INSTRUCTION SHEET

COMAR 26.12.01.01

Title: Regulations for the Control of Ionizing Radiation (1994)

SUPPLEMENT No. 30

Instructions: Supplement 30 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

Remove Pages	Insert Pages (future)
Cover Sheet	Cover Sheet
vii through viii	vii through viii
xi through xii	xi through xii
C17 through C18	C17 through C18
C45-2 through C46	C45-2 through C46
D15 through D16	D15 through D16
D31 through D32	D31 through D32
F1 through F2	F1 through F2
F9 through F9-1	F9 through F9-1
F9-4 through F10	F9-4 through F10
F22-7 through F22-8	F22-7 through F22-8
F23 through F26	F23 through F26
F31 through F31-1	F31 through F31-1
F35 through F38	F35 through F38
F49 through F50	F49 through F50-2 (add 2 pages)
G25 through G26	G25 through G26
G67 through G68	G67 through G68
H1 through H6	H1 through H14 (add 8 pages)

Verify to make certain that you have the pages listed above.

INQUIRIES TO: Kiera Saleem
Radiological Health Program
Maryland Department of the Environment
1800 Washington Boulevard
Baltimore, MD 21230

Telephone: (410) 537-3193

E-mail: kiera.saleem@maryland.gov

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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

RADIOLOGICAL HEALTH PROGRAM
AIR AND RADIATION ADMINISTRATION
MARYLAND DEPARTMENT OF THE ENVIRONMENT
1800 WASHINGTON BOULEVARD
BALTIMORE, MARYLAND 21230

CONTENTS

Appendix

PART F - X RAYS IN THE HEALING ARTS

General Regulatory Provisions

Diagnostic X-Ray Systems

PART H - RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT AND X-RAY SECURITY SCREENING

General Regulatory Provisions and Specific Requirements

General Regulatory Provisions and Specific Requirements for X-ray Security Screening

PART I - RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

Registration Procedure

Radiation Safety Requirements for the Use of Particle Accelerators

PART J - NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

General Regulatory Provisions and Specific Requirements

PART T - TRANSPORTATION OF RADIOACTIVE MATERIAL

General Regulatory Provisions

Exemptions

General Licenses

Package Approval Standards

Operating Controls and Procedures

(b) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

(iii) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

(iv) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(h) Reserved.

(i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.[7/]

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of C.22(i)(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.

7/ The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(ii) Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.

(iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.

(iv) Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.

(v) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(vi) Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.

(vii) Iron-59, in units not exceeding 20 microcuries (740 kBq) each.

(viii) Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by C.22(i)(1) until he has filed Agency Form MDE-211, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of Agency Form MDE 211 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form MDE 211 the following information and such other information as may be required by that form:

(i) Name and address of the physician, veterinarian, clinical laboratory or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in C.22(i)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by C.22(i)(1) shall comply with the following:

(f) Each person licensed under Part C shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with C31(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for certifying that all the received records are complete and accurate and will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

(1) Records of spills or other occurrences involving the spread of radioactive material in and around the facility, equipment, or site. These records may be limited to instances when radioactive material remains after any cleanup procedures or when there is reasonable likelihood that radioactive material may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(2) As built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of location of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations; and

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated restricted areas as defined in Part A, Section 2;

(ii) All areas outside of restricted areas that require documentation under D.1202;

(iii) All areas outside of restricted areas where current and previous wastes have been buried; and

(iv) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in §§D.1401-1406 or apply for approval for disposal under D.1002.

(4) Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning, and records of funding method used for assuring funds if either a funding plan or certification is used.

(g) Approval of decommissioning funding plans and certifications.

(1) Upon a determination that an application under this section meets the requirements of this section, the Agency shall approve such decommissioning funding plan or certification.

(2) No person shall receive, possess, use, transfer, own or acquire radioactive material of a type described in paragraph (a) or (b) of this section for more than 180 days following the dates prescribed in this section for submittal of a decommissioning funding plan or certification, if that decommissioning funding plan or certification has not been approved by the Agency.

(h) Financial assurance for decommissioning pursuant to termination under restricted conditions as described in Section D.1403 of Part D shall not be considered a potential financial mechanism until such time as the licensee has submitted its intent to decommission in accordance with C.32 and has submitted a License Termination Plan (LTP) in accordance with Section D.1403(d).

(i) In providing financial assurance under this section, each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the Agency, as follows:

(1) If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below 75 percent of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

(2) If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

(3) Within 30 days of taking the actions required by paragraph (i)(1) or (2) of this section, the licensee must provide a written report of such actions to the Program Manager, Radiological Health Program, Air and Radiation Administration, and state the new balance of the fund.

ii. The test for leakage for sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

iii. Test samples shall also be taken from the interior surfaces of the container in which sealed sources of radium are stored. This test shall be capable of detecting the presence of 185 Bq (0.005 μCi) of a radium daughter which has a half-life greater than 4 days.

iv. Notwithstanding the periodic test for leakage required, any sealed source is exempt from such tests for leakage when the sealed source contains 3.7 MBq (100 μCi) or less of beta or gamma emitting material or 370 KBq (10 μCi) or less of alpha emitting material.

b. Tests for leakage or contamination shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

c. The following shall be considered evidence that the sealed source is leaking:

i. The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample. If the test of a sealed source, other than radium, reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use, take action to prevent the spread of contamination, and cause the sealed source to be decontaminated and repaired or to be disposed of in accordance with Part D.

ii. Leakage of 37 Bq (0.001 μCi) of radon-222 per 24 hours for sealed sources manufactured to contain radium. If the test of a sealed source manufactured to contain radium reveals the presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium-226, the licensee or registrant shall immediately withdraw the sealed source from use, take action to prevent the spread of contamination, cause the sealed source to be decontaminated and repaired or to be disposed of in accordance with Part D.

d. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency.

e. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to D.1206.

SURVEYS AND MONITORING

Sec. D.501 General.

a. Each licensee or registrant shall make, or cause to be made, surveys of areas that:

   i. Are necessary for the licensee or registrant to comply with Part D; and

   ii. Are reasonable under the circumstances to evaluate:

      (1) The magnitude and extent of radiation levels; and

      (2) Concentrations or quantities of residual radioactivity; and

      (3) The potential radiological hazards of the radiation levels and residual radioactivity detected.

   iii. Each survey related to radiation machines shall be performed by a qualified expert as defined in F.2.

b. For radioactive materials licensees, surveys as described in D.501a. shall include surface and subsurface areas.

c. Notwithstanding the requirements of D.1103(a), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with Section C.29(f).

d. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated for the radiation measured at intervals not to exceed 12 months.

e. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with D.201, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

   i. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

   ii. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

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

Sec. D.502 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D. As a minimum:

Sec. D.1007 Transfer for Disposal and Manifests.

a. The requirements of D.1007 are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

b. The above requirements shall be conducted in accordance with the requirements in Appendix D and E to this Part.

c. Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2 intended for ultimate disposal at a land disposal facility licensed under NRC regulation 10 CFR Part 61 must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G of 10 CFR Part 20.

Sec. D.1008 Compliance with Environmental and Health Protection Regulations.

Nothing in Part D relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of pursuant to Part D.

Sec. D.1009 Disposal of Certain Byproduct Material.

a. Licensed material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2 may be disposed of in accordance with NRC's 10 CFR Part 61, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under NRC's 10 CFR Part 61, must meet the requirements of Section D.1007.

b. A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in Section A.2, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

RECORDS

Sec. D.1101 General Provisions.

a. Each licensee or registrant shall use the units curie, disintegrations per minute, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part D.

b. In the records required by this Part, the licensee or registrant may record quantities in SI units in parentheses following each of the units specified in D.1101(a).

c. Notwithstanding the requirements of paragraph (a) of this section, when recording information on shipment manifests, as required in Section D.1007, information must be recorded in the International System of Units (SI) or in SI and units as specified in D.1101(a).

d. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part D, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

Sec. D.1102 Records of Radiation Protection Programs.

a. Each licensee or registrant shall maintain records of the radiation protection program, including:

   i. The provisions of the program; and

   ii. Audits and other reviews of program content and implementation.

b. The licensee or registrant shall retain the records required by D.1102a.i. until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by D.1102a.ii. for 3 years after the record is made.

Sec. D.1103 Records of Surveys.

a. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by D.501 and D.906b. The licensee or registrant shall retain these records for 3 years after the record is made.

b. The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

   i. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

   ii. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

   iii. Records showing the results of air sampling, surveys, and bioassays required pursuant to D.703(c)(i) and (ii); and

   iv. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

Sec. D.1104 Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by D.401 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency or until the sealed source is transferred or disposed.

Sec. D.1105 Records of Prior Occupational Dose.

a. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in D.205 on Agency Form MDE 217 or equivalent until the Agency terminates each pertinent license or registration requiring this record or for such time as the Agency shall determine.

b. The licensee or registrant shall retain records used in preparing Agency Form MDE 217 or equivalent for 3 years after the record is made or for such time as the Agency shall determine.

PART F

X RAYS IN THE HEALING ARTS

Sec. F.1 Scope. This part establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

Sec. F.2 Definitions. As used in this part, the following definitions apply:

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Added filtration" means any filtration which is in addition to the inherent filtration.

“Air kerma” means kerma in air (see definition of Kerma).

“Air kerma rate (AKR)” means the air kerma per unit time.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or the owner’s employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having dimensions at least 20 centimeters (cm) by 20 centimeters (cm) by 3.8 centimeters (cm) that is large enough to intercept the entire x-ray beam, of type 1100 aluminum alloy[1] or other materials having equivalent attenuation.

"Authorized provider" means a licensed healing arts practitioner, which is limited to the following professions: physician, podiatrist, chiropractor, dentist, and veterinarian.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also "Phototimer").

“Automatic exposure rate control (AERC)” means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"Barrier" (See "Protective barrier").

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

“C-arm fluoroscope” means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

"Certified system" means any x-ray system which has one or more certified component(s).

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

"Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}}\left[\sum_{i=1}^{n}\frac{(X_i - \bar{X})^2}{n-1}\right]^{1/2}$$

where:

s = Estimated standard deviation of the population.
$\bar{x}$ = Mean value of observations in sample.
X_i = i^{th} observation sampled.
n = Number of observations in sample.

"Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

"Radiological physicist" means an individual who

(1) is certified by the American Board of Radiology or other comparable organization acceptable by the Department in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or

(2) has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology or other comparable organization acceptable by the Department. The work duties shall include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or

(3) has a Master's or a Doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had 1 year's full-time training in therapeutic radiological physics; and has had 1 year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a retrievable form of an image resulting from x-ray photons.

“Registered cardiovascular invasive specialist (RCIS)” means an individual who is credentialed by Cardiovascular Credentialing International or another credentialing body approved by the Maryland Board of Physicians to assist in cardiac catheterization procedures under the direct, in-person supervision of a licensed physician.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

"Secondary protective barrier" (See "Protective barrier")

"Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SID" (see "Source-image receptor distance")

“Solid state x-ray imaging device” means the assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

"Source" means the focal spot of the x-ray tube.

"Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

“Source-skin distance (SSD)” means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

"Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"SSD" (see “Source-skin distance”)

"Stationary x-ray equipment" (See "X-ray equipment")

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;

(3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

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Sec. F.3 General Requirements.

(a) Administrative Controls.

(l) Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the x-ray system(s).

(i) An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes.

(ii) Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.

(iii) A registrant must demonstrate that a dental radiation technologist employed by the registrant is adequately trained and competent to use a radiation machine as required under COMAR 10.44.19.03, and must conspicuously display the technologist's certificate as required under COMAR 10.44.19.11.

(iv) A registrant must demonstrate that a radiation therapist employed by the registrant is adequately trained and competent to use a radiation machine for medical diagnostic or therapeutic purposes as required under COMAR 10.32.10.05-1,and must conspicuously display each radiation therapist's certificate.

(v) A registrant must demonstrate that a Registered Cardiovascular Invasive Specialist (RCIS) employed by the registrant or allowed to work at the registrant's facility is adequately trained and competent to assist in a physician's performance of fluoroscopy during cardiac catheterization procedures as required under Section 14-306(f)(1) of the Health Occupations Article, Annotated Code of Maryland, and COMAR 10.32.12.06, and must conspicuously display each RCIS's certificate.

(vi) A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

(a) Patient's body part and anatomical size or body part thickness, or age (for pediatrics) versus technique factors to be utilized;

(b) Type and size of the film or film-screen combination to be used, if applicable;

(c) Type and focal distance of the grid to be used, if any;

(d) Source to image receptor distance to be used;

(e) Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

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

(vii) Written safety procedures shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

(6) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than +/- 35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.

(m) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of Sections F.5(a), F.5(c), F.5(d), and F.5(g) provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(2) Systems which do not meet the requirements of Section F.5(g) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(n) Qualifications for Users who Energize Fluoroscopic System.

(1) The registrant shall ensure that only a licensed practitioner of the healing arts or a radiological technologist be allowed to energize fluoroscopic x-ray systems. In addition, all persons energizing these systems shall have completed at least four hours of training as specified in Section F.5(n)(2) prior to clinical use of a fluoroscopic system, or provide documentation to demonstrate completion of four hours of training as specified in Section F.5(n)(2) prior to clinical use of a fluoroscopic system.

(2) Training to meet the requirements of Section F.5(n)(1) shall include, but is not limited to the following:

(i) Biological effects of x-ray;

(ii) Principles of radiation protection;

(iii) Factors affecting fluoroscopic outputs;

(iv) Dose reduction techniques;

(v) Principles and operation of the specific fluoroscopic x-ray system(s) to be used;

(vi) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used; and

(vii) Applicable requirements of these regulations.

(3) The registrant shall maintain records to demonstrate a minimum of one hour of in-service training or continuing medical education training for all users who energize fluoroscopic equipment every twenty-four months in fluoroscopic radiation safety and patient dose management.

(4) The registrant shall maintain documentation pertaining to the requirements of Sections F.5(n)(1), F.5(n)(2) and F.5(n)(3) for review for three years.

(5) Documentation to meet the requirements of Sections F.5(n)(1), F.5(n)(2) and F.5(n)(3) are not registrant specific and should be transferable to other work areas if authorized between the users who energize fluoroscopic radiation machines and the registrant(s).

(6) The registrant may exempt from the requirements of Sections F.5(n)(1) through F.5(n)(4):

(i) Radiologists, if the registrant verifies initially, and biennially thereafter, via original documentation of continued certification by an accepted professional organization; or

(ii) Licensed practitioners of the healing arts and radiation therapy technologists exclusively energizing fluoroscopic radiation machines for the purpose of therapy simulation. The registrant shall maintain records verifying exempt status per user a minimum of every twenty-four months.

(o) Equipment Operation.

(1) Fluoroscopy shall not be used as a positioning tool for radiographic examinations, except for therapy simulation.

(2) By the registrant's first certification date and biennially thereafter, the registrant shall perform an evaluation that will span no less than three months of cumulative electrophysiological and interventional, including cardiac catheterization, fluoroscopic exposure times by procedure and by licensed practitioner. The report shall include the number of fluorographic images recorded for examination.

Sec. F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinarian, or Medical Computed Tomography X-Ray Systems.

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

(1) General Purpose Stationary and Mobile X-Ray Systems.

(i) There shall be provided a means for stepless adjustment of the size of the x-ray field.

(ii) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent 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.

(2) Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of F.6(a)(1), stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

(i) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(ii) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

(iii) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such 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 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-Ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Systems Designed for Mammography.

(i) Radiographic systems designed only for mammography shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in F.6(a)(5)(iii). When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in F.6(a)(5)(iii)(a) and (b) shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(ii) Radiographic equipment designed for general purpose or special non-mammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography.

(5) X-Ray Systems Other Than Those Described in F.6(a)(1),(2),(3), and (4).

(i) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Podiatry units with a circular beam are exempted from the 2% limit provided the diameter of the x-ray field shall not exceed the diagonal dimension of the image receptor.

(ii) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(iii) F.6(a)(5)(i) and (ii) may be met with a system that meets the requirements for a general purpose x-ray system as specified in F.6(a)(1) or, when alignment means are also provided, may be met with either:

(a) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(b) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(6) Source to Image Distance

Except for certified systems, a method shall be provided to indicate the SID to within 2 inches.

(7) Positive Beam Limitation (PBL). This regulation applies only to radiographic systems which contain PBL.

(i) PBL shall prevent the production of x-rays when:

(a) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by F.6(a)(5)(iii), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

(b) The sum of the length and width differences as stated in F.6(a)(7)(i)(a) without regard to sign exceeds 4 percent of the SID; or

(c) The beam limiting device is at an SID for which PBL is not designed for sizing;

(ii) PBL systems shall function as described in Section F.6(a)(5)(i) whenever all the following conditions are met:

(a) The image receptor is inserted into a permanently mounted cassette holder;

(b) The image receptor length and width are less than 50 centimeters;

(c) The x-ray beam axis is within ± 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam is within ± 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(d) The x-ray beam axis is perpendicular to the plane of the image receptor to within ± 3 degrees; and

(e) Neither tomographic nor stereoscopic radiography is being performed;

(iii) Compliance with F.6(a)(5)(i) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and no sooner than 5 seconds after insertion of the image receptor;

(iv) The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters; and

(v) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in F.6(a)(5)(i), then any change of image receptor size or SID must cause the automatic return.

(b) Radiation Exposure Control Devices.

(1) Timers.

(i) 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. Such means shall provide that the resulting time interval product of current and time, number of pulses or radiation exposure is accurate to within ten percent of the true value.

(ii) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(iii) Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.

(2) X-Ray Control.

(i) An x-ray control with a dead-man switch shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(a) dental cone beam CT/3D (CBCT) machines installed prior to August 31, 2016, or

(b) during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(ii) An x-ray exposure switch shall be located in such a way as to meet the following requirements:

(a) stationary x-ray systems shall be required to have the x-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(b) mobile and portable x-ray systems which are:

(1) used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of F.6(b)(2)(ii)(a);

(2) used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirement of F.6(b)(2)(ii)(a) or the operator shall be protected by 6.5 feet (1.98 m) high or greater protective barrier with a minimum lead equivalent of 0.25 mm which is placed so as to intercept both direct radiation from the tube housing and radiation scattered from the patient; or

(3) used for less than 1 hour at the same location to make an exposure(s) of a patient, shall meet the requirement of F.6(b)(2)(ii)(a) or (b)(2) or be provided with a method of x-ray control which will permit the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure; and

(iii) means shall be provided so that the operator can view the patient during the exposure.

(iv) The x-ray control shall provide visual indication observable at or 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.

(v) Accuracy. Except for certified systems, means shall be provided to terminate an exposure at a preset time interval, preset product of current and time, or preset number of pulses. Such means shall produce a time interval, product of current and time, or number of pulses within 10 percent of the indicated preset value.

(3) Automatic Exposure Controls. When an automatic exposure control is provided:

(i) indication shall be made on the control panel when this mode of operation is selected;

(ii) if the x-ray tube potential is equal to or greater than 51 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

(iii) the minimum exposure time for all equipment other than that specified in F.6(b)(3)(ii) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

(iv) either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 51 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(v) a visible signal shall indicate when an exposure has been terminated at the limits required by F.6(b)(3)(iv), and manual resetting shall be required before further automatically timed exposures can be made.

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10\,(\bar{X}_1 + \bar{X}_2),$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(5) Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.4(e)(1).

(i) Additional Requirements Applicable to Systems Designed Specifically to be Hand-Held.

(1) Each hand-held diagnostic x-ray device shall be FDA approved for use in the United States and registered with the Department for hand-held operation as part of the facility registration. Registration shall include a description of how the hand-held device(s) will be secured in accordance with F.7(i)(4)(i) below.

(2) Each individual operating a hand-held diagnostic x-ray device shall, before using the device, complete the manufacturer's training for use of the device. The registrant shall maintain training certificates for operators of hand-held devices and make them available for inspection at the registered facility.

(3) Hand-held diagnostic x-ray devices shall comply with the following requirements:

(i) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

(ii) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10\,(\bar{X}_1 + \bar{X}_2),$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(iii) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(iv) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(v) Beam Quality. All certified hand-held dental x-ray devices shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.4(e)(1).

(4) The use of hand-held diagnostic x-ray devices shall be in accordance with the following:

(i) The device shall be secured between planned uses from unauthorized use or removal. A description of where and how the device will be secured shall be provided to the Department before first use of the device.

(ii) The device shall have an inherent safety mechanism to prevent accidental exposures when the device is "on" but not active between imaging procedures. The device shall be maintained in lock down (safety engaged) mode at all times between patient exposures so that the device cannot be accidentally operated.

(iii) The device shall have a permanent non-removable shield in order to protect the operator from backscatter of radiation.

(iv) Only persons who are licensed, registered or certified to operate radiographic equipment in Maryland may make exposures using the device.

(v) The operator of a device shall wear a whole-body dosimeter at all times when taking an exposure. ALARA practices shall be in place during use of the device.

(vi) The device shall not be operated if a person other than the patient, operator, and others directly involved in providing care, are present in the room in which the x-ray device will be operated. As provided in F.3(a)(1)(v), if such person(s) are required to be present for the purpose of aiding in the procedure, such person(s) shall be provided with and required to wear full body shielding of no less than 0.25 millimeter lead equivalent and shall be required to remain out of the direct beam. If other persons are present in the room who are not being treated and cannot be removed from the room, the shielding and distance requirements in F.3(a)(1)(v) shall apply.

(vii) Use of a hand-held device is allowed in dental offices as a replacement for or in addition to the use of permanent wall-mounted or free-standing portable dental x-ray machines, when it is determined by the authorized provider that it is not possible or is not safe to attempt to expose a radiograph using a wall mounted or portable stand mounted x-ray machine. A device designed to be hand-held may be permanently installed in an appropriate support frame and used as a free-standing portable dental x-ray machine.

(viii) Use of a hand-held device in a school or group environment for screening purposes is prohibited, except hand-held devices may be used for health diagnostic purposes only after an authorized practitioner's oral examination of a patient as part of an overall screening procedure and finding of clinical indication for device use. Provisions for protection of persons other than the patient set forth in F.3(a)(1)(v) shall be enforced.

(ix) The registrant shall keep a log of the hand-held device's usage on a form as provided by the Department. Devices shall only be transported to and from the registered facility in accordance with the provisions of D.802(b). Commercial transportation is permitted only for receipt and repair of the device.

(x) The Department reserves the right to perform an unannounced audit limited to the use of hand-held devices at facilities that are registered to use such devices in order to ensure that hand-held devices at the facility are being utilized and stored in accordance with these regulations.

(xi) Missing or stolen hand-held devices shall be reported to the Department immediately. A written report of the loss including all available details shall be submitted to the Department within 24 hours.

(xii) Hand-held devices shall only be used with dental film speeds E or faster or with digital imaging.

(i) Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

(ii) When 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.

(3) Additional Requirements for X-Ray Systems Capable of Operation Above 150 kVp.

(i) All protective barriers shall be fixed except for entrance doors or beam interceptors.

(ii) The control panel shall be located outside the treatment room.

(iii) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(iv) When any door referred to in F.8(b)(3)(iii) is opened while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgens (25.8 μC/kg) per hour.

(c) Surveys, Calibrations, Spot Checks, and Operating Procedures.

(1) Surveys.

(i) All new facilities, and existing facilities not previously surveyed, shall have a survey made in accordance with D.501. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(ii) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.

(iii) The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations.

(2) Calibrations.

(i) The calibration of an x-ray system shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output.

(ii) The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.

(iii) Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated at intervals not to exceed 12 months.

(iv) The calibrations shall be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty of 5 percent.

(v) The calibration of the x-ray system shall include, but not be limited to, the following determinations:

(a) verification that the x-ray system is operating in compliance with the design specifications;

(b) the exposure rates as a function of field size, technique factors, filter, and treatment distance used;

(c) the degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and

(d) an evaluation of the uniformity of the largest radiation field used.

(vi) Records of calibration shall be maintained by the registrant for 5 years after completion of the calibration.

(vii) A copy of the most recent x-ray system calibration shall be available at or in the area of the control panel.

(3) Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

(i) The spot-check procedures shall be in writing and shall have been developed by a qualified expert. A copy of the procedures shall be submitted to the Agency prior to their implementation.

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

(iii) The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall be performed during the calibration specified in F.8(c)(2). The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in F.8(c)(2) shall be stated.

(iv) The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation.

(v) Whenever a spot check indicates a significant 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 F.8(c)(2).

(vi) Records of spot-check measurements shall be maintained by the registrant for 2 years after completion of the spot-check measurements and any necessary corrective actions.

(vii) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of F.8(c)(2) or which has been intercompared with a system meeting those requirements within the previous year.

(4) Operating Procedures.

(i) X-ray systems shall not be left unattended unless the system is secured against unauthorized use.

(ii) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(iii) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

(iv) No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of D.201 of these regulations. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.

(v) The x-ray system shall not be used in the administration of radiation therapy unless the requirements of F.8(c)(2) and F.8(c)(3)(v) have been met.

Sec. F.9 X-Ray and Electron Teletherapy Systems with Energies of One MeV and Above. In addition to the provisions of Section F.9, Part I except I.11(d) and I.11(e) shall apply to medical facilities using teletherapy systems with energies 1 MeV and above.

(a) Definitions. In addition to the definitions provided in F.2, the following definitions shall be applicable to F.9:

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

"Beam scattering filter" means a filter used in order to scatter a beam of electrons.

"Central axis of the beam" means 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" means a system of devices for the detection, measurement, and display of quantities of radiation.

"Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

"Existing equipment" means therapy systems subject to F.9 which were manufactured on or before January 1, 1985.

"Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

"Field size" means the dimensions 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 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

"Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

"Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

"New equipment" means systems subject to F.9 which were manufactured after January 1, 1985.

"Normal treatment distance" means:

(1) for electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

(2) for x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

(b) which has been calibrated within the previous 2 years and after any servicing that may have affected its calibration;

(c) which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

(d) which has had constancy checks performed on the system as specified by a radiological physicist.

(iv) Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of 5 percent.

(v) The calibration of the therapy beam shall include but not be limited to the following determinations:

(a) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth,

(b) the absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam,

(c) the uniformity of the radiation field and any dependency upon the direction of the useful beam,

(d) verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions,

(e) verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

(vi) Records of calibration measurements under F.9(d)(2)(i) and dosimetry system calibrations under F.9(d)(2)(iii) shall be maintained for 5 years after completion of the full calibration.

(vii) A copy of the latest calibration and verification performed pursuant to F.9(d)(2)(i) shall be available in the area of the control panel.

(3) Spot checks. Spot checks shall be performed on systems subject to F.9 during calibrations and thereafter at intervals not to exceed 1 month. Such spot checks shall meet the following requirements:

(i) The spot-check procedures shall be in writing and shall have been developed by a radiological physicist.

(ii) If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

(iii) The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

(iv) At intervals not to exceed 1 week, spot checks shall be made of absorbed dose measurements at a minimum of 2 depths in a phantom.

(v) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.

(vi) The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.

(vii) Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in F.9(d)(2).

(viii) Records of spot-check measurements shall be maintained by the registrant for a period of 2 years after completion of the spot-check measurements and any necessary corrective actions.

(ix) Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of F.9(d)(2)(iii) or which has been intercompared with a system meeting those requirements within the previous year.

(4) Operating Procedures.

(i) No individual other than the patient shall be in the treatment room during treatment of a patient.

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

(iii) The system shall not be used in the administration of radiation therapy unless the requirements of F.9(d)(1), (2), and (3) have been met.

(e) Personnel Requirement. All persons utilized as a qualified expert or radiological physicist shall be licensed by the Agency under COMAR 26.12.02.03.

(f) Procedures for Therapeutic Administrations. The registrant shall develop, implement, and maintain written safety procedures for therapeutic administrations.

(1) Each administration shall be in accordance with the written directive and the registrant's written safety procedures.

(2) Prior to the administration of each course of radiation treatment, the patient's identity shall be verified by more than one method as the individual named in the written directive.

(3) Therapeutic radiation machine final plans of treatment and related calculations shall include the following:

(i) Checking both manual and computer-generated dose calculations to verify they are correct; and

(ii) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units.

(4) Any misadministration shall be identified, evaluated and appropriate action taken in accordance with D.1208.

(5) The registrant shall retain a copy of the written safety procedures for administrations, including any restrictions required for the safe operation of the particular therapeutic radiation machine, in the control area of a therapeutic radiation machine for the duration of the registration.

(g) Machine Operator Records Retention. The names and the training records of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two (2) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

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(c) A licensee shall conduct the surveys required by G.70(a) and G.70(b) so as to be able to measure dose rates as low as 0.1 millirem (1 μSv) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by G.70(a) and G.70(b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by G.70(e) so as to be able to detect contamination on each wipe sample of 200 disintegrations per minute (3.33 Bq).

(g) A licensee shall establish removable contamination action levels for the surveys required by G.70(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee shall retain a record of each survey required by G.70(a), (b), and (e) for 3 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

Secs. G.71 – G.74 Reserved.

Sec. G.75 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual has the potential to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, in any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with G.2075(b).

Secs. G.76 – G.79 Reserved.

[1] The current version of NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

Sec. G.80 Provision of Mobile Medical Service.

(a) A licensee providing mobile medical service shall--

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(3) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at the client's location of use;

(4) Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(5) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the daily check for proper function required by this paragraph must include a constancy check;

(i) Test each dose calibrator for accuracy upon receipt, at intervals not to exceed 12 months thereafter, and after repair by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(ii) Test each dose calibrator for linearity upon receipt, at least quarterly thereafter, and after repair over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries); and

(iii) Test each dose calibrator for geometry dependence upon receipt and after repair over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(6) Mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(7) Carry two calibrated survey meters in each vehicle that is being used to transport radioactive material. Survey instruments shall be checked for proper operation with a dedicated check source before use at each client's address; and

(8) Before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed. Contamination smears of the client's address confirming unrestricted release of the area must be less than 220 disintegrations per minute for 100 square centimeters.

(b) Provide to the Agency a signed certification from all proposed authorized users that they are willing and able to perform the responsibilities of authorized user as described in G.11(b) and G.27.

(c) Radioactive material may be delivered to a mobile medical service client if that client has a license allowing possession of the radioactive material. Radioactive material delivered to the licensed client must be received and handled in conformance with the client's license.

(d) A mobile medical service shall have radioactive material delivered from the manufacturer or the distributor to an unlicensed client's address only if the radioactive material is directly received by mobile medical service licensed personnel in accordance with procedures approved under the mobile medical service license.

(e) A licensee providing mobile medical services shall retain the letter required in G.80(a)(1) and the record of each survey required in G.80(a)(8) in accordance with G.2080(a) and (b), respectively.

(f) A licensee conducting mobile medical services shall provide accurate advance written notification to the Agency, describing client's addresses and times of work using a method and frequency approved by the Agency.

Secs. G.81 – G.99 Reserved.

(b) A licensee shall retain the record of each survey required by G.80(a)(8) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

Secs. G.2081 – G.2203 Reserved.

Sec. G.2204 Records of Molybdenum-99 Concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by G.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

Secs. G.2205 – G.2309 Reserved.

Sec. G.2310 Records of Safety Instruction.

A licensee shall maintain a record of safety instructions required by G.310, G.410, and G.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Secs. G.2311 – G.2403 Reserved.

Sec. G.2404 Records of Surveys after Source Implant and Removal.

A licensee shall maintain a record of the surveys required by G.404 and G.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Sec. G.2405 Reserved.

Sec. G.2406 Records of Brachytherapy Source Accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by G.406 for 3 years.

(b) For temporary implants, the record must include:

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

Secs. G.2407 – G.2431 Reserved.

Sec. G.2432 Records of Calibration Measurements of Brachytherapy Sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by G.432 for 3 years after the last use of the source.

(b) The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Sec. G.2433 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by G.433 for the life of the source.

(b) The record must include:

(1) The date and initial activity of the source as determined under G.432; and

(2) For each decay calculation, the date and the source activity as determined under G.433.

Secs. G.2434 – G.2604 Reserved.

Sec. G.2605 Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

PART H

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT AND X-RAY SECURITY SCREENING

Sec. H.1 Purpose and Scope. This part provides special requirements for analytical x-ray equipment and for x-ray security screening systems. The requirements of this part are in addition to, and not in substitution for, applicable requirements in other parts of these regulations.

Sec. H.2 Definitions. As used in this part, the following definitions apply:

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x or gamma rays to determine the elemental composition or to examine the microstructure of materials.

“Backscatter system” means a security screening system that makes use of radiation scattered or deflected from an object or person to form an image of the scattering object or person.

“Bystander” means any person other than the individual being screened who is not directly associated with operation of the system.

"Fail-safe characteristics" mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

“Full-body scanner” means any security screening system that images the full body of a person. Full-body scanners include systems in which the subject stands in place, portal systems, and multi-purpose scanners used to scan humans who are vehicle occupants. Any security screening system for which at least one dimension of the scan area is greater than 50 cm shall be considered a full-body scanner.

“General use security screening system” means a security screening system that delivers a reference effective dose equal to or less than 0.25 μSv (25 μrem) per screening.

“Inspection zone” means the general area established by the operating institution for the purpose of limiting or controlling access to the area where the screening will be performed. This includes but is not limited to any ingress, egress, gate, portal, traffic path, and areas, access to which is restricted due to the presence of radiation. The ambient dose equivalent outside of the inspection zone shall not exceed 20 μSv (2 mrem) in any 1 hour.

“Limited-use security screening system” means a security screening system that is capable of delivering an effective dose greater than 0.25 µSv (25 µrem) per screening but shall not exceed a reference effective dose of 10 µSv (1 mrem) per screening.

"Local components" mean part of an analytical x-ray system and include areas that are struck by x rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant [or licensee], and data recording procedures, which are related to radiation safety.

"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

“Operator” means any employee associated with the operation of the security screening system whose responsibilities include at least one of the following: initiating or stopping the scan, verifying the system is operating correctly, providing information and instructions to the screened individuals, and controlling access to the inspection zone.

“Portal system” means a system designed to image persons who move through the inspection zone under their own control, by a moving walkway, or within a vehicle. It does not include systems that move the individual through the inspection zone in a controlled manner, such as a moving platform on which the subject is normally required to remain still (see Stationary-subject system).

"Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

“Reference effective dose” means a quantity based on measurable parameters used by the ANSI/HPS N43.17-2009 standard for setting dose limits. It is derived from the effective dose to the average adult as defined in ICRU Report 57 (ICRU 1998) and as modified by ICRP Publication 103 (ICRP 2007). It is obtained from air kerma and HVL measurements as described in Section 6.1.3 of the ANSI/HPS standard, “Determination of the Reference Effective Dose.”

“Reference plane” means the plane containing the reference measuring point and is perpendicular to the beam direction at the reference point (used only for partial-body scanners).

“Scan” means the operation necessary to produce one image (e.g., front view) from one radiation source. One radiation source simultaneously producing multiple images also constitutes one scan. Two sources simultaneously producing two images constitute two scans. In some cases several scans may be required for a single screening of the subject.

“Scan area” means the total area on the reference plane that is covered by the primary beam as it scans.

“Screening” means the sum of radiation exposures or scans necessary to image objects concealed on all sides of the body as intended by the system design under normal conditions.

“Security screening system” means a system designed for the detection of contraband and weapons concealed on a person or in a vehicle while being occupied by one or more people.

“Stationary-subject system” means a system designed to image a person who remains stationary while a scan is occurring. This includes systems that move the individual through the inspection zone in a controlled manner, such as a moving platform on which the subject is normally required to remain still.

“Transmission security screening system” means a security screening system using the conventional means of radiographic imaging in which x-rays or gamma rays pass through a target (e.g., person or container) and create shadow-grams of enclosed objects (e.g., contraband) based on their radiation attenuating properties.

General Regulatory Provisions and Specific Requirements for Analytical X-Ray Equipment

Sec. H.3 Equipment Requirements.

(a) Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the Agency for an exemption from the requirement of a safety device. Such application shall include:

(1) a description of the various safety devices that have been evaluated;

(2) the reason each of these devices cannot be used; and

(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) Warning Devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of:

(i) x-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or

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

(2) An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:

(i) near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

(ii) in the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after October 10, 1982 warning devices shall have fail-safe characteristics.

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

(d) Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and

(2) "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; or

(3) "CAUTION - RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing in accordance with Part D of these regulations if the radiation source is a radionuclide.

(e) Shutters. On open-beam configurations installed after October 10, 1982 each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

(1) Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from its surface or for x-ray tubes at any specified tube rating is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour.

(g) Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 μSv) in one hour.

Sec. H.4 Area Requirements.

(a) Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such 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 dose limits given in Part D of these regulations. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(b) Surveys.

(1) Radiation surveys, as required by Part D of these regulations, of all analytical x-ray systems sufficient to show compliance with H.4(a) shall be performed:

(i) upon installation of the equipment, and at least once every 12 months thereafter;

(ii) following any change in the initial arrangement, number, or type of local components in the system;

(iii) following any maintenance requiring the disassembly or removal of a local component in the system;

(iv) 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;

(v) any time a visual inspection of the local components in the system reveals an abnormal condition; and

(vi) whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in Part D of these regulations.

(2) Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with H.4(a) to the satisfaction of the Agency.

(c) Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT" or words having a similar intent in accordance with Part D of these regulations.

Sec. H.5 Operating Requirements.

(a) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

(b) Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.

(c) Repair or Modification of X-Ray Tube Systems. Except as specified in H.5(b), no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall 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 Replacement, Testing, or Repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

Sec. H.6 Personnel Requirements.

(a) Instruction. No individual shall be permitted to operate or maintain analytical x-ray equipment unless such individual has received instruction in and demonstrated competence as to:

(1) identification of radiation hazards associated with the use of the equipment;

(2) significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) proper operating procedures for the equipment;

(4) recognition of symptoms of an acute localized exposure; and

(5) proper procedures for reporting an actual or suspected exposure.

(b) Personnel Monitoring.

(1) Finger or wrist dosimetric devices shall be provided to and shall be used by:

(i) analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

(ii) personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with D.201 of these regulations unless evaluated by a qualified expert.

General Regulatory Requirements and Specific Requirements for X-Ray Security Screening

Sec. H.7 Purpose and Scope.

(a) This section applies to the operation of full-body security screening systems that are intended to expose humans to primary beam x-rays. Such systems include:

(1) Direct screening of humans to detect objects hidden within an individual's body or clothing; and

(2) Knowingly exposing human occupants to the primary beam when screening vehicles or structures.

(3) These regulations do not apply to backscatter systems.

(4) These regulations do not apply to partial-body scanning systems.

(b) All security screening systems shall apply to the dose limitation requirements of Section H.9.

Sec. H.8 Security Screening System Categories.

Security screening systems subject to this regulation are used for full-body scanning and are divided into two categories based on the radiation output:

(1) Category 1 - general-use security screening systems are systems in which low doses are delivered and engineering controls are incorporated in the system. Category 1 systems shall conform to the dose limitation requirements in Section H.9(b).

(2) Category 2 limited-use security screening systems are systems that require additional administrative controls in order to ensure that members of the public are not subjected to a cumulative effective dose in excess of the allowed annual limit. Category 2 systems shall conform to the dose limitation requirements in Section H.9(c).

Sec. H.9 Dose Limitation.

(a) Dose to Scanned Individuals**.** The radiation dose delivered to a scanned individual shall be as low as reasonably achievable (ALARA) while meeting the required detection performance.

(b) For Category 1 general-use security screening systems, the reference effective dose shall not exceed 0.25 μSv (25 μrem) per screening. The cumulative reference effective dose received by any individual shall not exceed 250 μSv (25 mrem) over a 12-month period. Compliance with this requirement shall be demonstrated by retaining records to demonstrate that:

(1) the number of screenings received by any individual does not exceed 1,000 per 12-month period; and

(2) the reference effective dose multiplied by the number of screenings does not exceed 250 μSv (25 mrem) over a 12-month period for any individual.

(3) Cumulative records per screened individual shall be maintained for Agency review.

(c) For Category 2 limited-use security screening systems, the following regulations shall apply:

(1) The radiation dose delivered to a human shall be maintained ALARA while meeting the desired detection performance. The reference effective dose shall not exceed 10 μSv (1 mrem) per screening.

(2) Administrative controls are required for the operation of all limited-use, full body scanners. Administrative controls shall be in the form of documented procedures that ensure that the effective dose to any individual screened shall be limited to 250 μSv (25 mrem) in any 12-month period. This shall be accomplished by maintaining records to demonstrate that the reference effective dose multiplied by the number of screenings to any individual in a 12-month period does not exceed 250 μSv (25 mrem).

(3) Compliance with this requirement shall be demonstrated by retaining records to demonstrate that dose limits are not exceeded. Cumulative records per screened individual shall be maintained for Agency review.

(4) Table 1 can be used to aid in meeting the annual dose requirement.

(5) Sensitive Groups. Alternative security screening methods shall be considered when a declared pregnant woman is to be screened utilizing a limited-use security screening system.

Table 1. The number of allowed screenings for one individual.*

Reference effective dose per screening (μSv)	(μrem)	Standard is met if number of screenings per year does not exceed	Standard is met if number of screenings every month does not exceed	Standard is met if number of screenings every week does not exceed	Standard is met if number of screenings every day does not exceed
0.25	25	1,000	83	19	2
0.5*	50	500	41	9	
1.0*	100	250	20	4	
2.0*	200	125	10	2	
3.0*	300	80	6	1	
4.0*	400	62	5	1	
5.0*	500	50	4		
10.0*	1,000	25	2		

*Applies to limited-use systems only.

(d) Determination of Reference Effective Dose.[1] The reference effective dose for full-body scanners shall be determined from measurements of the half-value layer (HVL) and air kerma (or exposure). One of the equations (1) or (2) below shall be used.

$$E_{REF} = K_a \times C \qquad \text{(eq.1)}$$

where
E_{REF} is the reference effective dose in Sv,
K_a is the measured air kerma in Gy, and
C in Sv/Gy is given by
$C = 0.125 \times$ HVL in mm of Al or
$C = 1.14$, whichever is smaller.

Or, when using traditional units the equivalent equation is

$$E_{REF} = X \times C_R \qquad \text{(eq. 1a)}$$

where
E_{REF} is the reference effective dose in rem,
X is the measured exposure in R, and
C_R in rem/R is given by
$C_R = 0.110 \times$ HVL in mm of Al or
$C_R = 1.00$, whichever is smaller.

Note: C and C_R achieve their maximum value at HVL = 9.1 mm Al. This corresponds to an effective photon energy slightly less than 60 keV. Therefore, a C of 1.14 Sv/Gy (C_R of 1.00 rem/R) shall be used for systems using ^{60}Co, ^{137}Cs, or any other isotope whose emissions equal or exceed 60 keV.

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1 A full description of the rationale and derivation of "Reference Effective Dose" is found in ANSI/HPS N43.17-2009. This document also contains Determination of Half-Value Layer at 6.1.3.1 and Measurement of Reference Air Kerma at 6.1.3.2.

(e) Dose to Bystanders, Operators, and Other Employees

(1) An inspection zone shall be established around the x-ray security screening system where bystanders are prohibited during the operation of the device. A means shall be provided for any operator responsible for initiating a scan to maintain full visual surveillance of the inspection zone. The ambient dose equivalent outside of this inspection zone shall not exceed 20 μSv (2 mrem) in any 1 hour.

(2) Any area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (5 mrem) in 1 hour at no less than 30 cm from a beam exit surface, a tunnel wall or virtual tunnel wall shall be posted with a sign displaying the radiation symbol as specified in Section D.901 and the words "CAUTION, RADIATION AREA."

(3) Any area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (100 mrem) in any 1 hour at no less than 30 cm from the beam exit surface, a tunnel wall or virtual tunnel wall shall be posted with a sign displaying the radiation symbol as specified in Section D.901 and the words "CAUTION, HIGH RADIATION AREA." Access control shall be maintained at all times as described in Section D.601.

(4) The system shall be positioned and operated such that the ambient dose equivalent at any work station does not exceed 1 mSv (100 mrem) per year.

Sec. H.10 Shielding Requirements.

Under maximum operating parameters, the leakage ambient dose equivalent at any point 30 cm from any external surface of the system, outside of the primary beam, shall not exceed 2.5 μSv (0.25 mrem) in any 1 hour. For units that employ a shutter this limit shall also apply to the region of the primary beam while the shutter is closed. For units that employ a beam stop this limit shall also apply to the region adjacent to the beam stop opposite the source of radiation.

Sec. H.11 System Requirements.

(a) Indicators.

(1) There shall be at least one indicator, clearly visible from any location from which a scan can be initiated, that indicates when a scan is in progress.

(2) There shall be at least one lighted indicator clearly visible from the inspection zone. For portal systems the indicator shall be visible from any approach to the inspection zone to indicate that a scan is in progress.

(3) For any x-ray system that normally keeps high voltage applied to the x-ray tube at times other than during a scan, there shall be at least one lighted "x-ray on" indicator at the control console where x-rays are initiated indicating when x-rays are being produced.

(b) Controls.

(1) Power to the system shall be controlled by a key switch. The key shall be captured (unable to be removed) whenever it is in a position that allows exposures to be initiated. Turning on the key switch shall never result in the external emission of radiation.

(2) Each system shall have a means for the operator to initiate the emission of radiation other than the function of an interlock or the main power control.

(3) Each system shall have a means for the operator to terminate the emission of radiation other than the function of an interlock.

(4) Means shall be provided to ensure that operators have a clear view of the scanning area. This can be a direct, mirror view, or real-time video of the scanning area. Engineering controls should be provided to ensure that individuals do not reenter the scanning area from the exit while x-rays are being produced (e.g., one way turnstile).

(5) Technique factors for each mode of operation shall be preset by the manufacturer and shall not be alterable by the system operator. If there is more than one mode, prior to each scan, a mode indicator shall be clearly visible to the operator.

(6) The following warning label shall be permanently affixed or inscribed on the x-ray system at the location of any controls used to initiate x-ray generation: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED."

(7) X-ray emission shall automatically terminate after a preset time or exposure.

(c) Safety interlocks.

(1) Failure of any single component of the system shall not cause failure of more than one safety interlock.

(2) A tool or key shall be required to open or remove access panels. Each access panel to the x-ray source shall have at least one safety interlock to terminate the x-ray production when opened.

(3) For stationary-subject systems, the scanning motion of the x-ray beam relative to the subject shall be interlocked and the exposure shall terminate when the rate of motion of the beam in any direction falls below a preset minimum speed. The minimum speed shall be chosen so that the dose during the exposure period is within the applicable limit.

(4) Operational interlocks shall terminate the primary beam in the event of any system problem that could result in abnormal or unintended radiation emission. This shall include, but is not limited to, unintended stoppage of beam motion, abnormal or unintended x-ray source output, computer safety system malfunction, termination malfunction, and shutter or beam stop mechanism malfunction.

(5) In the event of a malfunction, the system shall terminate radiation exposure rapidly enough so that no location on the subject's body shall receive an ambient dose equivalent exceeding 250 μSv (25 mrem), regardless of the size of the exposed area.

(6) Following interruption of x-ray production by the functioning of any safety interlock, resetting the interlock shall not result in the production of x-rays. Use of the normal control sequence shall be necessary for resumption of x-ray generation.

Sec. H.12 Operating Requirements.

(a) Responsible Individual. The facility operating the security screening system shall designate a person(s) responsible for ensuring compliance with the requirements of this section The person(s) shall have direct access to senior management for radiation safety issues. The person(s) shall have training and experience as required commensurate with the scope of the radiation safety program.

(b) Operating Procedures. The facility shall document its procedures for operating the system. These procedures shall be consistent with the manufacturer's operator's manual, and shall be readily available to the operator of each screening system. The procedures shall include the following topics:

(1) Warnings of potential safety hazards (including unauthorized modification of the system);

(2) The requirements for registration of the system in accordance with B.5 and B.9;

(3) Operational procedures and training required to use the system safely;

(4) Preventive maintenance requirements for safe operation in accordance with F.3(d);

(5) Technique factors for each operating mode and the beam quality of the primary beam; and

(6) The reference effective dose per screening measured by the manufacturer. This information shall include a definition of "screening" for the system (e.g., number of scans required).

(c) Information To Be Provided to Screened Individuals. The facility operating the system shall inform each person being screened that the system emits radiation. A poster or sign is an appropriate method of providing this information.

Sec. H.13 Personnel Training.

(a) Each operator shall be provided with radiation safety training in the operation and use of the security screening system. This radiation safety training must include, at minimum:

(1) The concept of and how to achieve ALARA;

(2) Instructions and hands-on training in safe operation of the radiation machine;

(3) Operational and environmental emergency procedures;

(4) Safety hazards;

(5) Awareness and control of inspection zones;

(6) Requirements for personnel dosimetry;

(7) Pre-operational checks;

(8) Subject positioning;

(9) Interpretation of images.

(b) Applicable regulatory requirements. Proficiency shall be demonstrated at the conclusion of training.

(c) Refresher training including all subjects in this section must be provided and taken by all operators at intervals not to exceed 12 months.

Sec. H.14 Radiation Surveys. Radiation surveys shall be performed to verify the reference effective dose, radiation leakage, inspection zone, radiation area, and any other parameters specified by the manufacturer. The radiation surveys in this paragraph shall be performed at least once every 12 months, and after any maintenance that affects shielding, shutter, or x-ray production, and after any incident that may have damaged the system in such a way that unintended radiation emission occurs.

Sec. H.15 Records.

(a) Maintenance Logs. Records of upgrades, modifications, maintenance, and repair shall be maintained for the life of the system.

(b) System Operating Procedures. A complete set of operating procedures as required in H.12 shall be maintained for the life of the system.

(c) The facility operating a security screening system shall collect and maintain for a minimum of five years the following records on-site at the facility:

(1) Each operator's training records including sufficient information to show compliance with Section H13;

(2) Use logs for all screened individuals who could receive radiation doses approaching 0.25 mSv (25 mrem) in any 12month period, to include the name of each individual that was screened, reference effective dose per screening, the number of times and dates when each individual was screened, and cumulative reference effective dose for each individual screened, to demonstrate that the dose limits specified in Section H.9 are being met;

(3) Records of radiation surveys, to include the name of the person who performed the survey, survey date, survey and background measurements, and system parameters at which measurements were made;

(4) The number of scans conducted during each calendar year by month; and

(5) The name and contact information for the responsible individual to be contacted about the nature and use of the radiation machine(s) at the facility.