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.

120.524: 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.

120.551: 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.

120.556: 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:

120.558: 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).

120.440: 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.

120.521: 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

120.525: 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 fulltime 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:

120.587: continued

(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.

120.254: Treatment or Disposal by Incineration

A licensee may treat licensed material by incineration only in the form and concentration specified in 105 CMR 120.255 or as specifically approved by the Agency pursuant to 105 CMR 120.252.

120.255: Disposal of Specific Wastes

(A) A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:
(1) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and
(2) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(B) A licensee or registrant shall not dispose of tissue pursuant to 105 CMR 120.255(A)(2) in a manner that would permit its use either as food for humans or as animal feed.

(C) The licensee or registrant shall maintain records in accordance with 105 CMR 120.269.

120.256: Transfer for Disposal and Manifests

(A) The requirements of 105 CMR 120.256 and Appendix G to 10 CFR 20, herein incorporated into 105 CMR120.256 by reference are designed to:
(1) Control transfers of low-level waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G to 10 CFR 20, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in 105 CMR 120.803;
(2) Establish a manifest tracking system; and
(3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

(B) (1) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded information to the intended consignee in accordance with Appendix G to 10 CFR 20.
(2) Any licensee shipping byproduct material as defined in 105 CMR 120.005: Byproduct Material(2) and (3) intended for ultimate disposal at a land disposal facility licensed under 105 CMR 120.800 or equivalent NRC or Agreement State regulations must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G of 10 CFR Part 20.

(C) Each shipment manifest shall include a certification by the waste generator as specified in Appendix G to 10 CFR 20.

(D) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, and waste processor, shall comply with the requirements specified in 105 CMR 120.256 and Appendix to 10 CFR 20 as appropriate.

(E) Reports and notifications required to be made to the nearest NRC regional administrator by Appendix G to 10 CFR 20 shall, instead, be made to the Agency.

120.257: Compliance with Environmental and Health Protection Regulations

Nothing in 105 CMR 120.251, 120.253, 20.254, or 120.256 relieves the licensee from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of in accordance with 105 CMR 120.251, 120.253, 120.254, or 120.256.

120.258: Disposal of Certain Byproduct Material

(A) Licensed material as defined in 105 CMR 120.005: Byproduct Material(2) and (3) may be disposed of in accordance with 105 CMR 120.800, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 105 CMR 120.800 or equivalent Nuclear Regulatory Commission or Agreement State requirements, must meet the requirements of 105 CMR 120.256.

(B) A licensee may dispose of byproduct material, as defined in 105 CMR 120.005: Byproduct Material(2) and (3), at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

RECORDS

120.261: General Provisions

(A) Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by 105 CMR 120.261.

(B) Not withstanding the requirements of 105 CMR 120.261(A), when recording information on shipment manifests, as required in 105 CMR 120.256, information must be recorded in SI units or in SI units and special units as specified in 105 CMR 120.261(A).

(C) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by 105 CMR 120.200, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

120.262: Records of Radiation Protection Programs

(A) Each licensee or registrant shall maintain records of the radiation protection program, including:
(1) the provisions of the program; and,
(2) audits and other reviews of program content and implementation.

(B) The licensee or registrant shall retain the records required by 105 CMR 120.262(A)(1) until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 105 CMR 120.262(A)(2) for three years after the record is made.

120.263: Records of Surveys

(A) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 105 CMR 120.225 and 120.242(B). The licensee or registrant shall retain these records for three years after the record is made.

(B) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:
(1) records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;
(2) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;
(3) records showing the results of air sampling, surveys, and bioassays required pursuant to 105 CMR 120.233(A)(3)(a) and (b); and,
(4) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

120.032: continued

(4) In the case of diagnostic x-ray system which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30 (d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other by the assembler.

(B) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and use shall meet the requirements of 105 CMR 120.000.

120.033: Out-of-state Radiation Machines

(A) Whenever any radiation machine is to be brought into the Commonwealth, for any temporary use, the person proposing to bring such machine into the Commonwealth shall give written notice to the Agency at least ten working days before such machine is to be used in the Commonwealth. The notice shall include:

(1) The type of radiation machine;
(2) The nature, duration, and scope of use;
(3) The exact location(s) where the radiation machine is to be used; and,
(4) States in which this machine is registered.

(B) The person referred to in 105 CMR 120.033 shall:

(1) Comply with all applicable regulations of the Agency;
(2) Register the radiation machine(s) with the Agency; and,
(3) Submit payment of the required fee for registration.

(C) A pre-operational inspection may be required at the discretion of the Director of the Radiation Control Program.

(D) If, for a specific case, the ten working day period is not practical, notification to the Agency by telephone and hardcopy, permission to proceed sooner may be granted.

120.040: Notification to Fire Department

The user shall notify the local fire department of the presence on his premises of any radioactive material that may present special fire-fighting problems or require special precautionary measures in case of fire or other natural catastrophe, and he shall establish effective liaison with the fire department in regards to this matter.

120.100: LICENSING OF RADIOACTIVE MATERIAL

120.101: Purpose and Scope

(A) 105 CMR 120.100, 120.500 and 120.770, provide for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to 105 CMR 120.100, 120.500 or 120.770, or as otherwise provided in 105 CMR 120.000.

(B) In addition to the requirements of 105 CMR 120.100, all licensees are subject to the requirements of 105 CMR 120.000, 120.200, 120.750, and 120.770. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of 105 CMR 120.300; licensees using radionuclides in the healing arts are subject to the requirements of 105 CMR 120.500, licensees engaged in land disposal of radioactive material are subject to the requirements of 105 CMR 120.801 through 120.885, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 105 CMR 120.900.

120.124: continued

(E) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

(F) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

(G) An application for a specific license to authorize receipt, possession or use of radioactive material in the form of a sealed source or in a device that contains a sealed source shall either:

(1) identify the sealed source or device that contains a sealed source by manufacturer and model number as registered in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices" under 10 CFR 32.210, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 105 CMR 120.128(N);

(2) contain the information identified in 105 CMR 120.128(N);

(3) for sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with NRC under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 105 CMR 120.128(N)(2)(b) or (c) as applicable, the applicant must provide:

(a) All available information identified in 105 CMR 120.128(N)(2)(b) or (c) concerning the source, and, if applicable, the device; and,

(b) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

120.125: General Requirements for the Issuance of Specific Licenses

(A) A license application will be approved only if the Agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 105 CMR 120.000 in such a manner as to minimize danger to public health and safety or property;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(3) the issuance of the license will not be inimical to the health and safety of the public; and,

(4) the applicant satisfies any applicable special requirements in 105 CMR 120.126, 120.127, 120.128, 120.300, 120.500, 120.620 120.800, 120.890 or 120.900.

(B) Environmental Report, Commencement of Construction.

(1) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, a license application shall be reviewed and approved by the Agency before commencement of construction of the plant or facility in which the activity will be conducted. Issuance of the license shall be based upon a consideration by the Agency of the environmental, economic, technical and other benefits in comparison with the environmental costs and available alternatives and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values;

(2) Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in 105 CMR 120.125(B) the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

120.128: continued

The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label

CAUTION - RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (OR RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

_____
Name of manufacturer or initial transferor

(6) Each person licensed under 105 CMR 120.128(F) shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under 105 CMR 120.122(G). This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee under 105 CMR 120.122(G) or equivalent regulations of NRC or an Agreement State.

(G) Requirements for Other Specific Licenses (Reserved).

(H) Manufacture and Distribution of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 105 CMR 120.122(I) will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125.

(2) the radioactive material is to be prepared for distribution in prepackaged units of:

(a) carbon-14 in units not exceeding ten microcuries (370 kBq) each.

(b) cobalt-57 in units not exceeding ten microcuries (370 kBq) each.

(c) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(d) iodine-125 in units not exceeding ten microcuries (370 kBq) each.

(e) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(f) iodine-131 in units not exceeding ten microcuries (370 kBq) each.

(g) iron-59 in units not exceeding 20 microcuries (740 kBq) each.

(h) selenium-75 in units not exceeding ten microcuries (370 kBq) each.

(3) each prepackaged unit bears a durable, clearly visible label:

(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) and

(b) displaying the radiation caution symbol described in 105 CMR 120.237(A) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(4) The following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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 $4x10^3$ 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.

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[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

120.780: continued

(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.

120.781: continued

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 ^{233}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:

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

(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

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.

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)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$

120.104: continued

(a) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

1. 25 millicuries (925 MBq) of tritium per timepiece.
2. five millicuries (185 MBq) of tritium per hand.
3. 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).
4. 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.
5. 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.
6. 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).
7. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
   a. For wrist watches, 0.1 millirad (1 μGy) per hour at ten centimeters from any surface.
   b. For pocket watches, 0.1 millirad (1 μGy) per hour at one centimeter from any surface.
   c. For any other timepiece, 0.2 millirad (2 μGy) per hour at ten centimeters from any surface.
8. One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(b) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

(c) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

(d) Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(e) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of byproduct material:

1. 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.
2. 1 microcurie (37 kBq) of cobalt-60.
3. 5 microcuries (185 kBq) of nickel-63.
4. 30 microcuries (1.11 MBq) of krypton-85.
5. 5 microcuries (185 kBq) of cesium-137.
6. 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing byproduct material will not exceed one millirad (ten μGy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of 105 CMR 120.104(C)(1)(h), "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(f) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

1. Each source contains no more than one exempt quantity set forth in 105 CMR 120.196: *Appendix B, Table I*; and

120.005: continued

$$\frac{175 \text{ (grams U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

Supplied Air Respirator (SAR) or Airline Respirator means an atmosphere supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or presence of sources of radiation . When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

Test means the process of verifying compliance with an applicable regulation.

Tight-fitting Facepiece means a respiratory inlet covering that forms a complete seal with the face.

Total Effective Dose Equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Total Organ Dose Equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 105 CMR 120.267(A)(6).

Traceable to National Standard (*See* Instrument Traceability or Source Traceability]

U.S. Department of Energy means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*, to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

User Seal Check (Fit Check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Unrefined and Unprocessed Ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

Unrestricted Area (Uncontrolled Area) means area access to which is neither limited nor controlled by the licensee or registrant. For purposes of 105 CMR 120.000, Uncontrolled Area is an equivalent term.

Vendor means a supplier of products or services to be used by a licensee or registrant or a licensed or registered facility or activity.

Very High Radiation Area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates [*Note*: At very high doses rates, units of adsorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem].

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

120.551: 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.

120.557: 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 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 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).

120.567: 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.