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)

__X__ Proposed Rulemaking
____ 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 proposed 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 section 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 inspections by the Department.

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 standards.

(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 affect 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 have to modify or replace their equipment, or else obtain an exemption from the Department. Data maintained by the Department is not sufficiently detailed to determine how many such units exist in PA.

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 nothing 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 a X-ray calibration facility – One known, possible 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 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.

(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 affects, 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 the 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 proposed amendments to existing DEP regulations.

(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.

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 Cynthia L. Baldwin (DEPUTY ATTORNEY GENERAL) NOV 06 2000 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: BY: James M. Seif TITLE: JAMES M. SEIF, CHAIRMAN (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	Copy below is hereby approved as to form and legality. Executive or Independent Agencies. BY: R. E. Grimaldi 10/19/00 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.

NOTICE OF
PROPOSED RULEMAKING
DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

RADIOLOGICAL HEALTH (CHAPTERS 221, 227, and 228)

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

NOTICE OF PROPOSED RULEMAKING

Department of Environmental Protection

ENVIRONMENTAL QUALITY BOARD

25 PA. CODE CHAPTERS 221, 227, and 228

Radiological Health

The Environmental Quality Board (EQB) proposes to amend 25 Pa. Code Chapters 221 (relating to X-Rays in the Healing Arts), 227 (relating to Radiation Safety Requirements for Analytical X-Ray Equipment, X-Ray Gauging Equipment and Electron Microscopes), and 228 (relating to Radiation Safety Requirements for Particle Accelerators). The proposed regulations update the standards for protection against radiation.

This proposal was adopted by the EQB at its meeting on October 17, 2000.

A. Effective Date

These amendments will become effective immediately upon publication in the Pennsylvania Bulletin as final rulemaking.

B. Contact Persons

For further information, the contact persons are William Kirk, Chief, Radiation Control Division, Bureau of Radiation Protection, 13th Floor, Rachel Carson State Office Building, P.O. Box 8469, Harrisburg, Pennsylvania 17105-8469, (717) 787-2480; and Marylou Barton, Assistant Counsel, Bureau of Regulatory Counsel, RCSOB, 9th Floor, 400 Market Street, P.O. Box 8464, Harrisburg, Pennsylvania 17105-8464, (717) 787-7060. Information regarding submitting comments on this proposal appears in Section I of this preamble. Persons with a disability may use the AT&T Relay Service by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users). This proposal is available electronically through the DEP Web site (http://www.dep.state.pa.us).

C. Statutory Authority

These amendments are proposed under the authority of the following statutes:

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.

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

D. Background and Purpose

The proposed amendments, for the most part, correct printing errors, clarify existing wording, or modify existing wording to accommodate changes in equipment since the last amendments.

The only major change is the addition of four new sections in Chapter 227 for the purpose of specifically extending X-ray protection requirements to X-Ray Calibration Systems. Accompanying changes in the chapter title, contents, general provisions, and definitions are also recommended. These sections were originally proposed and approved by the Radiation Protection Advisory Committee (RPAC) in 1998 as part of Chapter 225 which pertains to industrial radiography. The Department decided, however, that these regulations would be more appropriately placed in Chapter 227, which deals with miscellaneous X-ray equipment.

As required by Section 301(c)(14) of the Radiation Protection Act (35 P.S. Sec. 7110.301), the Department provided the RPAC with an opportunity to review the proposed amendments and to advise the Department prior to submittal to the EQB. On May 10, 2000, the RPAC met and reviewed the proposed amendments. The Chairman announced by letter dated May 17, 2000, the committee's concurrence to forward the proposed regulations to the Environmental Quality Board.

E. Summary of Regulatory Requirements

A description of the proposed regulations is provided below:

Chapter 221, X-Rays in the Healing Arts.

§ 221.11 Registrant responsibilities.

Subsection (h)(4) is being deleted. Similar language exists in §221.56, which is being relocated to this section and renumbered as subsections (m) through (p). This consolidation of requirements was inadvertently omitted in the previous revisions to this chapter.

Subsection (k) is being modified to provide some regulatory flexibility. The proposal changes "shall" to "should" to make using spectrally compatible film and screen system a

recommendation rather than a mandatory requirement. This change 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.

Subsection (l) is being modified to allow the Department to establish guidelines for quality assurance programs rather than adopting guidelines from specified "accredited" organizations. 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.

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

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

§221.29. Kilovoltage accuracy.

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

§221.32a. Beam limitation.

Subsection (d)(1) is being 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 and mobile X-Ray units from the requirement. Typically, these units do not have this type of indicator.

§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.

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

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

§221.56. Administrative controls.

This section is deleted and moved to §221.11 as new subsections (m), (n), (o), and (p). No changes in the text are proposed.

§221.202. Equipment requirements.

Subsection (c) is being modified to delete paragraph (2), relating to an audible signal indicating termination of exposure. This change is recommended 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 and Electron Microscopes.

This chapter is being modified to add four new sections under the heading titled X-ray Calibration Systems. These sections were originally proposed and approved by the Radiation Protection Advisory Committee in 1998 as part of Chapter 225 which pertains to industrial radiography. The Department 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.

Chapter 228. Radiation Safety Requirements for Particle Accelerators.

Changes to Sections §228.22a and §228.36 are being recommended 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). As such, it recommended that the phrase be 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) that the system be tested for response, rather than calibrated, at least annually and after servicing or repair. The Department and the RPAC agree that calibration, which implies that the response be accurate within a specified limit, is not necessary for this function.

F. Benefits, Costs and Compliance

Executive Order 1996-1 requires a cost/benefit analysis of the proposed regulation.

Benefits

As set forth in this proposal, 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 proposed 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 proposals.

G. Sunset Review

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.

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 regulations 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 addition to submitting the proposed amendments, the Department has provided the 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.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review by the

Department, the Governor, and the General Assembly before final publication of the regulation.

I. Public Comments

Written Comments - Interested persons are invited to submit comments, suggestions or objections regarding the proposed regulations to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 15th floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions or objections must be received by the Board by March 12, 2001 (within 30 days following publication in the Pennsylvania Bulletin). Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must be received by March 12, 2001 (within 30 days following publication in the Pennsylvania Bulletin). The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final regulation will be considered.

Electronic Comments - Comments may be submitted electronically to the Board at RegComments@dep.state.pa.us and must also be received by the Board by March 12, 2001. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgement of electronic comments is not received by the sender within two working days, the comments should be retransmitted to ensure receipt.

James M. Seif
Chairperson

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.

*****

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

*****

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

*****

(k) 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 screens may not be used for any routine diagnostic radiological imaging, with the exception of standard dental radiography film packets.

(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.

(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 TUBE HOUSING NOR THE CONE 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)] 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. 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 PROVISION DOES NOT APPLY TO PORTABLE AND MOBILE UNITS.

*****

§ 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 diagnostic source assembly, with the beam-limiting device fully open.

§ 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.

(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 fluroscopy may not be used in dental examinations.]

§ 221.202. Equipment requirements.

*****

(c) *Status indicators and control switches.*

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

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

[3] (2) 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

*****

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

§ 227.101. SCOPE.

SECTIONS 227.101 THROUGH 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.

§ 227.102. AREA REQUIREMENTS.

A ROOM OR ENCLOSURE USED FOR 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 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),] AN independent radiation monitoring system shall be provided so that the individuals entering or present 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.]

image receptor shall be provided with means to limit the source-skin distance to not less than:

(i) Eighteen centimeters if operable above 50 kVp; or

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

(2) Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 centimeters.

(j) *Beam-on indicators.* The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(k) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(l) *Radiation from capacitor energy storage equipment.* Radiation emitted from the x-ray tube shall not exceed:

(1) 8.6×10^{-9} C/kg (0.03 mR) in 1 minute at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square centimeters, with no linear dimension greater than 20 centimeters; and

(2) 2.58×10^{-5} C/kg (100 mR) in 1 hour at 100 centimeters from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum exposure per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Transmission limit for image receptor supporting devices used for mammography.* For x-ray systems manufactured after September 5, 1978, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 2.58×10^{-8} C/kg (0.1 mR) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of the tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

[58 FR 26401, May 3, 1993; 58 FR 31067, May 28, 1993]

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopy and for the recording of images through an image intensifier except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier if provided, shall not exceed 3.34×10^{-3} percent of the entrance exposure rate, at a distance of 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in § 1020.30(g). Additionally, the manufacturer shall provide to users, pursuant to § 1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(2) *Measuring compliance.* The entrance exposure rate shall be measured in accordance with paragraph (d) of this section. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Nonimage-intensified fluoroscopy.* (i) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of the field size. The minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(ii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with paragraph (b)(1)(i) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of image receptor.

(2) *Image-intensified fluoroscopy.* For image-intensified fluoroscc equipment other than radiation t apy simulation systems, neither length nor the width of the x-ray f in the plane of the image receptor s exceed that of the visible area of image receptor by more than 3 perc of the SID. The sum of the ex length and the excess width shall be greater than 4 percent of the SID.

(ii) For rectangular x-ray fields u with circular image receptors, error in alignment shall be determi along the length and width dimensi of the x-ray field which pass thro the center of the visible area of image receptor.

(iii) For equipment manufactu after February 25, 1978, when the ar between the image receptor and be axis is variable, means shall be p vided to indicate when the axis of x-ray beam is perpendicular to plane of the image receptor. Com ance with paragraph (b)(2)(i) of t section shall be determined with beam axis indicated to be perpendi lar to the plane of the image recept

(iv) Means shall be provided to p mit further limitation of the fie Beam-limiting devices manufactu after May 22, 1979, and incorporated equipment with a variable SID and the capability of a visible area greater than 300 square centimet shall be provided with means stepless adjustment of the x-ray fie Equipment with a fixed SID and the pability of a visible area of no grea than 300 square centimeters shall provided with either stepless adju ment of the x-ray field or with a me to further limit the x-ray field size the plane of the image receptor to square centimeters or less. Stepless justment shall, at the greatest S provide continuous field sizes from maximum obtainable to a field s containable in a square of 5 cen meters by 5 centimeters.

(3) If the fluoroscopic x-ray field s is adjusted automatically as the SID image receptor size is changed, a ca bility may be provided for overridi the automatic adjustment in case system failure. If it is so provided

[Code of Federal Regulations]
[Title 21, Volume 8, Parts 800 to 1299]
[Revised as of April 1, 2000]
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TITLE 21--FOOD AND DRUGS

SERVICES--(Continued)

PART 900--MAMMOGRAPHY--Table of Contents

Subpart A--Accreditation

Subpart B--Quality Standards and Certification

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

Source: 62 FR 55976, Oct. 28, 1997, unless otherwise noted. Republished and corrected at 62 FR 60614, Nov. 10, 1997.

Effective Date Note: At 62 FR 55976, Oct. 28, 1997, part 900 was revised, and at 62 FR 60614, Nov. 10, 1997, it was republished and corrected, effective Apr. 28, 1999, with excepted provisions effective Oct. 28, 2002.

Pennsylvania Department of Environmental Protection

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January 29, 2001

The Secretary **717-787-2814**

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown II
Harrisburg, PA 17101

RE: Proposed Rulemaking – Radiological Health (Chapters 221, 227 & 228) (#7-360)

Dear Bob:

Enclosed is a copy of a proposed regulation for review and comment by the Commission pursuant to Section 5(a) of the Regulatory Review Act. This proposal is scheduled for publication as a proposed rulemaking in the *Pennsylvania Bulletin* on February 10, 2001. This proposal was approved by the Environmental Quality Board (EQB) on October 17, 2000.

This proposal updates and clarifies the standards for the safe use of radiation-producing machines. Aside from adding a new section entitled "X-Ray Calibration Systems" to Chapter 227, which is necessary to extend X-Ray protection requirements to calibration facilities, the proposed amendments largely correct typographical errors, clarify existing language, and modify language to accommodate changes in equipment.

The Radiation Protection Advisory Committee (RPAC) reviewed and endorsed the proposed amendments on May 10, 2000.

The Department will provide the Commission with any assistance required to facilitate a thorough review of this proposal. Section 5(g) of the Act provides that the Commission may, within ten days after the expiration of the Committee review period, notify the agency of any objections to the proposed regulation. The Department will consider any comments or suggestions received by the Commission, together with Committee and other public comments prior to final adoption.

For additional information, please contact Sharon Trostle, Regulatory Coordinator, at 783-1303.

Sincerely,

James M. Seif
Secretary

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7-360

SUBJECT: Radiological Health

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

X Proposed Regulation

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
1/29/01		HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
1-29-01	Bonita Castelli	SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
1-29-01	Elena Pagán	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
1-29-01	C Lee-Brown	LEGISLATIVE REFERENCE BUREAU

January 24, 2001