

* * * * *

(h) If a patient or **[~~film~~]** **IMAGE RECEPTOR** requires auxiliary support during a radiation exposure the following apply:

* * * * *

(3) An individual may not be used routinely to hold **[~~film~~]** **IMAGE RECEPTORS** or patients.

[~~(4) For intraoral dental radiography, neither the tube housing nor the cone shall be held during an exposure.~~]

* * * * *

(j) **[~~Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.~~]**

The screen and film system used shall [~~should~~] be spectrally compatible [~~and evaluated with respect to screen condition to assure proper system speed~~]. [~~Film cassettes without intensifying~~] DEFECTIVE screens [~~may~~] SHALL not be used for [any routine] diagnostic radiological imaging.[,]

(k) [w] With the exception of [standard] INTRAORAL dental radiography [film packets.], FILM MAY NOT BE USED WITHOUT INTENSIFYING SCREEN(S) FOR ROUTINE DIAGNOSTIC RADIOLOGICAL IMAGING.

(l) The registrant shall have a quality assurance program. This quality assurance program shall be in accordance with guidelines [~~promulgated by the ACR, the AAPM or another accredited organization~~] 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 WEB SITE AND ON REQUEST.

~~(m) [A dentist or an assistant may not hold patients or film during exposures.~~

~~(n) Only the patient shall be in the useful beam.~~

~~(o)~~] Neither the X-RAY tube housing nor the [~~eone~~] COLLIMATING DEVICE may be hand-held during the exposure.

~~[(p) Intraoral fluoroscopy may not be used in dental examinations.]~~

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

A person requesting that the Department approve a healing arts screening program shall submit in writing the following information and evaluation. If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

* * * * *

(14) [This section does not apply to operations conducted by registrants under 21 CFR Part 900 (relating to mammography)] [~~m~~] Mammography facilities shall comply with 21 CFR Part 900.

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.29. Kilovoltage (kV) accuracy.

The kV output shall not vary from the set-indicated value by more than 10% over the range of technique factors normally used. Discrepancies of more than 10% between set-indicated[-]and measured kV values shall be investigated by a qualified expert or service engineer and appropriate action taken.

§ 221.32a. RADIOGRAPHIC Beam Limitation.

* * * * *

(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,[~~and~~] mobile OR INTRA-ORAL DENTAL units.**

* * * * *

(i) Mobile or portable radiographic systems, **OTHER THAN INTRA-ORAL DENTAL X-RAY SYSTEMS,** shall be provided with a means to limit the source-to-skin distance to at least 30 centimeters.

* * * * *

§ 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 μ[m]C/kg) per hour at 5 centimeters from an accessible surface of **[~~the~~] A FULLY CHARGED** diagnostic source assembly, with the beam-limiting device fully open.

* * * * *

FLUOROSCOPIC X-RAY SYSTEMS

§221.35 [Reserved]

§221.35a Fluoroscopic X-ray systems.

* * * * *

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

* * * * *

(d) The minimum field size at the greatest source to image receptor distance shall be **[equal to or less than 25 square centimeters]** **containable in a square of 5 centimeters by 5 centimeters unless otherwise provided in 21 CFR 1020.32(b).**

* * * * *

§ 221.56. [Administrative controls.] **(RESERVED)**

[(a) A dentist or an assistant may not hold patients or film during exposures.

(b) Only the patient shall be in the useful beam.

(c) Neither the tube housing nor the cone may be hand-held during the exposure.

(d) Intraoral fluoroscopy may not be used in dental examinations.]

* * * * *

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 221.4**[2]**1**a** 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.

§ 221.202. Equipment requirements.

* * * * *

(c) *Status indicators and control switches.*

* * * * *

(2) **[A signal, audible to the operator, shall indicate that the exposure has terminated.]**

[3] The emergency buttons or switches shall be clearly labeled as to their function.

[4] (3) Each individual scan or series of scans shall require initiation by the operator.

* * * * *

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

GENERAL PROVISIONS

§ 227.1. Purpose and scope.

This chapter establishes the requirements for the use of analytical X-ray equipment, X-ray gauging equipment **[and]**, electron microscopes **and X-ray calibration systems.** Registrants who use analytical X-ray equipment, X-ray gauging equipment **[or]**, electron microscopes **or X-ray calibration systems** shall comply with this chapter. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of this article.

§ 227.2. Definitions.

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

* * * * *

X-ray calibration systems **--- radiation-producing machines and equipment used to calibrate radiation detection or measuring devices.**

* * * * *

X-RAY CALIBRATION SYSTEMS

X-RAY CALIBRATION SYSTEMS

§ 227.101. Scope.

This section and §§ 227.102--227.104 apply to registrants who [~~calibrate equipment used to measure the output of radiation for medical diagnosis and therapy, or for radiation survey meters and similar instrumentation~~] 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 [~~radiographic~~] 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.

§ 227.104. Personnel Requirements.

A registrant may not permit an individual to operate or conduct maintenance on any X-ray calibration system until the individual has received a copy of, instruction in, and demonstrated an understanding of, the operating procedures necessary to ensure radiation safety.

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

NOTIFICATION AND LICENSING PROCEDURES

§ 228.22a. Issuance of specific licenses.

(a) Upon determination that an application meets the requirements of the act**[,]and** this article, **[and the operation of the facility will not be inimical to the safety of the public,]** the Department will issue a specific license authorizing the proposed activity and containing conditions and limitations as it deems appropriate or necessary.

(b) After the issuance of the license, the Department may, by appropriate regulations or order, incorporate additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of the accelerator subject to this chapter as it deems appropriate or necessary in order to:

(1) Protect the public health and safety or property.

(2) Prevent loss or theft of material subject to this chapter.

§ 228.36. Radiation monitoring requirements.

[(a) In addition to the requirements of § § 219.91 and 219.154 (relating to control of access to high radiation areas; and posting of high radiation areas),] **[~~LAN~~]** **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 **[calibrated]** **tested for response** at least annually and after each servicing or repair.

[(b) The calibration of the independent radiation monitoring system described in subsection (b) shall verify the response of the instrument to radiation fields of different intensity, and does not require complete accuracy with respect to radiation energy if the accelerator produces radiations greater than 3.0 MeV.]

RADIOLOGICAL HEALTH AMENDMENTS
25 PA CODE CHAPTERS 221, 227, AND 228

ENVIRONMENTAL QUALITY BOARD

COMMENT AND RESPONSE DOCUMENT

Proposed Rulemaking (#7-360): Article V , Radiological Health, 25 PA Code Chapters 221, 227, and 228

This is a list of organizations and interested individuals from whom the Environmental Quality Board has received comments regarding the above referenced regulation.

ID	Name/Address	Zip	Submitted 1 pg Summary	Provided Testimony	Req Final Rulemaking
1	Faye L. Capiranno, AS, RDH President PA Dental Hygienists' Association P.O. Box 606 Mechanicsburg, PA	17055			
2	Independent Regulatory Review Commission 14th Floor, Harristown #2 333 Market Street Harrisburg, PA	17020			

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 221, 227 AND 228]

Radiological Health

ORDER

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

B. *Contact Persons.*

For further information, the contact persons are 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; 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.

C. *Statutory Authorit.y*

This final 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 amendments, 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 Section 221.11 were made in the final rule to eliminate separate requirements for dental X-ray operations and to make the requirements applicable to all types of medical X-ray uses.

Those persons to be affected by the regulations 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 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 (35 P. S. § 7110.301), the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the draft final amendments and to advise the Department prior to submittal to the Board. On May 17, 2001, RPAC met and reviewed the draft final rulemaking. The RPAC chairman announced by letter dated June 20, 2001, RPAC's concurrence to send the final 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 of this preamble. A description

of the amendments and the comments and responses are provided below.

Chapter 221, X-Rays in the Healing Arts.

§ 221.11. Registrant responsibilities.

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

The word "film" is replaced by the words "image receptor" in two places in subsection (h) in the final 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 requesting addition of the words "dental hygienist" in subsection 221.11(m). In the final rule, the prohibition against holding patients or film was made generic to all X-ray procedures and placed in subsection (h)(3), which does not identify any specific type of person holding the patient.

Subsection (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 subsection (m) in the final rulemaking. As noted above, this change 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, which is being deleted.

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

At proposed rulemaking, Subsection (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 such guidelines, as well as how registrants can obtain copies of the guidelines, be included in the regulations. Subsection (l) is revised in the final rule to also allow guidelines from organizations recognized by the Department. This change 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 revision also indicates that the Department will maintain a list of approved guidelines and make them available on the DEP web site and on request.

IRRC noted that subsections 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 subsections (m), (n) and (p) are deleted in the final regulations. Existing subsection (o) is renumbered as (m) and the word "cone" replaced by "collimating device," which is a more generally applicable term. Subsection (p) is deleted in its entirety because this type of equipment is not presently used. In the event that the 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.

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

§221.29. Kilovoltage 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. <u>RADIOGRAPHIC</u> beam limitation.

Subsection (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."

Subsection (i) was changed at final rulemaking to clarify that intra-oral 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.

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

§221.56. Administrative controls.

Subsections (a)-(c) are deleted as duplicative of requirements added at final rulemaking to § 221.11(h)(3), (e)(4), and (m), respectively.

§221.61. Radiation therapy simulation systems.

This section was changed in the final rule to correct an exemption erroneously identified as 221.42a. The correct reference is 221.41a.

§221.202. Equipment requirements.

Subsection (c) is modified to delete paragraph (2), relating to an audible signal indicating termination of exposure, because many units do not have such a feature which is not required by the FDA.

Chapter 227. Radiation Safety Requirements for Analytical X-ray Equipment, X-ray Gauging Equipment, Electron Microscopes and X-ray Calibration Systems.

This chapter is modified to add X-ray calibration systems. New sections 227.101-104 were originally approved by the RPAC in 1998 as part of an amendment to Chapter 225 (relating to industrial radiography). The Board decided, however, that the content would be more appropriately 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 rulemaking to more accurately describe the function of these systems. Minor language changes were also made in §§ 227.102 (relating to area requirements) and §§ 227.103 (relating to operating requirements).

Chapter 228. Radiation Safety Requirements for Particle Accelerators.

Changes to Sections §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 the RPAC. The 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 subsection (a). The Board concurs, and the phrase was removed from subsection (a).

§228.36. Radiation monitoring requirements.

This section is modified to provide that (1) 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 the RPAC agree that calibration, which implies that the response be accurate within a specified limit, is not necessary for this function. In the final 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 regulation.

Benefits

As set forth in these amendments, users of X-ray machines and particle accelerators will benefit from the regulations 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 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 amendments.

G. *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.

H. *Regulatory Review.*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Department submitted a copy of the proposed rulemaking on January 29, 2001, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the Senate and House Environmental Resources and Energy Committees. In compliance with Section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of the comments, as well as other documentation.

In preparing this final-form regulation, the Department has considered the comments received from IRRC and the public. These comments are addressed in the comment and response document and Section E of this preamble. The Committees did not provide comments on the proposed rulemaking.

Under section 5.1(d) of the Regulatory Review Act (71 P.S. § 745.5(a)(d)), on _____, these final-form regulation were deemed approved by the House and Senate Committees. Under Section 5.1(e) of the Regulatory Review Act, IRRC met on _____ and approved the final-form regulations.

I. *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 at *1 Pennsylvania 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 31 *Pennsylvania Bulletin* 792 (February 10, 2001).

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

J. *Order of the Board.*

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

(a) The regulations of the Department of Environmental Protection, *25 Pennsylvania Code,* Chapters 221, 227 and 228, are amended by amending the aforesaid chapters to read as set forth in Annex A, with ellipses referring to the existing test of the regulations.

(b) The Chairman 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 Chairman shall submit this order and Annex A to the Independent Regulatory Review Commission and the Senate and House Environmental Resource and Energy Committees as required by law.

(d) The Chairman 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

BY:

David E. Hess
Chairman
Environmental Quality Board

COMMENTS AND RESPONSES

Section 221.11 Registrant Responsibilities

Subsection (k) – "shall v. should"

Comment: This subsection replaces the word "shall" with the word "should." The preamble states this revision is "necessary due to the wide range of spectral characteristics of X-ray films on the market today, which makes it difficult for practitioners to maintain an exact match." However, it does not appear that the existing language requires an "exact match." Instead, the current language of this subsection uses the words "spectrally compatible." This subsection needs to use the word "shall" if this is to be a binding requirement. (2)

Response: The Department is retaining the existing word "shall." Subsection (k) was completely reworded and split into subsections (j) and (k). Subsection (j) reads " The screen and film system shall be spectrally compatible. Defective screens shall not be used for diagnostic radiological imaging." Subsection (k) now reads " With the exception of intraoral dental radiography, film may not be used without intensifying screen(s) for routine diagnostic radiological imaging."

Subsections (g), (m) and (n) – "reducing unnecessary exposure"

Comment: Each of these subsections contains rules designed to limit or prevent unnecessary exposure to X-rays. Are three subsections necessary? Can the three subsections be combined into a concise set of rules or a general rule? (2)

Response: The Department agrees that it is better to have rules that apply across the board whenever feasible. Although the title of Section 221.56 was "Administrative controls," in the 1998 printing of Chapter 221, the section fell under a heading of "Intraoral Dental Radiographic Systems" and was the last remnant of a group of sections applicable to dental radiography. In the final rulemaking, subsections (m) through (p) are deleted. The prohibitions contained in subsections (m), (n), and (o) exist generically in (h)(3), and (e)(4) and (m), respectively. The deleted rules, specific to dentists, are not considered to be necessary. Subsection (p) was deleted in its entirety because the technique is not currently in use. If authorized at a later date by the FDA, appropriate regulations will also be issued.

Subsection (l) --- guidelines

Comment: The existing language in this subsection states that a registrant's "quality assurance program shall be in accordance with guidelines promulgated by the ACR [American College of Radiology], the AAPM [American Association of Physicists in Medicine] or another accredited organization."

The proposed regulation revises this rule to state that a "quality assurance program shall be in accordance with guidelines established by the department [Department of Environmental Protection]."

The Preamble states:

> This change will make it easier for the Department to add and change guidelines as needed without specifically acknowledging each new quality assurance guideline issued by medical specialty organizations."

It is our understanding that the guidelines will be enforced as requirement and registrants can be cited for nonconformance to the guidelines. Only a regulation is enforceable and provides adequate notice to affected parties. Hence, the specific content or source of the guidelines should be included in the regulation. Additionally, the regulations should indicate how registrants can obtain copies of the guidelines. (2)

Response: This revision was proposed because specialty-specific quality assurance programs are proliferating as the specialties diverge from their parent disciplines; modify procedures, protocols and equipment; and discover that the QA programs of the parent discipline are no longer appropriate. The Department needs the authority to accept new QA/QC protocols without modifying the regulations to specifically name each group as it issues QA guidance to its membership. When the Department becomes aware that a professional association has promulgated new or revised QA/QC guidelines or procedures, the Department will review and, if appropriate, accept their use by registrants as written or with minor changes. In consultation with the RPAC, the Department agreed to maintain department guidelines and a list of recognized organizations and make them available on the Department's website or on request.

The Department is not aware of any way to identify each and every organization that may develop QA/QC guidance, and it is not reasonable to make one type of registrant comply with guidance appropriate to another use.

The objective of the Department's radiation regulations and inspections is to obtain compliance, not to issue Notices of Violations. The discrepancies are brought to the registrant's attention, and the opportunity is afforded to correct deficiencies. If the registrant does not cooperate, the violations will be treated, in accordance with the Bureau of Radiation Protection (BRP) Enforcement Policy, as any other violation of the regulations. The exact consequence would depend on factors such as: willfulness, cooperation of the registrant in correcting the violation, how long it had existed, and the savings accruing to the registrant by not complying.

The final rulemaking adds that the Department will maintain a list of approved guidelines and make them available on the DEP web site and on request.

Subsection (m) – holding patient during exposure

Comment: I am requesting an amendment (to Subsection (m)) to state, "A dentist, dental hygienist, or an assistant may not hold patients or film during exposures." A dental hygienist is a licensed dental health professional that performs radiologic procedures in this Commonwealth. For your reference this is stated in the Pennsylvania Code, Title 49 (Professional and Vocational Standards), Chapter 33 (State Board of Dentistry), subsection 33.302 (Auxiliary Personnel Performing Radiologic Procedures). (1)

Response: The requested change became moot when, in the final rule, the prohibition against holding patients or film was made generic to all X-ray procedures and placed in subsection (h)(3), which does not identify any specific type of person holding the patient.

Miscellaneous Typographical Errors - Clarity

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

Comment: In the *Pennsylvania Bulletin,* the word "mammography" in Paragraph (14) is moved to the beginning of the sentence. It should be capitalized. (2)

Response: The correction has been made.

Section 228.36. Radiation monitoring requirements.

Comment: Also in the *Pennsylvania Bulletin*, the first five words of this section read: "LAN independent radiation monitoring system..." "LAN is an apparent error and should be replaced by the word "An." (2)

Response: The correction has been made.

Pennsylvania Department of Environmental Protection

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September 21, 2001

The Secretary

Phone: 717-787-2814
E-Mail: DavidHess@state.pa.us

Mr. Robert E. Nyce, Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown #2
333 Market Street
Harrisburg, PA 17120

RE: Final Rulemaking: Radiological Health Amendments (Chs. 221, 227 & 228) (#7-360)

Dear Bob:

Pursuant to Section 5.1(a) of the Regulatory Review Act, enclosed is a copy of a final-form regulation for review by the Commission. This final rulemaking was approved by the Environmental Quality Board (EQB) on September 18, 2001.

These final amendments update three radiological health chapters and clarify standards for the safe use of radiation-producing machines. Minor changes to Chapter 221 clarify requirements for X-ray use in the healing arts to improve consistency with federal requirements. A new section on X-ray Calibration Systems is added to Chapter 227 to extend X-ray protection requirements to this type of facility. Radiation monitoring requirements in Chapter 228 are modified to better accommodate existing equipment.

The proposed rulemaking was adopted by the EQB on October 17, 2000, and published on February 10, 2001. A 30-day public comment period concluded on March 12, and comments were received from two entities. The Radiation Protection Advisory Committee (RPAC) endorsed the final amendments on May 17, 2001, and offered suggestions for improving the final language in response to commentators' concerns.

The Department will provide the Commission with any assistance required to facilitate a thorough review of this final-form regulation. Section 5.1(e) of the Act provides that the Commission shall, within ten days after the expiration of the committee review period, approve or disapprove the final-form regulation.

For additional information, please contact Sharon Trostle, Regulatory Coordinator, at 787-4526.

Sincerely,

David E. Hess
Secretary

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	7-360
SUBJECT:	Radiological Health Amendments
AGENCY:	DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
9/21/01	Kay O'Brien	HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
9/21/01	Pat Carrabba	SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
9/21/01	Elena Pagán	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

September 20, 2001