RULES AND REGULATIONS

Title 12—COMMERCE, TRADE AND LOCAL GOVERNMENT

DEPARTMENT OF COMMUNITY AND ECONOMIC DEVELOPMENT

[12 PA. CODE CH. 135]

Neighborhood Assistance Program

By this order, the Department of Community and Economic Development (Department), under the authority of Article XIX-A of the Neighborhood Assistance Act (72 P. S. §§ 8901-A—8906-A) (act) amends Chapter 135 (relating to Neighborhood Assistance Program). The purpose of the amendments is to establish special program priorities for the Fiscal Year (FY) 1997-98.

Introduction

Under the authority of the act, the Department administers the Neighborhood Assistance Tax Credit Program (NATCP) and the Enterprise Zone Tax Credit Program (EZTCP). The goal of NATCP is to encourage business firms to provide, either directly or indirectly through neighborhood organizations, neighborhood assistance and job training, education, crime prevention and community services. To meet this objective, the Department of Revenue grants tax credits, equivalent to 50% of the business firms' contributions, to business firms approved by the Department. The goal of EZTCP is to encourage private companies to invest in the rehabilitation, expansion and improvement of buildings or land which promote community economic development and which occur in portions of impoverished areas which have been designated as enterprise zones. To meet this objective, the Department of Revenue grants tax credits, equivalent to 20% of the private companies' investments, to private companies approved by the Department.

Section 8905-A of the act (72 P. S. § 8905-A) directs the Secretary of the Department to promulgate, during the first month of each fiscal year, regulations establishing special program priorities. Under the special program priorities of § 135.41(b) (relating to special program priorities), contributors may earn an additional 20%, for an overall 70% tax credit. Under the special program priorities of § 135.49(a) (relating to Enterprise Zone Tax Credit Program—special program priorities), contributors may earn a 30% tax credit.

Analysis

Section 135.41(b)—NATCP—special program priorities. No changes, except for the reference to the current fiscal year, have been made to this section. Special program priorities adopted for FY 1997-98 continue the priorities that were in effect last year.

Section 135.49(a)—EZTCP—special program priorities. No changes, except for the reference to the current fiscal year, have been made to this section. Special program priorities adopted for FY 1997-98 continue the priorities that have been in effect for several years.

Fiscal Impact

(a) *Commonwealth*. The tax credits extended to corporations and businesses under these regulations represent a proportionate reduction in Commonwealth Corporate Tax revenues. The costs are substantially justified by the creation and retention of jobs and the amelioration of the factors which tend to cause poverty within this Commonwealth.

(b) *Political subdivisions*. The amendments have no measurable cost-effect upon political subdivisions.

(c) *Public*. The amendments continue the tax credits to eligible business firms and private companies.

Paperwork

Organizations interested in participating in the special program priorities for NATCP shall submit an addendum to their original NAP proposal.

Private companies and neighborhood organizations interested in participating in the special program priorities for EZTCP shall submit an addendum to their original EZP project application proposal.

Notice

Notice of proposed rulemaking has been omitted under section 204(3) of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1204(3)) (CDL), which specifies that a regulation may be adopted without notice of proposed rulemaking if proposed rulemaking procedures are "in the circumstances impracticable, unnecessary, or contrary to the public interest." The proposed rulemaking procedures in this instance are not necessary because the special program priorities for the 1997-98 fiscal year continue the priorities that were in effect last year. The only changes being made to this regulation are to change the reference to the "1996-97" fiscal year to the "1997-98" fiscal year.

Regulatory Review

Under section 5.1(c) of the Regulatory Review Act (71 P. S. § 745.5a(c)), on August 12, 1998, the Department submitted a copy of the final-omitted regulations with proposed rulemaking omitted to the Independent Regulatory Review Commission (IRRC), the Chairpersons of the House Commerce and Economic Development Committee and the Senate Community and Economic Development Committee. On the same date, the final-omitted regulations were submitted to the Attorney General for review and approval under the Commonwealth Attorneys Act (71 P. S. §§ 732-101—732-506). In accordance with section 5.1(d) of the Regulatory Review Act, these final-omitted regulations were deemed approved by the House and Senate Committees on September 1, 1998. IRRC met on September 10, 1998, and approved the final-omitted regulations.

Effective Date/Sunset Date

(a) These final-omitted regulations will become effective upon final publication in the *Pennsylvania Bulletin*.

(b) The final-omitted regulations, by law, are monitored on an annual basis and updated as needed.

Contact Person

For an explanation of these regulations contact Jill B. Busch, Deputy Chief Counsel, Department of Community and Economic Development, 416 Forum Building, Harrisburg, PA 17120, (717) 783-8452.

Findings

The Department finds that:

(1) The proposed rulemaking procedures in sections 201 and 202 of the CDL (45 P. S. §§ 1201 and 1202), are impracticable and unnecessary, because the special program priorities for the 1997-98 fiscal year continue the priorities that were in effect last year. The only changes being made to these final-omitted regulations is to change the reference to the "1996-97" fiscal year to the "1997-98" fiscal year.

(2) Public notice of intention to adopt the final-omitted regulations has been omitted under section 204 of the CDL and the regulation thereunder, 1 Pa. Code § 7.4.

(3) Delay in implementing the final-omitted regulations will have a serious adverse impact on the public interest.

Order

The Department, acting under the authorizing statute, orders that:

(a) The regulations of the Department, 12 Pa. Code Chapter 135, are amended by amending §§ 135.41b and 135.49a to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

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

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

SAMUEL MCCULLOUGH,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4845 (September 26, 1998).)

Fiscal Note: 4-68. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 12. COMMERCE, TRADE AND LOCAL GOVERNMENT

PART V. COMMUNITY AFFAIRS AND DEVELOPMENT

Subpart B. COMMUNITY EMPOWERMENT

CHAPTER 135. NEIGHBORHOOD ASSISTANCE PROGRAM

TAX CREDITS

§ 135.41b. Special program priorities.

For Fiscal Year 1997-98, the special program priorities will be accepted in four categories: Community Development, Comprehensive Services, Affordable Housing Programs and Enterprise Zone Programs. Projects in each category shall relate to activities which will improve the physical and economic environment of low income neighborhoods or which will contribute to neighborhood stabilization by reversing patterns of deterioration and blight. The projects shall demonstrate the local commitment through partnerships of community based organizations, local government and the private sector. The following paragraphs set forth the requirements for the project to be eligible for tax credit valuation of 70%.

* * * * *

(5) *Limitations*. During Fiscal Year 1997-98, the Department will allocate no more than $1.3 million of the available tax credits for valuation at 70%. No more than $1 million dollars of the tax credits will be allocated to the combined applicants for Community Development and Affordable Housing Projects, and no more than $300,000 will be awarded for Comprehensive Service Programs. Approval of projects under special program priorities will be contingent upon the availability of tax credits.

(6) *Applicability*. The special program priorities in this section are applicable to programs implemented during Fiscal Year 1997-98.

* * * * *

§ 135.49a. Enterprise Zone Tax Credit Program—special program priorities.

(a) *Applicability*. The special program priorities in this section are applicable to projects for the Fiscal Year 1997-98.

(b) *Special program priority status*. For the Fiscal Year 1997-98, special program priority status may be granted for projects that will provide employment opportunities for low-income residents of this Commonwealth, or enhance public facilities. If approved under this section, projects will receive tax credits equal to 30% of eligible project costs, up to the maximum amount approved by the Department. The Commonwealth will consider all 20% tax credit requests prior to consideration of 30% tax credit addendum requests for Fiscal Year 1997-98. To qualify for the 30% tax credit, projects shall submit an addendum that addresses the following requirements:

(1) A demonstration that jobs will be created for low-income individuals as a result of the investment made through the Enterprise Zone Tax Credit Program. Project activities shall:

(i) Create at least one job for low-income individuals for each $15,000 of private investment.

(ii) Include coordination with a local private industry council, office of employment security or county assistance office to assure assistance in job placement of low-income individuals.

(2) A demonstration that the project will include construction of or substantial repairs to a publicly owned facility, for example, streets, sidewalks or street lights.

[Pa.B. Doc. No. 98-1596. Filed for public inspection October 2, 1998, 9:00 a.m.]

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 216, 218, 221, 223, 227 AND 228]

Radiological Health

The Environmental Quality Board (Board) by this order amends Chapters 216, 218, 221, 223, 227 and 228. The amendments update the standards for the safe use of radiation-producing machines.

This order was adopted by the Board at its meeting of July 21, 1998.

A. *Effective Date*

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

B. *Contact Persons*

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

C. *Statutory Authority*

The final rulemaking is being made under the authority of the following statutes:

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

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

D. *Background and Summary*

In 1987, the Board substantially updated its radiological health regulations to provide for compatibility with other states. These updates were published at 17 Pa.B. 5235 (December 19, 1987). Technological advances in the use of X-ray and accelerator equipment and the need to establish and maintain radiation protection standards at least as stringent as the Federal standards provide the basis for these revisions to the existing radiological health regulations.

The present requirements in these chapters were developed in 1982-1983, prior to the effective date of the existing regulations on December 19, 1987. In the meantime, certain advances have occurred, principally in the medical profession, which the existing regulations do not address. These are new modalities for diagnosis and treatment now which did not exist when the existing requirements were being developed and promulgated. Particle accelerators, particularly for use in medical applications, have undergone changes in design and function which were only beginning to emerge when the existing regulations were formulated.

The final amendments in this package are based on the current Parts B, F, H and I of the 1995 version of the Suggested State Regulations for Control of Radiation (SSR) which was published by the Conference of Radiation Control Program Directors (CRCPD). Federal and State regulations for radiation sources and radiation source users are based on the SSR. Amendments to Food and Drug Administration regulations are included in the SSR.

The purpose of these final amendments is to bring existing regulations up-to-date by offering better protection to the employes and patients (for medical diagnosis and treatment applications) and to address health and safety concerns, including the reduction in unnecessary radiation exposure to patients and employes/operators. The Department's regional staff have encountered difficulties in adapting existing regulations to new technologies and modalities, especially in the diagnostic and therapeutic application of radiation in medicine, some of which relate to the machines and equipment used in generating ionizing radiation. Some also relate to the safety of the personnel working with this equipment and to the safety of patients undergoing medical diagnosis and treatment. One of the goals of the Department is the reduction toward elimination of unnecessary radiation exposure, and the intent of the revisions in the regulations is to close some regulatory gaps and work toward achieving this goal.

As required by section 301(c)(14) of the act, the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the proposed amendments and to advise the Department prior to their submittal to the Board. The proposal was provided to RPAC for review on April 23, 1998. The Committee provided oral and written comments at the meeting.

There was concern that there was no existing guidance on how to apply for and obtain an accelerator license. The Department has indicated that it would issue the guidance October 4, 1999, as stated in § 228.21a(d) (relating to notification and licensure requirements).

There was also some confusion in Chapter 228 (relating to radiation safety requirements for particle accelerators) about the terms "registrant" and "licensee." The proposed rulemaking included new regulations for the licensing of accelerators. Therefore the term "registrant" would not be proper and was deleted from those sections where appropriate. In response to the RPAC members' comments, the Department revised the proposed amendments.

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

The Board published notice of proposed rulemaking at 27 Pa.B. 5703 (November 1, 1997) and solicited public comment. In response to the request for comments, the Board received comments from 21 persons. A summary, of the major comments and revisions follows:

There were some comments regarding the licensing requirements of X-ray technologists.

The requirements for licensing X-ray technologists are set by the Department of State. The Department's proposed regulation § 221.11(b) allows the Department to require registrants to comply with the State Department's licensing requirements.

The Department appreciates the concern expressed by the commentators, but suggested that the commentators express their concerns to the Department of State and the Department of Health. The Department has no legal authority to promulgate regulations for auxiliary X-ray operators which is granted by law to the Departments of State and Health.

The requirement for keeping records for 5 years under §§ 221.204(b)(6), 227.11a(h)(4), 227.12a(f), 228.12, 228.32a(a), 228.35(c), 228.38(b), 228.42, 228.61(a)(2), 228.61(b)(2), 228.75(f) and 228.76(6) was questioned as to how effectively an inspection of these 5 year old records will protect citizens from excessive exposure to radiation. There was also a concern about the cost of keeping these records for 5 years. The commentator suggested the length of time for keeping these records should be reduced to a shorter period such as 2 years.

The recordkeeping requirements in §§ 228.61(a)(2) and (b)(2), 228.75(f) and 228.76(6) were not changed. The Department believes 5 years is a minimum amount of time to keep records relating to human radiation exposure. The RPAC recommended the 5-year retention period be kept if the Department inspects the facility at that time.

Recordkeeping requirements not related to human radiation exposure such as spot surveys in §§ 221.204(b)(6), 227.11a(h)(4), 227.12a(f), 228.12, 228.35(c) and 228.38(b) were changed from 5 years to 4 years. Four years is the intended inspection cycle for most facilities under § 221.12 (relating to inspections).

In §§ 228.32a(a) and 228.42, the recordkeeping requirement was deleted.

References to the registrants were deleted in the following: §§ 228.31a(b), 228.37a, 228.44(a) and (b), 228.61(a)(2) and (b)(2), 228.62(b), 228.76(6), 228.11a, 228.12, 228.21a(a) and 228.32a(a).

Cross references to the other State and Federal regulations were made in the following: §§ 221.61, 228.24a(a), 228.25a and 228.39.

Section 216.2(c) (relating to registration) was changed at the suggestion of a commentator to indicate that the Department will issue the Certificate of Registration. Section 216.2(e) was amended by deleting the reference to "written Department approval." This change clarifies that the registrant is responsible for putting the request in writing. This deletion reduces paper work for the Department. Section 216.4(a) (relating to renewal of certificate of registration) was amended as a result of the § 218.11 (relating to registration, renewal of registration and license) name change.

Section 216.4a(c)(2) (relating to expiration and termination of certificate of registration) was amended at the request of the Office of Attorney General. The amendment to § 216.4a(c)(2) made subsection (c)(3) redundant and was therefore deleted. Section 216.4a(c)(4) and (5) was renumbered because of the deletion of paragraph (3).

Section 218.1 (relating to purpose and scope) was amended to add persons who renew registrations. Section 218.11 was amended by adding the words "renewal of registration" and deleting the word "annual" from the section title for clarity and consistency. Section 218.11(d) was amended for clarity and consistency.

Section 221.2 (relating to definitions) was amended by adding a definition of "research," deleting the definition of "gonads," and making minor corrections to "dental panoramic system," "protective barrier" and "qualified expert."

Sections 221.11(a)(2) and 228.35(g)(5) (relating to registrant responsibilities; and operating procedures) were amended for clarification since Subpart A has many nonradiologic requirements. These sections were also amended to distinguish this requirement from §§ 221.11(a)(3) and 228.35(g)(6).

Section 221.11(c)(6) relating to registrant's responsibilities was added because a commentator requested the addition. Section 221.11(e) was amended at the request of a commentator by including "other persons" to address the concern that persons such as parents may be in the room when necessary. In § 221.11(e)(1), the word "equivalency" was changed to "equivalent." Section 221.11(e)(2) was amended as recommended by the RPAC by adding a "2 meter" distance option as in § 221.11(e)(3). Section 221.11(e)(3) was amended as requested by a commentator to include an exception for shielding patients. Section 221.11(k) was amended by deleting "intraoral" as requested by a commentator. Also, the phrase, "veterinary radiography" was deleted because Chapter 221 (relating to X-rays in the healing arts) does not apply to veterinary radiography. A new § 221.11(m) was added as recommended by the RPAC which is identical to proposed § 228.11a(d) (relating to licensee responsibilities).

Section 221.13 (relating to information to be submitted by persons proposing to conduct healing arts screening) was amended to clarify that the submission for approval for healing arts screening be in writing.

Section 221.15 (relating to use of X-rays in research on humans) regarding the use of X-rays in research on humans was amended as requested for clarity by the Office of the Attorney General and several commentators.

Section 221.32a(e) and (g) (relating to a beam limitation) was amended for clarification of the applicability of the requirement to dental systems. Section 221.32a(h)(1) was amended by changing "size" to "linear dimensions" for clarity.

Section 221.34a(a) (relating to radiation exposure control) was rewritten for clarification.

Section 221.36a(e) (relating to limitation of useful beam of fluoroscopic equipment) was amended at the suggestion of a commentator to correct the cross reference to the Federal regulation. Section 221.36a(j) was renumbered to 221.36a(i)(5) to clarify that the requirement is for spot-film devices.

Section 221.41a (relating to fluoroscope timer) is the existing § 221.37 and was deleted in the original proposed rulemaking, but was inadvertently included in the *Pennsylvania Bulletin* as § 221.41a. It is being deleted and §§ 221.42a, 221.43a and 221.44a were appropriately renumbered.

The renumbered § 221.42a(b)(2) (relating to control of scattered radiation) was amended by clarifying the term "Bucky-slot cover" as requested by a commentator.

Section 221.202(f) (relating to equipment requirements) was amended by changing the requirement for total filtration from 3.5 mm of aluminum to the HVL of 3.2 mm of aluminum at 120 kVp as recommended by the RPAC. The Federal standard is an HVL of 3.2 mm of aluminum at 120 kVp. Section 221.202(g)(1) was amended by changing the 3 mm error limit to the FDA 5 mm error limit as recommended by the RPAC. Section 221.202(g)(2) was amended to clarify which indicators were being referenced in the second sentence. Section 221.202(g)(4) was amended as a result of a comment about other CT numbers. Section 221.202(h) was added at the recommendation of the RPAC to exempt CT units used solely for therapy simulations from the CT requirements.

Section 221.204(a)(1) (relating to radiation measurements and performance evaluation) was amended to correct a typographical error and to add the last sentence as suggested by a commentator. Section 221.204(a)(3) was amended at the suggestion of two commentators to change "12 months" to annually and to delete "major." Section 221.204(a)(3)(i) was amended to add "or 120 kVp." Section 221.204(b) was changed from 15 days to 48 hours because a commentator thought that 15 days was too long to wait to notify the qualified expert of a problem.

Section 223.2a (relating to definitions) was added to provide definitions for terms in Chapter 223 (relating to veterinary medicine). Section 223.8(c) was amended as recommended by the RPAC, by changing the distance for

protective shielding devices from 5 meters to 2 meters as recommended by the RPAC, and for consistency with the lead equivalent requirement in § 221.11(e)(2). Section 223.8(d) (relating to operating procedures) was amended to change the word "ordered" to "authorized." Section 223.12a(h)(2) (relating to fluoroscopic equipment) was amended to correct an erroneous reference and clarify the term "Bucky-slot cover."

Sections 227.11a(d)(1) and (f)(2), 227.12a(d) and (e) (relating to equipment requirements; and area requirements) were revised and §§ 227.11a(d)(2) and 227.13a(d) were deleted. This chapter does not include devices containing radioactive material.

Section 228.2 (relating to definitions) was amended by adding a definition of "virtual source" at the suggestion of two commentators. Section 228.21a(d) was changed from "90 days" to "1 year" to allow the Department sufficient time to generate a licensing guide. A typographical error was also corrected. Section 228.22a(b)(1) (relating to notification and license requirements) was amended by changing "minimize" to "protect." Section 228.22a(a) was amended to confirm that a license will be issued if the operation of the facility will not be harmful to the public.

Sections 228.31a(b), 228.37a, 228.44(a) and (b), 228.61(a)(2) and (b)(2) and 228.62(b) and 228.76(6) were amended to delete the reference to "registrant."

The § 228.11a (relating to licensee responsibilities) title was amended to delete "registrant" and replace with "licensee."

Section 228.12 (relating to information and maintenance record and associated information) was amended to delete reference to "registrant." Also, the requirement to keep records for 5 years was changed to 4 years at the suggestion of a commentator.

Section 228.21a(a) (relating to notification and license requirements) was changed to be the same § 228.22a(a) for "act and article."

Section 228.23a(a) (relating to expiration and termination of a license) was amended for clarification and to specify a period of effectiveness for the license.

Section 228.32a(a) (relating to shielding and safety design requirements) was amended to delete the reference to "registrant" and to delete the last two sentences of the paragraph because the requirements in these sentences appear in § 228.38 (relating to radiation safety surveys).

Section 228.35(b) (relating to operating procedures) was clarified by adding the phrase "or for testing the interlock." Two words in § 228.35(e) were reversed at the suggestion of a commentator. Section 228.35(g)(5) was modified to clarify to whom the section applied. Section 228.36(a) (relating to radiation monitoring requirements) was deleted because, as noted by a commentator, it is not a necessary requirement.

The title of § 228.38 was amended to read "radiation safety surveys." Sections 228.38 (a) and (b) were changed to indicate the "initial" survey and to maintain that survey for life of facility. The reference to Chapter 221 was deleted. In § 228.38(b) the reference to "registrant" was deleted.

Section 228.38(c)(7) was amended by changing the time period from "1 week" to "1 year" to be consistent with requirements in Chapter 219 (relating to standards for protection against radiation). Section 228.38(d) was deleted because of duplication in another requirement. Section 228.38(e) was amended to delete "registrant" and renumbered to subsection (d).

Section 228.64 (relating to filters) was amended by deleting the last sentence of subsection (a) requiring the wedge filter information. Section 228.65 (relating to electron beam quality) was renamed from "beam quality" to "electron beam quality." The references to "registrant" in § 228.65 (relating to electron beam quality) were deleted. Section 228.75(e)(8) (relating to calibrations) was amended to state when the requirement applies to each electron beam energy.

F. *Benefits, Costs and Compliance*

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

Benefits

As set forth in this proposal, users of radiation-producing machines will be required to comply with radiation protection standards that will not only protect operators of the machines but will also protect the general public.

Compliance Costs

Compliance costs are expected to be minimal. The Department has been implementing many of the proposed requirements by recommendation. No financial assistance is believed to be necessary.

Compliance Assistance Plan

Compliance assistance is available to existing holders of a registration of radiation-producing machines and equipment. These range from small X-ray facilities such as dentists, podiatrists, veterinarians and the like, to large institutions such as colleges and universities, medical centers and industrial complexes, all of which the Department presently regulates and inspects. The Department will issue technical guidance to registrants as recommended by the RPAC.

Paperwork Requirements

The final-form regulations will not significantly change paperwork requirements.

G. *Sunset Review*

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

H. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on October 16, 1997, the Department submitted a copy of the proposed amendments 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(b.1) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments, as well as other documentation.

In preparing these final-form regulations, the Department has considered 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.

These final-form regulations were deemed approved by the House and Senate Committees on August 31, 1998.

IRRC met on September 10, 1998, and approved the regulation in accordance with section 5(c) of the Regulatory Review Act.

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 Pa. Code §§ 7.1 and 7.2.

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

(3) These do not enlarge the purpose of the proposal published at 27 Pa.B. 5703.

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

K. *Order of the Board*

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

(a) The regulations of the Department, 25 Pa. Code Chapters 216, 218, 221, 223, 227 and 228, are amended by:

(1) Amending §§ 216.2, 216.4, 218.1, 218.11, 221.2, 221.11—221.13, 221.21, 221.28, 221.61, 223.11, 227.14, 227.33, 228.2 and Appendix A; by

(2) Deleting §§ 221.31—221.49, 221.51—221.55, 221.62, 221.81—221.102, 221.201—221.205, 223.12, 223.13, 227.11—227.13, 227.15, 228.11, 228.21—228.26, 228.31—228.34 and 228.41; and by

(3) Adding §§ 216.4a, 221.15, 221.29, 221.30, 221.31a—221.43a, 223.2a, 223.12a, 223.13a, 227.11a—227.13a, 228.11a, 228.21a—228.26a, 228.31a—228.34a, 228.35—228.39, 228.41a, 228.42—228.45, 228.61—228.76 and Appendix A to read as set forth in Annex A, with ellipses referring to the existing text of the regulations. (*Editor's Note*: The proposal to add § 221.44a included with the proposal at 27 Pa.B. 5703 was withdrawn. The amendment of § 221.61 and the addition of § 223.2a were not included in the proposal at 27 Pa.B. 5703.)

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

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

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

(e) This order shall take effect immediately.

JAMES M. SEIF,
Chairperson

Fiscal Note: Fiscal Note 7-329 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 216. REGISTRATION OF RADIATION-PRODUCING MACHINES

§ 216.2. Registration.

(a) A person possessing a radiation-producing machine shall:

(1) Register with the Department within 30 days after acquisition. Registration shall be completed on forms furnished by the Department and shall contain information required on the form and accompanying instructions.

(2) Designate on the registration form an individual to be responsible for radiation protection.

(3) Notify the Department in writing within 30 days of a change of address, owner or radiation safety officer or number of machines.

(b) The registration becomes valid upon receipt of the properly completed registration form and the fee required under Chapter 218 (relating to fees).

(c) A certificate of registration will be issued by the Department to a person whose registration becomes valid under subsection (b).

(d) A registrant shall have the currently valid certificate of registration available for inspection by the Department.

(e) A certificate of registration issued under this chapter may not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, to any person without submitting a written request by the registrant to the Department.

§ 216.4. Renewal of certificate of registration.

(a) The Department will send an application for renewal of the certificate of registration to the registrant at least 2 months prior to the expiration date on the certificate of registration. The application for renewal will include references to the fee due under § 218.11 (relating to registration, renewal of registration and license fees).

(b) An applicant for renewal of a registration shall submit a signed application and the fee required under § 218.11 prior to the expiration date of the certificate of registration.

(c) The renewal becomes valid upon receipt of the properly completed application and the fee required under Chapter 218 (relating to fees).

§ 216.4a. Expiration and termination of certificates of registration.

(a) A certificate of registration expires on the date specified on the certificate of registration. Expiration of the certificate of registration does not relieve the registrant from the requirements of this article.

(b) When a registrant decides to terminate all activities involving radiation-producing machines under the certificate of registration, the registrant shall notify the Department immediately, in writing, and request termination of the certificate of registration. This notification and re-

quest for termination of the certificate of registration shall be in accordance with subsection (c).

(c) If a registrant does not submit a renewal for a certificate of registration under § 216.4 (relating to renewal of certificate of registration), the registrant shall, on or before the expiration date specified in the certificate of registration, do the following:

(1) Terminate use of all radiation-producing machines.

(2) Transfer or dispose of all radiation-producing machines in accordance with § 216.6 (relating to assembly, transfer and disposal obligations).

(3) Remit any outstanding registration or renewal of registration fees owed to the Department under § 218.11 (relating to registration, renewal of registration and license fees).

(4) Request termination of the certificate of registration in writing to the Department.

CHAPTER 218. FEES

GENERAL

§ 218.1. Purpose and scope.

(a) This chapter establishes fees for registration and licensing and provides for their payment.

(b) Except as otherwise specifically provided, this chapter applies to a person who:

(1) Is required to register or renew registration for radiation-producing machines under Chapter 216 (relating to registration of radiation-producing machines).

(2) Is an applicant for or holder of a radioactive material license issued under Chapter 217 (relating to licensing of radioactive material).

PAYMENT OF FEES

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

(a) Annual registration fees for radiation producing machines are as follows:

(1) For dental, podiatric and veterinary facilities—$75 for the first X-ray tube, plus $25 for each additional tube.

(2) For hospital facilities—$520 for the first X-ray tube, plus $25 for each additional tube.

(3) For other facilities—$175 for the first X-ray tube, plus $25 for each additional tube.

(b) A registrant filing an initial registration under § 216.2 (relating to registration) or an application for renewal of a certificate of registration under § 216.4 (relating to renewal of certificate of registration) shall remit the appropriate fee calculated by using the information on the registration or application form and the fee schedule in subsection (a). Fees for any initial registration under § 216.2 are payable upon the filing of the registration. Fees for the renewal of a certificate of registration are payable upon the submission of an application for a renewal of a certificate of registration. If the number of tubes increases after an initial registration or after an application for renewal has been filed with the Department, no additional fee is required until the time of the next registration. Likewise, if the number of tubes decreases during the year, no refund will be made for that year.

(c) Annual license fees for radioactive material are set forth in this subsection.

(1) *Fees.*

(i) Licenses for radiography under § 217.65; radiopharmacy under §§ 217.90 and 217.91; manufacturing and distribution under §§ 217.81—217.89, 217.92 and 217.93; and, broad scope under §§ 217.71—217.73 (Category 1)—$1,530.

(ii) Licenses for source material used as shielding; special nuclear material used in gauges; radioactive material used in static eliminators, smoke detectors, fixed gauges and dew point measurers or used for calibration or civil defense activities and radioactive material maintained in storage (Category 2)—$125.

(iii) For other licenses not listed under this subsection (Category 3)—$600.

(2) *Exceptions.* This subsection does not apply to the low-level radioactive waste disposal facility operating license.

(d) An initial application for a license shall be accompanied by a check payable to the Department in accordance with the fee schedule in subsection (c). Thereafter, the Department will issue an annual license fee invoice at least 2 months prior to the last day of the license expiration month based on the fee schedule in subsection (c). Fees are payable by the last day of the license expiration month as shown on the license fee invoice.

(e) The Department will not accept an initial application for a license prior to payment of the fees required by subsection (c).

(f) If the registration involves more than one of the facilities in subsection (a), or if a license involves more than one of the categories in subsection (c), the highest applicable fee applies.

CHAPTER 221. X-RAYS IN THE HEALING ARTS

GENERAL

§ 221.2. Definitions.

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

AAPM—American Association of Physicists in Medicine.

ACR—American College of Radiology.

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

Automatic exposure control—A device which automatically controls one or more technique factors in order to obtain at preselected locations a desired quantity of radiation.

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

Cephalometric device—A device intended for the radiographic visualization and measurement of the dimensions of the human head.

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Control panel—The part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

Dead-man switch—A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Dental panoramic system—A device intended to produce a radiographic image of both dental arches on one film.

* * * * *

Filtration—Material placed in the useful beam to absorb the less penetrating radiation.

* * * * *

Fluoroscopic system—See fluoroscopic imaging assembly.

Focal spot—The area projected on the anode of the X-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

Half-value layer (HVL)—The thickness of specified material which attenuates the exposure rate by 1/2 when introduced into the path of a given beam of radiation.

* * * * *

Intensifying screen—A fluorescent screen which transforms incident X-ray photons into a visible image.

Intraoral dental radiography—A modality of dental radiography in which the image receptor is placed inside a patient's oral cavity.

kV—Kilovolts

kVp—Peak tube potential (see kilovolts peak).

Kilovolts peak (kVp)—The maximum value of the potential difference across the X-ray tube during an exposure.

Lead equivalent—The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

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Licensed practitioner of the healing arts—An individual licensed by the Commonwealth to practice the healing arts, which for the purposes of this article shall be limited to medicine, surgery, dentistry, osteopathy, podiatry and chiropractic.

* * * * *

mA—Milliampere.

mAs—Milliampere second.

mR—Milliroentgen.

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Mobile X-ray system—see X-ray equipment.

Patient—An individual subjected to healing arts examination, diagnosis or treatment.

Peak tube potential—The maximum value of the potential difference across the X-ray tube during an exposure.

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Portable radiation system—See X-ray equipment.

* * * * *

Positive beam limitation—The automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby an X-ray exposure cannot be made without an adjustment.

* * * * *

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

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

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

* * * * *

Qualified expert—An individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. For example, individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the preceding qualifications, training and experience in the clinical applications of radiation physics to radiation therapy. For example, individuals certified in therapeutic radiological physics or X-ray and radium physics by the American Board of Radiology, or radiation oncology physics by the American Board of Medical Physics; or those having equivalent qualifications.

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Registrant—A person who is legally obligated to register with the Department under this article and the act.

* * * * *

Research—One of the following:

(i) Theoretical analysis, exploration or experimentation.

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

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SID—Source-image receptor distance—The distance from the source to the center of the input surface of the image receptor.

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Serial radiography—Radiographic images produced in regular sequence.

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Source—The focal spot of the X-ray tube.

Specific prescription—A written or oral directive authorizing a radiographic or fluoroscopic examination of a specified individual.

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Technique factors—The following conditions of operation:

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(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV, number of X-ray pulses and either tube current or product of tube current and time.

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Therapeutic X-ray system—A system design for irradiation of a part of the human body for the purpose of treatment or alleviation of symptoms of disease.

Timer—An electronic device which is capable of measuring an X-ray exposure.

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X-ray equipment—An X-ray system, subsystem or component thereof. Types of X-ray equipment are as follows:

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(iii) *Stationary X-ray equipment*—X-ray equipment which is installed in a fixed location or vehicle.

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ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

(a) The registrant is responsible for directing the operation of X-ray systems under his administrative control and shall do the following:

(1) Assure that the requirements of this article are met in the operation of the X-ray systems.

(2) Permit only auxiliary personnel who have met the applicable radiologic requirements of 49 Pa. Code, Part I, Subpart A (relating to professional and occupational affairs) to operate X-ray systems for diagnostic or therapeutic purposes when employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices.

(3) Permit only auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government to operate X-ray systems for diagnostic or therapeutic purposes in accordance with written job descriptions and employe qualifications.

(b) An individual who operates an X-ray system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include, but not be limited to, items included in Appendix A (relating to determination of competence).

(c) A chart, which specifies the techniques for examinations performed with the system, shall be provided in the vicinity of each diagnostic X-ray system's control panel. This chart shall include information pertinent to the particular examination, such as:

(1) The patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized.

(2) The type and size of the film or film-screen combination.

(3) The type of grid, if any.

(4) The type and location of placement of patient shielding-for example, gonad, and the like.

(5) For mammography, indication of kVp/target/filter combination.

(6) Source to image receptor distance to be used, except for dental intra-oral radiography.

* * * * *

(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:

(1) Individuals shall be positioned so that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent material. The lead equivalent of the material is to be determined at 60 kV.

(2) All persons required for the medical procedure shall be protected from the scatter radiation by protective aprons or whole protective barriers of at least 0.25 millimeter lead equivalent or shall be so positioned that the persons are not in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(3) A patient who cannot be removed from the room shall be protected from the scatter radiation by protective barriers of at least 0.25 millimeter lead equivalent material unless the shield would compromise the health of the individual or shall be so positioned that the patient is not in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(f) During diagnostic procedures in which the gonads are in the useful beam, gonad shielding of at least 0.5 millimeter lead equivalent shall be used for patients except for cases in which this would interfere with the diagnostic procedure.

(g) An individual may not be exposed to the useful beam except for healing arts purposes or under § 221.15 (relating to use of X-rays in research on humans). An exposure shall be authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration or other nonhealing arts purposes.

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Department. When requesting authorization, the registrant shall submit the information as outlined in § 221.13 (relating to information to be submitted by persons proposing to conduct healing arts screening).

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

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

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

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(k) The screen and film system used shall 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.

(m) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

§ 221.12. Records, maintenance and associated information.

The registrant shall maintain records of surveys, calibrations, maintenance and modifications performed on

the X-ray systems including the names of persons who performed the services. The registrant shall keep these records for inspection by the Department for 5 years.

§ 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.

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

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

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

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

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

(6) An evaluation by a qualified expert of the X-ray systems to be used in the screening program. The evaluation shall show that the systems satisfy the requirements of this article. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

(7) A description of the diagnostic film quality control program.

(8) A copy of the technique chart for the X-ray examination procedures to be used.

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

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

(11) The name and address of the individual who will interpret the radiographs.

(12) A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and further medical needs indicated.

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

(14) This section does not apply to operations conducted by registrants under 21 CFR Part 900 (relating to mammography).

§ 221.15. Use of X-rays in research on humans.

(a) Registrants conducting research using X-rays involving human subjects are exempted from the requirements of this section if the research is conducted, funded, regulated or supported by a Federal agency which has implemented the Federal policy for the protection of human subjects or if the research is carried out in an institution which conducts other Federally funded or supported human research and follows all Federal requirements for protocol review and research subject protection.

(b) If not exempted under subsection (a), a person shall submit, in writing, the following information and evaluation to the Department and receive approval by the Department before conducting the research. If the information submitted to the Department becomes invalid or outdated, the person shall immediately, in writing, notify the Department.

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

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

(3) An evaluation of known alternate methods not involving ionizing radiation which could achieve the goals of the research program and why these methods are not used in preference to the X-ray examinations.

(4) An evaluation by a qualified expert of the X-ray system to be used in the research program. This evaluation shall show that the system satisfies the requirements of this article. The evaluation shall include a projected measurement of individual and cumulative patient exposures from the X-ray examinations to be performed.

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

(6) A copy of the chart which specifies the information for the X-ray examination procedures to be used.

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

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

(9) The name and address of the individual who will interpret the radiographs.

(10) A copy of the research protocol authorized by a committee consisting of at least three persons. One of the committee members shall be knowledgeable in radiation effects on humans.

(c) Proposed subjects or their legal representative shall sign a statement acknowledging that they have been informed of their anticipated radiation exposure and possible consequences arising from this exposure.

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.21. Diagnostic equipment requirements.

Diagnostic systems incorporating one or more certified components shall comply with 21 CFR 1020.30—1020.33.

§ 221.28. Technique indicators.

(a) The technique factors for radiographic systems shall be indicated before exposure except for units utilizing automatic exposure controls, in which case the maximum mAs shall be indicated.

(b) The requirement of subsection (a) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by a fluoroscopist.

§ 221.29. Kilovoltage accuracy.

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.

§ 221.30. Exposure reproducibility.

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

§§ 221.31—221.49. (Reserved).

§§ 221.51—221.55. (Reserved).

§ 221.62. (Reserved).

§§ 221.81—221.102. (Reserved).

§ 221.31a. Locks.

Position locking, holding and centering devices on X-ray systems shall function as intended.

§ 221.32a. A beam limitation.

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

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

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

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

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

(d) A means shall be provided to:

(1) Indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

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

(3) Indicate the SID to within 2%.

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

(1) Eighteen centimeters if operable above 50 kVp.

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

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

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

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

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

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

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

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

(i) Mobile or portable radiographic systems shall be provided with a means to limit the source-to-skin distance to at least 30 centimeters.

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

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

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

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

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

§ 221.34a. Radiation exposure control.

(a) *Radiation exposure control.* A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure may not be initiated without such an action.

(b) *Visual indication and audible signal.* A means shall be provided for visual indication observable from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) *Termination of exposure.* A means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the time to its initial setting or to "zero."

(d) *Manual exposure control.* An X-ray control shall be incorporated into each X-ray system which allows the operator to terminate an exposure at any time except for one or more of the following:

(1) Exposure of 1/2 second or less.

(2) During serial radiography in which case a means shall be provided to permit completion of any single exposure of the series in process.

(e) *Automatic exposure control.*

(1) Indication shall be made on the control panel when this mode of operation is selected.

(i) A means shall be provided to terminate irradiation at an appropriate exposure for the projection if the automatic exposure control fails to terminate irradiation.

(ii) A visible signal shall indicate when an exposure has been terminated at the limits required by subparagraph (i), and manual resetting shall be required before further automatically timed exposures can be made.

(2) For X-ray systems operating in automatic exposure control mode, and which lack engineered safeguards that prevent exposure in the event of either a malfunction or a mispositioned X-ray beam with respect to film cassette sensors, the back-up or default mAs shall be set by the operator to an appropriate maximum value for the projection.

(3) X-ray systems utilizing automatic exposure control, in which the back-up mAs values are preset and cannot be selected by the operator, shall prominently indicate the preset mAs value on the console, along with an appropriate warning notice to the operator.

(f) *Exposure control location.*

(1) Stationary X-ray systems shall have X-ray controls permanently mounted in a protected area and situated so that the operator is required to remain in that protected area during the entire exposure.

(2) For mobile and portable X-ray systems the exposure switch shall be arranged so that the operator can stand at least 2 meters from the patient and from the tube head and away from the direction of the useful X-ray beam.

FLUOROSCOPIC X-RAY SYSTEMS

§ 221.35a. Fluoroscopic X-ray systems.

Fluoroscopic X-ray systems shall use an image intensifier and in addition to the requirements of §§ 221.1—221.34a, shall meet the requirements of §§ 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate).

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

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-to-image receptor distance.

(b) The X-ray tube used for fluoroscopy may not produce X-rays unless a barrier is in position to intercept the useful beam and the imaging device is in place and operable.

(c) A means shall be provided for stepless (continuous) adjustment of the field size.

(d) The minimum field size at the greatest source to image receptor distance shall be equal to or less than 25 square centimeters.

(e) Equipment may not be operated at a source to skin distance less than 30 centimeters or as required under 21 CFR 1020.32(g) (relating to source-skin distance fluoroscopic equipment).

(f) The width of the X-ray field in the plane of the image receptor may not exceed that of the visible area of the image receptor by more than 3% of the source to image receptor distance. The sum of the excess length and the excess width may not be greater than 4% of the source to image receptor distance.

(g) For rectangular X-ray fields used with a circular image receptor, the error in alignment shall be determined along the length and width dimensions of the X-ray field which passes through the center of the visible area of the image receptor.

(h) Compliance with subsections (a)—(g) shall be determined with the beam axis perpendicular to the plane of the image receptor.

(i) Spot-film devices shall meet the following additional requirements:

(1) A means shall be provided between the source and the patient for adjustment of the X-ray field size to the size of the portion of film which has been selected on the spot-film selector.

(2) The adjustments shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the film.

(3) The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor may not exceed 3% of the source-to image receptor when adjusted for full coverage of the selected portion of the image receptor.

(4) The sum, without regard to sign, of the misalignment along any two orthogonal dimensions, may not exceed 4% of the source, to image receptor distance.

(5) The center of the X-ray field in the plane of the film shall be aligned with the center of the film within 2% of the source to image receptor distance.

§ 221.37a. Activation of fluoroscopic tube.

X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of the exposure (dead-man switch). When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate X-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

§ 221.38a. Entrance exposure rate.

(a) *Fluoroscopic systems without high level control.* The exposure rate may not exceed 10 roentgens (2.58 mC/kg) per minute except during recording of fluoroscopic images.

(b) *Fluoroscopic systems with high level control.*

(1) When the high level control is activated, the maximum exposure rate shall be 20 roentgens (5.16 mC/kg) per minute.

(2) When the high level control is not activated, the maximum exposure rate shall be 10 roentgens (2.58 mC/kg) per minute.

(3) Special means of activation of high level controls are required. The high level control shall only be operable when continuous manual activation is provided by the operator.

(4) There shall be an indication to the fluoroscopist that the high level control is being used.

(c) *Frequency of output measurements.* Output measurements required by this section shall be made annually and after maintenance that could affect the output of the machine.

(d) *Compliance requirements.* Compliance with subsections (a)—(c) shall be determined as follows:

(1) If the source is below the table, the exposure rate shall be expressed for the center of the useful beam 1 centimeter above the tabletop or cradle with the image intensifier 30 centimeters above the tabletop or cradle.

(2) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(3) In a c-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source at its closest possible position of operation.

(4) The tube potential and current shall be set to give the maximum exposure possible from the X-ray system. For systems with automatic exposure control, at least 3 millimeters of lead shall be placed between the measuring device and image receptor.

(5) The measurement shall be made at the center of the useful beam.

§ 221.39a. Barrier transmitted radiation rate limits.

The protective barrier may not transmit more than 2 milliroentgens (.516 µmC/kg) per hour at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly for each roentgen per minute of entrance exposure rate.

§ 221.40a. Indication of tube voltage and current.

During fluoroscopy and cinefluorography, the voltage and the current shall be continuously indicated.

§ 221.41a. Fluoroscopic timer.

A cumulative timing device activated by the fluoroscope switch shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary or permanent interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

§ 221.42a. Control of scattered radiation.

(a) Fluoroscopic table designs when combined with normal operating procedures shall be of a type so no unprotected part of the staff or an ancillary individual's whole body is exposed to unattenuated scattered radiation which originates from under the table. The attenuation required may be not less than .25 millimeter lead equivalent.

(b) Equipment configuration when combined with normal operating procedures shall be of a type so that no portion of the staff or an ancillary individual's whole body, except the extremities, is exposed to the unattenuated scattered radiation emanating from above the table top unless one of the following criteria is met:

(1) The individual is at least 120 centimeters from the center of the useful beam.

(2) The radiation has passed through at least .25 millimeter of lead equivalent material—for example, drapes, bucky-slot cover (film-tray cover panel), sliding or folding panel or self supporting curtains—in addition to lead equivalency provided by the protective apron referred to in § 221.11(e) (relating to registrant responsibilities).

§ 221.43a. Mobile fluoroscopes.

In addition to the other requirements of §§ 221.35a—221.42a, mobile fluoroscopes shall provide image intensification.

§ 221.61. Radiation therapy simulation systems.

Radiation therapy simulation systems shall comply with §§ 221.35a—221.44a. Radiation therapy simulation systems are exempt from §§ 221.36a, 221.38a, 221.39a and 221.42a if the systems that do not meet the requirements in § 221.42a (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.

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.201. Definitions.

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

CS—Contrast scale—The change in the linear attenuation coefficient per CT number relative to water; that is:

$$CS = (U_x - U_w)/((CT)_x - (CT)_w)$$

Where:

U_x = Linear attenuation coefficient of the material of interest

U_w = Linear attenuation coefficient of water

$(CT)_x$ = CT number of the material of interest

$(CT)_w$ = CT number of water

CT number—The number used to represent the X-ray attenuation associated with each elemental area of the CT image.

CT—Computed tomography—The production of a tomogram by the acquisition and computer processing of X-ray transmission data.

CTDI—Computed tomography dose index—The integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan.

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

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

Gantry—The tube housing assemblies, beam-limiting devices, detectors, transformers, if applicable, and the supporting structures and frames which hold these components.

Lux—A unit illumination equivalent to 1 lumen per square centimeter or .0929 foot-candles.

MSAD—Multiple scan average dose—The calculated average dose to the tissue within each slice in a series utilizing an ion chamber. The MSAD is calculated using the following equation:

$$MSAD = (F \times K \times L \times E)/(T \times N)$$

Where

F = Factor to convert exposure in air to absorbed dose in lucite in RADS/mR

K = Calibration factor to account for the ion chamber's response and volume.

L = Effective length of ion chamber in millimeters (mm)

E = Exposure reading in milliroentgen (mR)

T = Nominal slice thickness in millimeters (mm) and

N = Number of slices per scan

Multiple tomogram system—A computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Noise—The standard deviation of the fluctuations in the CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = 100 \times CS \times S/U_w$$

Where:

CS = Contrast scale

U_w = Linear attenuation coefficient of water.

S = Estimated standard deviation of the CT number of picture elements in a specified area of the CT image.

Nominal tomographic section thickness—The full-width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

Performance phantom—A phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the CT system for low and high contrast objects, and measuring the mean CT number for water or other reference materials.

Picture element—See elemental area.

Pixel—See elemental area.

Reference plane—A plane which is at a known fixed distance—which could be zero—to the tomographic plane and parallel to it.

Scan—The complete process of collecting X-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan increment—The amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of the displacement.

Scan sequence—A preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Scan time—The period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

Sensitivity profile—The relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

Single tomogram system—A CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

Technique factors—The conditions of operation, specified as follows:

(i) For CT equipment designed for pulsed operations, peak tube potential, scan time in seconds, X-ray pulse width in seconds and the number of X-ray pulses per second or per mAs.

(ii) For CT equipment not designed for pulsed operation, peak tube potential, and either tube current and scan time in seconds or the product of tube current and exposure time in mAs.

Tomogram—The depiction of the X-ray attenuation properties of a section through a body.

Tomographic plane—The geometric plane which is identified as corresponding to the output tomogram.

Tomographic section—The volume of an object whose X-ray attenuation properties are imaged in a tomogram.

§ 221.202. Equipment requirements.

(a) *Termination of exposure.* The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under X-ray system control, of greater than 0.5 second duration. Termination of the X-ray exposure shall necessitate resetting of the conditions of operation prior to initiation of another scan.

(b) *Tomographic plane indication and alignment.*

(1) For any single tomogram system, a means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, a means shall be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic plane.

(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) The emergency buttons or switches shall be clearly labeled as to their function.

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

(d) *Indication of CT conditions of operation.* The CT X-ray system shall be designed so that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(e) *Leakage radiation.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(f) *Beam quality.* The HVL shall be at least 3.2 millimeters aluminum at 120 kVp.

(g) *Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.*

(1) The total error in the indicated location of the tomographic plane or reference plane by the light field or laser indicator may not exceed 5 millimeters.

(2) If the X-ray production period is less than 0.5 second, the indication of X-ray production shall be actuated for at least 0.5 second. Beam-on and shutter status indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The CT X-ray system shall be normalized to water.

(4) The CT number for water for a region of interest, not exceeding 100 square millimeters, shall be 0 ± 10.0 CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the qualified expert, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the qualified expert may establish and maintain an equivalent value.

(5) With the performance phantom, the mean CT number of water of one group of pixels may not differ from the mean CT number of water of a second group of pixels equal size within the same image by more than the manufacturer's published specifications.

(6) The noise, utilizing the facility's performance phantom, may not exceed the manufacturer's published specifications.

(7) The total error between the indicated and actual slice thickness may not exceed 2.0 millimeters.

(8) A distance of at least 100 millimeters measured in a CT image shall agree with the actual distance to within ± 5%.

(9) Premature termination of the X-ray exposure by the operator shall necessitate resetting the CT conditions of operation prior to the initiation of another scan.

(h) *Exemption of CT units used solely for therapy simulations.* CT units used solely for therapy simulations are exempt from §§ 221.202—221.205.

§ 221.203. Facility design requirements.

(a) *Oral communication.* Provision shall be made for oral communication between the patient and the operator at the control panel.

(b) *Viewing systems.*

(1) A means shall be provided to permit continuous observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

(2) If the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

§ 221.204. Radiation measurements and performance evaluations.

(a) *Radiation measurements.*

(1) The CTDI or MSDAD along the two axes specified in paragraph (2)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry at the point of maximum surface exposure identified. The CT conditions of operation shall be reproducible and correspond to typical values used by the registrant. If the point of maximum surface exposure constantly changes due to system design, then measurements shall be taken at four different locations—top left, top right, bottom left, bottom right—1 centimeter from the outer surface of the phantom.

(2) CT dosimetry phantoms shall be used in determining the radiation output of a CT X-ray system. The phantoms shall meet the definition for a CT dosimetry phantom under 21 CFR 1020.33(b)(6) (relating to computed tomography (CT) equipment).

(i) The phantoms shall be specifically designed for CT dosimetry and deemed appropriate by the facility's qualified expert and the Department.

(ii) CT dosimetry phantoms shall provide a means for the placement of dosimeters along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. The means for the placement of dosimeters or alignment devices at other locations may be provided.

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(iv) Dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(3) In addition to the items in subsection (b), the following items shall be evaluated annually or after any component repair or change which in the opinion of the qualified expert may effect the performance of the CT unit:

(i) HVL (half value layer) determination at the most commonly used kVp or 120 kVp.

(ii) CTDI or MSAD as specified in § 221.201 (relating to definitions) for commonly used techniques.

(iii) Tomographic plane indication (light/laser alignment).

(iv) Slice thickness as specified in § 221.202(g)(7) (relating to equipment requirements).

(v) Distance readout calibration.

(4) The measurement of the radiation output of a CT X-ray system shall be performed with a dosimetry system that has calibration traceable to National Institute of Standards and Technology. The calibration of the system shall be in accordance with an established calibration protocol. The calibration protocol published by the AAPM is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent.

(5) An mR/mAs value shall be determined at least annually for the head and body.

(6) Procedures and results shall be maintained for 5 years and be available for review by the Department.

(b) *Performance evaluations.*

(1) Written performance evaluation procedures shall be developed by a qualified expert. These procedures shall be available for review by the Department.

(2) The performance evaluation procedures shall include at least the following using the facility's performance phantom:

(i) Noise.

(ii) Contrast scale.

(iii) Spatial resolution (low and high contrast).

(iv) Mean CT number for water.

(v) Acceptable tolerances.

(3) The performance evaluation shall be performed at intervals not to exceed 3 months by the qualified expert or an individual designated by the qualified expert.

(4) The qualified expert need not be present during the performance evaluation, but shall be informed within 48 hours of any problems or unacceptable deviations.

(5) Performance evaluations shall include acquisition of images obtained with the performance phantom using the same processing mode and CT conditions of operation as are used to perform the measurements required by subsection (a).

(6) Records of the performance evaluations shall be maintained for inspection by the Department for at least 4 years.

§ 221.205. Operating procedures.

(a) Information shall be available at the control panel regarding the operation and performance evaluations of the system. The information shall include the following:

(1) The dates of the latest radiation measurements and performance evaluation and the location within the facility where the results of those tests may be obtained.

(2) Instructions on the use of the CT phantoms including a schedule of performance evaluations appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent performance evaluation conducted on the system.

(3) The distance in millimeters between the tomographic plane and the reference plane if the reference plane is utilized.

(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

(b) If the radiation measurements and performance evaluation of the CT X-ray system indicates that a system operating parameter has exceeded a tolerance established by the qualified expert, the use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

APPENDIX A

DETERMINATION OF COMPETENCE

The following are areas in which an individual shall have expertise for the competent operation of diagnostic X-ray equipment:

(1) *Familiarization with equipment.*

(i) Identification of controls.

(ii) Function of each control.

(iii) How to use a technique chart.

(2) *Radiation protection.*

(i) Collimation.

(ii) Filtration.

(iii) Gonad shielding and other patient protection devices if used.

(iv) Restriction of X-ray tube radiation to image receptor.

(v) Personnel protection.

(vi) Grids.

(vii) Proper use of personnel dosimetry, if required.

(viii) Understanding units of radiation.

(3) *Film processing.*

(i) Film speed as related to patient exposure.

(ii) Film processing parameters.

(iii) Quality assurance program.

(iv) Identification of film artifacts and corrective actions, if necessary.

(v) Identification of adequate film exposure on the resultant radiograph, and corrective actions, if necessary.

(4) *Procedures.*

(i) Knowledge of anatomy and physiology.

(ii) Knowledge of positioning and radiographic demonstration of the requested anatomy with corrective actions, if necessary.

(5) *Emergency procedures.* Termination of exposure in event of automatic timing device failure.

(6) *Continuing education.* Continuing education annually to include radiation protection.

CHAPTER 223. VETERINARY MEDICINE

GENERAL PROVISIONS

§ 223.2a Definitions.

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

C—Coefficient of variation—The ratio of the standard deviation to the mean value of a population of observations.

Dead-man switch—A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Fluoroscopic imaging assembly—A subsystem in which X-ray photons produce a fluoroscopic image. The term includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Image receptor—A device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Leakage radiation—Radiation emanating from the diagnostic or therapeutic source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

§ 223.7. Structural shielding.

Facilities regularly used for diagnostic or therapeutic veterinary X-ray procedures shall have protective barriers sufficient to assure compliance with § 219.51 (relating to radiation dose limits for individual members of the public).

§ 223.8. Operating procedures.

(a) Individuals, whose presence is not necessary to conduct the X-ray procedures, shall be located in a shielded area or at least 2 meters from the primary X-ray beam and X-ray tubehead.

(b) Mechanical supporting or restraining devices shall be used during X-ray procedures to hold the animal patient or films in position, when the technique permits.

(c) Individuals whose presence is necessary to conduct X-ray procedures and who are not located behind protective barriers or at least 2 meters from the X-ray tubehead and primary X-ray beam shall be protected with appropriate shielding devices such as lead aprons and gloves, and be positioned so that no part of their body except hands and forearms will be exposed to the primary beam. Appropriate shielding devices shall have a lead equivalent at least 0.25 millimeters of lead.

(d) X-ray exposures shall be authorized by a veterinarian.

X-RAY EQUIPMENT

§ 223.11. Radiographic equipment.

(a) *Leakage radiation.*

(1) The leakage radiation from the tube housing assembly with a beam-limiting device attached measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 µC/kg) in 1 hour when the X-ray tube is operated at its maximum technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) The radiation emitted by a component other than the tube housing assembly with a beam-limiting device attached may not exceed 2 milliroentgens (0.516 µC/kg) in 1 hour at 5 centimeters from an accessible surface of the component when it is operated in an assembled X-ray system under conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(b) *X-ray beam restriction.*

(1) The primary X-ray beam shall be restricted to the area of clinical interest and equal to or smaller than the image receptor.

(2) Collimating devices capable of limiting the primary beam to the appropriate image receptor to within 2% of the source to image distance shall be provided and used. They shall provide the same degree of protection as is required in subsection (a)(1) for a diagnostic source assembly.

(3) A means shall be provided to align the center of the X-ray field to the center of the image receptor to within 2% of the source to image distance.

(c) *X-ray beam filtration.* The total filtration permanently in the useful beam may not be less than .5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50—70 kVp and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(d) *Exposure control devices.*

(1) An exposure control device shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to zero. It may not be possible to initiate an exposure with the exposure control device in the zero or off position, if either position is available, unless equipped for current adjustment.

(2) A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator such as the depression of a switch. The switch shall be of the dead man type.

(e) The coefficient of variation for exposure may not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure (a) is greater than or equal to 5 times the maximum exposure (e(max)) minus the minimum exposure (e(min)).

(f) Veterinary portable X-ray units shall be supported by a tube stand when the technique permits unless the unit is designed to be hand held during X-ray procedures.

(g) The X-ray control shall provide indication of the production of X-rays that is observable from the operator's position. The technique factors that are set prior to the exposure shall be indicated on the X-ray control and shall be visible to the operator from the operator's position.

§ 223.12. (Reserved).

§ 223.12a. Fluoroscopic equipment.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the primary beam at the maximum source to image receptor distance.

(b) The X-ray tube used for fluoroscopy may not produce X-rays unless the primary barrier is in position to intercept the entire primary beam.

(c) X-ray production in the fluoroscopic mode shall be controlled by a dead-man switch for the duration of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposures at any time. A means may be provided to permit completion of a single exposure of the series in process.

(d) The protective barrier may not transmit more than 2 milliroentgens (.516 µC/kg) per hour at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly for each roentgen per minute of entrance exposure rate.

(e) During fluoroscopy and cinefluorography, the voltage and the current shall be continuously indicated.

(f) A cumulative timing device activated by the fluoroscope switch shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary or permanent interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

(g) Fluoroscopic table designs when combined with normal operating procedures shall be of a type that no unprotected part of the staff or an ancillary individual's whole body is exposed to unattenuated scattered radiation which originates from under the table. The attenuation required may be not less than 0.25 millimeter lead equivalent.

(h) Equipment configuration when combined with normal operating procedures shall be of a type that no portion of the staff or an ancillary individual's whole body, except the extremities, is exposed to the unattenuated scattered radiation emanating from above the tabletop unless one of the following criteria is met:

(1) The individual is at least 120 centimeters from the center of the primary beam.

(2) The radiation has passed through at least 0.25 millimeter of lead equivalent material—for example, drapes, bucky-slot cover (film-tray cover panel), sliding or folding panel or self-supporting curtains—in addition to the lead equivalency provided by the protective apron referred to in § 223.8(c) (relating to operating procedures).

(i) In addition to the other requirements of this section, mobile fluoroscopes shall have image intensification.

§ 223.13. (Reserved).

§ 223.13a. Therapeutic systems.

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

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

(2) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 0-500 kVp systems.

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

(b) Beam limiting devices used for limiting the primary beam shall provide at least the same protection as required by the tube housing assembly.

(c) Therapeutic X-ray systems shall be secured to prevent unauthorized use whenever the system is unattended.

(d) Interlocks shall be provided so that, when a door of the treatment room is opened, either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than 2 milliroentgens (0.516 μC/kg) per hour and a maximum of 10 milliroentgens (2.58 μC/kg) per hour at a distance of 1 meter in any direction from the target; or interlocks will energize a conspicuous visible or audible alarm signal so that the individual entering and the operator are made aware of the entry. After a shut-off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

(e) Interlocks, on-off beam control mechanisms and safety and warning devices shall be checked and appropriately serviced at least once in a calendar year.

(f) Treatment room entrances shall be provided with warning lights, which will indicate when the primary beam is on, in a readily observable position near the outside of access doors.

(g) Exposure factors shall be displayed on the control panel.

(h) Provision shall be made to permit continuous observation of the animal patient from the control panel during irradiation.

(i) A registrant may not permit an individual to operate a therapeutic X-ray system until the individual has received a copy of, and instruction in, the operating procedures for the system and has demonstrated understanding of the operating procedures and competence in the use of the system.

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

ANALYTICAL X-RAY EQUIPMENT

§ 227.11. (Reserved).

§ 227.11a Equipment requirements.

(a) Open-beam configurations shall have a device which either prevents the entry of any portion of an individual's body into the primary X-ray beam path, or causes the beam to be terminated or interrupted upon entry into the path. A registrant may apply to the Department for an exemption from the requirement of a safety device. The application for an exemption shall include the following:

(1) A description of the various safety devices that have been evaluated.

(2) The reason each of these devices cannot be used.

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Open-beam configurations shall be provided with a readily discernible indication of one or both of the following:

(1) X-ray tube status (on-off) located near the radiation source housing, if the primary beam is controlled in this manner.

(2) Shutter status (open-closed) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(c) Warning devices shall be labeled so that their purpose is easily identified. In addition, equipment manufactured after December 17, 1987, shall have fail-safe characteristics.

(d) An easily visible warning light located immediately adjacent to the tube head or port and labeled with the words "X-ray on," or words containing a similar warning, shall be provided and shall be illuminated when the X-ray tube is energized.

(e) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(f) Analytical X-ray equipment shall be labeled with a readily discernible sign bearing the radiation symbol and both of the following:

(1) "CAUTION—HIGH INTENSITY X-RAY BEAM" or words having a similar intent on the X-ray source housing.

(2) "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an X-ray tube.

(g) On equipment with an open-beam configuration manufactured and installed after December 19, 1987, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or coupling has been connected to the port.

(h) Equipment exclusively designed and exclusively used for vacuum spectroscopy where the tube housing and sample chamber is located behind all external surfaces of the unit shall be exempt from the requirements of this section, §§ 227.12a and 227.13a (relating to area requirements; and operating requirements), but shall meet the requirements of § 227.14 (relating to personnel procedures) and the following:

(1) The unit shall be designed so that when the unit is operating at the maximum kilovoltage and current ratings, the leakage radiation will not be in excess of 0.5 milliroentgens (.129 μC/kg) per hour at a distance of 4 centimeters from any external surface.

(2) Radiation surveys using appropriate radiation survey equipment shall be performed on the analytical X-ray unit upon installation, after moving the unit to a new location, and after maintenance or repair requiring the disassembly or removal of a local component or radiation shielding.

(3) Safety and warning devices shall be tested for proper operation at least annually. If the test reveals that a safety or warning device is not working properly, the unit may not be operated until the warning device is repaired or replaced.

(4) Records of all tests and surveys sufficient to show compliance with subsection (h) shall be maintained and kept available for inspection by the Department for 4 years.

(5) A sign bearing the radiation symbol and the words "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words of similar intent shall be placed next to any switch or device that activates the X-ray tube.

(6) A sign bearing the radiation symbol and the words "CAUTION—RADIATION," or words of similar intent shall be placed next to the opening of the sample chamber.

§ 227.12. (Reserved).

§ 227.12a. Area requirements.

(a) The source housing construction shall be of a type that when all the shutters are closed and the source is in any possible operating mode, the leakage radiation will not be in excess of 2.5 milliroentgens (.645 μC/kg) per hour at a distance of 5 centimeters from the housing surface.

(b) The X-ray generator shall have a protective cabinet constructed so that the leakage radiation will not be in excess of 0.5 milliroentgen (.129 μC/kg) per hour at a distance of 5 centimeters from the housing surface.

(c) The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control so that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the limits given in § 219.51 (relating to dose limits for individual members of the public). For systems utilizing X-ray tubes, these requirements shall be met at any specified tube rating.

(d) To show compliance with subsections (a)—(c), the registrant shall perform radiation surveys:

(1) Upon installation of the equipment and at least every 12 months thereafter.

(2) Following a change in the initial arrangement, number or type of local components in the system.

(3) Following maintenance requiring the disassembly or removal of a local component in the system.

(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when a local component in the system is disassembled or removed.

(5) When a visual inspection of the local components in the system reveals an abnormal condition.

(6) When personnel monitoring devices show a significant increase in radiation exposure over the previous monitoring period or the readings are approaching the radiation dose limits.

(7) When the machine is operated in a manner other than the routine manner specified in § 227.13a (relating to operating requirements).

(e) The registrant shall test and inspect all safety and warning devices at least annually to insure their proper operation. If a safety or warning device is found to be malfunctioning, the machine shall be removed from service until repairs to the malfunctioning device are completed.

(f) Records of surveys and tests sufficient to show compliance with this chapter shall be maintained for 4 years and kept available for inspection by the Department.

(g) The equipment used to conduct the surveys and tests required in this chapter shall be adequate to measure the radiation produced by the radiation source.

§ 227.13. (Reserved).

§ 227.13a. Operating requirements.

(a) Operating procedures shall be written and available to the analytical X-ray equipment operators. These procedures shall include instructions for sample insertion and manipulation, equipment alignment, routine maintenance and data recording procedures which are related to radiation safety. An individual may not operate analytical X-ray equipment in a manner other than that specified in the operating procedures unless the individual has obtained written approval from the radiation safety officer.

(b) An individual may not bypass or otherwise circumvent a safety device unless the individual has obtained the prior written approval of the radiation safety officer. The radiation safety officer may grant the permission only if the following conditions are met:

(1) The radiation safety officer establishes administrative controls and procedures to assure the radiation safety of individuals working around the system.

(2) The period for the bypass of the safety device is not more than 30 days unless written permission is obtained from the Department for a longer period.

(3) A readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words containing a similar warning, is placed on the radiation source housing.

(c) Except as specified in subsection (b), an operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops may not be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

§ 227.14. Personnel requirements.

(a) An individual may not operate or maintain analytical X-ray equipment unless the individual has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment.

(2) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment, and the extra precautions necessary if the devices are absent or bypassed.

(3) Written operating procedures for the equipment.

(4) Symptoms of an acute localized radiation exposure.

(5) Procedures for reporting an actual or suspected exposure.

(6) Use of survey and personnel monitoring equipment.

(b) Finger or wrist personnel monitoring devices shall be provided to and shall be used by:

(1) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device as described in § 227.12(c) (relating to safety devices and requirements).

(2) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when a local component in the analytical X-ray system is disassembled or removed or when safety devices are bypassed.

(c) Reported dose values may not be used for the purpose of determining compliance with § 219.31 (relating to occupational dose limits for adults) unless they are evaluated by a qualified expert.

(d) The registrant or licensee shall notify the Department within 5 days of a suspected radiation overexposure to an individual from analytical X-ray machines. This notification is required even if subsequent investigation reveals no actual over-exposure actually occurred.

§ 227.15. (Reserved).

ELECTRON MICROSCOPES

§ 227.33. Personnel requirements.

A registrant may not permit an individual to operate or conduct maintenance upon any electron microscope until the individual has received a copy of, instruction in, and demonstrated an understanding of, the operating procedures necessary to insure radiation safety.

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

GENERAL PROVISIONS

§ 228.2. Definitions.

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

Accelerator—A radiation-producing machine that imparts kinetic energies of one of the following:

(i) One-tenth of one MeV or greater to electrons if the electron beam is brought out of the evacuated region of the unit.

(ii) One MeV or greater to electrons if the electrons are utilized for X-ray production.

(iii) One-tenth of one MeV or greater to other particles.

Applicator—A structure which determines the extent of the treatment field at a given distance from the virtual source.

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

Beam scattering filter—A filter used to scatter a beam of electrons.

Central axis of the beam—A line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

Dose monitoring system—A system of devices for the detection, measurement and display of quantities of radiation.

Dose monitor unit—A unit response from the dose monitoring system from which the absorbed dose can be calculated.

Existing equipment—Systems manufactured on or before October 3, 1998.

Field flattening filter—A filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

Field size—The configuration of the radiation field along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50% isodose line.

Filter—Material placed in the useful beam to absorb the less penetrating radiation.

Isocenter—A fixed point in space located at the center of the smallest sphere through which the central axes of the beams pass.

Leakage radiation—Radiation emanating from the source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

Moving beam therapy—Radiation therapy with relative displacement of the useful beam and the patient during irradiation.

New equipment—Systems manufactured after January 1, 1985.

Normal treatment distance—

(i) For isocentric equipment, the isocenter.

(ii) For nonisocentric equipment, the target to patient skin distance along the central axis as specified by the manufacturer.

Phantom—A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Primary dose monitoring system—A system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been attained.

Qualified expert—An individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs. For example, individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics or the American Board of Medical Physics or those having equivalent

qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the preceding qualifications, training and experience in the clinical applications of radiation physics to radiation therapy. For example, individuals certified in therapeutic radiological physics or X-ray and radium physics by the American Board of Radiology, or radiation oncology physics by the American Board of Medical Physics; or those having equivalent qualifications.

Radiation detector—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Radiation head—The structure from which the useful beam emerges.

Secondary dose monitoring system—A system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Shadow tray—A device attached to the radiation head to support auxiliary beam limiting material.

Spot check—A procedure to assure that a previous calibration continues to be valid.

Stationary beam therapy—Radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Subsystem—A combination of two or more components of an accelerator.

Target—The part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

Tube housing assembly—The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

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

Virtual source—The nominal location of either the first scattering foil (for equipment providing electrons only) or the photon focal spot (for equipment capable of delivering both photons and electrons).

Wedge filter—An added filter effecting continuous progressive attenuation on all or part of the useful beam.

§ 228.3. Sale and installation.

A person may not sell or install an accelerator that does not meet the provisions of this article.

ADMINISTRATIVE CONTROLS

§ 228.11. (Reserved).

§ 228.11a. Licensee responsibilities.

(a) A person may not operate or permit the operation of an accelerator unless the accelerator and installation meet the applicable requirements of this article.

(b) Written safety procedures and rules shall be available at a facility, including restrictions of the operating technique required for the safe operation of the particular accelerator. The operator shall be able to demonstrate familiarity with the rules.

(c) An individual may not be exposed to the useful beam except for healing arts purposes. An exposure shall be authorized by a licensed practitioner of the healing arts.

(d) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

§ 228.12. Information and maintenance record and associated information.

The licensee shall maintain records of surveys, calibrations, maintenance, machine malfunctions and modifications performed on the accelerators, including the names of persons who performed the services. The registrant or licensee shall keep these records for inspection by the Department for 4 years.

NOTIFICATION AND LICENSING PROCEDURES

§ 228.21. (Reserved).

§ 228.21a. Notification and license requirements.

(a) A person who intends to purchase, construct or acquire an accelerator shall notify the Department of this intent by filing an application for a specific license within 30 days after the initial order is issued to obtain any or all parts of the accelerator.

(1) The application shall be filed in duplicate on a form prescribed by the Department.

(2) The application shall contain pertinent information to permit the Department to evaluate the accelerator facility for compliance with the requirements of the act and this article.

(b) In addition to the notification requirement in subsection (a), a person who intends to install an accelerator shall notify the Department within 30 days after the initial construction or installation begins.

(c) Except as provided in subsection (d), a person may not operate a particle accelerator after October 3, 1998, without having obtained a license from the Department.

(d) A registrant possessing an accelerator before October 3, 1998, may continue to operate the accelerator provided an application for a license is filed in duplicate with the Department by October 4, 1999.

(e) The Department may, after the filing of an original application, and before the expiration of the license, require further information to enable the Department to determine whether the application will be granted or denied or whether a license will be modified or revoked.

(f) The application shall be signed by the applicant or licensee or an individual authorized by the applicant or licensee.

§ 228.22. (Reserved).

§ 228.22a. Issuance of specific licenses.

(a) Upon determination that an application meets the requirements of the act, 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.

§ 228.23. (Reserved).

§ 228.23a. Expiration and termination of a license.

(a) Except as provided in § 228.24a (relating to renewal of licenses), and subject to subsection (d)(5)(ii), a specific license expires on the date specified in the license. A license is effective for 5 years.

(b) A licensee shall notify the Department in writing when the licensee decides to permanently discontinue activities involving the accelerator authorized under the license and request termination of the license. The notification and request for termination shall include the reports and information specified in subsection (d)(3)—(5). The licensee is subject to subsections (d) and (e), as applicable, until termination.

(c) At least 30 days before the expiration date specified in a specific license, the licensee shall do one of the following:

(1) Submit an application for license renewal under § 228.24a.

(2) Notify the Department in writing if the licensee decides not to renew the license.

(d) If the licensee does not submit an application for license renewal under § 228.24a on or before the expiration date specified in the license, the licensee shall:

(1) Terminate the use of the accelerator.

(2) Properly dispose of incidental radioactive material generated by the operation of the accelerator.

(3) Submit a completed Department Form ER-BRP-314, "Certificate of Disposition of Materials," describing the disposition of materials in paragraph (2).

(4) Submit a radiation survey report to confirm the absence of radioactive materials or establish the levels of residual radioactive contamination unless the Department determines a radiation survey report is not necessary. This report shall include:

(i) The levels of beta and gamma radiation (in units of microrems or microsieverts, or in microrads or micrograys per hour) at 1 centimeter and gamma radiation at 1 meter from surfaces, levels of removable and fixed alpha, beta and gamma contamination on surfaces (in becquerels or microcuries per 100 square centimeters), and concentrations of contamination in soils (in units of picocuries or becquerels per gram) or in water (in units of picocuries or becquerels per liter) where soil and water concentrations are reported.

(ii) The survey instrumentation used to perform these surveys.

(5) Proceed with one of the following:

(i) Submit a certification that no detectable radioactive contamination was found if no residual contamination attributable to activities conducted under the license is detected. If the information submitted under this section is adequate, the Department will notify the licensee in writing that the license is terminated.

(ii) Continue the license in effect beyond the expiration date. If necessary, with respect to possession of residual radioactive material present as contamination if detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall comply with subsection (e), in addition to the information submitted under paragraphs (3) and (4) and this paragraph, the licensee shall submit a plan for decontamination, if necessary.

(e) A licensee who possesses residual radioactive material under subsection (d)(5)(ii) following the expiration date specified in the license, shall:

(1) Limit activities involving radioactive materials to those activities which are solely related to decontamination and other activities related to preparation for release for unrestricted use.

(2) Continue to control entry to restricted areas until the restricted areas are suitable for release for unrestricted use and until the Department notifies the licensee in writing that the license is terminated.

§ 228.24. (Reserved).

§ 228.24a. Renewal of licenses.

(a) An application for renewal of a specific license shall be filed under § 228.21a (relating to notification and license requirements).

(b) If a renewal application is filed prior to 30 days before the expiration of a license, the existing license does not expire until definitive notice has been given by the Department of its action on the renewal application. This subsection also applies to new license applications incorporating other licenses.

§ 228.25. (Reserved).

§ 228.25a. Amendment of license at the request of the licensee.

A licensee filing an application for an amendment shall utilize the procedures in § 228.21a (relating to notification and license requirements). The application shall specify the requested amendment and the reason for the amendment.

§ 228.26. (Reserved).

§ 228.26a. Department action on applications to renew and amend.

In considering an application by a licensee to renew or amend a license, the Department will apply criteria in the act and this article.

GENERAL RADIATION SAFETY REQUIREMENTS

§ 228.31. (Reserved).

§ 228.31a. Limitations.

(a) The facility shall operate within the terms and conditions of the license issued for the operation of the accelerator.

(b) A licensee may not permit an individual to act as an operator of an accelerator until the individual:

(1) Has been instructed in radiation safety and has demonstrated an understanding thereof.

(2) Has received copies of and instruction in this chapter and Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers; inspections), pertinent registration and license conditions and the licensee's operating and emergency procedures and demonstrated understanding thereof.

(3) Has demonstrated competence to use the accelerator, related equipment and survey instruments which will be utilized in that individual's assignment.

(c) The radiation safety officer shall have the authority to restrict or terminate operations at an accelerator facility if the action is necessary to minimize danger to health and safety, property or the environment.

§ 228.32. (Reserved).

§ 228.32a. Shielding and safety design requirements.

(a) The licensee shall consult a qualified expert for the shielding design of accelerator installation and shall have the expert perform a radiation safety survey prior to the first use of the accelerator and when changes are made in shielding operations, equipment or occupancy of adjacent areas.

(b) An accelerator facility shall have primary and secondary protective barriers that are necessary to assure compliance with § 219.51 (relating to dose limits for individual members of the public).

§ 228.33. (Reserved).

§ 228.33a. Facility and shielding requirements.

In addition to the requirements in Chapter 219 (relating to standards for protection against radiation), the following are required:

(1) The control panel shall be located outside the treatment or irradiation room.

(2) For accelerators not used in the healing arts, provision shall be made to permit continuous observation of the material being irradiated and any transfer or conveyance of material within the irradiation room.

(3) For accelerators used in the healing arts, provision shall be made to permit continuous observation of and communication with the patient during irradiation.

(4) Windows, mirror systems or closed-circuit television viewing screens used for observing the patient or the material being irradiated shall be located so that the operator can maintain direct surveillance over both the control panel and the patient or the material being irradiated.

(5) If the surveillance conducted under paragraph (4) is provided solely by electronic means, and if a malfunction of this surveillance equipment occurs, irradiation activities shall cease until repair of that surveillance equipment is performed and the equipment is found to be functioning normally.

(6) Irradiation or treatment room entrances shall be provided with warning lights in a readily observable position near the outside of access doors. These will indicate when the useful beam is on.

(7) Interlocks shall be provided so that entrance or access doors are closed before irradiation or treatment can be initiated or continued.

(8) For accelerators used to irradiate materials by means of a transfer or conveyance system, a means shall be provided which either terminates the irradiation or prevents entry if an individual attempts access to the irradiation room.

§ 228.34. (Reserved).

§ 228.34a. Accelerator controls and interlock systems.

(a) Instrumentation, readouts and controls on the accelerator control console shall be clearly identified and easily discernible.

(b) Entrances into a target room or high radiation areas shall have interlocks that meet the requirements of §§ 219.91 and 219.154 (relating to control of access to high radiation areas; and posting of high radiation areas). If the radiation beam is interrupted by a door opening, it shall be possible to reinitiate the radiation exposure only by closing the door first and then by manual action at the control panel.

(c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the interlock position, and lastly at the main control console.

(d) Safety interlocks shall be fail-safe, that is, designed so that a defect or component failure in the interlock system prevents operation of the accelerator.

(e) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. The cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

§ 228.35. Operating procedures.

(a) Accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) An interlock may not be used to turn off the accelerator beam except in an emergency or for testing the interlock.

(c) Each safety and warning device, including interlocks, shall be checked at least every 3 months for proper functioning and shall be repaired as necessary. Results of these checks and records of repairs shall be maintained for 4 years at the accelerator facility for inspection by the Department.

(d) In the event of a malfunction of a safety or warning device, the accelerator may not be operated unless appropriate interim precautions are instituted to provide equivalent protection.

(e) If it is necessary to intentionally bypass a safety interlock system or component thereof, the action shall be the following:

(1) Authorized in writing by the radiation safety officer.

(2) Recorded in a permanent log and a notice posted at the accelerator operator's position.

(3) Terminated as soon as possible.

(f) A copy of the current operating and emergency procedures shall be maintained in the accelerator operator area.

(g) For accelerators used in the healing arts, operating procedures shall meet the following requirements:

(1) No individual other than the patient is in the treatment room during treatment of a patient.

(2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(3) The system may not be used in the administration of radiation therapy unless the requirements of this chapter have been met.

(4) Misadministrations, as defined in § 215.2 (relating to definitions), shall be reported as required under § 219.228 (relating to reports of misadministrations).

(5) Only auxiliary personnel who have met the applicable radiologic requirements of 49 Pa. Code Part I, Subpart A (relating to professional and occupational affairs) when employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices shall be permitted to operate accelerators for therapeutic purposes.

(6) Only auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government shall be permitted to operate accelerator systems for therapeutic purposes in accordance with written job descriptions and employe qualifications.

(7) An individual who operates an accelerator system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include, but not be limited to, items included in Appendix A (relating to determination of competence).

§ 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 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.

§ 228.37. Production of radioactive material.

(a) A licensee who produces radioactive material incidental to the operation of an accelerator shall comply with the general license requirements of § 217.48 (relating to a general license for incidental radioactive material produced by an accelerator).

(b) A licensee possessing radioactive material intentionally produced by bombarding nonradioactive material with the accelerator beam shall comply with the specific license requirements of §§ 217.51—217.57 (relating to specific licenses—general conditions).

§ 228.38. Radiation safety surveys.

(a) A facility shall have an initial survey made by, or under the direction of, a qualified expert. A survey shall also be done after a change in the facility or equipment, including a relocation of the equipment within the irradiation or treatment room.

(b) The qualified expert shall report the survey results in writing to the individual in charge of the facility and a copy of the initial report shall be maintained by the licensee for inspection by the Department for the life of the facility. Other survey reports shall be maintained for inspection by the Department for 4 years. The facility shall be operated in compliance with limitations indicated by the survey.

(c) The report of the survey results shall include:

(1) The date of the measurements.

(2) The reason the survey is required.

(3) The manufacturer's name, model number and serial number of the therapeutic radiation machine accelerator.

(4) The instrument used to measure radiation levels.

(5) A plan of the areas surrounding the treatment room that were surveyed.

(6) The measured dose rate at several points in each area expressed in microsieverts or millirems per hour.

(7) The calculated maximum level of radiation over a period of 1 year for each restricted and unrestricted area.

(8) The signature of the individual who conducted or is responsible for conducting the survey.

(d) If the survey required by subsection (a) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by § 219.31 or § 219.51 (relating to occupational dose limits for adults; and dose limits for members of the general public), the licensee shall do the following:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Chapter 219 (relating to standards for protection against radiation).

(2) Perform the survey required by subsection (a) again.

(3) Prepare and submit the report required by subsection (a). The report shall also include:

(i) The results of the initial survey.

(ii) A description of the modification made to comply with this section.

(iii) The results of the second survey.

§ 228.39. Records.

In addition to the requirements of §§ 219.201—219.211 (relating to records), the licensee shall maintain:

(1) Records of the tests and safety and warning devices described in § 228.35.

(2) The surveys described in §§ 228.32a and 228.38.

(3) The radiation monitoring equipment calibrations and repairs of that equipment under § 228.36 (relating to radiation monitoring requirements).

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL AND RESEARCH ACCELERATORS

§ 228.41. (Reserved).

§ 228.41a. Warning devices.

(a) A location designated as a high radiation area and an entrance to the location shall be equipped with easily observable warning lights that operate only when radiation is being produced.

(b) A high radiation area shall meet the requirements of § 219.91 (relating to control of access to high radiation areas).

§ 228.42. Circuit diagrams.

Electrical circuit diagrams of the accelerator and the associated safety, warning and interlock systems shall be kept current and maintained for inspection by the Department and shall be available to the operator at an accelerator facility.

§ 228.43. Radiation surveys.

(a) Periodic surveys shall be made to determine the amount of airborne radioactivity present in areas of airborne hazards.

(b) Periodic smear surveys shall be made to determine the amount of contamination in target and other pertinent areas.

(c) Area surveys shall be made in accordance with the written procedures established by a qualified expert or the radiation safety officer of the accelerator facility.

(d) Records of surveys shall be kept current and on file at an accelerator facility. Records of surveys shall be maintained as described in Chapter 219, Subchapter L (relating to records).

§ 228.44. Ventilation systems.

(a) A licensee shall control the concentration of radioactive material in air to meet the requirements of § 219.34 (relating to determination of internal exposure).

(b) A licensee may not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which does not meet the requirements of § 219.51 (relating to dose limits for individual members of the public). Every reasonable effort shall be made to maintain releases of radioactive material to uncontrolled areas as far below these limits as practicable. Compliance with this section shall be demonstrated as described in § 219.52 (relating to compliance with dose limits for individual members of the public).

§ 228.45. Portable or mobile accelerators.

Portable or mobile accelerators used for industrial radiography or research shall comply with Chapter 225 (relating to radiation safety requirements for industrial radiographic operations).

RADIATION SAFETY REQUIREMENTS FOR ACCELERATORS USED IN THE HEALING ARTS

§ 228.61. Leakage radiation to the patient area.

(a) New equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the dose due to leakage radiation, including X-rays, electrons and neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, may not exceed 0.1% of the maximum dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.

(2) For each system, the licensee shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in paragraph (1) for the specified operating conditions. The registrant or licensee shall maintain records for 5 years on leakage radiation measurements for inspection by the Department.

(b) Existing equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose due to leakage radiation, including neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam 1 meter from the virtual source, may not exceed 0.1% of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(2) For each system, the licensee shall have available the leakage radiation data existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records on radiation leakage for 5 years for inspection by the Department.

§ 228.62. Leakage radiation outside the patient area for new equipment.

(a) The absorbed dose due to leakage radiation except in the area specified in § 228.61(a)(1) (relating to leakage radiation to the patient area) when measured at any point 1 meter from the path of the charged particles, before the charged particles strike the target or window, may not exceed 0.1% for X-ray leakage nor 0.5% for neutron leakage of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in § 228.61(a)(1).

(b) The licensee shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in subsection (a) for specified operating conditions. Radiation measurements, including neutrons, shall be averaged over an area up to but not exceeding 200 square centimeters.

§ 228.63. Beam limiting devices.

Adjustable or interchangeable beam limiting devices shall be provided and the devices may transmit no more than 5% of the useful beam at the normal treatment distance. The neutron component of the useful beam may not be included to comply with this requirement.

§ 228.64. Filters.

(a) A filter which is removable from the system shall be clearly identified. Documentation shall contain a description of the filter which includes a drawing showing dimensions and noting materials of construction.

(b) For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters the following apply:

(1) Irradiation may not be possible until a selection of a filter has been made at the control panel.

(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

(3) An interlock shall be provided to prevent irradiation if a filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the control panel.

§ 228.65. Electron beam quality.

The licensee shall determine that the following beam quality requirements are met:

(1) The absorbed dose resulting from X-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons may not exceed the values in Table I. Linear interpolation shall be used for values not stated.

Table I

Maximum Energy of Electron Beam in MeV	*X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose*
1	0.03
15	0.05
35	0.10
50	0.20

(2) Compliance with paragraph (1) shall be determined using:

(i) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam.

(ii) The largest field size available which does not exceed 15 centimeters by 15 centimeters.

(iii) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

(3) The licensee shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose due to stray neutrons in the useful beam for specified operating conditions.

§ 228.66. Beam monitors.

(a) Therapy systems shall be provided with radiation detectors in the radiation head.

(b) New equipment shall be provided with at least two radiation detectors incorporated into two separate dose monitoring systems.

(c) Existing equipment shall be provided with at least one radiation detector incorporated into a primary dose monitoring system.

(d) The detector in a dose monitoring system shall be:

(1) Permanently installed and interlocked to prevent incorrect positioning.

(2) Part of a dose monitoring system that provides readings in dose monitor units which can be used to calculate the absorbed dose at a reference point in the treatment volume.

(3) Capable of independently monitoring and controlling the useful beam.

(e) For new equipment, the design of dose monitoring systems shall assure that:

(1) The malfunctioning of one system does not affect the correct functioning of the second system.

(2) The failure of an element common to both systems which could affect the correct function of both systems terminates irradiation.

(f) A dose monitoring system shall have a legible display at the control panel. For new equipment, a display shall:

(1) Maintain a reading until intentionally reset to zero.

(2) Have only one scale and no scale multiplying factors.

(3) Utilize a design so that increasing dose is displayed by increasing numbers and that the absorbed dose may be accurately determined under all conditions of use.

(4) Provide that, in the event of a power failure, the dose monitoring information required in this subsection displayed at the control panel at the time of failure shall be retrievable.

§ 228.67. Beam symmetry.

(a) In new equipment inherently capable of producing useful beams with asymmetry exceeding 5%, at least four different parts of the radiation beam shall be monitored before the beam passes through the beam limiting device.

(b) If the difference in dose rates between two of the different parts required in subsection (a) exceeds 10%, the irradiation shall be terminated.

§ 228.68. Selection and display of dose monitor units.

(a) Irradiation may not be possible until a selection of a number of dose monitor units has been made at the control panel.

(b) The preselected number of dose monitor units shall be displayed at the control panel until reset manually to zero before subsequent treatment can be initiated.

§ 228.69. Termination of irradiation by the dose monitoring system or systems.

(a) A dose monitoring system shall be capable of independently terminating irradiation.

(b) A primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(c) A secondary dose monitoring system shall terminate irradiation when either 110% of the preselected number of dose monitor units or 10 dose monitor units (whichever is greater) has been detected by the secondary dose monitoring system.

(d) For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

§ 228.70. Interruption and termination switches.

The operator shall be able to interrupt or terminate irradiation and equipment movement at any time from the control panel. Following an interruption, the operator shall be able to resume irradiation without reselection of operating conditions.

§ 228.71. Timer.

(a) The control panel shall have a timer that is graduated in minutes and fractions of minutes or seconds. The timer shall have a preset time selector and an elapsed time indicator.

(b) The timer shall be cumulative and activated only during irradiation and shall retain its reading after irradiation is interrupted or terminated.

(c) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.

§ 228.72. Selection of radiation type.

Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation may not be possible until a selection of radiation type and appropriate energy has been made and displayed at the control panel.

(2) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

(3) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the control panel.

(4) An interlock system shall be provided to prevent:

(i) Irradiation with X-rays except to obtain a port film when electron applicators are fitted.

(ii) Irradiation with electrons when accessories specific for X-ray therapy are fitted.

(5) For new equipment, a system shall be provided to terminate irradiation if the energy of the electrons striking either the X-ray target or electron window deviates by more than +20% or 3 MeV, whichever is smaller, from the selected nominal energy.

§ 228.73. Selection of stationary beam therapy or moving beam therapy.

Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following additional requirements:

(1) Irradiation may not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the control panel.

(2) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

(3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment rooms do not agree with the selected operations carried out at the control panel.

(4) The mode of operation shall be displayed at the control panel.

(5) An interlock system shall be provided to terminate irradiation if one of the following occurs:

(i) Movement of the gantry during stationary beam therapy.

(ii) Movement of the gantry stops during moving beam therapy unless the stoppage is a preplanned function.

(6) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered along an arc differs by more than 10% from the selected value. Termination of irradiation shall be as required by § 228.70 (relating to interruption and termination switches).

§ 228.74. Absorbed dose rate.

New equipment shall have a system that provides information from which the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in § 228.66 (relating to beam monitors) may form part of this system. The dose monitor unit rate shall be displayed at the control panel.

§ 228.75. Calibrations.

(a) The calibration of systems subject to this subchapter shall be performed in accordance with an established calibration protocol. The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent. The calibration shall be performed as follows:

(1) Before the system is first used for irradiation of a patient and, at time intervals which do not exceed 1 year.

(2) After a change which alters the calibration, spatial distribution or other characteristics of the therapy beam.

(b) The calibration shall be performed by, or under the direct supervision of, a qualified expert.

(c) Calibration radiation measurements required by subsection (a) shall be performed using a dosimetry system meeting the following specifications:

(1) The system has an exposure calibration factor appropriate to the beam energy measured and traceable to a National standard.

(2) The system has been calibrated within the previous 2 years and after servicing that may have affected its calibration.

(3) The system has been calibrated so that an uncertainty can be stated for the radiation quantities monitored by the system.

(4) The system has had constancy checks performed on the system as specified by a qualified expert.

(d) Calibrations made under this section shall be made so that the dose at a reference point in soft tissue may be calculated as accurately as possible but with an uncertainty of no greater than 5%.

(e) The calibration of the therapy beam shall include, but is not limited to, the following determinations:

(1) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and beam limiting device (collimator) system.

(2) The absorbed dose rate at various depths (depth dose) and beam profile measured in water and the beam flatness and symmetry for the range of field sizes used, for each beam energy.

(3) The uniformity of the radiation field and a dependency upon the direction of the useful beam.

(4) Verification of depth-dose data and isodose curves applicable to the specific machine.

(5) Verification of the applicability of transmission factors of accessories such as wedges, shadow trays, compensators and their effects on electron buildup.

(6) The dose per monitor unit, end effect, linearity and dose rate dependence of the dose monitor systems.

(7) For photon beams, the congruence of the light field and the radiation field.

(8) For electron beams, the validity of commissioning data for virtual source distances or effective source-to-skin distances is to be verified at a single electron energy with a beam restriction device. When the replacement of a beam restriction device occurs, the determination will be required for each electron energy.

(f) Records of calibration measurements under subsection (a) and dosimetry system calibrations under subsection (c) shall be preserved for 5 years.

(g) A copy of the latest calibration performed under subsection (a) shall be available at the facility.

§ 228.76. Spot checks.

Spot checks shall be performed on systems subject to this subchapter during full calibrations and thereafter once in each calendar month. The spot checks shall meet the following requirements:

(1) The procedures shall be in writing and shall have been developed by a qualified expert.

(2) If a qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a qualified expert within 15 days of the completion of the spot check.

(3) The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure.

(4) The spot-check procedures shall specify the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the full calibration.

(5) If a spot check indicates a change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as required in § 228.75 (relating to calibrations).

(6) Records of spot-check measurements performed under this section shall be maintained by the licensee for 5 years after completion of the spot-check measurements and necessary corrective actions.

(7) Spot check measurements shall be performed using a dosimetry system that has been calibrated in accordance with § 228.75(c). Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with § 228.75(c). This alternative calibration method shall have been performed within the previous year and after a servicing that may have affected the system calibration.

APPENDIX A

DETERMINATION OF COMPETENCE

The following are areas in which an individual shall have expertise for the competent operation of radiation therapy equipment, the administration of radiation therapy treatment and determination of treatment portals:

(1) *Familiarization with equipment.*

(i) Identification of controls.

(ii) Function of each control.

(2) *Radiation protection.*

(i) Personnel protection.

(ii) Use of shielding blocks.

(iii) Understanding of dose units.

(iv) Grids.

(3) *Film processing.*

(i) Ability to produce quality films for use by a physician.

(ii) Knowledge of portal film exposure factors.

(iii) Film processing parameters.

(4) *Procedures.*

(i) Knowledge of anatomy and physiology.

(ii) Knowledge of patient immobilization devices to allow treatment with minimal patient movement.

(iii) Ability to position patient to allow for treatment of desired area.

(5) *Emergency procedures.*

(i) Termination of treatment in event of machine primary and secondary and dose monitoring system failure.

(ii) Termination of treatment in the event of patient movement during treatment.

(6) *Continuing education.* Continuing education annually to include radiation protection.

[Pa.B. Doc. No. 98-1597. Filed for public inspection October 2, 1998, 9:00 a.m.]

Title 40—LIQUOR

LIQUOR CONTROL BOARD

[40 PA. CODE CH. 13]

Promotion

The Liquor Control Board (Board) under the authority of section 207(i) of the Liquor Code (47 P. S. § 2-207(i)), adopts amendments to §§ 13.1 and 13.51 (relating to definitions; and general prohibition).

The Board's regulations amended by this order will define "routine business entertainment" and set limits on the extent to which in-State or out-of-State manufacturers, licensees or trade organizations may give or receive entertainment in the course of conducting business. It permits the giving of specific items, if the items are given without a corresponding obligation on the part of the recipient to purchase alcoholic beverages or to provide any other benefit to the donor. It further prohibits the improper influencing of the recipient to exclude or restrict from sale, the products of any other licensee or manufacturer.

Upon reviewing comments and suggestions initiated by the malt beverage industry after the public comment period, the Board determined that a modification of the language in Annex A of the proposed rulemaking would be appropriate. Therefore, the $200 per person, per event limitation as well as the six occasions per person limit was replaced with a combined limit of $800 per licensee, per calendar year. This limitation will be applicable to and will include the licensee, the licensee's employes, spouse and guests.

Comments:

Notice of proposed rulemaking was published at 28 Pa.B. 488 (January 31, 1998), with a 30-day written public comment period. Written comments were received from the Independent Regulatory Review Commission (IRRC) and from the Executive Secretary of the Malt Beverage Distributors Association of Pennsylvania (MBDA).

The MBDA expressed concern that the restrictions and limitations imposed on routine business entertainment would affect § 13.51(b). Subsection (b) permits manufacturers of alcoholic beverages and their representatives to participate in the activities of conventions of State or National organizations of retail liquor licensees or distributor or importing distributor malt beverage licensees.

The response of the Board was that routine business entertainment would not amend or alter in any manner the existing subsection (b).

IRRC questioned the reasonableness of and need for § 13.51(c)(6) which requires that the donor of routine business entertainment accompany the recipient on each occasion that entertainment is provided. It is the Board's position that by deleting this requirement as IRRC suggested, the conduct of business would not necessarily be an element of routine business entertainment. Therefore, the Board respectfully declined IRRC's recommendation.

The Board received no other comments either in support of or in opposition to the proposed amendments during the public comment period.

Fiscal Impact:

These final-form regulations will not impose additional costs on the regulated community, the State or local governments.

Regulatory Review:

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on January 16, 1998, the Board submitted a copy of the notice of proposed rulemaking to IRRC and the Chairpersons of the House Committee on Liquor Control and the Senate Committee on Law and Justice for review and comment. These final-form regulations were submitted to the Chairpersons of the Senate Committee on Law and Justice and the House Committee on Liquor Control and IRRC on August 7, 1998.

These final-form regulations were deemed approved by the House Committee on Liquor Control and the Senate Committee on Law and Justice on August 28, 1998, and were approved by IRRC on September 10, 1998, in accordance with section 5.1(c) of the Regulatory Review Act.

Contact Person:

Persons requiring an explanation of the final-form regulations, or information related thereto should contact Jerry Danyluk, Liquor Control Board, Room 401, Northwest Office Building, Harrisburg, PA 17124-0001.

Findings:

The Board finds that:

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

(2) The adoption of the final-form regulations set forth in this order is necessary and appropriate for the administration and enforcement of the authorizing statute.

Order:

The Board, acting under the enabling statute, orders that:

(a) The regulations of the Board, 40 Pa. Code Chapter 13, are amended by amending §§ 13.1 and 13.51 to read as set forth in Annex A.

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

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

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

JOHN E. JONES III,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4845 (September 26, 1998).)

Fiscal Note: Fiscal Note 54-53 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 40. LIQUOR

PART I. LIQUOR CONTROL BOARD

CHAPTER 13. PROMOTION

Subchapter A. ADVERTISING

GENERAL PROVISIONS

§ 13.1. Definitions.

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

Advertisement—Any promotion through the medium of newspapers, magazines or similar publications, except that the term does not include the following:

(i) Any label affixed to a container of distilled spirits or wine, or any covering, carton or wrapper of the container.

(ii) Any editorial or other reading matter in any periodical, publication or newspaper for the preparation or publication of which no money or other valuable consideration is paid or promised, directly or indirectly, by any person subject to this subchapter.

Person—An individual, partnership, joint-stock company, business trust, association, corporation or other form of business enterprise, including a receiver, trustee or liquidating agent.

Routine business entertainment—Meals, beverages, tickets or passes to concerts, theaters, arts, sporting or charitable events provided to licensees, trade organizations or in-State manufacturers by licensees, trade organizations, in-State manufacturers or out-of-State manufacturers. For purposes of this definition, the term "licensee" includes all entities licensed under the Liquor Code including liquor importer licensees and vendor permittees.

Wine—Any fermented alcoholic beverage produced from grapes, fruit or other agricultural products, which contains 7.0% or more alcohol by volume, and includes, but is not limited to, still wines, sparkling wines, carbonated wines, imitation wines, vermouth, cider, perry, sake or any product offered for sale as wine.

GIVING AND ACCEPTING THINGS OF VALUE

§ 13.51. General prohibition.

(a) Except as provided in subsections (b), (c) and § 13.52 (relating to advertising novelties), no in-State or out-of-State manufacturer, licensee or group of licensees, their servants, agents or employes, may directly or indirectly, in person, individually or through a trade organization, contribute to or accept from another licensee or group of licensees of a different class, their servants, agents or employes or a trade organization of licensees of a different class, anything of value by means of advertisements, contributions, purchase, sale of tickets, donations or by any device, for any purpose.

(b) Manufacturers of alcoholic beverages and their servants, agents, employes or representatives are not prohibited from participating in the activities of conventions of State or National organizations of retail liquor licensees, or distributor or importing distributor malt beverage licensees. The participation shall be limited to the payment of registration fees entitling registrant to admission to the convention, to the insertion of advertising in the convention program of the State or National convention and to the furnishing of food, beverages and entertainment to persons who are bona fide registrants at the conventions.

(c) This section does not prohibit an in-State or out-of-State manufacturer, licensee or trade organization from providing another in-State or out-of-State manufacturer, licensee or trade organization routine business entertainment as defined in § 13.1 (relating to definitions). The routine business entertainment shall be subject to the following conditions:

(1) Routine business entertainment shall be provided without a corresponding obligation on the part of the recipient to purchase alcoholic beverages or to provide any other benefit to the donor or to exclude or restrict from sale the products of any other licensee or in-State or out-of-State manufacturer.

(2) The donor, its servants, agents or employes shall accompany the recipient during routine business entertainment. When items such as tickets are donated by manufacturers to importing distributors for the ultimate use of retailers, the donor is considered to be the importing distributor and it is the importing distributor, or its servants, agents or employes, who shall accompany the retailer.

(3) Routine business entertainment that requires or includes an overnight stay is prohibited.

(4) No more than $800 may be spent in a calendar year on any recipient licensee.

(5) Included under the $800 yearly entertainment cap for a recipient licensee are the licensee, his spouse, employes and guests.

(6) Licensees, in-State manufacturers and out-of-State manufacturers shall keep complete and accurate records of all expenses incurred and all routine business entertainment received for 2 years. These records shall contain the name of the recipient and donor of the entertainment, the type of routine business entertainment, the date and, in the case of a donor, the amount of expenditure for each occasion.

[Pa.B. Doc. No. 98-1598. Filed for public inspection October 2, 1998, 9:00 a.m.]