120.440: continued

III. THERAPEUTIC RADIATION MACHINES OVER 150 kV

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and/or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [*ie*: photon, electron]. The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at one meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = one foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [*ie*: room may be designed for six MV unit although only a four MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [*ie*: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. NEUTRON SHIELDING

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above ten MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [*ie*: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility.

120.440: continued

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. REFERENCES

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

120.500: USE OF RADIONUCLIDES IN THE HEALING ARTS

GENERAL INFORMATION

120.501: Purpose and Scope

105 CMR 120.500 establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of 105 CMR 120.500 are in addition to, and not in substitution for, others in 105 CMR 120.000. The requirements and provisions of 105 CMR 120.000 apply to applicants and licensees subject to 105 CMR 120.500 unless specifically exempted. (*See* exemption in 105 CMR 120.104(C)(5)).

120.502: Definitions

As used in 105 CMR 120.500, the following definitions apply:

Address of Use means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

Area of Use means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

Authorized Medical Physicist means an individual who:

(1) Meets the requirements in 105 CMR 120.525(A) and 120.529; or

(2) Is identified as a medical physicist or teletherapy physicist on:

(a) A specific medical use license or equivalent permit issued by the Agency, Nuclear Regulatory Commission or Agreement State;

(b) A permit issued by the Agency, Nuclear Regulatory Commission or Agreement State medical use license of broad scope that is authorized to permit the use of radioactive material;

(c) A medical use permit issued by a NRC master material licensee; or

(d) A permit issued by a NRC master material license broad scope medical use permittee.

Authorized Nuclear Pharmacist means a pharmacist as defined in 105 CMR 120.005 who:

(1) Meets the requirements in 105 CMR 120.526(A) and 120.529; or

120.502: continued

(2) Is identified as an authorized nuclear pharmacist on:
(a) A specific license issued by NRC or Agreement State that authorizes medical use or the practice of nuclear pharmacy;
(b) A permit issued by a NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
(c) A permit issued by a NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
(d) A permit issued by a NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
(4) Is designated as an authorized nuclear pharmacist in accordance with 105 CMR 120.128(J)(2)(d).

Authorized User means a physician, dentist, or podiatrist who:
(1) Meets the requirements in 105 CMR 120.529 and 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), 120.569(A), or 120.587(A); or
(2) Identified as an authorized user on:
(a) A NRC or Agreement State license that authorizes the medical use of byproduct material;
(b) A permit issued by a NRC master material licensee that is authorized to permit the medical use of byproduct material;
(c) A permit issued by a NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or
(d) A permit issued by a NRC master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Brachytherapy means a method of radiation therapy in which sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

Brachytherapy Source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's Address means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with 105 CMR 120.541.

Dedicated Check Source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

Dentist means an individual licensed by the Commonwealth to practice dentistry.

Diagnostic Clinical Procedures Manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical p rocedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

High Dose-rate Remote Afterloader (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

Low Dose-rate Remote Afterloader (LDR) means a device that remotely delivers a dose rate of less than or equal to two gray (200 rads) per hour at the treatment site.

Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

120.502: continued

Manual Brachytherapy means a type of therapy in which brachytherapy sources are manually applied or inserted.

Medical Institution means an organization in which several medical disciplines are practiced.

Medical Use means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

Medium Dose-rate Remote Afterloader (MDR) means a device that remotely delivers a dose rate of greater than two gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

Mobile Medical Service means the transportation of radioactive material and its medical use at the client's address.

Output means the Exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient Intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Preceptor means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Prescribed Dosage means the quantity of a radiopharmaceutical activity as documented:

(1) In a written directive as specified in 105 CMR 120.521; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to 105 CMR 120.544, 120.547 and 120.552.

Prescribed Dose means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(3) For manual brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed Dose-rate Remote Afterloader (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who:

(1) Meets the requirements in 105 CMR 120.524(A) or (C)(1) and 120.529; or

(2) Is identified as a Radiation Safety Officer on:

(a) A specific medical use license issued by NRC or Agreement State; or

(b) A medical use permit issued by NRC master material license.

Sealed Source means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

120.502: continued

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both Nuclear Regulatory Commission and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic Radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a tissue volume.

Structured Educational Program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy as used in 105 CMR 120.500, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary Jobsite means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic Dosage means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic Dose means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

Treatment Site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of Use means use of radioactive material as specified under 105 CMR 120.544, 120.547, 120.552, 120.559, 120.569, 120.570 or 120.589.

Unit Dosage means a dosage that:

(1) Is obtained or prepared in accordance with 105 CMR 120.544, 120.547, 120.552; and,
(2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Visiting Authorized User means an authorized user who is not identified on the license of the licensee being visited.

Written Directive means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 105 CMR 120.521.

120.503: Maintenance of Records

Each record required by 105 CMR 120.500 must be legible throughout the retention period specified by each Agency regulation. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing 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.

120.504: Provisions for Research Involving Human Subjects

A licensee may conduct research involving human subjects using radioactive material provided:

120.504: continued

(A) That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(B) The research involving human subjects authorized in 105 CMR 120.504(A) shall be conducted using radioactive material authorized for medical use in the license; and

(C) Nothing in 105 CMR 120.504 relieves licensees from complying with the other requirements in 105 CMR 120.500.

(D) FDA, Other Federal, and State Requirements. Nothing in 105 CMR 120.500 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

120.505: Implementation

(A) A licensee shall implement the provisions in 105 CMR 120.500 on October 6, 2006.

(B) When a requirement in 105 CMR 120.500 differs from the requirement in an existing license condition, the requirement in 105 CMR 120.500 shall govern.

(C) Any existing license condition that is not affected by a requirement in 105 CMR 120.500 remains in effect until there is a license amendment or license renewal.

(D) If a license condition exempted a licensee from a provision of 105 CMR 120.500 on October 6, 2006, it will continue to exempt a licensee from the corresponding provision in 105 CMR 120.500.

(E) If a license condition cites provisions in 105 CMR 120.500 that will be deleted on October 6, 2006, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(F) Licensees shall continue to comply with any license condition that requires it to implement procedures required by 105 CMR 120.573, 120.579, 120.580 and 120.581 until there is a license amendment or renewal that modifies the license condition.

120.506: License Required

(A) A person shall only manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in 105 CMR 120.506(B)(1) or (2)

(B) (1) Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with 105 CMR 120.500 under the supervision of an authorized user as provided in 105 CMR 120.519.
(2) Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with 105 CMR 120.500 under the supervision of an authorized nuclear pharmacist or an authorized user as provided in 105 CMR 120.519.

120.507: Application for License, Amendments, or Renewal

(A) An application must be signed by the applicant's or licensee's management.

(B) An application for a license for medical use of radioactive material as described in 105 CMR 120.544, 120.547, 120.552, 120.559, 120.568, 120.570 or 120.589 must be made by:

120.507: continued

(1) Filing an original and one copy of Agency application form MRCP 120.100- 4 that includes the facility diagram, equipment, and training, experience and qualifications of the Radiation safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s), and

(2) Submitting procedures required by 105 CMR 120.522, 120.531, 120.573, 120.579, 120.580 and 120.581, as applicable.

(C) A request for a license amendment or renewal must be made by:

(1) Submitting an original and one copy of either:

(a) Agency form MRCP 120.100- 4; or

(b) a letter requesting the amendment or renewal; and

(2) Submitting procedures required by 105 CMR 120.522, 120.531, 120.573, 120.579, 120.580 and 120.581, as applicable.

(D) In addition to the requirements in 105 CMR 120.507(B) and (C), an application for a license or amendment for medical use of radioactive material as described in 105 CMR 120.589 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 105 CMR 120.501 through 120.543, as well as any specific information on:

(1) Radiation safety precautions and instructions;

(2) Training and experience of proposed users;

(3) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(4) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(E) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

(F) An applicant that satisfies the requirements specified in 105 CMR 120.127(B) may apply for a Type A specific license of broad scope.

120.508: License Amendments

A licensee shall apply for and must receive a license amendment:

(A) Before it receives, prepares or uses radioactive material for a type of use that is permitted under 105 CMR 120.500, but that is not authorized on the licensee's current license issued pursuant to 105 CMR 120.500;

(B) Before permitting anyone, except a visiting authorized user, a visiting authorized medical physicist or visiting authorized nuclear pharmacist described in 105 CMR 120.511, to work as an authorized user, authorized medical physicist or an authorized nuclear pharmacist, respectively, under the license except an individual who is:

(1) for an authorized user, an individual who meets the requirements in 105 CMR 120.529 and 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), 120.569, 120.569(A), or 120.587(A);

(2) for an authorized nuclear pharmacist, an individual who meets the requirements in 105 CMR 120.526(A) and 120.529;

(3) for an authorized medical physicist, an individual who meets the requirements in 105 CMR 120.525(A) and 120.529;

(4) identified as an authorized user or an authorized nuclear pharmacist or authorized medical physicist on an Agency, or the U.S. Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or,

(5) identified as an authorized user or an authorized nuclear pharmacist or authorized medical physicist on a permit issued by the Agency, or the U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or the practice of nuclear pharmacy, respectively;

120.508: continued

(C) Before changing a Radiation Safety Officer, except as provided in 105 CMR 120.515(C).

(D) Before receiving radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(E) Before adding to or changing the areas of use identified in the application or on the license, except as specified in 105 CMR 120.509; and

(F) Before changing the address(es) of use identified in the application or on the license;

(G) Before changing statements, representations, and procedures which are incorporated into the license; and

(H) Before releasing licensed facilities for unrestricted use.

120.509: Notifications

(A) A licensee shall provide to the Agency a copy of the board certification, the Agency, NRC, Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to 105 CMR 120.508(B).

(B) A licensee shall notify the Agency by letter no later than 30 days after:
(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;
(2) The licensee's mailing address changes;
(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 105 CMR 120.131(B); or,
(4) The licensee has added to or changed the areas where radioactive material is used in accordance with 105 CMR 120.544 and 120.547.

120.510: Exemptions Regarding Type A Specific Licenses of Broad Scope

A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(A) The provisions of 105 CMR 120.507(D) regarding the need to file an amendment to the license for medical use of radioactive material as described in 105 CMR 120.589;

(B) The provisions of 105 CMR 120.508(B) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or authorized medical physicist under the license;

(C) The provisions of 105 CMR 120.508(E) regarding additions to or changes in the areas of use at the addresses specified in the license;

(D) The provisions of 105 CMR 120.509(A) regarding notification to the Agency for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists; and,

(E) The provisions of 105 CMR 120.523(A) regarding suppliers for sealed sources.

120.511: License Issuance

(A) The Agency shall issue a license for the medical use of radioactive material if:
(1) The applicant has filed Agency application form MRCP 120.100- 4 in accordance with the instructions in 105 CMR 120.507;
(2) The applicant has paid any applicable fee;

120.511: continued

(3) The applicant meets the requirements of 105 CMR 120.100; and
(4) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.

(B) The Agency shall issue a license for mobile services if the applicant:
(1) Meets the requirements in 105 CMR 120.511(A); and,
(2) Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with 105 CMR 120.540.

120.513: Specific Exemptions

The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in 105 CMR 120.500 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

GENERAL ADMINISTRATIVE REQUIREMENTS

120.515: Authority and Responsibilities for the Radiation Protection Program

(A) In addition to the radiation protection program requirements of 105 CMR 120.210, a licensee's management must approve in writing:
(1) Requests for license application, renewal, or amendments before submittal to the Agency;
(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and
(3) Radiation protection program changes that do not require a license amendment and are permitted under 105 CMR 120.517.

(B) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(C) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 105 CMR 120.515(E), provided the licensee takes the actions required in 105 CMR 120.515(B), (D), (E) and (H). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

(D) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(E) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:
(1) Identify radiation safety problems;
(2) Initiate, recommend, or provide corrective actions;
(3) Stop unsafe operations; and,
(4) Verify implementation of corrective actions.

(F) Licensees that are authorized for two or more different types of radioactive material use under 105 CMR 120.552, 120.559, 120.570, and 120.589, or two or more types of units under 105 CMR 120.570 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

120.515: continued

(G) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each meeting in accordance with 105 CMR 120.590(A).

(H) A licensee shall retain a record of actions taken pursuant to 105 CMR 120.515(A), (B) and (D) in accordance with 105 CMR 120.590(A).

120.517: Radiation Protection Program Changes

(A) A licensee may revise its radiation protection program without Agency approval if:
(1) The revision does not require an amendment under 105 CMR 120.508;
(2) The revision is in compliance with the regulations and the license;
(3) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and,
(4) The affected individuals are instructed on the revised program before the changes are implemented.

(B) A licensee shall retain a record of each change in accordance with 105 CMR 120.590(B).

120.518: Duties of Authorized User and Authorized Medical Physicist

120.519: Supervision

(A) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 105 CMR 120.506(B)(1) shall:
(1) In addition to the requirements in 105 CMR 120.753, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures in 105 CMR 120.500, and license conditions with respect to the use of radioactive material;
(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of 105 CMR 120.500, and license conditions with respect to the medical use of radioactive material; and
(3) Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.

(B) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 105 CMR 120.506(B)(2), shall:
(1) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures in 105 CMR 120.500, and license conditions.

(C) Unless physical presence as described in other sections of 105 CMR 120.500 is required, a licensee that permits supervised activities under 105 CMR 120.519(A) and (B) shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification; and

(D) A licensee that permits supervised activities under 105 CMR 120.519(A) and (B) is responsible for the acts and omissions of the supervised individual.

120.520: Visiting Authorized User, Visiting Authorized Nuclear Pharmacist or Visiting Medical Physicist

(A) A licensee may permit any visiting authorized user, visiting authorized nuclear pharmacist or visiting authorized medical physicist to work as an authorized user, authorized nuclear pharmacist or medical physicist, respectively, under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user, the visiting authorized nuclear pharmacist or the visiting authorized medical physicist has the prior written permission of the licensee's management and, if the work is performed on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user, the visiting authorized nuclear pharmacist or the visiting authorized medical physicist by name as an authorized user for medical use, as an authorized nuclear pharmacist, or as an authorized medical physicist respectively; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license are performed by that individual.

(B) A licensee need not apply for a license amendment in order to permit a visiting authorized user, a visiting authorized nuclear pharmacist or a visiting authorized medical physicist to use licensed material as described in 105 CMR 120.520(A).

(C) A licensee shall retain copies of the records specified in 105 CMR 120.520(A), as specified in 105 CMR 120.590(A).

120.521: Written Directives

(A) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 μCi), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name and the following:

(1) For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;

(2) For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

(3) For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

(4) For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(5) For all other brachytherapy including LDR, MDR, and PDR:

(a) Prior to implantation: treatment site, the radionuclide, and dose; and,

(b) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose).

(C) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

120.521: continued

(D) The licensee shall retain the written directive in accordance with 105 CMR 120.590(C).

120.522: Procedures for Administrations Requiring a Written Directive

(A) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

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

(B) The procedures required by 105 CMR 120.522(A) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 105 CMR 120.570 or 120.589.

120.523: Suppliers for Sealed Sources or Devices Containing Sealed Sources for Medical Use

For medical use, a licensee may only use:

(A) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 105 CMR 120.100 and 120.128(L) or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(B) Sealed sources or devices non-commercially transferred from a 10 CFR Part 35 licensee or an Agreement State medical use licensee.

(C) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 105 CMR 120.100 or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State.

120.524: Training for Radiation Safety Officer

Except as provided in 105 CMR 120.528, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in 105 CMR 120.515 to be an individual who:

(A) Is certified by a specialty board whose certification process includes all of the requirements in 105 CMR 120.524(B) and (C) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) (a) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(b) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(c) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

120.524: continued

(2) (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; (b) Have two years of full-time practical training and/or supervised experience in medical physics.

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

2. In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in 105 CMR 120.528, 120.551 or 120.556;

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(B) (1) Has completed a structured educational program consisting of both:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and,
5. Radiation dosimetry; and,

(b) One year of full time experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of use(s) of radioactive material involving the following:

1. Shipping, receiving and performing related radiation surveys;
2. Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;
3. Securing and controlling radioactive material;
4. Using administrative controls to avoid mistakes in the administration of radioactive material;
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
6. Using emergency procedures to control radioactive material;
7. Disposing of radioactive material; or

(2) Training and Experience for Radiation Safety Officer [Reserved]

(C)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under 105 CMR 120.525(A) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in 105 CMR 120.524(D) and (E); or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and,

(D) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in 105 CMR 120.524(E) and in 105 CMR 120.524(A)(1)(a) and (b) or (A)(2)(a) and (b) or (B)(1) or (C)(1) or (2), and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(E) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

120.525: Training for Authorized Medical Physicist

The licensee shall require the authorized medical physicist to be an individual who:

(A) Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.525(B)(2) and (C). (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have two years of full-time practical training and/or supervised experience in medical physics;

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(b) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 105 CMR 120.528, 120.566 or 120.587; and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(B)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

(a) Performing sealed source leak tests and inventories;

(b) Performing decay corrections;

(c) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(d) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.525(C) and 105 CMR 120.525(A)(1) and (2), or 120.525(B)(1) and (C), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 105 CMR 120.525, 120.528, or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(C) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

120.526: Training for an Authorized Nuclear Pharmacist

Except as provided in 105 CMR 120.528, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

120.526: continued

(A) Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.526(B)(2). (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(B) (1) Has completed 700 hours in a structured educational program consisting of both:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and
5. Chemistry of radioactive material for medical use; and

(b) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
4. Using administrative controls to avoid medical events in the administration of radioactive material; and
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 105 CMR 120.526(A)(1) through (3) or 120.526(B)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

120.528: Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist

(A)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002 need not comply with the training requirements of 105 CMR 120.524 through 120.526, respectively.

(2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of 105 CMR 120.524 through 120.526, respectively.

120.528: continued

(3) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-producedradioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Federal Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 105 CMR 120.524 through 120.526, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in 105 CMR 120.528, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of 105 CMR 120.500.

(B)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before October 24, 2002 who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556 through 120.558, 120.566, 120.567, 120.569 and 120.587.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005, need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556 through 120.558, 120.566, 120.567, 120.569 and 120.587.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556 through 120.558, 120.566, 120.567, 120.569 and 120.587 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in 105 CMR 120.528(B)(3), qualifies as an authorized user for those materials and uses performed before these dates, for purposes of 105 CMR 120.500.

(C) Individuals who need not comply with training requirements as described in 105 CMR 120.528 may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

120.529: Recentness of Training

The training and experience specified in 105 CMR 120.500 must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

GENERAL TECHNICAL REQUIREMENTS

120.531: Quality Control of Diagnostic Equipment

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

120.532: Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material

(A) For direct measurements performed in accordance with 105 CMR 120.534, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(B) A licensee shall calibrate the instrumentation required in 105 CMR 120.532(A) in accordance with nationally recognized standards or the manufacturer's instructions.

(C) A licensee shall retain a record of each instrument calibration required by 105 CMR 120.532 in accordance with 105 CMR 120.590(F).

120.533: Calibration of Survey Instruments

(A) A licensee shall ensure that the survey instruments used to show compliance with 105 CMR 120.200 and 120.500 have been calibrated before first use, annually, and following repair.

(B) To satisfy the requirements of 105 CMR 120.533(A), the licensee shall:
(1) Calibrate all required scale readings up to ten millisieverts (1000 mrem) per hour with a radiation source;
(2) Have each radiation survey instrument calibrated;
(a) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;
(b) For linear scale instruments, at two points located approximately ⅛ and ¾ of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and ten millisieverts (two and 1000 mrem) per hour; and
(c) For dose rate instruments, so that an accuracy within plus or minus 20% of the true radiation dose rate can be demonstrated at each point checked.
(3) Conspicuously note on the instrument the date of calibration.

(C) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20%.

(E) The licensee shall retain a record of each survey instrument calibration in accordance with 105 CMR 120.590(G).

120.534: Determination of Dosages of Unsealed Radioactive Material for Medical Use

(A) A licensee shall determine and record the activity of each dosage prior to medical use.

(B) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission, or an Agreement State.

(C) For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent provisions of the Nuclear Regulatory Commission, or an Agreement State.

(D) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20%.

(E) A licensee shall retain a record of the dosage determination required by 105 CMR 120.534 in accordance with 105 CMR 120.590(H).

120.535: Authorization for Calibration, Transmission and Reference Sources

Any person authorized by 105 CMR 120.506 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

(A) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 105 CMR 120.128(L) or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11 gigabecquerels (30 mCi) each;

(B) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

(C) Any radioactive material with a half life greater than 120 days in individual amounts not to exceed the smaller of 7.4 megabecquerels (200 μCi) or 1000 times the quantity in 105 CMR 120.196: *Appendix B*, Table 1; and

(D) Technetium-99m in amounts as needed.

120.536: Requirements for Possession of Sealed Sources and Brachytherapy Sources

(A) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency.

(B) A licensee in possession of a sealed source shall:
(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and,
(2) Test the source for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(C) To satisfy the leak test requirements of 105 CMR 120.536(B), the licensee shall measure the sample so that the leak test can detect the presence of 185 becquerels (0.005 μCi) of radioactive material in the sample. If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:
(1) Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of 105 CMR 120.100 and 120.200; and,
(2) File a report with the Agency within five days of receiving the leak test results with the Agency describing the equipment involved, the test results, and the action taken.

(D) A licensee shall retain leak test records in accordance with 105 CMR 120.590(I)(1).

(E) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with 105 CMR 120.590(I)(2).

120.537: Labeling of Vials and Syringes

Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

120.539: Surveys for Ambient Radiation Dose Rate and Contamination

(A) In addition to the surveys required by 105 CMR 120.200, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

120.539: continued

(B) A licensee does not need to perform the surveys required in 105 CMR 120.539(A) in area(s) where patients or human research subjects are confined when they can not be released pursuant to 105 CMR 120.540.

(C) A licensee shall retain a record of each survey in accordance with 105 CMR 120.590(J).

120.540: Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material

(A) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisievert (0.5 rem). [NOTE: NRC Regulatory Guide, NUREG-1566, Vol. 9, *Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses*, describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding five millisieverts (0.5 rem).]

(B) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and
(2) Information on the potential consequences, if any, of failure to follow the guidance.

(C) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 105 CMR 120.590(K)(1).

(D) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 105 CMR 120.590(K)(2).

(E) The licensee shall immediately notify the Agency in accordance with 105 CMR 120.594(D) if a patient departs prior to an authorized release.

120.541: Provision of Mobile Medical Service

The Agency may license mobile medical services and/or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(A) A licensee providing mobile medical service shall:

(1) Obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use and clearly delineates the authority and responsibility of the licensee and the client. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile medical service;

(2) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by 105 CMR 120.541(A)(2) must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and,

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in 105 CMR 120.200.

120.541: continued

(B) A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(C) A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

(D) A mobile medical service licensee shall maintain all records required by 105 CMR 120.200 and 120.500 at a location within the Agency's jurisdiction that is:

(1) A single address:
   (a) identified as the records retention location; and,
   (b) staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or
(2) When no address is identified on the license for records retention, the mobile unit:
   (a) identified in the license; and,
   (b) whose current client's address schedule and location schedule is reported to the Agency.

(E) A licensee providing mobile medical services shall:
(1) Retain the letter required in 105 CMR 120.541(A)(1) in accordance with 105 CMR 120.590(L); and
(2) Retain a record of each survey required by 105 CMR 120.541(A)(4) in accordance with 105 CMR 120.590(L).

(F) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency for compliance with airborne release standards.

120.542: Storage of Volatiles and Gases

(A) A licensee shall store volatile radiopharmaceuticals and radioactive gases in a radiation shield and container.

(B) A licensee shall store and use a multidose container in a properly functioning fume hood.

(C) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in 105 CMR 120.200.

(D) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(E) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for three years.

120.543: Decay-in-storage

(A) A licensee may hold radioactive material with a physical half-life of less than 120 days (or longer, if the Agency has approved it) for decay-in-storage before disposal without regard to its radioactivity if the licensee:

(1) Monitors radioactive material at the surface and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
(2) Removes or obliterates all radiation labels except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
(3) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

120.543: continued

(B) For radioactive material disposed in accordance with 105 CMR 120.543(A), the licensee shall retain a record of each disposal in accordance with 105 CMR 120.590(M).

SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, OR EXCRETION STUDIES

120.544: Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is not Required

A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion:

(A)(1) Obtained from a manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent regulations of another Agreement State, or the Nuclear Regulatory Commission; or

(2) A PET radioactive drug producer licensed under 105 CMR 120.100 or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or

(B) Excluding production PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551, or 120.556 and 120.551(C)(1)(b)7.; or

(3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 105 CMR 120.544(B)(1) or the physician who is an authorized user in 105 CMR 120.544(B)(2); or

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

120.545: Possession of Survey Instrument

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsieverts (100 mrems) per hour. The instrument shall be operable and calibrated in accordance with 105 CMR 120.533.

120.546: Training for Uptake, Dilution, and Excretion Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 105 CMR 120.544 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.546(C)(2). (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in 105 CMR 120.546(C)(1)(a) through (b)6.; and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

120.546: continued

(B) Is an authorized user under 105 CMR 120.551 or 120.556, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C) (1) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements 105 CMR 120.528, 120.546,120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.546, 120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.546(A)(1) or (C)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120 544.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED BYPRODUCT MATERIAL WRITTEN DIRECTIVE NOT REQUIRED

120.547: Use of Unsealed Byproduct Material for Imaging and Localization Studies for which a Written Directive is not Required

A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 105 CMR 120.521 that is:

(A) Obtained from:

(1) A manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent regulations of another Agreement State, or the Nuclear Regulatory Commission;

(2) A PET radioactive drug producer licensed under 105 CMR 120.100 or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or

(B) Excluding production PET radionuclides prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 120.556 and 120.551(C)(1)(b)7.; or

(3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 105 CMR 120.547(B)(1) or the physician who is an authorized user in 105 CMR 120.547(B)(2); or

120.547: continued

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(E) Provided the conditions of 105 CMR 120.542 are met, a licensee may use radioactive aerosols or gases if specific application is made to and approved by the Agency.

120.548: Radionuclide Contaminants

(A) A licensee shall not administer to humans a radiopharmaceutical containing:
(1) more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m);
(2) more than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μCi of Sr-82 per mCi of Rb-82 chloride);
(3) more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μCi of Sr-85 per mCi of Rb-82).

(B) To demonstrate compliance with 105 CMR 120.548(A), the licensee preparing radioactive drugs from radionuclide generators shall:
(1) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;
(2) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

(C) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with 105 CMR 120.590(N).

(D) A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in 105 CMR 120.548(A).

120.551: Training for Imaging and Localization Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 105 CMR 120.547 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.551(C)(2). (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in 105 CMR 120.551(C)(1)(a) through (b)7.; and
(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(B) Is an authorized user under 105 CMR 120.556 and meets the requirements of 105 CMR 120.551(C)(1)(b)7., or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

120.551: continued

(C)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies; the training and experience must include, at a minimum:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use;
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements of 105 CMR 120.528, 120.551, or 120.556 and 120.551(C)(1)(b)7. or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects;
7. 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, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.551 or 120.556 and 120.551(C)(1)(b)7., or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.551(A)(1) or (C)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.544 and 120.547.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED BYPRODUCT MATERIAL WRITTEN DIRECTIVE REQUIRED

120.552: Use of Unsealed Byproduct Material for which a Written Directive is Required

A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

(A) Obtained from a manufacturer or preparer licensed in accordance with 105 CMR 120128(J); or

(B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 120.556, or an individual under the supervision of either as specified in 105 CMR 120 519; or

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or Agreement State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

120.553: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

(A) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who have received therapy with with a radioactive drug, and cannot be released in accordance with 105 CMR 120.540. To satisfy the requirement in 105 CMR 120.553(A), the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control to include the following:

(a) Routine visitation to hospitalized individuals in accordance with 105 CMR 120.221(A)(1) and (C);

(b) Contamination control;

(c) Waste control; and

(d) Notification of the RSO, or his or her designee, and the 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 105 CMR 120.590(P).

120.554: Safety Precautions

(A) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 105 CMR 120.540, a licensee shall:

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

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

(b) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with 105 CMR 120.540; and

(2) Visibly post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

(3) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination 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 these materials and items as radioactive waste.

(B) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

120.556: Training for Use of Unsealed Byproduct Material for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of radioactive material for the uses authorized under 105 CMR 120.552 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.556(B)(1)(b)7. and (2). (Specialty boards whose certification processes have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's 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 105 CMR 120.556(B)(1)(a) through (b)5.. 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 of the American Osteopathic Association; and

120.556: continued

(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 byproduct 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 byproduct material requiring a written directive. The training and experience must include:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of byproduct material for medical use;
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in 105 CMR 120.556(B), must also have experience in administering dosages in the same dosage category or categories (*i.e.*,105 CMR 120.556(B)(1)(b)7.) as the individual requesting authorized user status. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
7. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status.

a. Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

b. Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 [Note: *Experience with at least three cases in category (b) also satisfies the requirement in category (a)]*;

c. Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

d. Parenteral administration of any other radionuclide for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.556(A)(1) and (B)(1)(b)7. or 120.556(B)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.552. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556 or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements of 105 CMR 120.556(B), must have experience in administering dosages in the same dosage category or categories listed in 105 CMR 120.556(B)(1)(b)7. as the individual requesting authorized user status.

120.557: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicurie) for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

120.557: continued

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.557(C)(1) and (2) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission and who meets the requirements in 105 CMR 120.557(C)(3). (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(B) Is an authorized user under 105 CMR 120.556, for uses listed in 105 CMR 120.556(B)(1)(b)7.a. or b., and 120.558 or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

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

(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 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 105 CMR 120.556(B) must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.a. or b. The 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 medical event involving the use of unsealed radioactive material;
(e) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
(f) Administering dosages to patients or human research subjects that includes at least three 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 105 CMR 120.557(C)(1) and (2), and has achieved a level of competency sufficient to independently function as an authorized user for medical uses authorized under 105 CMR 120.552. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.a. or 105 CMR 120.556(B)(1)(b)7.b.

120.558: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabequerels (33 millicurie) for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.558(C)(1) and (2) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission, and who meets the requirements in 120.558(C)(3). (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

120.558: continued

(B) Is an authorized user under 105 CMR 120.556, for uses listed in 105 CMR 120.556(B)(1)(b)1.a. or b. and 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or

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

(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 105 CMR 120.528, 120.556, or 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b.; the 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 medical event involving the use of byproduct material;

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

(f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration greater than 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 105 CMR 120.558(C)(1) and (2), and has achieved a level of competency sufficient to independently function as an authorized user for medical uses authorized under 105 CMR 120.552. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556, 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b.

120.558A: Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(A) Is an authorized user under 105 CMR 120.556 for uses listed in 105 CMR 120.556(B)(1)(b)7.c. or d., or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or

(B) Is an authorized user under 105 CMR 120.566, 120.587, or equivalent Agreement State, or Nuclear Regulatory commission requirements and who meets the requirements in 105 CMR 120.558A(D); or

(C) Is certified by a medical specialty board whose certification process has been recognized under 105 CMR 120.566 or 120.587 or by the Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in 105 CMR 120.558A(D).

120.558A: continued

(D)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Chemistry of byproduct 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 105 CMR 120.528, 120.556, 120.558A, or equivalent Agreement State, or Nuclear Regulatory Commission requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 105 CMR 120.556 must have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.c., and/or d. The 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 medical event involving the use of unsealed byproduct material;

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

(f) Administering dosages to patients or human research subjects that includes at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.558A(B) or (C), and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in 105 CMR 120.556 must have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.c. and/or d.

MANUAL BRACHYTHERAPY

120.559: Use of Sealed Sources for Manual Brachytherapy

A licensee shall use only brachytherapy sources for therapeutic medical uses:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 105 CMR 120.523(A) are met.

120.560: Surveys After Source Implant and Removal

(A) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

120.560: continued

(B) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(C) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.590(Q).

120.561: Brachytherapy Sources Accountability

(A) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(B) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(C) A licensee shall maintain a record of the brachytherapy source accountability in accordance with 105 CMR 120.592(A).

120.562: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

(A) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subject that are undergoing brachytherapy and cannot be released in accordance with 105 CMR 120 540. Instruction must be commensurate with the duties of the personnel and shall include the following:

(1) Size and appearance of the brachytherapy sources;
(2) Safe handling and shielding instructions;
(3) Patient or human research subject control;
(4) Visitor control, including both;
  (a) Routine visitation of hospitalized individuals in accordance with 105 CMR 120.221(A)(1);
  (b) Visitation authorized in accordance with 105 CMR 120.221(C); and
(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or human research subject dies or has a medical emergency.
(6) A licensee shall retain a record of individuals receiving instruction in accordance with 105 CMR 120.590(P).

120.563: Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy

(A) For each patient or human research subject receiving brachytherapy and cannot be released in accordance with 105 CMR 120.540, a licensee shall:

(1) Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;
(2) Visibly post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(B) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

(1) Dislodged from the patient; or
(2) Lodged within the patient following removal of the source applicators.

(C) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

120.564: Calibration Measurement of Brachytherapy Sealed Sources

(A) Prior to the first medical use of a brachytherapy sealed source on or after October 6, 2006, a licensee shall perform the following:

(1) Determine the source output or activity using a dosimetry system that meets the requirements of 105 CMR 120.575(A);

(2) Determine source positioning accuracy within applicators; and

(3) Use published protocols accepted by nationally recognized bodies to meet the requirements of 105 CMR 120.564(A)(1) and (2).

(B) A 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 105 CMR 120.564(A).

(C) A licensee shall mathematically correct the outputs or activities determined in 105 CMR 120.564(A) for physical decay at intervals consistent with 1.0% physical decay.

(D) An authorized medical physicist shall perform or review the calculation measurements made pursuant to 105 CMR 120.564(A), (B), or (C).

(E) Only an authorized medical physicist shall 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 in accordance with paragraphs 105 CMR 120.564(A) through (C).

(F) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(B).

(G) A licensee shall retain a record of decay calculations required by 105 CMR 120.564(E) in accordance with 105 CMR 120.592(C).

120.565: Therapy-related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system 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. The licensee shall perform regular quality assurance testing on the treatment planning computer. Said testing shall be in accordance with TG40 or current AAPM recommendation.

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

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

120.566: Training for Use of Manual Brachytherapy Sources

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the Nuclear Regulatory Commission, and who meets the requirements in 105 CMR 120.566(B)(3) (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

120.566: continued

(1) Successfully complete a minimum of three 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 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:

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

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and,
4. Radiation biology; and

(b) 500 hours work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Checking survey meters for proper operation;
3. Preparing, implanting, and removing brachytherapy sources;
4. Maintaining running inventories of material on hand;
5. Using administrative controls to prevent a medical event involving the use of byproduct material;
6. Using emergency procedures to control byproduct material; and

(2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State or Nuclear Regulatory Commission 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 on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.566(B)(1)(b); and

(3) Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.566(A)(1), or (B)(1) and (2) and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 105 CMR 120.559.

120.567: Training for Ophthalmic Use of Strontium-90

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is an authorized user under 105 CMR 120.566 or equivalent Agreement State or Nuclear Regulatory Commission 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:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Radiation biology; and

120.567: continued

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user who meets the requirements in 105 CMR 120.566 or 120.567, and that includes the use of strontium-90 for ophthalmic treatment of five individuals that includes:
(a) Examination of each individual to be treated;
(b) Calculation of the dose to be administered;
(c) Administration of the dose;
(d) 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 105 CMR 120.528, 120.566, 120.567 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.567(B) and has achieved a level of competency sufficient to independently function as an authorized user of strontium-90 for ophthalmic use.

SEALED SOURCES FOR DIAGNOSIS

120.568: Sealed Sources for Diagnosis

A licensee shall use only sealed source for diagnostic medical uses.

(A) Approved in the Sealed Source and Device Registry; and

(B) Handled in accordance with the manufacturer's radiation safety instructions.

120.569: Training for Use of Sealed Sources for Diagnosis

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a diagnostic sealed source for use in a device authorized under 105 CMR 120.568 to be a physician, dentist, or podiatrist who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.569(B) and (C) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or

(B) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:
(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity; and,
(4) Radiation biology; and,

(C) Has completed training in the use of the device for the uses requested.

PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

120.570: Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses:

(A) As approved in the Sealed Source and Device Registry; or

(B) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 105 CMR 120.523(A) are met.

120.571: Surveys of Patients and Human Research Subjects Treated with Remote Afterloader Unit

(A) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(B) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.590(Q).

120.572: Installation, Maintenance, Adjustment, and Repair

(A) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) drive unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(B) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, an Agreement State, or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(C) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, an Agreement State, or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(D) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 105 CMR 120.592(D).

120.573: Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(A) A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or is unattended;

(2) Permit only individuals approved by authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(c) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(B) A copy of the procedures required by 105 CMR 120.573(A)(4) must be physically located at the unit console.

(C) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 105 CMR 120.573(A)(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

120.573: continued

(D) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual"s assigned duties, in:
(1) The procedures identified in 105 CMR 120 573(A)(4); and
(2) the operating procedures for the unit.

(E) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(F) A licensee shall retain a record of individuals receiving instruction required by 105 CMR 120.573(D), in accordance with 105 CMR 120.590(P).

120.574: Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(A) A licensee shall control access to the treatment room by a door at each entrance.

(B) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:
(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
(2) Cause the source(s) to be shielded promptly when an entrance door is opened; and
(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(C) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(D) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(E) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(F) In addition to the requirements specified in 105 CMR 120.574(A) through (E), a licensee shall:
(1) For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:
(a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and,
(b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
(2) For high dose-rate remote afterloader units, require:
(a) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
(b) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

120.574: continued

(4) Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(G) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

(1) Remains in the unshielded position; or

(2) Lodges within the patient following completion of the treatment.

120.575: Dosimetry Equipment

(A) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(B) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 105 CMR 120.575(A). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 105 CMR 120.575(A).

(C) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with 105 CMR 120.592(E).

120.576: Full Calibration Measurements on Teletherapy Units

(A) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and,

(c) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and,

(3) At intervals not exceeding one year.

(B) To satisfy the requirement of 105 CMR 120.576(A), full calibration measurements shall include determination of:

(1) The output within 3% for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

120.576: continued

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
(4) Timer accuracy;
(5) "On-off" error; and,
(6) The accuracy of all distance measuring and localization devices in medical use.

(C) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 105 CMR 120.576(B)(1) may then be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by 105 CMR 120.576(A) in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall correct mathematically the outputs determined in 105 CMR 120.576(B)(1) for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137, or at intervals consistent with 1% decay for all other nuclides.

(F) Full calibration measurements required by 105 CMR 120.576(A) and physical decay corrections required by 105 CMR 120.576(E) shall be performed by the authorized medical physicist.

(G) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.577: Full Calibration Measurements on Remote Afterloader Units

(A) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:
(1) Before the first medical use of the unit; and
(2) Before medical use under the following conditions:
(a) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
(b) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
(3) At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
(4) At intervals not exceeding one year for low dose-rate remote afterloader units.

(B) To satisfy the requirement of 105 CMR 120.577(A), full calibration measurements shall include, as applicable, determination of:
(1) the output within +/- 5%;
(2) Source position accuracy to within +/- 1 millimeter;
(3) Source retraction with backup battery upon power failure;
(4) Length of the source transfer tubes;
(5) Timer accuracy and linearity over the typical range of use;
(6) Length of applicators; and
(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(C) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 105 CMR 120.577(B), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(D) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output.

(E) A licensee shall make full calibration measurements required by 105 CMR 120.577(A) in accordance with published protocols accepted by nationally recognized bodies.

120.577: continued

(F) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 105 CMR 120.577(A) through (E).

(G) A licensee shall mathematically correct the outputs determined in 105 CMR 120.577(B)(1) for physical decay at intervals consistent with 1% physical decay.

(H) Full calibration measurements required by 105 CMR 120.577(A) and physical decay corrections required by 105 CMR 120.577(G) must be performed by the authorized medical physicist.

(I) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.578: Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

(A) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(a) Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and,

(c) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and,

(3) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(B) To satisfy the requirement of 105 CMR 120.578(A), full calibration measurements shall include determination of:

(1) The output within ± 3%;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitchs;

(9) Emergency timing circuits; and,

(10) Stereotactic frames and localizing devices (trunnions).

(C) A licensee shall use the dosimetry system described in 105 CMR 120.575(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 105 CMR 120.578(B)(1) may be made using a dosimetry system that indicates relative dose rates.

(D) A licensee shall make full calibration measurements required by 105 CMR 120.578(A) in accordance with published protocols accepted by nationally recognized bodies.

(E) A licensee shall mathematically correct the outputs determined in 105 CMR 120.578(B)(1) at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1% physical decay for all other radionuclides.

(F) Full calibration measurements required by 105 CMR 120.578(A) and physical decay corrections required by 105 CMR 120.578(E) must be performed by the authorized medical physicist.

120.578: continued

(G) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(F).

120.579: Periodic Spot-checks for Teletherapy Units

(A) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(1) Timer accuracy, and timer linearity over the range of use;

(2) "On-off" error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in 105 CMR 120.575(B); and

(6) The difference between the measurement made in 105 CMR 120.579(A)(5) and the anticipated output, expressed as a percentage of the anticipated output (*i.e.*, the value obtained at last full calibration corrected mathematically for physical decay).

(B) A licensee shall perform measurements required by 105 CMR 120.579(A) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the output spot-check measurements.

(C) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each output spot-check.

(D) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and,

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(E) If the results of the checks required in 105 CMR 120.579(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(F) A licensee shall retain a record of each spot-check required by 105 CMR 120.579(A) and (D), in accordance with 105 CMR 120.592(G).

120.580: Periodic Spot-checks for Remote Afterloader Units

(A) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks on each remote afterloader facility and on each unit:

(1) At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;

(2) Prior to each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(B) A licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in 105 CMR 120.580(A). The authorized medical physicist need not actually perform the spot-check measurements.

120.580: continued

(C) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each output spot-check.

(D) To satisfy the requirement of 105 CMR 120.580(A), spot-checks must, at a minimum, assure proper operation of:
(1) Electrical interlocks at each remote afterloader unit room entrance;
(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
(3) Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
(4) Emergency response equipment;
(5) Radiation monitors used to indicate the source position;
(6) Timer accuracy;
(7) Clock (date and time) in the unit's computer; and
(8) Decayed source(s) activity in the unit's computer.

(E) If the results of the checks required in 105 CMR 120.580(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(F) A licensee shall retain a record of each spot-check required by 105 CMR 120.580(D), in accordance with 105 CMR 120.592(H).

120.581: Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units

(A) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks on each gamma stereotactic radiosurgery facility and on each unit:
(1) Monthly;
(2) At the beginning of each day of use; and
(3) After each source installation.

(B) A licensee shall have the authorized medical physicist:
(1) Establish written procedures for performing the spot-checks required in 105 CMR 120.581(A); and
(2) Review the results of each spot-check required by 105 CMR 120.581(A)(1) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot check.

(C) To satisfy the requirement of 105 CMR 120.581(A)(1), spot-checks must, at a minimum:
(1) Assure proper operation of:
(a) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
(b) Helmet microswitchs;
(c) Emergency timing circuits; and
(d) Stereotactic frames and localizing devices (trunnions).
(2) Determine:
(a) The output for one typical set of operating conditions measured with the dosimetry system described in 105 CMR 120.575(B);
(b) The difference between the measurement made in 105 CMR 120.581(C)(2)(a) and the anticipated output, expressed as a percentage of the anticipated output (*i.e.*, the value obtained at last full calibration corrected mathematically for physical decay);
(c) Source output against computer calculation;
(d) Timer accuracy and linearity over the range of use;
(e) On-off error; and
(f) Trunnion centricity.

(D) To satisfy the requirements of 105 CMR 120.581(A)(2) and (3), spot-checks must assure proper operation of:

120.581: continued

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance
(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
(3) Viewing and intercom systems;
(4) Timer termination;
(5) Radiation monitors used to indicate room exposure; and,
(6) Emergency off buttons.

(E) A licensee shall arrange for prompt repair of any system identified in 105 CMR 120.581(C) that is not operating properly.

(F) If the results of the checks required in 105 CMR 120.581(D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(G) A licensee shall retain a record of each check required by 105 CMR 120.581(C) and (D) in accordance with 105 CMR 120.592(I).

120.582: Additional Technical Requirements for Mobile Remote Afterloader Units

(A) A licensee providing mobile remote afterloader service shall:
(1) Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and
(2) Account for all sources before departure from a client's address of use.

(B) In addition to the periodic spot-checks required by 105 CMR 120.580, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:
(1) Electrical interlocks on treatment area access points;
(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
(3) Viewing and intercom systems;
(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
(5) Radiation monitors used to indicate room exposures;
(6) Source positioning (accuracy); and
(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(C) In addition to the requirements for checks in 105 CMR 120.582(B), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(D) If the results of the checks required in 105 CMR 120.582(B) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(E) A licensee shall retain a record of each check required by 105 CMR 120.582(B) in accordance with 105 CMR 120.592(J).

120.583: Radiation Surveys

(A) In addition to the survey requirements in 105 CMR 120.225, a person licensed pursuant to 105 CMR 120.500 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 does not exceed the levels stated in the Sealed Source and Device Registry.

(B) The licensee shall make the survey required by 105 CMR 120.583(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).

120.583: continued

(C) A licensee shall retain a record of the radiation surveys required in 105 CMR 120.583(A) in accordance with 105 CMR 120.592(K).

120.584: 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 teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(B) This inspection and servicing may 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 maintain a record of the inspection and servicing in accordance with 105 CMR 120.592(L).

120.585: Therapy-related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system 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. The licensee shall perform regular quality assurance testing on the treatment planning computer. Said testing shall be in accordance with TG40 or current AAPM recommendation.

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

(D) The accuracy of the software used to determine radioactive 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.

120.587: Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a sealed source for a use authorized under 105 CMR 120.570 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by an Agreement State or the Nuclear Regulatory Commission and who meets the requirements in 105 CMR 120.587(B)(3) and (C). (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three 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 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:

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(a) 200 hours of classroom and laboratory training in the following areas:
1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical institution, involving:
1. Reviewing full calibration measurements and periodic spot checks;
2. Preparing treatment plans and calculating treatment doses and times;
3. Using administrative controls to prevent a medical event involving the use of radioactive material;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
5. Checking and using survey meters;
6. Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 105 CMR 120.528, 120.587 or equivalent Agreement State or Nuclear Regulatory Commission 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 on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.587(B)(1)(b); and

(3) Has obtained written attestation, that the individual has satisfactorily completed the requirements in 105 CMR 120.587(A)(1) or (B)(1) and (2), and 120.587(C) and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorize user status. The written attestation must be signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.587, or equivalent Agreement State or Nuclear Regulatory requirements for an authorized user for each type therapeutic medical unit for which the individual is requesting authorized user status; and

(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.

OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

120.589: 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 that is not specifically addressed in 105 CMR 120.500 if:

(A) The applicant or licensee has submitted the information required by 105 CMR 120.507(B) through (D); and

(B) The applicant or licensee has received written approval from the Agency in a license and uses the material in accordance with 105 CMR 120.000 and specific conditions the agency considers necessary for the medical use of the material.

RECORDS

120.590: Requirements for Record Keeping

(A) Records of Authority and Responsibilities for Radiation Protection Programs.
(1) A licensee shall retain a record of actions taken by the licensee's management in accordance with 105 CMR 120.515(A) for five years. The record must include a summary of the actions taken and a signature of licensee management.

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(2) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 105 CMR 120.515(D), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 105 CMR 120.515(B) The record must include the signature of the Radiation Safety Officer and licensee management.

(B) Records of Radiation Protection Program Safety Changes. A licensee shall retain a record of each radiation protection program change made in accordance with 105 CMR 120.517(A) for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(C) Records of Written Directives. A licensee shall retain a copy of each written directive as required by 105 CMR 120.521 for three years.

(D) Records of Medical Events. A licensee shall retain a record of medical events reported in accordance with 105 CMR 120.594(A) for three years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event; medical event a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(E) Record of a Dose to an Embryo/Fetus or a Nursing Child. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 105 CMR f20.594(B) for three years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned of the embryo/fetus or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(F) Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material. A licensee shall maintain a record of instrument calibrations required by 105 CMR 120.532 for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(G) Records of Survey Instrument Calibrations. A licensee shall maintain a record of instrument calibrations required by 105 CMR 120.533 for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(H) Records of Dosages of Unsealed Radioactive Material for Medical Use. A licensee shall maintain a record of dosage determinations required by 105 CMR 120.534 for three years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(I) Records of Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee shall retain a record of the leak test required by 105 CMR 120.536(B) for three years. The record must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the results of the test, the date of the test, and the name of the individual who performed the test.

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(2) A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 105 CMR 120.536(E) for three years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(J) Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by 105 CMR 120.539 for three 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.

(K) Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.

(1) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(a) Using the retained activity rather than the activity administered;
(b) Using an occupancy factor less than 0.25 at one meter;
(c) Using the biological or effective half-life; or
(d) Considering the shielding by tissue.

(2) A licensee shall retain a record, for three years after the date of release, that the instructions required by 105 CMR 120.540(B) were provided to a breast-feeding woman [if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five mSv (0.5 rem)].

(L) Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.

(1) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by 105 CMR 120.541(A)(1), for three years after the last provision of service.

(2) A licensee shall retain the record of each survey required by 105 CMR 120.541(A)(4) for three 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.

(M) Records of Decay-in-storage. A licensee shall maintain records of the disposal of licensed materials, as required by 105 CMR 120.543, for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(N) Records of Radionuclide Purity. A licensee shall maintain a record of the radionuclide contaminant concentration tests required by 105 CMR 120.548 for three years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

(P) Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by 105 CMR 120.553, 120.562 and 120.573 for three years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(Q) Records of Radiation Surveys of Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by 105 CMR 120.560 and 120.571 for three 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.

120.592: Requirements for Record Keeping Pertaining to the Use of Sealed Sources

(A) Records of Brachytherapy Source Inventory.

(1) A licensee shall maintain a record of brachytherapy source accountability required by 105 CMR 120.561 for three years.

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

(a) 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

(b) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them from storage.

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

(a) 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;

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

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

(B) Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by 105 CMR 120.564 for three years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(C) Records of Decay of Strontium-90 Sources for Opthalmic Treatments. A licensee shall maintain a record of the activity of a strontium-90 source required by 105 CMR 120.564. The record must include the date and initial activity of the source as determined under 105 CMR 120.564, and for each decay calculation, the date and the source activity.

(D) Records of Installation, Maintenance, Adjustment, and Repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 105 CMR 120.572 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(E) Records of Dosimetry Equipment.

(1) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 105 CMR 120.575 for the duration of the license.

(2) For each calibration, intercomparison, or comparison, the record must include:

(a) The date;

(b) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 105 CMR 120.575(A) and (B);

(c) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(d) The names of the individuals who performed the calibration, intercomparison, or comparison.

(F) Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

(1) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by 105 CMR 120.576, 120.577 and 120.578 for three years.

(2) The record must include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

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(c) The results and assessments of the full calibrations;
(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and
(e) The signature of the authorized medical physicist who performed the full calibration.

(G) Records of Periodic Spot-checks for Teletherapy Units.
(1) A licensee shall retain a record of each periodic spot-check for teletherapy units required by 105 CMR 120.579 for three years.
(2) The record must include:
(a) The date of the spot-check;
(b) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
(c) An assessment of timer linearity and constancy;
(d) The calculated on-off error;
(e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
(f) The determined accuracy of each distance measuring and localization device;
(g) The difference between the anticipated output and the measured output;
(h) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(H) Records of Periodic Spot-checks for Remote Afterloader Units.
(1) A licensee shall retain a record of each spot-check for remote afterloader units required by 105 CMR 120.580 for three years.
(2) The record must include, as applicable:
(a) The date of the spot-check;
(b) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
(c) An assessment of timer accuracy;
(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
(e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(I) Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.
(1) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 105 CMR 120.581 for three years.
(2) The record must include:
(a) The date of the spot-check;
(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
(c) An assessment of timer linearity and accuracy;
(d) The calculated on-off error;
(e) A determination of trunnion centricity;
(f) The difference between the anticipated output and the measured output;
(g) An assessment of source output against computer calculations;
(h) Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

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(J) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.
(1) A licensee shall retain a record of each check for mobile remote afterloader units required by 105 CMR 120.582 for three years.
(2) The record must include:
(a) The date of the check;
(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;
(c) Notations accounting for all sources before the licensee departs from a facility;
(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
(e) The signature of the individual who performed the check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(K) Records of Surveys of Therapeutic Treatment Units.
(1) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 105 CMR 120.583 for the duration of use of the unit.
(2) The record must include:
(a) The date of the measurements;
(b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
(d) The signature of the individual who performed the test.

(L) Records of Five-year Inspection for Teletherapy and Gamma Stereotactic Surgery Units
(1) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by 105 CMR 120.584 for the duration of use of the unit.
(2) The record must contain:
(a) The inspector's radioactive materials license number;
(b) The date of inspection;
(c) The manufacturer's name and model number and serial number of both the treatment unit and source;
(d) A list of components inspected and serviced, and the type of service; and
(f) The signature of the inspector.

REPORTS

120.594: Reports and Notifications

(A) Reports and Notifications of Medical Events.
(1) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:
(a) A dose that differs from the prescribed dose by more than 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either
1. The total dose delivered differs from the prescribed dose by 20% or more;
2. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or
3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.
(b) A dose that exceeds 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:
1. An administration of a wrong radioactive drug;
2. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

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3. An administration of a dose or dosage to the wrong individual or human research subject;
4. An administration of a dose or dosage delivered by the wrong mode of treatment; or
5. A leaking sealed source.

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(2) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

(a) The written report must include:
1. The licensee's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the individual(s) who received the administration;
6. Actions, if any, that have been taken, or are planned, to prevent recurrence;
7. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The licensee shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event because of any delay in notification. To meet the requirements of 105 CMR 120.504(A)(5), the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) Aside from the notification requirement, nothing in 105 CMR 120.594 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall retain a record of a medical event in accordance with 105 CMR 120.590(D). A copy of the record required under 105 CMR 120.590(D) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the medical event.

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(B) Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than five mSv (500 mrem) 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.

(2) A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

(a) Is greater than five mSv (500 mrem) total effective dose equivalent; or

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

(3) 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 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

(4) 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 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

(a) The written report must include:

1. The licensee's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect 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.

(b) 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.

(5) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require reporting under 105 CMR 120.594(B)(1) or (2), 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 event because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. 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 event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with 105 CMR 120.590(E). A copy of the record required under 105 CMR 120.590(E) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(C) Reports of Leaking Sources. A licensee shall file a report with the Agency within five days if a leakage test required by 105 CMR 120.536 reveals the presence of 185 Becquerel (0.005 μCi) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(D) Reports of Patient Departure Prior to Authorized Release.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 105 CMR 120.540(A).

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(2) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

(a) The licensee's name;

(b) The date and time of the unauthorized departure;

(c) The projected date and time when release would have occurred;

(d) The general location address of the patient's or human research subject's home or anticipated destination following departure;

(e) The radionuclide, chemical and physical form and calculated activity at time of release;

(f) The apparent reason(s) for the departure prior to authorized release; and,

(g) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(E) Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 105 CMR 120.221 as a result of the deceased's body.

(2) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in 105 CMR 120.594(E)(1) has died. The written report must include:

(a) The licensee's name;

(b) The date of death;

(c) The radionuclide, chemical and physical form and calculated activity at time of death; and

(d) The names (or titles) and address(es) of known individuals who might have received exposures exceeding five mSv (500 mrem).

120.600: RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

120.601: Purpose and Scope

105 CMR 120.600 provides special requirements for analytical x-ray equipment. The requirements of 105 CMR 120.600 are in addition to, and not in substitution for, applicable requirements in other Sections of 105 CMR 120.000.

120.602: Definitions

As used in 105 CMR 120.600, the following definitions apply:

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

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

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

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

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

120.752: continued

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
(3) The operating procedures applicable to activities under the license or registration; and,
(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 105 CMR 120.001, and any response from the licensee or registrant.

(B) If posting of a document specified in 105 CMR 120.752(A)(1), (2), or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(C) Form MRCP 120.750-1 "Notice to Employees" shall be posted by each licensee or registrant as required by 105 CMR 120.000.

(D) Agency documents posted pursuant to 105 CMR 120.752(A)(4) shall be posted within five working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

(E) Documents, notices, or forms posted pursuant to 105 CMR 120.752 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

120.753: Instructions to Workers

(A) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of one mSv (100 mrem)
(1) shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;
(2) shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
(3) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of 105 CMR 120.000 and licenses for the protection of personnel from exposures to radiation or radioactive material;
(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, 105 CMR 120.000, and licenses or unnecessary exposure to radiation or radioactive material;
(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and,
(6) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 105 CMR 120.754.

(B) In determining those individuals subject to the requirements of 105 CMR 120.753(A), licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

120.754: Notifications and Reports to Individuals

(A) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in 105 CMR 120.750. The information reported shall include data and results obtained pursuant to 105 CMR 120.000, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 105 CMR 120.267.

120.754: continued

Each notification and report shall:

(1) Be in writing;

(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number;

(3) Include the individual's exposure information; and,

(4) Contain the following statement:

"This report is furnished to you under the provisions of 105 CMR 120.750. You should preserve this report for future reference."

(B) Each licensee or registrant shall furnish to each worker annually a written report of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to 105 CMR 120.267. The licensee shall provide an annual report to each individual monitored under 105 CMR 120.226 of the dose received in that monitoring year if:

(1) The individual's occupational dose exceeds one mSv (100 mrem) TEDE or one mSv (100 mrem) to any individual organ or tissue; or

(2) The individual requests his or her annual dose report.

(C) Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to 105 CMR 120.226. Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(D) When a licensee or registrant is required pursuant to 105 CMR 120.282, 120.283 or 120.284 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his or her exposure data included in the report to the Agency. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

(E) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

120.755: Presence of Representatives of Licensees or Registrants and Workers During Inspection

(A) Each licensee or registrant shall afford to the Agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to 105 CMR 120.000.

(B) During an inspection, Agency inspectors may consult privately with workers as specified in 105 CMR 120.756. The licensee or registrant may accompany Agency inspectors during other phases of an inspection.

(C) If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(D) Each worker's representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 105 CMR 120.753.

120.755: continued

(E) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(F) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

(G) Notwithstanding the other provisions of 105 CMR 120.755, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

120.756: Consultation with Workers During Inspections

(A) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of 105 CMR 120.000 and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(B) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of M.G.L. c. 111, §§, 5N, and 5P, 105 CMR 120.000, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 105 CMR 120.757(A).

(C) The provisions of 105 CMR 120.756(B) shall not be interpreted as authorization to disregard instructions pursuant to 105 CMR 120.753.

120.757: Requests by Workers for Inspections

(A) Any worker or representative of workers believing that a violation of the Act, 105 CMR 120.000, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

(B) If, upon receipt of such notice, the Agency determines that the complaint meets the requirements set forth in 105 CMR 120.757(A), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to 105 CMR 120.757 need not be limited to matters referred to in the complaint.

(C) No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under 105 CMR 120.000 or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by 105 CMR 120.750.

120.758: Inspections not Warranted; Informal Review

(A) (1) If the Agency determines, with respect to a complaint under 105 CMR 120.757, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Department. The Department will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Department. The Department will provide the complainant with a copy of such statement by certified mail.

(2) Upon the request of the complainant, the Department may hold an informal conference in which the complainant and the licensee or registrant may, orally present their views. An sssssinformal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Department shall affirm, modify, or reverse the determination of the Agency and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

(B) If the Agency determines that an inspection is not warranted because the requirements of 105 CMR 120.757(A) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 105 CMR 120.757(A).

120.760: Emergency Plans

The user should formulate suitable emergency plans as may be indicated to protect his employees and the public against potential hazards due to his specific source(s), and should make known the details and existence of such plans to the Agency and such other public agencies having a concern; including, but not limited to, boards of health, fire departments and police departments.

120.770: TRANSPORTATION OF RADIOACTIVE MATERIAL

120.771: Purpose and Scope

(A) 105 CMR 120.770 establishes requirements for packaging, preparation for shipment, and transportation of licensed material.

(B) The packaging and transport of licensed material are also subject to other sections of 105 CMR 120.000 and to the regulations of other agencies (such as the United States Department of Transportation, the United States Postal Service and the United States Nuclear Regulatory Commission) having jurisdiction over means of transport. The requirements of 105 CMR 120.770 are in addition to, and not in substitution for, other requirements

(C) 105 CMR 120.770 applies to any licensee authorized by specific or general license issued by the Agency to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Agency license, or transports that material on public highways. No provision of 105 CMR 120.770 authorizes possession of licensed material.

(D) Exemptions from the requirement for license are specified in 105 CMR 120.774. General licenses for which no package approval is required are issued in 105 CMR 120.777 through 120.782. The general license in 105 CMR 120.777 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license. The transport of licensed material or delivery of licensed material to a carrier for transport is subject to the operating control requirements and procedures of 105 CMR 120.785 through 120.793 to the quality assurance requirements of 105 CMR 120.794, and to the general provisions of 105 CMR 120.771 through 120.775, including referenced United States Department of Transportation regulations.

120.772: continued

Nuclear Waste means a quantity ofsource, byproduct or special nuclear material required to be in US Nuclear Regulatory Commission-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

Package means the packaging together with its radioactive contents as presented for transport.
(1) Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.
(2) Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR part 173.
(3) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in §71.19.

Packaging means the assembly of components necessary to ensure compliance with the packaging requirements of 49 CFR Part 173. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

Regulations of the U.S. Department of Transportation (DOT) means the regulations in 49 CFR Parts 100 through 189 and Parts 390 through 397.

Regulations of the U.S. Nuclear Regulatory Commission (NRC) means the regulations in 10 CFR 71 for purposes of 105 CMR 120.770.

Special Form Radioactive Material means radioactive material which satisfies the following conditions:
(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
(2) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch); and
(3) It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

Specific Activity of a radionuclide means the activity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the activity per unit mass of the material.

Surface Contaminated Object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

120.772: continued

(1) SCO-I: A solid object on which:
(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed four Bq/cm^2 (10^{-4} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} microcurie/cm^2) for all other alpha emitters;
(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters; and,
(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (one microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or $4x10^1$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters.

(2) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:
(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} microcurie/cm^2) for all other alpha emitters;
(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8x10^5$ Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (two microcuries/cm^2) for all other alpha emitters; and,
(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8x10^5$ Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (two microcuries/cm^2) for all other alpha emitters.

Transport Index means the dimensionless number (rounded up to the next tenth) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)).

Type A Quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in 105 CMR 120.795: *Appendix A* or may be determined by procedures described in 105 CMR 120.795: *Appendix A*.

Type B Quantity means a quantity of radioactive material greater than a Type A quantity.

Unirradiated Uranium means uranium containing not more than 2×10^3 Bq of plutonium per gram of uranium 235, not more than 9×10^6 Bq of fission products per gram of uranium 235, and not more than 5×10^{-3} g of uranium 236 per gram of uranium 235.

Uranium - Natural, Depleted, Enriched.
(1) Natural Uranium means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).
(2) Depleted Uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.
(3) Enriched Uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

GENERAL REGULATORY PROVISIONS

120.773: Requirement for License

Except as authorized in a general license or a specific license issued by the Agency, or as exempted in 105 CMR 120.775, no licensee may:

120.773: continued

(A) Deliver licensed material to a carrier for transport; or

(B) Transport licensed material.

120.774: Transportation of Licensed Material

(A) Each licensee who transports licensed material outside the site of usage, as specified in the Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

(1) The licensee shall particularly note DOT regulations in the following areas:

(a) Packaging - 49 CFR Part 173: Subparts A and B and I.

(b) Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.441, and Subpart E.

(c) Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.

(d) Accident reporting - 49 CFR Part 171: §§ 171.15 and 171.16.

(e) Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.

(f) Hazardous material employee training - 49 CFR Part 172: Subpart H.

(g) Security plans - 49 CFR Part 172: Subpart I

(h) Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(a) Rail - 49 CFR Part 174: Subparts A through D and K.

(b) Air - 49 CFR Part 175

(c) Vessel - 49 CFR Part 176: Subparts A through F and M.

(d) Public Highway - 49 CFR Part 177 and Parts 390 through 397.

(3) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 105 CMR 120.242(E).

(B) If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 107, 171 through 180 and 390 through 397 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Radiation Control Program.

120.775: Exemptions

(A) Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from 105 CMR 120.774 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under 105 CMR 120.775 must be licensed under 10 CFR Part 35 or the equivalent Agreement State regulations.

(B) Common and contract carriers, freight forwarders, and warehouse workers who are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), and the U.S. Postal Service are exempt from the requirements of 105 CMR 120.770 to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 105 CMR 120.773 and other applicable requirements of 105 CMR 120.000.

(C) A licensee is exempt from all requirements of 105 CMR 120.770, with respect to shipment or carriage of the following low-level materials:

(1) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed ten times the values specified in 105 CMR 120.795: *Appendix A, Table A-2.*

120.775: continued

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in 105 CMR 120.795: *Appendix A, Table A-2*, or for which the consignment activity is not greater than the limit for an exempt consignment found in 105 CMR 120.795: *Appendix A, Table A-2*.

(D) Fissile materials meeting one of the following requirements are exempt from the classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 10 CFR 71.59, but are subject to all other requirements of 10 CFR 71, except as noted.

(1) Individual package containing two grams or less fissile material.

(2) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

(3) (a) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

1. There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and

2. There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

(b) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

(c) Uranium enriched in uranium-235 to a maximum of 1% by weight, and with total plutonium and uranium-233 content of up to 1% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5% of the uranium mass.

(d) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2% by mass, with a total plutonium and uranium-233 content not exceeding 0.002% of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of two. The material must be contained in at least a DOT Type A package.

(e) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20% by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

120.776: General Licenses for Carriers

(A) A general license is hereby issued to any common or contract carrier not exempt under 105 CMR 120.775 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(B) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(C) Persons who transport radioactive material pursuant to the general licenses in 105 CMR 120.776(A) or (B) are exempt from the requirements of 105 CMR 120.200 and 120.750 to the extent that they transport radioactive material.

[3] Notification of an incident shall be filed with, or made to, the Agency as prescribed in 49 CFR, regardless of, and in addition to, notification made to U.S. Department of Transportation or other agencies.

120.777: General License: Nuclear Regulatory Commission - Approved Packages

(A) A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the Nuclear Regulatory Commission.

(B) This general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.790 through 120.793.

(C) This general license applies only to a licensee who:
(1) Has a copy of the specific license, certificate of compliance, or other approval by the Nuclear Regulatory Commission of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;
(2) Complies with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of 105 CMR 120.770;
(3) Before the licensee's first use of the package, submits in writing to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

(D) The general license in 105 CMR 120.777(A) applies only when the package approval authorizes use of the package under this general license.

(E) For a Type B or fissile material package, the design of which was approved by the Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

120.779: General License: U.S. Department of Transportation Specification Container

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

(B) This general license applies only to a licensee who:
(1) Has a copy of the specification;
(2) Complies with the terms and conditions of the specification and the applicable requirements of 105 CMR 120.770; and,
(3) Has a quality assurance program as required by 105 CMR 120.790.

(C) This general license in 105 CMR 120.779(A) is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

(D) The general license specified in 105 CMR 120.779 expires on October 1, 2008.

120.780: General License - Use of Foreign Approved Package

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

(B) This general license applies only to shipments made to or from locations outside the United States.

(C) The general license applies only to a licensee who:
(1) Has a quality assurance program approved by the Agency.
(2) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and

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(3) Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of 105 CMR 120.770 with respect to the quality assurance provisions 105 CMR 120.790, the licensee is exempt from design, construction, and fabrication considerations.

120.781: General License: Fissile Material, Limited Quantity per Package

(A) A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with 105 CMR 120.781. The fissile material need not be contained in a package which meets the standards of subparts E and F of of 10 CFR 71; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.790 through 120.793.

(C) The general license applies only when a package's contents:
(1) Contain less than a Type A quantity of fissile material; and,
(2) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(D) The general license applies only to packages containing fissile material that are labeled with a CSI which:
(1) Has been determined in accordance with 105 CMR 120.781(E);
(2) Has a value less than or equal to ten; and
(3) For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(E)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } {}^{235}U}{X} + \frac{\text{grams of } {}^{233}U}{Y} + \frac{\text{grams of Pu}}{Z}\right]$$

(2) The calculated CSI must be rounded up to the first decimal place;
(3) The values of X, Y, and Z used in the CSI equation must be taken from Tables I or II, as appropriate;
(4) If Table II is used to obtain the value of X, then the values for the terms in the equation for uranium 233 and plutonium must be assumed to be zero; and,
(5) Table I values for X, Y, and Z must be used to determine the CSI if:
(a) Uranium 233 is present in the package;
(b) The mass of plutonium exceeds 1% of the mass of uranium 235;
(c) The uranium is of unknown uranium 235 enrichment or greater than 24 weight percent enrichment; or
(d) Substances having a moderating effectiveness (*i.e.*, an average hydrogen density greater than H2O) (*e.g.*, certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

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TABLE I -- Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per 105 CMR 120.781(E)

Fissile Materials	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O* (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

* When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15% of the moderating substance has an average hydrogen density greater than H2O.

Table II Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per 105 CMR 120.781(E)

Uranium Enrichment in Weight Percent of ^{235}U Not Exceeding	Fissile Material Mass of ^{235}U (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

120.782: General License: Plutonium Beryllium Special Form Material

(A) A general license is issued to any licensee to transport fissile material in the form of plutonium beryllium (Pu Be) special form sealed sources, or to deliver Pu Be sealed sources to a carrier for transport, if the material is shipped in accordance with 105 CMR 120.782. This material need not be contained in a package which meets the standards of subparts E and F of 10 CFR 71; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.790 through 120.793.

(C) The general license applies only when a package's contents:
(1) Contain no more than a Type A quantity of radioactive material; and,
(2) Contain less than 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

(D) The general license applies only to packages labeled with a CSI which:
(1) Has been determined in accordance with 105 CMR 120.782(E);
(2) Has a value less than or equal to 100; and,
(3) For a shipment of multiple packages containing Pu Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(E)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } {}^{239}\text{Pu} + \text{grams of } {}^{241}\text{Pu}}{24}\right];$$

(2) The calculated CSI must be rounded up to the first decimal place.

PACKAGE APPROVAL STANDARDS

120.783: External Radiation Standards for All Packages

(A) Except as provided in 105 CMR 120.783(B), each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed ten.

(B) A package that exceeds the radiation level limits specified in 105 CMR 120.783(A) must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:
(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):
(a) The shipment is made in a closed transport vehicle;
(b) The package is secured within the vehicle so that its position remains fixed during transportation; and,
(c) There are no loading or unloading operations between the beginning and end of the transportation;
(2) 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and
(3) 0.1 mSv/h (10 mrem/h) at any point two meters (80 in) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point two meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

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(4) 0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with 105 CMR 120.226.

(C) For shipments made under the provisions of 105 CMR 120.783(B), the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

(D) The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

OPERATING CONTROLS AND PROCEDURES

120.784: Assumptions as to Unknown Properties of Fissile Material

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

120.785: Preliminary Determinations

Prior to the first use of any packaging for the shipment of licensed material:

(A) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

(B) Where the maximum normal operating pressure will exceed 35 kPa (five lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50% higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

(C) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Nuclear Regulatory Commission.

120.786: Routine Determinations

Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies applicable requirements of 10 CFR 71 and of the license. The licensee shall determine that:

(A) The package is proper for the contents to be shipped;

(B) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(C) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(D) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(E) Any pressure relief device is operable and set in accordance with written procedures;

(F) The package has been loaded and closed in accordance with written procedures;

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(G) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(H) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

(I) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

(J) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10 CFR 71.47 at any time during transportation; and

(K) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

120.787: Air Transport of Plutonium

Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in 105 CMR 120.770 or included indirectly by citation of the U.S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air, or delivered to a carrier for air transport, unless:

(A) The plutonium is contained in a medical device designed for individual human application;

(B) The plutonium is contained in a material in which the specific activity is not greater than or equal to the activity concentration values for plutonium specified in 105 CMR 120.770: *Appendix A, Table A-2*, and in which the radioactivity is essentially uniformly distributed;

(C) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with 105 CMR 120.774;

(D) The plutonium is shipped in a package specifically authorized (in the Certificate of Compliance issued by the Nuclear Regulatory Commission for that package) for the shipment of plutonium by air; or

(E) For a shipment of plutonium by air which is subject to105 CMR 120.787(D), the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

120.788: Opening Instructions

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 105 CMR 120.242(E).

120.789: Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste

(A) As specified in 105 CMR 120.789(B) through (D), each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, through, or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(B) Advance notification is required under 105 CMR 120.789 for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required under 105 CMR 120.789 for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

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(1) The licensed material is required by 10 CFR 71 to be in Type B packaging for transportation;
(2) The licensed material is being transported into, within, or through a state en route to a disposal facility or to a collection point for transport to a disposal facility; and,
(3) The quantity of licensed material in a single package exceeds the least of the following:
(a) 3000 times the A_1 value of the radionuclides as specified in 105 CMR 120.795: *Appendix A*, Table A-1 for special form radioactive material;
(b) 3000 times the A_2 value of the radionuclides as specified in 105 CMR 120.795: *Appendix A*, Table A-1 for normal form radioactive material; or,
(c) 1000 TBq (27,000 Ci).

(C) Procedures for Submitting Advance Notification.
(1) The notification must be made in writing to the office of each appropriate governor or governor's designee, the Agency, and to the Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response.
(2) A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-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 at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.
(a) 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).
(b) The list will be published annually in the Federal Register on or about June 30th to reflect any changes in information.
(c) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
(4) The licensee shall retain a copy of the notification as a record for three 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 seven-day period during which departure of the shipment is estimated to occur;
(4) The seven-day period during which arrival of the shipment at State boundaries is estimated to occur;
(5) The destination of the shipment, and the seven-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.

(E) Revision Notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee, in accordance with 105 CMR 120.789, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor'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 three years.

(F) 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, the Agency, previously notified, and to the Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response.
(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 three years.

QUALITY ASSURANCE

120.790: Quality Assurance Requirements

(A) Purpose. 105 CMR 120.790 describes 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 subpart, "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. The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to this subpart.

(B) Establishment of Program. Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 CFR 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(C) Approval of Program. Before the use of any package for the shipment of licensed material subject to 105 CMR 120.790, each licensee shall obtain Agency approval of its quality assurance program.

(D) Radiography Containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 10 CFR 34.31(b) or equivalent Agreement State requirement, is deemed to satisfy the requirements of 105 CMR 120.777 and 120.790(B).

120.791: Quality Assurance Organization

(A) The "licensee" [while the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued], certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(B) The quality assurance functions are:

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

120.793: Quality Assurance Program

(A) The licensee, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of 10 CFR 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

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(B) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The impact of malfunction or failure of the item to safety;
(2) The design and fabrication complexity or uniqueness of the item;
(3) The need for special controls and surveillance over processes and equipment;
(4) The degree to which functional compliance can be demonstrated by inspection or test; and
(5) The quality history and degree of standardization of the item.

(C) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

120.795: Appendix A -- Determination of A_1 and A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. (a) For individual radionuclides whose identities are known, but which are not listed in Table A-1, the A_1 and A_2 values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Agency approval of the A_1 and A_2 values for radionuclides not listed in Table A-1, before shipping the material.
(b) For individual radionuclides whose identities are known, but which are not listed in Table A-2, the exempt material activity concentration and exempt consignment activity values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Agency approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2, before shipping the material.
(c) The licensee shall submit requests for prior approval, described in Appendix AII(a) and II(b), to the Agency, in accordance with 10 CFR 71.1.

NON-TEXT PAGE

Appendix A: continued

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than ten days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i, and $A_1(i)$ is the A_1 value for radionuclide i.

(b) For normal form radioactive material, the maximum quantity transported in a Type A package is:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i and $A_1(i)$ and $A_2(i)$ are the A_1 and A_2 values for radionuclide i.

(c) Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

$$A_1 = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity of nuclide i in the mixture and $A_1(i)$ is the appropriate A_1 value for nuclide i.

(d) Alternatively, the A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of nuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide i.

Appendix A: continued

(e) The exempt activity concentration for mixtures of nuclides may be determined as follows:

Exempt activity concentration for mixture

$$= \frac{1}{\Sigma_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and [A] is the activity concentration for exempt material containing radionuclide I.

(f) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows: Exempt consignment activity limit for mixture

$$= \frac{1}{\Sigma_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and A is the activity limit for exempt consignments for radionuclide I.

V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	(Tbq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	$2.7X10^{0}$	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	$2X10^{0}$	$5.4X10^{1}$	$2X10^{0}$	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	$2.7X10^{0}$	$1.0X10^{-1}$	$2.7X10^{0}$	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	$3.4X10^{0}$
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		$5.0X10^{0}$	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$2.0X10^{1}$	$5.4X10^{2}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.3X10^{0}$	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		$1.0X10^{0}$	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$