INSTRUCTION SHEET

COMAR 26.12.01.01

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

SUPPLEMENT No. 32

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
v through x	v through x
C17 through C21-1	C17 through C21-1
D35 through D36	D35 through D36
D41 through D42	D41 through D42
D42-5 through D42-6	D42-5 through D42-6
E17 through E24	E17 through E24
F3 through F6	F3 through F6
F23 through F26	F23 through F26
F31-2 through F32	F31-2 through F32
F35 through F38	F35 through F38 (add 4 pages)
F50-1 through F50-2	F50-1 through F50-2
G31 through G32	G31 through G32
G33 through G34	G33 through G34
G37 through G38	G37 through G38
G43 through G46	G43 through G46
G61 through G64	G61 through G64
G67 through G68	G67 through G68
T17 through T18	T17 through T18
T35 through T36	T35 through T36
V5 through V6	V5 through V6
V11 through V12	V11 through V12
V17 through V20	V17 through V20
W7 through W8	W7 through W8
X11 through X12	X11 through X12

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

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Supplement 27 – Effective: October 26, 2015
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Supplement 30 – Effective February 22, 2021
Supplement 31 – Effective December 27, 2021
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REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

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PART E – INDUSTRIAL RADIOGRAPHIC OPERATIONS

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(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:

~~(iii)~~(i) The general licensee shall not possess at any one time, pursuant to the general license in C.22(i)(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).

~~(iv)~~(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

~~(v)~~(iii) The general licensee shall use the radioactive material only for the uses authorized by C.22(i)(1).

~~(vi)~~(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

~~(vii)~~(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in C.22(i)(1)(v) as required by D.1001 of these regulations.

~~(6)~~(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.22(i)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to C.28(h) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under C.22(i) or its equivalent, and

(ii) unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(a) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the

Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

(b) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

_____
Name of manufacturer

~~(7)~~(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of C.22(i)(1) shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Agency Form MDE-211. The report shall be furnished within 30 days after the effective date of such change.

~~(8)~~(6) Any person using radioactive material pursuant to the general license of C.22(i)(1) is exempt from the requirements of Parts D and J of these regulations with respect to radioactive material covered by that general license, except that such persons shall comply with the provisions of D.1201, D.1202, and D.1207 of these regulations.

~~(h)~~(j) Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Agency or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in C.22(j)(1),

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of D.1001 of these regulations;

(ii) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) are exempt from the requirements of Parts D and J of these regulations except that such persons shall comply with the provisions of D.1001, D.1201, D.1202, and D.1207.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of A.4 through A.9, C.31, C.40, C.50, and Part T of these regulations.

~~(i)~~(k) Registration of Generally licensed Devices.

(1) All persons, within 30 days of initial receipt of a generally licensed device, as defined in C.22~~(a),~~ (d)~~,~~ and (e) (excluding tritium exit signs), shall register that device with the Agency in accordance with C.22(k)(5). Registration shall be done by submitting new information, verifying previously submitted registration information, correcting, and/or adding to the information from a previous registration. All registration information shall be updated with the Agency on an annual basis.

(2) All persons who possess generally licensed devices as defined in C.22~~(a),~~ (d)~~,~~ and (e) (excluding tritium exit signs) prior to the effective date of this regulation shall register such devices within ninety days of the effective date of this regulation in accordance with C.22(k)(5). All registration information submitted for these devices shall be updated with the Agency on an annual basis.

(3) For the purposes of registration of devices received or possessed under C.22~~(a),~~ (d)~~,~~ and (e), each address that represents a location of use is a separate general licensee and requires separate registration.

(4) Persons generally licensed by the U.S. Nuclear Regulatory Commission or another Agreement State with respect to devices meeting the criteria in C.22~~(a),~~ (d)~~,~~ and (e) are required to register those devices with the Agency, if used in Maryland for a period of greater than 180 days in any calendar year.

(5) Registration of generally licensed devices shall include submission of the following information to the Agency:

(i) Name and mailing address of the general licensee.

(ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

(iii) Name, title, and telephone number of the responsible person designated as the representative of the general licensee.

(iv) Address or location at which the device(s) is (are) used and/or stored and for portable devices, the address of the primary place of storage.

~~(j)~~(l) General License for Certain Items and Self-Luminous Products Containing Radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with Section C.22(l)(2)-(4), radium-226 contained in the following products manufactured prior to November 30, 2007.

(i) Antiquities originally intended for use by the general public. For purposes of this paragraph, antiquities mean products intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(ii) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(iii) Luminous items installed in air, marine, or land vehicles.

(iv) All other luminous products provided that no more than 100 items are used or stored at the same location at any one time.

(v) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of the paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or designated by the NRC.

(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in Section C.22(l)(1) are exempt from the provisions of Parts D and J, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under Part C.

b. The licensee shall retain the records required by D.1109 until the Department terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in §C.38 for activities licensed under this part.

Sec. D.1110 Records of Testing Entry Control Devices for Very High Radiation Areas.

a. Each licensee or registrant shall maintain records of tests made pursuant to D.602 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

b. The licensee or registrant shall retain the records required by D.1110a. for 3 years after the record is made or for such time as the Agency shall determine.

Sec. D.1111 Form of Records.

Each record required by Part D shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

Sec. D.1201 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

a. Immediate Report.
i. Each licensee or registrant shall report by telephone immediately and in writing within 24 hours to the Agency the theft or loss of any source of radiation immediately after such occurrence becomes known.

ii All other licensees shall make reports by telephone to the Agency at 410-537-330 or 800-633-6101 ext. 3300.

b. Following Report. Each licensee or registrant required to make a report pursuant to D.1201a. shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

i. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and

ii. A description of the circumstances under which the loss or theft occurred; and

iii. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

iv. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

v. Actions that have been taken, or will be taken, to recover the source of radiation; and

vi. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

c. Subsequent to filing the written report required in D.1201(b), the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

d. The licensee or registrant shall prepare any report filed with the Agency pursuant to D.1201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

Sec. D.1202 Notification of Incidents.

a. Immediate Notification. In addition to other requirements for notification, each licensee or registrant shall immediately report by telephone each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

i. An individual to receive:

(1) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(2) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

(3) A shallow dose equivalent to the skin or extremities 2.5 Gy (250 rad) or more; or

ii. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

iii. All other licensees shall make the reports required by section a (i) and (ii) of this section and twenty-four hour notification by telephone to the Agency as specified in D.1201(a)(ii).

b. Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency in writing by telegram, mailgram or facsimile, each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees, registrants or physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

g. A licensee or registrant shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the individual who is the subject of the misadministration; and

(2) ~~Social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration~~Identification number or, if no other identification number is available, the social security number of the individual who is the subject of the event; and

ii. Provide the appended report in Sec. D.1208g.i. to the referring physician, if other than the licensee or registrant, no later than 15 days after the discovery of the misadministration.

h. Each licensee or registrant shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), identification number or if no other identification number is available, the social security number of the individual ~~if one has been assigned~~, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

Sec. D.1209 Report and Notification for an Eluate Exceeding Permissible Molybdenum-99 Strontium82, and Strontium-85 Concentrations

a. The licensee shall notify by telephone Maryland's Radioactive Materials Program, the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in G.204(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

b. By an appropriate method listed in 10 CFR § 30.6(a), the licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR § 30.6 within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution; and to Maryland's Radioactive Materials Program, to the address listed in Section A.12. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by D.1209(a)~~Reserved~~.

Sec. D.1210 Report and Notification of a Dose to an Embryo/fetus or a Nursing Child.

a. A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

b. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

i. Is greater than 5 rem (50 mSv) total effective dose equivalent; or

ii. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

c. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in D.1210(a) or (b).

d. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in D.1210(a) or (b).

i. The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

(5) The effect, if any, on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

ii. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

e. The licensee shall provide notification of the misadministration to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of a misadministration that would require reporting under D.1210(a). or (b)., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of D.1210(e)., the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. A licensee shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the pregnant individual or the nursing child who is the subject of the misadministration; and

(2) ~~Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the misadministration~~Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

ii. Provide the appended report in D.1210f.(i.) to the referring physician, if other than the licensee, no later than 15 days after the discovery of the misadministration.

Sec. D.1211 Additional Reporting Requirements for Radioactive Materials.

a. Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or release of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

b. Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

i. An unplanned contamination event that:

(1) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

(3) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

ii. An event in which equipment is disabled or fails to function as designed when:

(1) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(2) The equipment is required to be available and operable when it is disabled or fails to function; and

(3) No redundant equipment is available and operable to perform the required safety function.

iii. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

iv. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and

(2) The damage affects the integrity of the licensed material or its container.

c. Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

i. Licensees shall make reports required by paragraphs a. and b. of this section by telephone to the Agency as specified in Sec. D.1201(a) (ii). To the extent that the information is available at the time of notification, the information provided in these reports must include:

(1) The caller's name and call back number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

ii. Written report. Each licensee who makes a report required by paragraph a. or b. of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These reports must be sent to the Agency. The reports must include the following:

(1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(2) The exact location of the event;

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(4) Date and time of event;

(5) Corrective actions taken or planned and the results of any evaluations or assessments; and

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

d. Each specific licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

i. The licensee;

ii. An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

iii. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

e. The notification specified in D.1211d. shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

f. A specific licensee shall notify the Agency in writing of the possession of a device containing a sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, that has not been used for a period longer than 3 years.

Sec. D.1220 Notification of Failure To Comply or Existence of a Defect and Its Evaluation.

a. Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to--

i. Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(ii) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected;

ii. Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Department through a director or responsible officer or designated person as discussed in Sec. D.1220(d)(v). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply; and

iii. Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in Sec. D.1220(a)(i) or Sec. D.1220(a)(ii) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity--

(1) Fails to comply with COMAR 26.12.01.01 Regulations for the Control of Ionizing Radiation (1994), or any applicable rule, order, or license of the Department relating to a substantial safety hazard, or

(2) Contains a defect.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

Sec. D.1401 General Provisions and Scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under Part C of this regulation, as well as other facilities subject to the Department's jurisdiction. For low-level waste disposal facilities (COMAR 26.13.05 through .10), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities.

(b) The criteria in this subpart do not apply to sites which:

(1) Have been decommissioned prior to the effective date of this regulation in accordance with criteria identified in the Site Decommissioning Management Plan (SDMP) Action Plan of April 16, 1992 (57 FR 13389);

(2) Have previously submitted and received Agency approval on a license termination plan (LTP) or decommissioning plan that is compatible with the SDMP Action Plan criteria; or

(3) Submit a sufficient LTP or decommissioning plan prior to the [effective date of this regulation] and such LTP or decommissioning plan is approved by the Department before March 1, 2001 and in accordance with the criteria identified in the SDMP Action Plan, except that if an EIS is required in the submittal, there will be a provision for day-for-day extension.

(c) After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, the Department will require additional cleanup only if, based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(d) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

Sec. D.1402 Radiological Criteria for Unrestricted Use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

Sec. D.1403 Criteria for License Termination Under Restricted Conditions. A site will be considered acceptable for license termination under restricted conditions if:

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of C.1402 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

(c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are--

(1) Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return on investment;

(2) A statement of intent in the case of Federal, State, or local Government licensees, as described in Sec. C.29(e)(4) of this chapter; or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with Sec.C.32 and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning--

(i) Whether provisions for institutional controls proposed by the licensee --

(a) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;

(b) Will be enforceable; and

(c) Will not impose undue burdens on the local community or other affected parties.

(iii) Inspection and maintenance of equipment;

(4) The requirements of pertinent Agency regulations; and

(5) Case histories of accidents in radiography.

(h) Licensees will have until May 28, 2000 to comply with the additional training requirements specified in paragraphs (b)(1) and (c)(1) of this section.

Sec. E.45 Operating and Emergency Procedures.

(a) Operating and emergency procedures must include, as a minimum, instructions in the following:

(1) Appropriate handling and use of radiation machines, licensed sealed sources and radiographic exposure devices so that no person is likely to be exposed to radiation doses in excess of the limits established in Part D of this chapter "Standards for Protection Against Radiation";

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for controlling access to radiographic areas;

(4) Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

(5) Personnel monitoring and the use of personnel monitoring equipment;

(6) Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the sealed sources during transportation (refer to Part T of these regulations);

(7) The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, transport containers, and storage containers;

(8) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly;

(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by COMAR 26.12.01.01D.1220 of this chapter;

(10) The procedure for notifying proper persons in the event of an accident;

(11) Minimizing exposure of persons in the event of an accident;

(12) Source recovery procedure if licensee will perform source recovery;

(13) Maintenance of records.

(b) The licensee shall maintain copies of current operating and emergency procedures in accordance with Secs. E.81 and E.89.

Sec. E.46 Supervision of Radiographers' Assistants.

Whenever a radiographer's assistant uses radiation machines, radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by Sec. E.49(b) to determine that the sealed source has returned to the shielded position or the radiation machine has turned off after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision must include:

(a) The radiographer's physical presence at the site where the radiation machines or sealed sources are being used;

(b) The availability of the radiographer to give immediate assistance if required; and

(c) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

Sec. E.47 Personnel Monitoring.

(a) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters must have a range from zero to 2 millisieverts (200 millirems) and must be recharged at the start of each shift. Electronic personnel dosimeters may only be used in place of ion-chamber pocket dosimeters.

(2) Each personnel dosimeter must be assigned to and worn by only one individual.

(3) Film badges must be replaced at periods not to exceed one month and other personnel dosimeters that require replacement must be replaced at periods not to exceed ~~one month~~thirty (30) days. All personnel dosimeters ~~must~~shall be evaluated ~~at least monthly~~every thirty (30) days or promptly after replacement, whichever is more frequent. ~~processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed one month.~~

~~(4) After replacement, each personnel dosimeter must be processed as soon as possible.~~

(b) Direct reading dosimeters such as pocket dosimeters or electronic personnel dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with Sec. E.82.

(c) Pocket dosimeters, or electronic personnel dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with Sec. E.82. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket ~~dosimeter~~ chamber is found to be off-scale, or if his or her electronic personnel dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter that requires processing must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use or radiation machines until a determination of the individual's radiation ~~exposure~~dose has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with Sec. E.82.

(e) If the personnel dosimeter that is required by Sec. E.47(a) is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in Sec. E.47(a) is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with Sec. E.82.

(f) Dosimetry ~~reports received from the accredited NVLAP personnel dosimeter processor~~results must be retained in accordance with Sec. E.82.

(g) Each alarm ratemeter must--

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with Sec. E.82(b).

Sec. E.49 Radiation Surveys.

The licensee shall:

(a) Not conduct a radiographic operation unless at least one calibrated and operable radiation survey instrument, as described in Sec. E.25, is available and used by each radiographic person at the site of each exposure.

(b) Survey with a radiation survey instrument after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube. If using a radiation machine, a similar survey shall be performed to determine if the machine has turned off.

(c) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in Sec. E.3), to ensure that the sealed source is in its shielded position.

(d) Maintain records in accordance with Sec. E.85.

Sec. E.51 Surveillance.

During each radiographic operation the radiographer, or the other individual present, as required by Sec. E.41, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part D of this chapter except at permanent radiographic installations where all entryways are locked and the requirements of Sec. E.33 are met.

Sec. E.53 Posting.

All areas in which industrial radiography is being performed must be conspicuously posted as required by Sec. D.902 of this chapter. Exceptions listed in Sec. D.903 of this chapter do not apply to industrial radiographic operations.

Subpart E - Recordkeeping Requirements

Sec. E.61 Records of the Specific License for Industrial Radiography.

Each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license.

~~Sec. E.63 Records of Receipt and Transfer of Sealed Sources.~~

Sec. E.63 Records of Receipt and Transfer of Sealed Sources.

(a) Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using depleted uranium for shielding and retain each record for 3 years after it is made.

(b) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for depleted uranium), and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

Sec. E.65 Records of Radiation Survey Instruments.

Each licensee shall maintain records of the calibrations of its radiation survey instruments that are required under Sec. E.25 and retain each record for 3 years after it is made.

Sec. E.67 Records of Leak Testing of Sealed Sources and Devices Containing Depleted Uranium.

Each licensee shall maintain records of leak test results for sealed sources and for devices containing depleted uranium. The results must be stated in units of becquerels (microcuries). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

Sec. E.69 Records of Quarterly Inventory.

(a) Each licensee shall maintain records of the quarterly inventory of sealed sources and of devices containing depleted uranium as required by Sec. E.29 and retain each record for 3 years after it is made.

(b) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sealed source and/or devices, and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

Sec. E.71 Utilization Logs.

(a) Each licensee shall maintain utilization logs showing for each radiation machine or sealed source the following information:

(1) A description, including the make, model, and serial number of the radiation machine, radiographic exposure device or transport or storage container in which the sealed source is located;

(2) The identity and signature of the radiographer to whom assigned; and

(3) The plant or site where used and dates of use, including the dates removed and returned to storage.

(b) The licensee shall retain the logs required by paragraph (a) of this section for 3 years after the log is made.

Sec. E.73 Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) Each licensee shall maintain records specified in Sec. E.31 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

(b) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

Sec. E.75 Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations.

Each licensee shall maintain records of alarm system and entrance control device tests required under Sec. E.33 and retain each record for 3 years after it is made.

Sec. E.79 Records of Training and Certification.

Each licensee shall maintain the following records (of training and certification) for 3 years after the record is made:

(a) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

(b) Records of annual refresher safety training and quarterly inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliances observed by the Radiation Safety Officer.

Sec. E.81 Copies of Operating and Emergency Procedures.

Each licensee shall maintain a copy of current operating and emergency procedures until the Department terminates the license. Superseded material must be retained for 3 years after the change is made.

~~Each licensee shall maintain a copy of current operating and emergency procedures until the Department terminates the license. Superseded material must be retained for 3 years after the change is made.~~

Sec. E.82 Records of Personnel Monitoring Procedures.

Each licensee shall maintain the following exposure records specified in Sec. E.47:

(a) Direct reading dosimeter readings and yearly operability checks required by Sec. E.47(b) and (c) for 3 years after the record is made.

(b) Records of alarm ratemeter calibrations for 3 years after the record is made.

(c) Personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the Department terminates the license.

(d) Records of estimates of exposures as a result of: off-scale personnel direct reading dosimeters, or lost or damaged personnel dosimeters, until the Department terminates the license.

Sec. E.85 Records of Radiation Surveys.

Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in Sec. E.49(c), if that survey is the last one performed in the workday. Each record must be maintained for 3 years after it is made.

Sec. E.87 Form of Records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Sec. E.89 Location of Documents and Records.

(a) Each licensee or registrant subject to Part E shall maintain copies of records required by this part and other applicable parts of this chapter at the location specified in the person's license or registration.

(b) Each licensee or registrant subject to Part E shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary job site:

(1) The license or registration authorizing the use of sources of radiation;

(2) A copy of COMAR 26.12.01.01 Regulations for Control of Ionizing Radiation (1994);

(3) Utilization records for each radiation machine or radiographic exposure device dispatched from that location as required by Sec. E.71;

(4) Records of equipment problems identified in daily checks of equipment as required by Sec. E.73(a);

(5) Records of alarm system and entrance control checks required by Sec. E.75, if applicable;

(6) Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeter readings as required by Sec. E.82;

(7) Operating and emergency procedures required by Sec. E.81;

(8) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by Sec. E.65;

(9) Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by Sec. E.82;

(10) Latest survey records required by Sec. E.85;

(11) The shipping papers for the transportation of radioactive materials required by Sec. T.5 of this chapter; and

(12) When operating under reciprocity pursuant to Sec. C.90, a copy of the NRC or Agreement State license authorizing the use of licensed materials.

Subpart F - Notifications

Sec. E.101 Notifications.

(a) In addition to the reporting requirements specified in Sec. D.1201 through D.1206, D.1211, and D.1220 of these regulations, each licensee or registrant shall immediately notify the Department and shall provide a written report to the Maryland Department of the Environment, Radiological Health Program, 1800 Washington Boulevard,

“Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" (See "Computed tomography").

“Cumulative air kerma” means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

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

“Dental tomographic x-ray unit” means any unit or system used for taking tomograms of parabolically curved objects such as the dentition, jawbones and other bony structures of the head and dento-facial region. Systems may include the capability and software for 3-D imaging.

"Detector" (See "Radiation detector").

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

“Electronic brachytherapy” means a method of radiation therapy using electrically-generated x-rays to deliver a radiation dose at a distance of up to a few centimeters by intracavitary, intraluminal, or interstitial application, or by applications with the source in contact with the body surface or very close to the body surface.

“Electronic brachytherapy device” means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

“Electronic brachytherapy source” means the x-ray tube component used in an electronic brachytherapy device.

"Entrance exposure rate" means the exposure per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (See "X-ray equipment")

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to absorb preferentially selected radiations.

“Fluoroscopic air kerma display device” means a device, subsystem, or component that provides the display of AKR and cumulative air kerma. It includes radiation detectors, if any, and electronic and computer components, and associated software and data displays.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

“Fluoroscopic irradiation time” means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

“Fluoroscopy” means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

"Focal spot" means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

"General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate, or AKR, is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

"HVL" (See "Half-value layer")

“High energy facility” means a facility with equipment utilizing energies in excess of 150 keV.

"Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

"Image receptor" means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term “image receptor” shall mean the preselected portion of the device.

"Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor in a plane perpendicular to the beam during a mammographic examination and to provide a primary protective barrier.

“Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Irradiation" means the exposure of matter to ionizing radiation.

“Isocenter” means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

“Kerma” means the quantity as defined by the International Commission of Radiation Units and Measurements. The kerma, K, is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus
$K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as “air kerma”.

“~~Kilovolt (kV) [~~Kilo electron volt (keV)~~]~~” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. ~~Note: current convention is to use kV for photons and keV for electrons.~~

"Kilovolts peak" (See "Peak tube potential")

"kV" means kilovolts.

"kVp" (See "Peak tube potential")

"kWs" means kilowatt second. It is equivalent to 10^3 (kV)(mA)(s)~~., i.e.,~~

~~kWs = (kV)(mA)(s)~~ $\left(\frac{kWs}{(10^3)(mA)(s)}\right) = \frac{kWs}{10^3}$

“Last image hold (LIH) radiograph” means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

“Lateral fluoroscope” means the X-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

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

"Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

(1) the useful beam, and

(2) radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

(l) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(3) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"Linear attenuation coefficient" or "μ" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100\ (V_n-V_l)/V_l$

where:

V_n = No-load line potential, and
V_l = Load line potential.

"mA" means milliampere.

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

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

(~~iii~~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.

(~~iv~~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.

(j) Requirements for Patient Safety.

Thyroid shielding consisting of a ≥0.5 mm lead equivalent thyroid collar or shield shall be provided to and used for all patients, so long as such shielding does not interfere with diagnostic x-ray procedures.

Sec. F.8 Therapeutic X-Ray Systems of Less Than One MeV Including Electronic Brachytherapy Systems.

(a) Equipment Requirements.

(1) Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system.

(i) Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 μC/kg) per hour at 5 centimeters from the surface of the tube housing assembly.

(ii) 0-150 kVp Systems. Systems which were manufactured or installed prior to December 6, l982 shall have a leakage radiation which does not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source.

(iii) 0-150 kVp Systems. Systems which are manufactured on or after December 6, l982 shall have a leakage radiation which does not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour at 1 meter from the source.

(iv) 151 to 999 kVp Systems. The leakage radiation shall not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam 1 meter from the source.

(2) Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

(3) Removable and Adjustable Beam Limiting Devices.

(i) Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

(ii) Adjustable beam limiting devices installed after December 6, l982 shall meet the requirements of F.8(a)(3)(i).

(iii) Adjustable beam limiting devices installed before December 6, l982 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

(4) Filter System. The filter system shall be so designed that:

(i) the filters cannot be accidentally displaced at any possible tube orientation;

(ii) the radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions; and

(iii) each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

(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) Shielding and Safety Design Requirements. Shielding and safety design must be adequate to meet the following requirements:

(i) Each therapeutic radiation machine shall be provided with such shielding barriers as are necessary to assure compliance with Part D of these regulations.

(ii) Facility design information including shielding specifications for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine into a room not previously approved for a radiation machine of that energy shall be submitted for Agency approval prior to actual installation of the therapeutic radiation machine.

(4) Facility Design Requirements for Electronic Brachytherapy Devices. In addition to shielding adequate to meet requirements of F.8(b)(3), the treatment room shall meet the following design requirements:

(i) If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.

(ii) Access to the treatment room shall be controlled to prevent the presence of unauthorized parties during treatment.

~~(3)~~(5) 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.

(~~b~~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 within the preceding 12 months.

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(~~ii~~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.

(~~ii~~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.

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

(~~iv~~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.

(d) Training for Therapeutic Radiation Machine Authorized Providers. The registrant for any therapeutic radiation machine subject to F.8 shall require the authorized provider to be a physician who:

(1) Is certified in:

(i) Radiation oncology or therapeutic radiology by the American Board of Radiology, or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or

(ii) Radiation oncology by the American Osteopathic Board of Radiology; or

(iii) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology;" or

(iv) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

(i) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of ionizing radiation; and

(d) Radiation biology.

(ii) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized provider and shall include:

(a) Review of the full calibration measurements and periodic quality assurance checks;

(b) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;

(c) Using administrative controls to prevent misadministrations;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(e) Checking and using radiation survey meters.

(iii) To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized provider. The supervised clinical experience shall include:

(a) Examination of patients including the review of their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(b) Selecting proper dose and how it is to be administered;

(c) Calculating ~~the~~ therapeutic radiation machine doses and collaborating with the authorized provider in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and

(d) Post-administration follow-up and review of case histories.

(3) Notwithstanding the requirements of F.8(d)(i) and F.8(d)(ii), the registrant for any therapeutic radiation machine subject to F.8 may also submit the training of the prospective authorized provider physician for Agency review on a case-by-case basis.

(e) Qualifications and Training of Operators.

(1) Individuals who operate a therapeutic radiation machine in Maryland shall be licensed or certified by the Maryland Department of Health to energize a radiation machine. Operation of a therapeutic radiation machine shall be by, or in accordance with, a specific order by~~,~~ a physician who is a licensed practitioner of the healing arts.

(2) Individuals, including physicians, who will be operating the x-ray systems shall recieve adequate instruction in order to competently and safely operate the equipment. A registrant must demonstrate that a radiation therapist employed by the registrant is adequately trained and competent to use a radiation machine as required under COMAR 10.32.10.05-1~~,~~ and must conspicuously display the therapist's certificate.

(3) The names and 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.

(f) Procedures for Administrations. The registrant shall develop, implement, and maintain written procedures for administrations to ensure the following are met:

(1) Prior to the administration of each course of radiation treatments, the patient's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives. This is verified by:

(i) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and

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

(4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

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.

(~~1~~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.

(~~ag~~) 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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(d) Chemistry of radioactive material for medical use;

(e) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in G.57, G.290, or G.290(c)(1)(ii)(g) and G.390, or equivalent Agreement State or NRC requirements. An authorized nuclear pharmacist who meets the requirements in G.55 or G.57 may provide the supervised work experience for G.290 (c)(1)(ii)(g). Work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(f) Administering dosages of radioactive drugs to patients or human research subjects; and

(g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.290(c)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under G.100 and G.200. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G..57, G..290, or G..390 and G..290(c)(1)(ii)(-g), or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements; or

ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in .G.57, G.290, or G.390 and G.290(c)(1)(ii)(g), or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.290(c)(1).

Secs. G.291 – G.299 Reserved.

Unsealed Radioactive Material—Written Directive Required

Sec. G.300 Use of Unsealed Radioactive Material for Which a Written Directive is Required.

A licensee may use any unsealed byproduct material identified in G.390(b)(1)(ii)(g) prepared for medical use and for which a written directive is required that is:

(a) Obtained from a manufacturer or preparer licensed under Sec. C.28(j) or equivalent NRC requirements or Agreement State requirements; or

(b) Prepared by a PET radioactive drug producer licensed under Section C.26(g) or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements; or

(c) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and who meets the requirements specified in G.290, G.390; or an individual under the supervision of either as specified in G.27. The authorization given in G.300(c) to obtain unsealed byproduct material excludes the production of PET radionuclides; or

(d) Obtained from and prepared by an Agreement State or NRC licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(e) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

Secs. G.301 – G.309 Reserved.

Sec. G.310 Safety Instruction.

In addition to the requirements of Sec. J.12:

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including:

(i) Routine visitation to hospitalized individuals in accordance with Sec. D.301(a)(1); and

(ii) Visitation authorized in accordance with Sec. D.301(d);

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with G.2310.

Secs. G.311 – G.314 Reserved.

Sec. G.315 Safety Precautions.

(a) For each patient or human research subject who cannot be released under G.75, a licensee shall:

(1) Quarter the patient or the human research subject either in:

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under G.75;

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the materials and items as radioactive waste;

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Secs. G.316 – G.389 Reserved.

Sec. G.390 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.

Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.300 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.390(b)(1)(ii)(g) and G.390(b)(2). The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in G.390(b)(1)(i) through G.390(b)(1)(ii)(e). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Post-Graduate Training~~ Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(b) (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(i) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Chemistry of radioactive material for medical use; and

(e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements. A supervising authorized user who meets the requirements in G.390(b) must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(*1*) or (*2*). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.392(c)(1) and G.392(c)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under G.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.35.G.57, G.390, G.392, G.394, or equivalent NRC requirements or ~~equivalent~~ Agreement State requirements and has experience in administering dosages as specified in G.390(b)(1)(ii)(g)(1) or .390(b)(1)(ii)(g)(2); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.390, G.392, G.394, or equivalent NRC requirements or ~~equivalent~~ Agreement State requirements, has experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.392(c)(1) and G.392(c)(2)..

Sec. G.393 Reserved.

Sec. G.394 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 1.22 Gigabecquerels (33 millicuries).

Except as provided in G.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in G.394(c)(1) and G.394(c)(2), and whose certification has been recognized by the NRC or an Agreement State. The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit web page); or

Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(2) or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements; or

(b) (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in G.57, G.390, G.394, or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements. A supervising authorized user, who meets the requirements in G.390(b), must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

Secs. G.416 – G.431 Reserved.

Sec. G.432 Calibration Measurements of Brachytherapy Sources.

(a) Before the first medical use of a brachytherapy source on or after the effective date of these regulations, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of G.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of G.432(a)(1) and G.432(a)(2).

(b) Instead of a licensee making its own measurements as required in G.432(a), the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with G.432(a).

(c) A licensee shall mathematically correct the outputs or activities determined in G.432(a) for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with G.2432.

Sec. G.433 Decay of Strontium-90 Sources for Ophthalmic Treatments.

(a) Licensees who use Strontium-90 for ophthalmic treatments must ensure that certain activities as specified in G.433(b) are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the NRC or an Agreement State; permit issued by the NRC or Agreement State broad scope medical use licensee; medical use permit issued by an NRC master material licensee; or permit issued by an NRC master material broad scope medical use permitee; and

(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) has documented training in:

(a) the creation, modification, and completion of written directives;

(b) ~~(b)~~ procedures for administrations requiring a written directive;

(c) performing the calibration measurements of brachytherapy sources as detailed in G.432

~~(c) performing the calibration measurements of brachytherapy sources as detailed in G.432~~.

(b) The individuals who are identified in paragraph (a) of this section must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § G.432; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(c) A licensee shall retain a record of the activity of each strontium-90 source in accordance with G.2433.

Secs. G.434 – G.456 Reserved.

Sec. G.457 Therapy-related Computer Systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

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(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

Secs. G.458 – G.489 Reserved.

Sec. G.490 Training for Use of Manual Brachytherapy Sources.

Except as provided in G.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under G.400 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Use Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate Training~~ Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b) (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.490 or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements at a medical institution authorized to use radioactive materials under G.400, involving:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing brachytherapy sources;

(d) Maintaining running inventories of material on hand;

(e) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(f) Using emergency procedures to control radioactive material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.57, G.490 or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.490(b)(1)(ii); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.490(b)(1) and (b)(2) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under G.400. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in ~~§§~~ Sections G.57, G.490, or equivalent NRC requirements or Agreement State requirements, or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in ~~§§~~ Sections G.57, G.490, or equivalent NRC requirements or Agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in ~~§§~~ Sections G.490(b)(1) and G.490(b)(2).

Sec. G.491 Training for Ophthalmic Use of Strontium-90.

Except as provided in G.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(a) Is an authorized user under G.490 or equivalent NRC requirements or Agreement State requirements; or

(b) (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ G.57, G.490, G.491, or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements, that the individual has satisfactorily completed the requirements in § G.491(b) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Secs. G.492 – G.499 Reserved.

Sealed Sources for Diagnosis

Sec. G.500 Use of Sealed Sources for Diagnosis.

(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of G.49(a) are met.

Secs. G.501 – G.589 Reserved.

Sec. G.590 Training for Use of Sealed Sources for Diagnosis.

Except as provided in G.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.500 to be a physician, dentist, or podiatrist who:

Sec. G.652 Radiation Surveys.

(a) In addition to the survey requirement in Sec. D.501, a person licensed under this part shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by G.652(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by G.652(a) in accordance with G.2652.

Secs. G.653 – G.654 Reserved.

Sec. G.655 Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inpsection servicsing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

(b) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Agency, an Agreement State, or the U.S. Nuclear Regulatory Commission.

(c) A licensee shall keep a record of the inspection and servicing in accordance with G.2655.

Sec. G.656 Reserved.

Sec. G.657 Therapy-Related Computer Systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Secs. G.658 – G.689 Reserved.

Sec. G.690 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

Except as provided in G.57, the licensee shall require an authorized user of a sealed source for a use authorized under G.600 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.690(c). The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate Training~~Council on Postdoctoral Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b) (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.57, G.690, or equivalent NRC requirements or ~~equivalent~~ Agreement State requirements, at a medical facility that is authorized to use radioactive materials in G.600, involving:

(a) Reviewing full calibration measurements and periodic spot-checks;

(b) Preparing treatment plans and calculating treatment doses and times;

(c) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(e) Checking and using survey meters; and

(f) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in G.57, G.690, or equivalent NRC requirements or ~~equivalent~~ Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.690(b)(1)(ii); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.690(b)(1) G.690(b)(2), and G.690(c), and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in G.57, G.690, or equivalent NRC requirements or ~~equivalent~~ Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status ; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in G.57, G.690, or equivalent NRC requirements or Agreement State ~~or NRC~~ requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in G.690(b)(1) and G.690(b)(2).

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Secs. G.691 – G.999 Reserved.

Other Medical Uses of Radioactive Material or Radiation From Radioactive Material

Sec. G.1000 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material.

A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in G.100 through G.690 if:

(a) The applicant or licensee has submitted the information required by G.12(a)(2) through G.12(b); and

(b) The applicant or licensee has received written approval from the Agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the material.

Secs. G.1001 – G.2023 Reserved.

Records

Sec. G.2024 Records of Authority and Responsibilities for Radiation Protection Programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with G.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by G.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by G.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

(c) For each Associate Radiation Safety Officer appointed under G.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

Secs. G.2025 – G.2039 Reserved.

Sec. G.2040 Records of Written Directives.

A licensee shall retain a copy of each written directive as required by G.40 for 3 years.

Sec. G.2041 Records for Procedures for Administrations Requiring a Written Directive.

A licensee shall retain a copy of the procedures required by G.41(a) for the duration of the license.

(b) A licensee shall retain the record of each survey required by G.80(a)(~~6~~8) for three (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-99 per millicurie of technetium-99m), 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 operational and safety instructions required by 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.

(c) Procedures for submitting advance notification.

(1) The notification must be made in writing to:

(i) The office of each appropriate governor or governor's designee;

(ii) The office of each appropriate Tribal official or Tribal official's designee; and

(iii) The Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

(2) A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

(ii) Contact information for each State, including telephone and mailing addresses of governors and governor's designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC Web site at: https://scp.nrc.gov/special/designee.pdf.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, ~~Division of Material Safety, State, Tribal, and Rulemaking Programs~~ Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for 3 years.

(d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(2) A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) The 7-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(6) A point of contact, with a telephone number, for current shipment information.

(c) Revision notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee or to a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for 3 years.

(d) Cancellation notice.

(1) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and the Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

(2) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for 3 years.

Secs. T.98 – T.100 Reserved.

QUALITY ASSURANCE

Sec. T.101 Quality Assurance Requirements.

(a) Purpose. Secs. T.101 through T.137 describe quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this these sections, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to these sections.

(b) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Secs. T.101 through T.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

Table A-1—A_1 and A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-10}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$

Table A-1—A_1 and A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$

b. General Performance Objective. The licensee's access authorization program must ensure that the individuals specified in V.21(c)(i) are trustworthy and reliable.

c. Applicability.

i. Licensees shall subject the following individuals to an access authorization program in accordance with V.23:

(1) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(2) Reviewing officials.

ii. Licensees need not subject the categories of individuals listed in Subsections V.29(a)(i) – (xiii) to the investigation elements of the access authorization program.

iii. Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

iv. Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under Sections V21 – V33.

Sec. V.22 [Reserved].

Sec. V.23 Access Authorization Program Requirements.

a. Granting Unescorted Access Authorization.

i. Licensees shall implement the requirements of Sections V.21 – V.33 for granting initial or reinstated unescorted access authorization.

ii. Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by V.43(c) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

b. Reviewing Officials.

i. Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

ii. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the address listed in ~~§~~Section A.12. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with Section V.25(c).

iii. Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

iv. Reviewing officials cannot approve other individuals to act as reviewing officials.

v. A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(1) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(2) The individual is subject to a category listed in Section V.29(a).

c. Informed Consent.

i. Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of Section V.25(b). A signed consent must be obtained prior to any reinvestigation.

ii. The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(1) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(2) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

Sec. V.27 Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material.

a. General Performance Objective and Requirements.

i. Except for those individuals listed in Section V.29 and those individuals grandfathered under Section V.25(b), each licensee subject to the provisions of this Part shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as Part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

ii. The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

iii. Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

(1) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(2) The previous access was terminated under favorable conditions.

iv. Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this Part, the Fingerprint Orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of V.31(c).

v. Licensees shall use the information obtained as Part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. Prohibitions.

i. Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(1) An arrest more than 1 year old for which there is no information of the disposition of the case; or

(2) An arrest that resulted in dismissal of the charge or an acquittal.

ii. Licensees may not use information received from a criminal history records check obtained under this Part in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. Procedures for Processing of Fingerprint Checks.

i. For the purposes of complying with this Part, licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail~~Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail~~ Stop T-~~03B46M~~07D04M~~8B20~~, Rockville, Maryland 20852~~-2738~~, one completed, legible standard fingerprint card (Form FD–258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by calling 1-630-829-9565, or by e-mail to~~ **Error! Hyperlink reference not valid.**emailing MAILSVS.Resource@nrc.gov. –Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/~~site-help/e-submittals~~security/chp.html.

ii. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to ''U.S. NRC.'' (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at 301–415–7513.~~Division of Physical and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov). Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the ~~Electronic Submittals~~Licensee Criminal History Records Checks & Firearms Background Check information page at http://www.nrc.gov/security/chp.html~~site-help/e-submittals.html~~ and see the link for ~~the~~ How do I determine how much to pay for the request?~~Criminal History Program under Electronic Submission Systems.~~).

iii. The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

Sec. V.28 [Reserved].

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Supp. 32~~28~~

(2) Identify the security resources, equipment, and technology used to satisfy the requirements of this Part.

ii. The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

iii. A licensee shall revise its security plan as necessary to ensure the effective implementation of Agency requirements. The licensee shall ensure that:

(1) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(2) The affected individuals are instructed on the revised plan before the changes are implemented.

iv. The licensee shall retain a copy of the current security plan as a record for 3 years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

b. Implementing Procedures.

i. The licensee shall develop and maintain written procedures that document how the requirements of this Part and the security plan will be met.

ii. The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

iii. The licensee shall retain a copy of the current procedure as a record for 3 years after the procedure is no longer needed. Superseded portions of the procedure must be retained for 3 years after the record is superseded.

c. Training.

i. Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

(1) The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

(2) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Agency requirements;

(3) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

(4) The appropriate response to security alarms.

ii. In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

iii. Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(1) Review of the training requirements of paragraph (c) of this section and any changes made to the security program since the last training;

(2) Reports on any relevant security issues, problems, and lessons learned;

(3) Relevant results of Agency inspections; and

(4) Relevant results of the licensee's program review and testing and maintenance.

iv. The licensee shall maintain records of the initial and refresher training for 3 years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. Protection of Information.

i. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

ii. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, and implementing procedures, and the list of individuals who have been approved for unescorted access.

iii. Before granting an individual access to the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access, licensees shall:

(1) Evaluate an individual's need to know the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access; and

(2) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in V.25(a)(ii) through (a)(vii).

iv. Licensees need not subject the following individuals to the background investigation elements for protection of information:

(1) The categories of individuals listed in V.29(a)(i) through (a)(xiii); or

(2) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in V.25(a)(ii) though (a)(vii), has been provided by the security service provider.

v. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan ,~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access.

vi. Licensees shall maintain a list of persons currently approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access.

vii. When not in use, the licensee shall store its security plan, ~~and~~ implementing procedures, and the list of individuals who have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

viii. The licensee shall retain as a record for 3 years after the document is no longer needed:

(1) A copy of the information protection procedures; and

(2) The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access.

Sec. V.44 [Reserved].

Sec. V.45 LLEA Coordination.

a. A licensee subject to this Part shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

i. A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this Part; and

ii. A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

b. The licensee shall notify the Agency listed in § A.12 within 3 business days if:

i. The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

ii. The LLEA notifies the licensee that the LLEA does not plan to Participate in coordination activities.

c. The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for 3 years.

d. The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

Sec. V.46 [Reserved].

Sec. V.47 Security Zones.

a. Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

(c) The licensee or registrant shall maintain employee training records for inspection by the Agency for 2 years following termination of the individual's employment.

Sec. W.202 Operating and Emergency Procedures. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Part D of these regulations;

(b) methods and occasions for conducting radiation surveys;

(c) methods and occasions for locking and securing sources of radiation;

(d) personnel monitoring and the use of personnel monitoring equipment;

(e) transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

(f) minimizing exposure of individuals in the event of an accident;

(g) maintenance of records;

(h) use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(i) procedure to be followed in the event a sealed source is lodged downhole;

(j) procedures to be used for picking up, receiving, and opening packages containing radioactive material;

(k) for the use of tracers, decontamination of the environment, equipment, and personnel;

(l) maintenance of records generated by logging personnel at temporary jobsites;

(m) notifying proper persons in the event of an accident; and

(n) actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by W.104.

Sec. W.203 Personnel Monitoring.

(a) No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ at all times during the handling of licensed radioactive materials. ~~Each~~ personnel dosimeter shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. ~~After replacement, each personnel dosimeter must be promptly processed~~All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

(b) The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

(c) The licensee shall retain records of personnel dosimeters required by Sec. W.203(a) and bioassay results for inspection until the Agency authorizes disposition of the records.

Precautionary Procedures in Logging and Subsurface Tracer Studies

Sec. W.301 Security. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in Part A of these regulations.

Sec. W.302 Handling Tools. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

Sec. W.303 Subsurface Tracer Studies.

(a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

(b) No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the Agency.

Sec. W.304 Particle Accelerators. No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of D.201 and D.301 of these regulations, as applicable, are met.

Sec. W.305 Uranium Sinker Bars. The licensee may use a uranium sinker bar in well logging applications only if it is legibly impressed with the words "CAUTION – RADIOACTIVE-DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

Sec. W.306 Energy Compensation Source

The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 3.7 MBq [100 microcuries].

(a) For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of Sections W.105, W.106 and W.107.

(b) For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of Sections C.26(d), W.105, W.106, W.107, and W.501.

Sec. W.307 Tritium Neutron Generator Target Source.

(a) Use of a tritium neutron generator target source, containing quantities not exceeding 1,110 MBq [30 curies] and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this part except Sections C.26(d), W.108, and W.501.

(b) Use of a tritium neutron generator target source, containing quantities exceeding 1,110 MBq [30 curies] or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this part except Section W.108.

Radiation Surveys and Records

Sec. W.401 Radiation Surveys.

(a) Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.

(b) Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

(c) If the sealed source assembly is removed from the logging tool before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

as appropriate for the geographical location of the facility; and

(10) The jamming of automatic conveyor systems.

Sec. X.55 Personnel Monitoring.

(a) Irradiator operators shall wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter ~~processor~~ must be ~~accredited by NVLAP~~capable of detecting ~~for~~ high energy photons in the normal and accident dose ranges. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be ~~processed~~ replaced at least monthly, and other personnel dosimeters that require replacement must be ~~processed~~ replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, all persons who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

Sec. X.57 Radiation Surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) If the radiation levels specified in Section X.25 are exceeded, the facility must be modified to comply with the requirements in Section X.25.

(c) Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(d) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Part D, Table 2, Column 2 or Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

(e) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.0005 millisievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.0005 millisievert (0.05 millirem) per hour.

Sec. X.59 Detection of Leaking Sources.

(a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Agency, Agreement State or NRC. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Agency, Agreement State or NRC to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as possible, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an Agreement State or NRC licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an Agreement State or NRC licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B of Part D.

Sec. X.61 Inspection and Maintenance.

(a) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(1) Operability of each aspect of the access control system required by Section X.23;

(2) Functioning of the source position indicator required by Section X.31(b);

(3) Operability of the radiation monitor for radioactive contamination in pool water required by Section X.59(b) using a radiation check source, if applicable;

(4) Operability of the over-pool radiation monitor at underwater irradiators as required by Section X.29(b);

(5) Operability of the product exit monitor required by Section X.29(a);