PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

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

Radiological Health

The Environmental Quality Board (Board) proposes to amend Chapters 216, 218, 221, 223, 227 and 228. The proposed amendments update the standards for the safe use of radiation-producing machines.

This proposal was adopted by the Board at its meeting of August 19, 1997.

A. *Effective Date*

These proposed 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, RCSOB, 9th Floor, 400 Market Street, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060.

C. *Statutory Authority*

These amendments are proposed 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 of Environmental Protection (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 Purpose*

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 regulations in these chapters were written in 1982-1983, prior to their effective date of December 19, 1987. In the meantime, certain advances have occurred, principally in the medical profession, which existing regulations do not address. These are new modalities for diagnosis and treatment now which did not exist when the existing regulations were being written 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 proposed amendments 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. Included in the SSR are amendments to Food and Drug Administration regulations.

The purpose of these proposed 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. Department 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 not only to the machines and equipment used in generating ionizing radiation, but also in the safety of the personnel working with this equipment and in 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 (Committee) with an opportunity to review the proposed amendments and to advise the Department prior to submittal to the Board. The proposal was provided to the Committee for review on October 24, 1996, December 12, 1996, and March 20, 1997. The Committee provided oral and written comments at each meeting.

In response to the Committee members' comments, the Department revised the proposed amendments during the meetings.

E. *Summary of Regulatory Requirements*

The proposed amendments revise current radiation protection regulations to reflect the current technological advancements in radiation equipment design. A description of the proposed amendments is provided as follows:

Chapter 216. Registration of Radiation-Producing Machines.

Section 216.2(c)—(e) is proposed to be added to address the certificates of registration which are sent to registrants after they have properly completed their registration form and remitted the correct registration fee to the Department.

Section 216.4 is proposed to be renamed from "Re-registration" to "Renewal of certificate of registration." Subsection (a) is proposed to be revised to allow the Department to combine the renewal and fee processes into one form. The Department and registrant would realize a cost and resource savings by eliminating one mailing.

A new § 216.4a is proposed to be added to clarify the requirements for terminating the use of X-ray equipment. A registrant will be required to: (1) terminate use of

radiation-producing machines; (2) properly transfer or dispose of radiation-producing machines; (3) submit a record of disposal of each radiation-producing machine to the Department; (4) remit any outstanding registration fees owed to the Department; and (5) request termination of the certificate of registration in writing to the Department.

Chapter 218. Fees.

Section 218.1(b)(1) is proposed to be rewritten for clarification to state that the fee chapter applies to a person who is required to register a radiation-producing machine.

Section 218.11(b) is proposed to be revised to allow the Department to combine the registration renewal and the annual invoice into one form. The current system of separate forms for renewal of registration and an invoice is too cumbersome, expensive and time consuming for both the registrant and the Department.

Section 218.11(d) contains a proposed change of the payment time from 15 to 30 days to make it consistent with Chapter 216.

Chapter 221. X-Rays in the Healing Arts.

In general, the diagnostic X-ray sections of Chapter 221 are proposed to be rearranged and updated as necessary. The updated portions are based on the SSR. A new heading for CT machines is an expansion of the current § 221.62 (relating to computerized tomography).

In § 221.2 (relating to definitions), some definitions are proposed to be added and some deleted to maintain similarity with the SSR's. The added definitions are: "AAPM," "ACR," "dental panoramic system," "filtration," "fluoroscopic system," "intensifying screen," "intraoral dental radiography," "kV," "kVp," "licensed practitioner of the healing arts," "mA," "mAs," "mR," "mobile X-ray system," "patient," "peak tube potential," "portable radiation system," "positive beam limitation," "protective barrier," "qualified expert," "registrant," "SID," "serial radiography" and "timer."

Definitions that are proposed to be deleted are: "assembler," "attenuation block," "beam monitoring system," "cooling curve," "filter," "gonad shield," "irradiation," "kilowatt second (kWs)" and "source receptor distance (SID)."

Section 221.11 (relating to registrant responsibilities) is proposed to be amended as follows: subsection (a)(2) is proposed to be added to allow the Department to require registrants to comply with the Department of State's professional licensing requirements; subsection (a)(3) is proposed to be added to allow the Department to require registrants to comply with the Department of Health's requirements for auxiliary personnel using X-ray equipment; subsection (c) is proposed to be amended to include the information needed on the X-ray technique chart; subsection (k) is proposed to be added to require the use of compatible film and intensifying screen combinations; and, subsection (l) is proposed to be added to require a registrant to have a quality assurance program.

Section 221.15 (relating to use of X-rays in research on humans) contains new proposed regulations on the use of X-rays in research on humans. Registrants are exempted from the requirements of this section if the research is conducted, funded, supported or regulated by a Federal agency which has implemented the Federal policy for the protection of human subjects.

Section 221.21 (relating to diagnostic equipment requirements) is proposed to be updated to include the reference to 21 CFR 1020.33 (relating to computed tomography equipment).

Section 221.21, 221.28—221.30 and 221.32a—221.44a are derived from the current §§ 2221.22—221.56.

Sections 221.29 and 221.30 (relating to kilovoltage accuracy; and exposure reproducibility) are proposed to be added.

Sections 221.31—221.49 and 221.51—221.56, 221.61, 221.62, 221.71—221.76 and 221.81—221.102 are proposed to be deleted.

Proposed § 221.38a (relating to entrance exposure rate) is added to update the entrance exposure rates for fluoroscopes with and without a high level control. The new section is derived from current § 221.33 (relating to entrance exposure rate limits) has no limit when the high level control is activated. The proposed amendment will limit the output to 20 R per minute when the high level control is activated and also limit all image intensified fluoroscopes to 10 R per minute.

The current version of § 221.62 (relating to computerized tomography) is proposed to be replaced by a new heading, "Computed Tomography X-ray Systems" found in §§ 221.201—221.205. The current regulation pertaining to computerized tomography addresses only the location of the control panel, auxiliary support for the patient and visual indication of X-ray production at the control panel. The proposed amendments were developed to improve the quality of computed tomography (CT) imaging while minimizing the radiation dose to the patient. The proposed regulations are based on the SSR, 21 CFR 1020.33 (relating to computed tomography (CT) equipment) and the Department's CT study.

Proposed § 221.201 (relating to definitions) is a new section of definitions specifically for the CT regulation. The new definitions are: "CT—computed tomography," "CTDI—computed tomography dose index," "CS—contrast scale," "CT conditions of operation," "CT number," "elemental area," "gantry," "lux," "MSAD—multiple scan average dose," "multiple tomogram system," "noise," "nominal tomographic section thickness," "performance phantom," "picture element," "pixel," "reference plane," "scan," "scan increment," "scan sequence," "scan time," "sensitivity profile," "single tomogram system," "technique factors," "tomogram," "tomographic plane" and "tomographic section."

The entire heading containing requirements for therapeutic X-ray and electron beam systems with energies of 1 MeV and above was deleted because it was superseded by the new requirements in Chapter 228 (relating to radiation safety requirements for particle accelerators).

Proposed § 221.202 (relating to equipment requirements) includes subsections concerning termination of exposure, tomographic plane indication and alignment, status indicators and control switches, indication of CT conditions of operation, extraneous radiation, beam quality and additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

Proposed § 221.203 (relating to design requirements) contains requirements for oral communication between the patient and operator and viewing systems.

Proposed § 221.204 (relating to radiation measurements and performance evaluations) contains the requirements for radiation measurements and performance evaluations.

Proposed § 221.205 (relating to operating procedures) contains two subsections. Subsection (a) requires that certain information be available at the control panel such as instructions on using CT phantoms. Subsection (b) limits the use of the CT if measurements or performance evaluations exceed tolerances established by the facility's qualified expert.

Chapter 223. Veterinary Medicine.

Proposed § 223.7 (relating to structural shielding) is the current § 223.12 with the cross reference to § 219.21 (relating to radiation protection programs) corrected to § 219.51 (relating to radiation dose limits for individual members of the public).

Proposed § 223.8 (relating to operating procedures) has been renumbered from § 223.13 and clarifies the wording of the current § 223.13 but does not change the intent. Subsection (d) requires that all exposures be ordered by a veterinarian.

The heading of § 223.11 is proposed to be amended to read "Radiographic equipment."

Section 223.11(a)(2) is proposed to be added so that the veterinarians will not have to refer to Chapter 221 (relating to X-rays in the healing arts).

Section 223.11(b)(2) and (3) were poorly written and were vague about what was required. These proposed amendments clarify the requirement for proper collimation.

The proposed amendments to § 223.11(d)(1) and (2) expand on timer requirements and require X-ray timers to be accurate.

The proposed amendment to § 223.11(e) adds a new requirement taken in part from the SSR. It requires that the X-ray output from an X-ray unit be consistent. This will prevent repeat exposures due to X-ray equipment with an inconsistent output.

The proposed amendment to § 223.11(f) states a tube stand is now only required when it would not interfere with the procedure. This would allow the veterinarian to hold the tube head when this would be more efficient and when the X-ray unit would be in danger of destruction from the moving and kicking by large animals.

Proposed § 223.11(g) is from the SSR and is also found in the regulations of other states. This requirement is met by newer X-ray equipment.

The proposed § 223.12a is a modification of the current § 223.11(g) fluoroscopic equipment requirements. This modification is a relaxation of the current regulations since it exempts veterinary fluoroscopes from the entrance exposure rate requirements and addresses only the health and safety of the operators.

A new proposed § 223.13a (relating to therapeutic systems) is a modification of the current § 223.11(g) (equipment used for therapeutic purposes). This is a relaxation of the current regulations, since it exempts the therapeutic systems from calibration and spot check requirements.

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

Chapter 227 is proposed to be rearranged for clarity and some of the wording was also modified. Current §§ 227.11 and 227.12 were combined into the proposed §§ 227.11a and 221.12a (relating to equipment requirements; and area requirements). Current § 227.13 became the proposed § 227.13a (relating to operating requirements).

Proposed § 227.11a(h) has been added to provide regulation for vacuum spectroscopy. Vacuum spectrographs will be exempted from §§ 227.12a and 227.13a, but shall meet the requirements of § 227.14 (relating to personnel procedures).

Proposed § 227.13a(c) and (d) are additions to the current regulations to provide compatibility with the SSR.

Chapter 228. Radiation Safety Requirements for Particle Accelerators.

Definitions are proposed to be added to § 228.2 (relating to definitions) as a result of the expansion of the regulations concerning accelerators in the healing arts. The additional definitions are: "applicator," "beam-limiting device," "beam scattering filter," "central axis of the beam," "dose monitoring system," "dose monitor unit," "existing equipment," "field flattening filter," "field size," "filter," "isocenter," "leakage radiation," "moving beam therapy," "new equipment," "normal treatment distance," "phantom," "primary dose monitoring system," "qualified expert," "radiation detector," "radiation head," "secondary dose monitoring system," "shadow tray," "spot check," "stationary beam therapy," "subsystem," "target," "tube housing assembly," "useful beam" and "wedge filter."

A proposed new heading titled, "administrative controls," was adapted from §§ 221.11 and 221.12 and placed in this chapter.

A proposed new heading titled, "notification and licensing procedures," was added to allow the Department to license particle accelerators. Sections 228.21a, 228.22a, 228.23a, 228.24a, 228.25a and 228.26a were adapted from §§ 217.51—217.57 (relating to specific licenses-general conditions) which relate to the licensing of radioactive material.

The current heading, "General Radiation Safety Requirements," is proposed to be renumbered from §§ 228.21—228.26 to §§ 228.31a, 228.32a, 228.33a and 228.34a—228.39. A new § 228.36(c) is proposed to be added to inform the licensee or registrant what is required for and exempted from the calibration of an independent radiation monitor. Proposed § 228.39 (relating to records) is added to clarify the recordkeeping requirements.

The heading, "Radiation Safety Requirements for Industrial and Research Accelerators" is proposed to be renumbered from §§ 228.31—228.34 to §§ 228.41a, 228.42, 228.43 and 228.44. Proposed § 228.45 (relating to portable or mobile accelerators) is added to cover portable and mobile particle accelerators.

The proposed heading, "Radiation Safety Requirements for Accelerators Used in the Healing Arts," is expanded by adapting the appropriate sections from Chapter 221, titled, Therapeutic X-ray and Electron Beam Systems With Energies of 1 Mev And Above." These proposed sections are numbered §§ 228.61—228.76. Section 221.41 is proposed to be deleted.

F. *Benefits, Costs and Compliance*

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

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 Committee.

Paperwork Requirements

The proposed amendments will not significantly change paperwork requirements.

G. *Sunset Review*

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

H. *Regulatory Review Act*

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

If IRRC has objections to any portion of the proposed amendments, it will notify the Department within 10 days of the close of the Committees' comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, by the Department, the Governor and the General Assembly before final publication of the regulations.

I. *Public Comments*

Written comments—Interested persons are invited to submit comments, suggestions or objections regarding the proposed amendments to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 15th Floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions or objections must be received by the Board by December 30, 1997. Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must be received by December 30, 1997. The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final-form regulations will be considered.

Electronic comments—Comments may be submitted electronically to the Board at RegComments@A1.dep.state.pa.us and must also be received by the Board by December 30, 1997. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgment of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt.

JAMES M. SEIF,
Chairperson

Fiscal Note: 7-329. No fiscal impact; (8) recommends adoption.

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.

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(c) A certificate of registration will be issued 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 the written approval of the Department.

§ 216.4. **[Re-registration] Renewal of certificate of registration**

(a) The Department will send **[a] an application for** renewal **[form] of the certificate of registration** to the registrant **at least 2 months** prior to the expiration date **[of the existing registration] on the certificate of registration. The application for renewal will include references to the fee due under § 218.11 (relating to annual registration and license fees). [The registrant shall return the completed renewal form within 30 days after receipt of the renewal form.]**

(b) **[The renewal becomes valid upon receipt of the properly completed form and the fee required under Chapter 218 (relating to fees)] 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 request 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) Properly transfer or dispose of all radiation-producing machines.

(3) Submit a record of disposal of each radiation-producing machine to the Department.

(4) Remit any outstanding registration fees owed to the Department.

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

CHAPTER 218. FEES

GENERAL

§ 218.1. Purpose and scope.

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

(1) **[Has filed a registration] Is required to register or renew registration** for radiation-producing machines **[required]** under Chapter 216 (relating to registration of radiation-producing machines).

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PAYMENT OF FEES

§ 218.11. Annual registration and license fees.

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(b) **[Upon receipt of a] A registrant filing an initial** registration **under § 216.2 (relating to registration)** or **[re-registration form, the Department will issue] an application for renewal of a certificate of registration under § 216.4 (relating to renewal of certificate of registration)** shall **remit the appropriate** fee **[invoice]** calculated **by** using the **[registered]** information **on the registration or application form** and the fee schedule in subsection (a). Fees **for any initial registration under § 216.2** are payable **[within 15 days after receipt of a fee invoice] 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 **[a] an initial** registration or **[re-registration form] 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.

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(d) An initial application for a license shall be accompanied by a check payable to the Department **[of Environmental Resources]** in accordance with the fee schedule in subsection (c). Thereafter, the Department will issue an annual fee invoice based on the fee schedule in subsection (c). Fees are payable within **[15] 30** days after receipt of a fee invoice.

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CHAPTER 221. X-RAYS IN THE HEALING ARTS

GENERAL

§ 221.2. Definitions.

[As used in this chapter, the] 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.**

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[*Assembler*—A person who assembles, replaces or installs one or more components into an x-ray system or subsystem.

***Attenuation block*—A block or stack of type 1100 aluminum alloy—the nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, .12% copper—or other materials having equivalent attenuation, having a thickness of 3.8 centimeters and a width and a length not less than 15 centimeters.]**

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[*Beam monitoring system*—A system designed to detect and measure the radiation present in the useful beam.]

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[*Cooling curve*—The graphical relationship between heat units stored and cooling time.]

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***Dental panoramic system*—A device intended to produce a radiographic image of the entire dental arch on one film.**

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[*Filter*] *Filtration*—* * *

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***Fluoroscopic system*—(See fluoroscopic imaging assembly).**

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[*General purpose radiographic x-ray system*—A radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

***Gonad shield*] *Gonads*—[A protective barrier for] The** testes or ovaries.

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***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.**

[*Irradiation*—The exposure of matter to ionizing radiation.]

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***kV*—Kilovolts**

***kVp*—Peak tube potential (See Kilovolts peak).**

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[*Kilowatt second (kWs)*—The term is equivalent to 10^3. kV. mA s, or

$$(A)kWs = (X)kV \times (Y)mA \times (Z)s \times \frac{kWs}{10^3 kV \times mA \times s} = \frac{XYZ\ kWs}{10^3}$$

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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.**

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***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)**

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***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.**

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

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

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

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***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, the American Board of Health Physics or the American Board of Medical Physics, or those having equivalent qualifications. With reference to the calibration or radiation therapy equipment, an individual having, in addition to these 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, 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.**

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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-image receptor distance (SID)*—The distance from the source to the center of the input surface of the image receptor.]

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Technique factors—**[The conditions of operation specified as follows] The following conditions of operation:**

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

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Therapeutic **[*x-ray or electron*] *X-ray*** *system*—* * *

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

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

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(iii) *Stationary* **[*x-ray*] *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) **[No person may operate or permit the operation of radiation-producing machines unless the machines and installation meet the applicable requirements of this article.] 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 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.

(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 **[the x-ray] an X-ray [systems] system** shall be **[adequately]** 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 **[the] each** diagnostic **[x-ray] 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.

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(e) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel 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 **[shielding] material. The lead equivalent material is to be determined at 60 kV.**

(2) **[Staff and ancillary personnel] 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.

(3) **[Other patients not being radiographed] 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 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 **[not less than .25] 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 **[unless there are also healing arts requirements and proper prescription has been provided]**.

(2) Exposure of an individual for the purpose of healing arts screening except as **[approved] authorized** by the Department. When requesting **[approved] 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). **[If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.]**

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

* * * * *

(3) **[No] 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.

* * * * *

(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 veterinary radiography and standard intraoral 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.

§ 221.12. **[Information and maintenance record] Records, maintenance** and associated information.

* * * * *

§ 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 the following information and evaluation. **If information submitted**

to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

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

* * * * *

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

* * * * *

(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 this section if the research is conducted, funded, supported or regulated by a Federal agency which has implemented the Federal policy for the protection of human subjects.

(b) A research protocol regarding the use of X-rays in research on humans shall be authorized by a committee consisting of at least three persons. One of the committee members shall be knowledgeable in radiation effects on humans.

(c) All 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.

(d) A person requesting that the Department approve a program using X-rays for research on humans shall submit, in writing, the following information and evaluation to the Department. If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify, in writing, 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 the committee established under subsection (b).

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.21. Diagnostic equipment requirements.

[Diagnostic x-ray equipment and its use shall satisfy the applicable requirements of Subchapter A.] Diagnostic systems incorporating one or more certified components shall comply with 21 CFR 1020.30**[, 1020.31 and 1020.32 (relating to diagnostic x-ray systems and their major components; radiographic equipment; and fluoroscopic equipment)]—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 **[preset factors may] 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.

(*Editor's Note:* As part of this proposal, the Board is proposing to delete the existing text of §§ 221.31—221.49, 221.51—221.56, 221.61, 221.62, 221.71—221.76 and 221.81—221.102, which appears at 25 Pa. Code pages 221-30—221-58, serial pages (123698)—(123726).)

§§ 221.31—221.49. (Reserved.)

§§ 221.51—221.56. (Reserved.)

§ 221.61. (Reserved.)

§ 221.62. (Reserved.)

§§ 221.71—221.76. (Reserved.)

§§ 221.81—221.102. (Reserved.)

§ 221.31a. Locks.

All 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) 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) Radiographic systems designed for use with an intraoral image receptor shall be provided with a means to limit the X-ray beam so that if the minimum SSD is:

(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 size 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 μC/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.* Radiation exposure shall be possible only through intentional switch actuation by the operator. The radiation exposure control switch and associated circuitry shall preclude unintended actuation not initiated by the operator.

(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 cases 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 (relating to 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 2 orthogonal dimensions, may not exceed 4% of the source to image receptor distance.

(j) 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. Source-skin distance.

The source to skin distance may not be less than 30 centimeters.

§ 221.42a. 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.

§ 221.43a. 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 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 not less than .25 millimeter lead equivalent material—for example, drapes, Bucky-slot cover, 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).

§ 221.44a. Mobile fluoroscopes.

In addition to the other requirements of §§ 221.35a—221.43a, mobile fluoroscopes shall provide image intensification.

(*Editor's Note:* Sections 221.201—221.205 are new. They have been printed in regular type to enhance readability.)

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 (relating to computed tomography 2-ray systems), 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—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.

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

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 total filtration (inherent plus added) shall be at least 3.5 millimeters aluminum equivalent. This requirement will be considered to have been met if it can be demonstrated that the half value layer of the primary beam is not less than 4.60 millimeters of aluminum equivalent 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 3 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. 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.

(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 in the indicated 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.

§ 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 MSAD along the two axes specified in subsection (b)(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 as the point of maximum surface exposure identified. The CT conditions of operation shall be reproducible and correspond to typical values used by the registrant.

(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 during an interval not exceeding 12 months or after any major 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.

(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) *Peformance 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 15 days 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 5 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, 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.*

(1) Identification of controls.

(2) Function of each control.

(3) 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.

(Editor's Note: Sections 223.7 and 223.8 are new. They have been printed in regular type to enhance readability.)

CHAPTER 223. VETERINARY MEDICINE

GENERAL PROVISIONS

§ 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 5 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) All individuals whose presence is necessary to conduct X-ray procedures and who are not located behind protective barriers or at least 5 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 0.5 millimeters of lead.

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

[X-RAYS] X-RAY EQUIPMENT

§ 223.11. **[Equipment] Radiographic** equipment.

(a) ***Leakage radiation.***

(1) The leakage radiation from the **[diagnostic source assembly] 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] X-ray** tube is operated at its **[leakage] 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) **[Collimators capable of restricting the useful beam to the area of clinical interest shall be provided and shall provide the same degree of protection as is required in subsection (a).]** ***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. * * ****

(d) **[A device shall be provided to terminate the exposure after a preset time or exposure.]** ***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) **[An x-ray control shall have a dead-man type exposure switch and shall be located behind a protective barrier or arranged so that the operator may stand at least 2 meters from the animal and from the tube head.] 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) **[Portable] Veterinary portable [x-ray] tube heads] 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) **[Fluoroscopic equipment shall satisfy the requirements of §§ 221.31—221.40 (relating to fluoroscopic x-ray systems).] 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.**

[(h) Equipment used for therapeutic purposes shall satisfy the requirements of §§ 221.71—221.76 and 221.81—221.102 (relating to therapeutic x-ray systems with energies less than 1 meV; and therapeutic x-ray and electron beam systems with energies of 1 meV and above).]

§ 223.12. **[Structural shielding] (Reserved).**

[Facilities regularly used for veterinary x-ray procedures shall have protective barriers sufficient to assure compliance with § 219.21 (relating to radiation protection programs).]

§ 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 not less than 0.25 millimeter of lead equivalent material—for example, drapes, bucky-slot cover, sliding or folding panel or self-supporting curtains—in addition to the lead equivalency provided by the protective apron referred to in § 223.8(b)(1) (relating to operating procedures).

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

§ 223.13. [Operating procedures] (Reserved).

[(a) The operator shall stand well away from the useful beam and the animal during radiographic exposures.

(b) Individuals, other than those whose presence is necessary to conduct the x-ray procedures, shall be outside the x-ray room or, for field procedures, shall stand at least 5 meters away from the x-ray tube and from the animal.

(c) In an application in which the operator and other assisting individual are not located behind a protective barrier, a protective apron having a lead equivalent of at least .5 millimeter shall be worn by individuals during exposures.

(d) Whenever possible, restraining, supporting or positioning devices for the animal or film shall be used for radiation exposures.

(e) No individual may be regularly employed to hold or support animals or hold film or the x-ray tube head during radiation exposures. Occupationally exposed individuals may not perform this service except in cases in which no other method is available. An individual holding or supporting an animal or film during radiation exposure shall wear protective gloves and apron having a lead equivalent of not less than .5 millimeter and shall be positioned so that no part of that individual's body will be struck by the useful beam. The exposure of an occupationally exposed individual used for this purpose shall be monitored.]

§ 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 (0.16 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) All 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. [Warnings] (Reserved).

[(a) An analytical X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and one of the following groups of words:

(1) "Caution—High Intensity X-Ray Beam," or words containing a similar warning, on the X-ray source housing and "Caution Radiation—This Equipment Produces Radiation when Energized," or words containing a similar warning, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube.

(2) "Caution—Radioactive Material," or words containing a similar warning, on the source housing if the radiation source is a radionuclide.

(b) 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 one of the following:

(1) Illuminated only when the X-ray tube is energized.

(2) Illuminated only when the shutter is open, in the case of a radioactive source.

(c) Open beam configurations shall have easily identified devices located near one of the following:

(1) The radiation source housing that gives a clear, visible indication of the X-ray tube status (on-off) if the primary beam is controlled in this manner.

(2) Each port on the radiation source housing that gives a clear indication of the shutter status (open-closed) if the primary beam is controlled in this manner.

(d) Warning lights and devices on equipment manufactured and installed after December 19, 1987, shall have fail-safe characteristics.]

§ 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:

(1) The X-ray tube is energized.

(2) In the case of a radioactive source, the shutter is open.

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

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

(1) "Caution—High Intensity X-ray Beam" or words having a similar intent on the X-ray source housing; and "Caution Radiation—This Equipment Produces Radiation When Energized," or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube.

(2) "Caution—Radioactive Material," or words having a similar intent, on the source housing if the radiation source is a radionuclide.

(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 5 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. [Safety devices and requirements] (Reserved).

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

(b) 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.

(c) 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 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.]

§ 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 or licensee shall perform radiation surveys:

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

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

(3) Following any 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 any local component in the system is disassembled or removed.

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

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

(e) The registrant or licensee 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 5 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. [Radiation levels, surveys and tests] (Reserved).

[(a) The source housing construction shall be such 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 (0.645 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 .5 milliroentgen (129 nC/kg) per hour at a distance of 5 cm. from the cabinet surface.

(c) The analytical X-ray system shall have its local components and shielding or access control arranged so that in the area surrounding the local component group, the radiation dose to an individual will not be in excess of the limits given in § 219.51 (relating to dose limits to individual members of the public). For systems utilizing X-ray tubes, these requirements shall be satisfied for the maximum tube rating.

(d) To show compliance with subsections (a)—(c), the registrant or licensee shall perform radiation surveys upon installation of the equipment, and at least once every 12 months thereafter. In addition, to show compliance with subsection (c), the registrant or licensee shall perform radiation surveys:

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

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

(3) 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.

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

(5) When the machine is operated in a manner other than the routine manner specified § 227.15(a) (relating to operating requirements).

(e) The registrant or licensee 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 nonfunctional, the machine shall be removed from service until repairs to the nonfunctioning device are completed.

(f) Records of surveys and tests sufficient to show compliance with this chapter shall be maintained 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.]

§ 227.13a. Operating requirements.

(a) Operating procedures shall be written and available to all 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 exist:

(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.

(d) Radioactive source housings shall be opened for source replacement, leak testing or other maintenance or repair procedures only by individuals authorized to specifically conduct the procedures under a license issued by the NRC, the Department or an agreement state.

§ 227.14. Personnel requirements.

(a) **[The registrant or licensee may not permit an individual to] An individual may not** operate or maintain analytical X-ray equipment unless the individual has received instruction in and demonstrated competence as to:

* * * * *

(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.

* * * * *

(4) Symptoms of acute localized radiation **[injury] exposure.**

* * * * *

§ 227.15. **[Operating requirements] (Reserved).**

[(a) Written operating procedures shall be available to 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. No individual may operate analytical x-ray equipment in a manner other than that specified in the procedures unless the individual has obtained written approval from the radiation safety officer.

(b) No individual may bypass or otherwise circumvent a safety device unless the individual has obtained the written approval of the radiation safety officer. The radiation safety officer shall grant the permission only if the following exist:

(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 no more than 30 days unless 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.]

ELECTRON MICROSCOPES

§ 227.33. Personnel requirements.

[No] A registrant **[shall] may not** permit an individual to operate or conduct maintenance upon any electron microscope until the individual has received a copy of **[and],** 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.

* * * * *

***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 the effective date of adoption of this proposal.

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—For isocentric equipment, the isocenter; 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.

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.

[NOTIFICATION PROCEDURES] ADMINISTRATIVE CONTROLS

§ 228.11. [Notification requirements] (Reserved).

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

(b) In addition to the notification 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.]

§ 228.11a. Registrant 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 registrant or 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 5 years.

[GENERAL RADIATION SAFETY REQUIREMENTS] NOTIFICATION AND LICENSING PROCEDURES

§ 228.21. **[Limitations] (Reserved).**

[(a) No registrant may permit an individual to act as an operator of an accelerator until the individual:

(1) Has been instructed in radiation safety and shall have 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 conditions and the registrant's operating and emergency procedures and shall have demonstrated understanding thereof.

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

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

§ 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. The application shall be filed in duplicate on a form prescribed by the Department. The application shall contain pertinent information to permit the Department to evaluate the requirements specified in this chapter.

(b) In addition to the notification 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), no person may operate a particle accelerator after_____ (*Editor's Note:* Blank refers to effective date of adoption of the proposed rulemaking.**), without having obtained a license from the Department.**

(d) A registrant possessing an accelerator before _____(*Editor's Note:* Blank refers to effective date of adoption of the proposed rulemaking.), **may continue to operate the accelerator provided in application for a license is filed in duplicate with the Department within 90 days of the adoption of the proposed rulemaking.**

(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. **[Shielding and safety design requirements] (Reserved).**

[(a) The registrant shall consult a qualified expert for the design of accelerator installation and shall have the expert perform a radiation survey prior to the first use of the accelerator and when changes are made in shielding operations, equipment or occupancy of adjacent areas. The expert shall report the findings of these surveys in writing to the registrant and a copy of this report shall be available for inspection by the Department. The registrant shall comply with limitations indicated by the survey.

(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).]

§ 228.22a. Issuance of specific licenses.

(a) Upon determination that an application meets the requirements of the act and this article, 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) Minimize danger to public health and safety or property.

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

§ 228.23. **[Particle accelerator controls and interlock systems] (Reserved).**

[(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 control of access to high radiation areas; and posting of high radiation areas).

(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.]

§ 228.23a. 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 at the end of the specified day, in the month and year stated in the license.

(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.

(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 the requirements of 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. [Operating procedures] (Reserved).

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

(b) No interlock may be used to turn off the accelerator beam except in an emergency.

(c) A 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 repairs shall be maintained 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 bypass intentionally a safety interlock system or component thereof, the action shall be:

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

(2) Recorded in a permanent log and a notice posted at the accelerator control console.

(3) Terminated as soon as possible.

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

§ 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 regulations).

(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. **[Radiation monitoring requirements] (Reserved).**

[(a) An accelerator facility shall have appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. The equipment shall be tested for proper operation each day it is used and calibrated at least annually and after each servicing or repair.

(b) In addition to the requirements of §§ 219.91 and 219.154 (relating 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. Area monitors shall be calibrated at least annually and after each servicing or repair.]

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

A licensee shall file an application for an amendment under § 228.21 (relating to notification and license requirements). The application shall specify the requested amendment and the reason for the amendment.

§ 228.26. **[Production of radioactive material] (Reserved).**

[(a) Radioactive material produced incidental to the operation of a particle accelerator shall be subject to § 217.48 (relating to a general license for incidental radioactive material produced by a particle accelerator).

(b) Radioactive material intentionally produced by bombarding nonradioactive material with the accelerator beam shall require a specific license under §§ 217.51—217.57 (relating to specific licenses—general conditions).]

§ 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 **[FOR INDUSTRIAL AND RESEARCH ACCELERATORS]**

§ 228.31. **[Warning devices] (Reserved).**

[(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 when, and only when, radiation is being produced.

(b) A high radiation area shall meet the requirements of § 219.43 (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 or registrant 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 registrant's or 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. **[Circuit diagrams] (Reserved).**

[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.]

§ 228.32a. Shielding and safety design requirements.

(a) The registrant or licensee shall consult a qualified expert for the shielding design of accelerator installation and shall have the expert perform a radiation survey prior to the first use of the accelerator and when changes are made in shielding operations, equipment or occupancy of adjacent areas. The expert shall report the findings of these surveys in writing to the registrant or licensee and a copy of this report shall be kept for 5 years and be available for inspection by the Department. The registrant or licensee shall comply with any limitations indicated by the survey.

(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. **[Radiation surveys] (Reserved).**

[(a) When applicable, periodic surveys shall be made to determine the amount of airborne radioactivity present in areas of airborne hazards.

(b) When applicable, 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.]

§ 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, which will indicate when the useful beam is on in a readily observable position near the outside of access doors.

(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. [Ventilation systems] (Reserved).

[(a) A registrant shall control the concentration of radioactive material in air to meet the requirements of § 219.31 (relating to occupational dose limits for adults).

(b) A registrant 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 to 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.]

§ 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.

(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 5 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 bypass intentionally 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 the 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 requirements of 49 Pa. Code Part I, Subpart A (relating to professional and occupational affairs) 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) An accelerator facility shall have appropriate survey equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. The equipment shall be tested for proper operation each day it is used and calibrated at least annually and after each servicing or repair.

(b) In addition to the requirements of §§ 219.91 and 219.154 (relating 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.

(c) 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 registrant or 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 registrant or 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. Surveys.

(a) A facility shall have a survey made by, or under the direction of, a qualified expert as defined under § 221.2 (relating to definitions). 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 report shall be maintained by the registrant or licensee for 5 years for inspection by the Department. 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 week for each restricted and unrestricted area.

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

(d) Safety and warning devices and safety interlocks shall be checked annually and serviced as necessary.

(e) 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 registrant or 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 or registrant shall maintain records of the tests and safety and warning devices described in § 228.35; the surveys described in §§ 228.32a and 228.37; and the radiation monitoring equipment calibrations and repairs of that equipment under § 228.36 (relating to radiation monitoring requirements).

RADIATION SAFETY REQUIREMENTS FOR [ACCELERATORS USED IN THE HEALING ARTS] INDUSTRIAL AND RESEARCH ACCELERATORS

§ 228.41. [Applicable regulations] (Reserved).

[The requirements of §§ 221.81—221.102 (relating to therapeutic systems with energies of 1 MeV and above) shall apply to medical facilities using accelerators with an energy of 1 MeV and above.]

§ 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 5 years 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 registrant or 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 registrant or 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 registrant or 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 registrant or licensee shall have available the leakage radiation data existing at the positions specified in paragraph (1) for the specified operating conditions, the registrant or 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 strikes 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 registrant or licensee shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in sub-

section (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. For wedge filters, the wedge factor and the wedge angle shall appear on the wedge or wedge tray.

(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. Beam quality.

The registrant or 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 subsection (a) 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 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 registrant or 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 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 backpointer 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 determination of the virtual source distance for each electron energy and beam restriction device.

(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 registrant for a period of 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) Able to produce quality films for use by a phycisian.

(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) Able 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

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