

PROPOSED AMENDMENTS TO THE RULES OF THE
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION
RADIOACTIVE MATERIALS, CHAPTER 391-3-17

The Rules of the Department of Natural Resources, Chapter 391-3-17, Radioactive Materials, are hereby amended, added to, repealed in part, revised, as hereinafter explicitly set forth in the attached amendments, additions, partial repeals, and revisions for specific rules, or such subdivisions thereof as may be indicated.

[Note: Underlined text is proposed to be added. Lined-through text is proposed for deletion.]

Rule 391-3-17-.04, “Special Radiation Safety Requirements for Industrial Radiographic Operations,” is amended to read as follows:

391-3-17-.04 Special Radiation Safety Requirements for Industrial Radiographic Operations

(1) Purpose.

The provisions of this Rule establish radiation safety requirements and certification procedures for persons utilizing radioactive materials for industrial radiography. Each licensee and certificate holder is responsible for ensuring compliance with these Rules, his license conditions, and Orders of the Director. Each licensee and certificate holder is also responsible for ensuring that persons performing activities under a license comply with the Rules, license conditions, and Orders of the Director.

(2) Scope.

(a) The provisions of this Rule are in addition to and not a substitution for the other requirements of this Chapter. The provisions of this Rule apply to all licensees who use radioactive materials for industrial radiography; provided, however, that nothing in this Rule shall apply to the use of radioactive materials in the healing arts.

(b) The licensee shall inform the Division within three days of work to be performed at temporary job sites within the State of Georgia. If the licensee was not given three days notice for a particular job site the licensee shall provide notification to the Division prior to starting work at the site. The following information is required in the notification: the location of the job site; the employing company; a point of contact for the employing company; the dates of the job; and the starting and ending times on the job site.

(3) Definitions. The definitions set forth for certain terms in Rule 391-3-17-.01 are applicable to those terms as used in this Rule. The following additional definitions also apply:

- (a) "Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.
- (b) "ANSI" means American National Standards Institute.
- (c) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source. (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when used as an exposure head.)
- (d) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that radiation levels at every location on the exterior meet the conditions specified in Rule 391-3-17-.03(5)(i).
- (e) "Certifying entity" means an independent certifying organization meeting the requirements in Appendix A of this Rule or an Agreement State regulatory program meeting the requirements in Appendix A, Parts II and III of this Rule.
- (f) "Collimator" means a device used to limit the size, shape, and direction of the primary beam of radiation.
- (g) "Control cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.
- (h) "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.
- (i) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.
- (j) "Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.
- (k) "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. An exposure head is also known as a source stop.
- (l) "Field station" means a facility from which sources of radiation may be stored or used and from which equipment is dispatched.
- (m) "Guide tube" means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

- (n) "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.
- (o) "Independent certifying organization" means an independent organization that meets all of the criteria of Appendix A of this Rule.
- (p) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.
- (q) "Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.
- (r) "Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.
- (s) "Permanent radiographic installation" means a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed.
- (t) "Personal supervision" means guidance and instruction provided to a radiographer's assistant by a radiographer who is present at the site, in visual contact with the radiographer's assistant while the radiographer's assistant is using radioactive material, and in such proximity that immediate assistance can be given if required.
- (u) "Pigtail" see "Source assembly".
- (v) "Pill" see "Sealed source".
- (w) "Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.
- (x) "Radiation Safety Officer" means an individual named by the licensee who has a knowledge of, responsibility for, and authority to impose appropriate radiation protection rules, standards, and practices on behalf of the licensee and who meets the requirements of (15) of this Rule.
- (y) "Radiographer" means any individual who performs or who, in attendance at the site where radioactive materials are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of this Chapter and all license conditions.
- (z) "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in (16) of this rule.
- (aa) "Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, radioactive materials, related handling tools, or

radiation survey instruments in industrial radiography.

(bb) "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to an unshielded position for purposes of making a radiographic exposure (e.g. camera).

(cc) "Radiographic operations" means all activities performed with a radiographic exposure device. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries.

(dd) "Residential location" means any area where structures in which people live or lodge are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

(ee) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

(ff) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(gg) "Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

(hh) "Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in Rule 391-3-17-.03(5)(i) of this Chapter.

(ii) "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ball stop to secure the source in the shielded position.

(jj) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

(kk) "Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

(ll) "Storage container" means a shielded device in which sealed sources are secured and stored.

(mm) "Temporary job site" means any location where radiographic operations are performed and where sources of radiation may be stored other than the location(s) listed specifically on the

license.

(nn) "Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the U.S. Department of Transportation.

(oo) "Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.

(4) Licensing Requirements for Industrial Radiography Operations. The Director will approve an application for a specific license for the use of licensed material if the applicant meets the following requirements:

(a) The applicant satisfies the general requirements specified in Rule 391-3-17-.02(8), as applicable, and any special requirements contained in this Rule;

(b) The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of .04(16):

1. After April 18, 2004, the applicant need not describe the initial training and examination program for radiographers in the subjects outlined in .04(16)(g).

2. The applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in .04(16)(g).

(c) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

(d) The applicant submits written operating and emergency procedures as described in .04(17);

(e) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six months as described in .04(16)(e);

(f) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

(g) The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in .04(15)(a);

(h) If an applicant intends to perform leak testing of sealed sources or exposure devices

containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test. The description must include the:

1. Methods of collecting the samples;
2. Instruments to be used;
3. Methods of analyzing the samples; and
4. Qualifications of the individual who analyzes the samples.

(i) If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in .04(8)(b) and .04(19)(g)4.;

(j) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations;

(k) The applicant identifies the location(s) where all records required by this and other Rules in this Chapter will be maintained;

(l) If a license application includes underwater radiography the applicant must submit a description of:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
2. Radiographic equipment and radiation safety equipment unique to underwater radiography; and
3. Methods for gas-tight encapsulation of equipment; and

(m) If an application includes offshore platform and/or lay-barge radiography the applicant must submit a description of:

1. Transport procedures for radioactive material to be used in industrial radiographic operations;
2. Storage facilities for radioactive material; and
3. Methods for restricting access to radiation areas.

(5) Performance Requirements for Radiography Equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) Each radiographic exposure device, source assembly or sealed source and all associated equipment must meet the requirements specified in American National Standards Institute

(ANSI) N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). (This publication may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402 and from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036, Telephone (212) 642-4900. Copies of the document are available for inspection at the Department of Natural Resources, Environmental Protection Division, Radioactive Materials Program, 4244 International Parkway, Suite 120, Atlanta, Georgia 30354 or current address.)

(b) In addition to the requirements specified in (5)(a) of this Rule, the following requirements apply to radiographic exposure devices, source changers, source assemblies or sealed sources:

1. Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the:

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model number (or product code) and serial number of the sealed source;

(iv) Manufacturer of the sealed source; and

(v) Licensee's name, address, and telephone number.

2. Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR Part 71.

3. Modification of any radiographic exposure devices, source changers, source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(c) In addition to the requirements specified in .04(5)(a) and (5)(b) the following requirements apply to radiographic exposure devices, source assemblies and associated equipment that allow the source to be moved out of the device for routine operation or to source changers:

1. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

2. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

3. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.
 4. Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER - RADIOACTIVE." The label must not interfere with the safe operation of the exposure device or associated equipment.
 5. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.
 6. Guide tubes must be used when moving the source out of the device.
 7. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.
 8. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.
 9. Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.
- (d) All radiographic exposure devices and associated equipment in use after January 10, 1996 must comply with the requirements of .04(5).
- (e) Notwithstanding (5)(a) equipment used in industrial radiographic operations need not comply with section 8.9.2(c) of the Endurance Test in ANSI N432-1980 if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.
- (6) Equipment Control. Limits on External Radiation Levels From Storage Containers and Source Changers.** The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at one meter from any exterior surface with the sealed source in the shielded position.
- (7) Locking and Storage of Radiographic Devices, Storage Containers, and Source Changers.**
- (a) Each radiographic exposure device shall be provided with a lock or outer locked container designed to prevent unauthorized or accidental removal of a sealed source from its shielded position. The exposure device and/or its container shall be kept locked¹ at all times except when

¹ If a keyed lock, the key must be removed at all times.

not under the direct surveillance of a radiographer or a radiographer's assistant except at a permanent radiographic installations as stated in .04(21).

(b) Each sealed source storage container and source changer shall be provided with a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be and kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

(c) Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.

(d) During radiographic operations the sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. A survey shall be performed to determine that the sealed source is in the shielded position.

(e) Storage Precautions.

1. Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

2. Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This Rule does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with (7)(e)3. of this Rule and if the vehicle does not constitute a permanent storage location as described in (7)(e)4. of this Rule.

3. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing the radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in Rule .03(5)(i) of this Chapter at the exterior surface of the vehicle.

(i) If this vehicle is parked in a residential location a 360° survey of the vehicle must be performed before leaving the vehicle unattended to ensure that radiation levels do not exceed the limits specified in Rule .03(5)(i) of this Chapter.

(ii) An unattended vehicle shall have the name, local address, and local telephone number of the person responsible for the vehicle, posted on it in a conspicuous place on the vehicle.

4. A storage or use location is considered permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

(i) Telephone service is established by the licensee;

- (ii) Industrial radiographic services are advertised for or from the location;
- (iii) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

(8) Radiation Survey Instruments.

(a) The licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this Rule and Rule 391-3-17-.03(7)(a)1. and 2. Instrumentation required herein shall have a range such that two milliroentgens per hour through one Roentgen per hour can be measured.

(b) The licensee shall have each radiation survey instrument required under .04(4)(d) calibrated:

1. By a person licensed or certified by the Director, another Agreement State, or the U.S. Nuclear Regulatory Commission to perform such service;
2. At energies appropriate for the licensee's use;
3. At intervals not to exceed six months and after each instrument servicing, except for battery changes;
4. To demonstrate an accuracy within ± 20 percent ; and
5. At two points located approximately $1/3$ and $2/3$ of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and at approximate points for digital instruments.

(c) The licensee shall maintained records of the results of the instrument calibrations in accordance with .04(25).

(9) Leak Testing and Replacement of Sealed Sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source shall be performed only by persons specially authorized to do so by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State.

(b) The opening, repair, or modification of any sealed source shall be performed only by persons specially authorized to do so by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State.

(c) Testing and Record keeping Requirements

1. Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six months. The leak testing of the source must be performed using a method approved

by the Division, the U.S. Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcuries (185 bequerel) of radioactive material on the test sample and must be performed by a person specifically authorized by the Division, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

2. The licensee shall maintain records of the leak test in accordance with .04(26)

3. Unless a sealed source is accompanied by a certificate from a transferor that shows that it has been leak tested within the six months before the transfer, it shall not be used by the licensee until tested for leakage. Sealed sources authorized for storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months.

4. Any test conducted pursuant to the requirements of (9)(c)1. and 3. of this Rule which reveals the presence of 0.005 microcuries (185 bequerel) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Division Rules. A report shall be filed, within five (5) days after obtaining results of the test, with the Division, describing the equipment involved, the test results, and the corrective action taken.

5. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 0.005 microcuries (185 becquerel) of radioactive material on the test sample and must be performed by a person specifically authorized by the Division, the U.S. Nuclear Regulatory Commission, or another Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with .04(26).

(10) Quarterly Inventory.

(a) Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and devices containing depleted uranium received or possessed under the license.

(b) The licensee shall maintain records of the quarterly inventories in accordance with .04(27)

(11) Inspection and Maintenance of Radiographic Exposure Devices, Transport and

Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) The licensee shall perform visual and operability checks on survey meters radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

1. The equipment is in good working condition;
2. The sources are adequately shielded; and
3. Required labeling is present.

(b) Survey instrument operability must be performed using check sources or other appropriate means.

(c) If equipment problems are found, the equipment must be removed from service until repaired.

(d) Each licensee shall have written procedures for and perform inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

(e) The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(f) Records of equipment problems and of any maintenance performed under .04(11)(c) and (d) shall be maintained in accordance with .04(29).

(12) Permanent Radiographic Installations.

(a) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have either:

1. An entrance control of the types described in Rule 391-3-17-.03(9)(a)1., or .03(9)(a)2. that causes the radiation level upon entry into the area to be reduced; or
2. Both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the source is exposed. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed.

(b) The alarm system shall be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as

designated in .04(12)(a) must be tested monthly. If an entrance control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven day period, provided the licensee implements the continuous surveillance requirements of .04(21) and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms and records of repairs must be maintained in accordance with .04(30).

(13) Labeling, Storage, and Transportation.

(a) The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION *

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES [or " NAME OF COMPANY"]

* --- or "DANGER"

(b) The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Rule 391-3-17-.06.

(c) Radiographic exposure devices, source changers, and storage containers, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

(d) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(e) The licensee's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material for temporary job site use.

(14) Conducting Industrial Radiographic Operations.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of .04(16)(c). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(b) All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless otherwise specifically authorized by the Division.

(c) Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

(d) A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Division.

(15) **Radiation Safety Officer.** A Radiation Safety Officer (RSO) shall be designated on every industrial radiography license issued by the Director. The Radiation Safety Officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(a) The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

1. Completion of the training and testing requirements of .04(16);
2. 2,000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and
3. Formal training in the establishment and maintenance of a radiation protection program.

(b) The Division will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(c) The specified duties of the RSO include, but are not limited to, the following:

1. Establishing and overseeing all operating, emergency, and ALARA procedures, and to review them regularly to ensure that the procedures are current and conform with these Rules;
2. Overseeing and approving all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;
3. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with these Rules, including any corrective measures when levels of radiation exceed established limits;
4. Ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by this Chapter;

5. Ensuring that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;
6. Investigating and reporting to the Division each known or suspected case of radiation exposure to an individual, or radiation level detected, in excess of limits established by this Chapter and each theft or loss of source(s) of radiation, to determine the cause and to take steps to prevent its recurrence;
7. Having a thorough knowledge of management policies and administrative procedures of the licensee;
8. Assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
9. Maintaining records as required by this Chapter;
10. Ensuring the proper storing, labeling, transport, and use of exposure devices and sources of radiation;
11. Ensuring that inventory and inspection and maintenance programs are performed in accordance with (10) and (11) of this Rule;
12. Ensuring that personnel are complying with this Chapter, the conditions of the license, and the operating and emergency procedures of the licensee.

(16) Training.

(a) The licensee shall not permit any individual to act as a radiographer until such individual has received at least 40 hours of training in the subjects outlined in .04(16)g, in addition to on the job training consisting of hands- on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of this Rule. The on the job training shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material.

(b) In addition, the licensee may not permit any individual to act as a radiographer until the individual:

1. Has received copies of and instruction in the requirements described in the regulations contained in this Rule, and applicable sections of Rules 391-1-7-.03, .06, and .07, in the license under which the radiographer will perform industrial radiography, and the licensee's operating and emergency procedures;
2. Has demonstrated an understanding of items in .04(16)(b)1. by successful completion of a written or oral examination;

3. Has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in .04(16)(b)3. by successful completion of a practical examination.

(c) The licensee may not permit any individual to act as a radiographer's assistant until the individual:

1. Has received copies of and instruction in the requirements described in these regulations contained in this Rule, and applicable sections of Rules 391-3-17-03, .06 , and .07, in the license under which the radiographer's assistant will perform industrial radiography, and the licensee's operating and emergency procedures;

2. Has demonstrated an understanding of items in .04(16)(c)1. by successful completion of a written or oral examination;

3. Under the personal supervision of a radiographer, has received training in the use of the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in .04(16)(c)3. by successful completion of a practical examination.

(d) The licensee shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(e) Except as provided in .04(16)(e)4., the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Division's Rules, the license, and operating and emergency procedures are followed. The inspection program must:

1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

2. Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of .04(16)(b)3. and the radiographer's assistant must demonstrate knowledge of the training requirements of .04(16)(c)3. by a practical examination before these individuals can next participate in a radiographic operation.

3. The Division may consider alternative in those situations where the individual serves as both radiographer and radiation safety officer.

4. In those operations where a single individual serves as both radiographer and radiation safety

officer, and performs all radiography operations, an inspection program is not required.

(f) The licensee shall maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with .04(31).

(g) The licensee shall include the following subjects required in .04(16)(a):

1. Fundamentals of Radiation Safety including:

(i) Characteristics of gamma and x-radiation.

(ii) Units of radiation dose (rem or Sievert) and quantity of radioactivity (Curie or becquerel).

(iii) Significance of radiation dose:

(I) Radiation protection standards;

(II) Biological effects of radiation dose; and

(III) Case histories of radiography accidents.

(iv) Levels of radiation from sources of radiation.

(v) Methods of controlling radiation dose:

(I) Working time;

(II) Working distances; and

(III) Shielding.

2. Radiation Detection Instrumentation including.

(i) Use of radiation survey instruments:

(I) Operation;

(II) Calibration; and

(III) Limitations.

(ii) Survey techniques.

(iii) Use of personnel monitoring equipment including but not limited to:

- (I) Film badges;
- (II) Thermoluminescent dosimeters (TLDs);
- (III) Pocket dosimeters;
- (IV) Alarm ratemeters; and
- (V) Optically stimulated luminescent devices.

3. Radiographic Equipment to be Used including:

- (i) Remote handling equipment.
- (ii) Operation and control of radiographic exposure equipment, remote handling equipment, storage containers, and sealed sources, including pictures or models of source assemblies (pigtailed).
- (iii) Storage control, and disposal of sources of radiation; and transport containers and source changers.
- (iv) Collimators.

4. Inspection and maintenance of equipment.

5. The Requirements of Pertinent Federal and State Regulations.

6. The Licensee's Written Operating and Emergency Procedures.

7. Case histories of accidents in radiography.

(h) Licensees will have one year from the effective date of this rule to comply with the additional training requirements specified in .04(16)(b)1. and .04(16)(c)1.

(17) Operating and Emergency Procedures.

(a) The operating and emergency procedures of the licensee shall include, as a minimum, instruction in the following:

- 1. Appropriate handling and use of sources of radiation so that no individual is likely to be exposed to radiation doses in excess of the limits established in Rule 391-3-17-.03, "Standards for Protection Against Radiation";
- 2. Methods and occasions for conducting radiation surveys;
- 3. Methods for posting and controlling access to radiographic areas;

4. Methods and occasions for locking and securing sealed sources;
 5. Personnel monitoring and the use of personnel monitoring equipment;
 6. Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in Rule .06 of this Chapter;
 7. The inspection, maintenance and operability checks of radiographic exposure devices, survey instruments, alarming ratemeters, transport containers, and storage containers.
 8. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;
 9. The procedure(s) for identifying and reporting defects and noncompliance, as required by .04(37);
 10. The procedure for notifying proper persons in the event of an accident or incident;
 11. Minimizing exposure of individuals in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;
 12. Source recovery procedure if licensee will perform source recoveries; and
 13. Maintenance of records.
- (b) The licensee shall maintain copies of current operating and emergency procedures in accordance with .04(32) and .04(36).

(18) Supervision of Radiographer's Assistants.

- (a) Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment, or a sealed source, or conducts radiation surveys required by (20)(b) and (c) of this Rule to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer. The personal supervision shall include:
1. The radiographer's physical presence at the site where the sealed sources are being used;
 2. The ability of the radiographer to give immediate assistance if required; and
 3. The radiographer's direct observation of the assistant's performance of the operations referred to in .04(18) of this Rule.

(19) Personnel Monitoring Control.

(a) The licensee shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct-reading dosimeter, an alarming ratemeter, and a personal monitoring device. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use the use of an alarming ratemeter is not required.

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

2. Each personal monitoring device shall be assigned to and worn by only one individual.

3. Personal monitoring devices must be exchanged at periods not to exceed one month. After replacement each personal monitoring device must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. If circumstances exist which make it impossible to return each personal monitoring device within 14 calendar days, such circumstances must be documented and available for review by the Division.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters shall be read and exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with .04(33).

(c) Pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed one year for correct response to radiation, and records must be maintained in accordance with .04(33). Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 200 mrem (2 millisieverts), the personal monitoring device must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter may be started within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with .04(33).

(e) If a personal monitoring device is lost or damaged, the worker shall cease work immediately until a replacement personal monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the personal monitoring device. The results of the calculated exposure and the time period for which the personal monitoring device was lost or damaged must be included in the records maintained in accordance with .04(33).

(f) Reports received from personal monitoring devices shall be retained in accordance with

.04(33).

(g) Each alarm ratemeter must:

1. Be checked to ensure that the alarm functions properly prior to use at the start of each shift;
2. Emit an alarm signal at a preset dose-rate of 500 mr (5 mSv) per hour; with an accuracy of plus or minus 20 percent of the true radiation dose rate.
3. Require special means to change the preset alarm function; and
4. Be calibrated at periods not to exceed one year for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with .04(33).

(20) **Radiation Surveys.** The license shall:

- (a) Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of .04(8);
- (b) Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey shall be to determine that the sealed source has been returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.
- (c) Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in .04(3), to ensure that the sealed source is in its shielded position; and
- (d) Maintain records in accordance with .04(34).

(21) **Surveillance.** During each radiographic operation, the radiographer shall ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Rule .01 of this Chapter, except at permanent radiographic installations where all entryways are locked and the requirements of .04(12) are met.

(22) **Posting.** Notwithstanding any provisions of Rule 391-3-17-.03(12)(c) all areas in which industrial radiography is being performed shall be conspicuously posted as required by Rule 391-3-17-.03(12)(b)1. and 2.

(23) **Records for Industrial Radiography.** Each licensee shall maintain a copy of its license, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Division, or until the Director terminates the license.

(24) **Records of Receipt and Transfer of Sources of Radiation.**

- (a) Each licensee shall maintain records showing the receipts and transfers of sealed sources,

devices using DU for shielding, and radiation machines, and retain each record for three years after it is made.

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

(25) Records of Radiation Survey Instruments. Each licensee shall maintain records of the calibrations of its radiation survey instruments that are required under .04(8) and retain each record for three years after it is made.

(26) Records of Leak Testing of Sealed Sources and Devices Containing DU. Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of microcuries (becquerels). The licensee shall retain each record for three years after it is made or until the source in storage is removed.

(27) Records of Quarterly Inventory.

(a) Each licensee shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by .04(10), and retain each record for three years.

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

(28) Utilization Logs.

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

1. A description, including the make, model, and serial number the radiographic exposure device, transport, or storage container in which the sealed source is located;
2. The identity and signature of the radiographer to whom assigned;
3. The location and dates of use, including the dates removed and returned to storage; and
4. For permanent radiographic installations, the dates each radiographic exposure device is used.

(b) The licensee shall retain the logs required by .04(28)(a) for three years.

(29) Records of Inspection and Maintenance of Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) Each licensee shall maintain records specified in .04(11) of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for three years after it is made.

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

(30) Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations. Each licensee shall maintain records of alarm system and entrance control device tests required by .04(12) and retain each record for three years after it is made.

(31) Records Of Training and Certification. Each licensee shall maintain the following records for three years:

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

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

(32) Copies of Operating and Emergency Procedures. Each licensee shall maintain a copy of current operating and emergency procedures until the Director terminates the license. Superseded material must be retained for three years after the change is made.

(33) Records of Personnel Monitoring. Each licensee shall maintain the following exposure records specified in .04(19):

(a) Direct reading dosimeter readings and yearly operability checks required by .04(19)(b) and .04(19)(c) for three years after the record is made;

(b) Records of alarming ratemeter calibrations for three years after the record is made;

(c) Reports received from the personal dosimeter processor until the Director terminates the license; and

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

(34) **Records of Radiation Surveys.** Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in .04(20)(c). Each record must be maintained for three years after it is made.

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

(36) **Location Of Documents and Records.**

(a) Each licensee shall maintain copies of records required by this Rule and other applicable Rules of this Chapter at the location specified in .04(4)(k).

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

1. The license authorizing the use of sources of radiation;
2. Operating and emergency procedures as required by .04(32);
3. A copy of Rules .02, .03, .04 of this Chapter;
4. Survey records required by .04(34) and Rule .03(8) of this Chapter as applicable for the period of operation at the site;
5. Records of dosimeter readings as required by .04(33);
6. Valid radiographer's identification cards issued by a certifying entity for each radiographer working at the temporary job site or field location;
7. Evidence of the latest instrument calibration of the radiation survey instruments in use at the site as required by .04(25);
8. Utilization logs for each source of radiation dispatched from that location as required by .04(28);
9. Records of equipment problems identified in daily checks of equipment as required by .04(29)(a);
10. Records of alarm system and entrance control checks required by .04(30), if applicable;

11. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by .04(33);
12. The shipping papers for the transportation of radioactive materials required by Rule .06 of this Chapter; and
13. When operating under reciprocity pursuant to Rule 391-3-17-.02(20) of this Chapter, a copy of the applicable Agreement State license or Nuclear Regulatory Commission license authorizing the use of sources of radiation.

(37) Notifications.

(a) In addition to the reporting requirements specified in 10CFR 30.50 and in Rule 391-3-17 .03 of this Chapter, each licensee shall provide a written report to the Division within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

1. Unintentional disconnection of the source assembly from the control cable.
2. Inability to retract the source assembly to its fully shielded position and secure it in this position.
3. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function.

(b) The licensee shall include the following information in each report submitted under (37)(a)1. of this Rule and in each report of overexposure submitted under Rule 391-3-17-.03(15)(c) which involves failure of safety components of radiography equipment:

1. A description of the equipment problem;
2. Cause of each incident, if known;
3. Name of the manufacturer and model number of equipment involved in the incident;
4. Place, time, and date of the incident;
5. Actions taken to establish normal operations;
6. Corrective actions taken or planned to prevent recurrence; and
7. Qualifications of personnel involved in the incident.

(c) Any licensee conducting radiographic operations or storing sources of radiation at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the Division prior to exceeding the 180 days.

(38) ~~Application and Examinations.~~ [Reserved]**(a) ~~Application~~**

- ~~1. Candidates for certification must submit to the Division a fully completed "Georgia Certification of Radiographers Application Form" accompanied by two passport-sized photographs and shall submit through the Division all fees required by the testing agency.~~
- ~~2. A non-refundable fee to cover the cost of the examination, training documentation review, and issuance of certification shall be submitted with the application.~~
- ~~3. The application and the non-refundable fee shall be submitted to the Division, and the fees shall be submitted through the Division to the testing agency, on or before the dates specified by the Division.~~
- ~~4. An individual whose certification ID card has been suspended or revoked shall obtain written approval from the Division to apply to retake the examination.~~

(b) ~~Examination.~~ The examination shall be given for the purpose of determining the qualifications of applicants.

- ~~1. A written examination shall be held at times and places determined by the Division. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the Division. The examination will assess the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of this Chapter.~~
- ~~2. The examination will be administered by the Division to persons authorized by the Division.~~
- ~~3. A candidate failing an examination may apply for re-examination in accordance with (38)(a) of this Rule and will be re-examined. A candidate shall not retake the same version of the Division-administered examination.~~
- ~~4. The examination will be held in Atlanta and other locations designated by the Division. Dates, times, and locations of the examination will be furnished by the Division.~~
- ~~5. The examination will be in the English language.~~
- ~~6. To take the examination, an individual shall have a picture identification card, such as a driver's license, at the time of the examination.~~
- ~~7. Calculators will be permitted during the examination. However, calculators or computers with preprogrammed data or formulas, including exposure calculators, will not be permitted during the examination.~~
- ~~8. The examination will be a "closed-book" examination.~~

~~9. Any individual observed by a Division proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individuals may resubmit a new application and an additional examination fee and must wait at least 90 days before taking a new examination.~~

~~10. Examination material shall be returned to the Division at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by an individual of the contents of any examination prior to its administration is prohibited.~~

~~11. The names and scores of individuals taking the examination shall be a public record.~~

(39) Certification Identification (ID) Card: Reserved

~~(a) A certification (ID) card shall be issued to each person who successfully completes the requirements of .04(16)(a)1. and the examination prescribed in .04(38)(b).~~

~~1. Each person's identification card shall contain his/her photograph. The applicants will provide two passport-sized photographs at the time the examination is administered.~~

~~2. The certification ID card remains the property of the State of Georgia and may be revoked or suspended.~~

~~3. Any individual who wishes to replace their ID card shall submit to the Division a written request for a replacement certification card, stating the reason a replacement certification card is needed. A non-refundable fee shall be paid through the Division to the issuing agency for each replacement of an certification card. The prescribed fee shall be submitted with the written request for a replacement certification card. The individual shall maintain a copy of the request in their possession while performing industrial radiographic operations until a replacement certification card is received from the Division.~~

~~(b) Each certification ID card is valid for a period of five years, unless revoked in accordance with .04(39)(d). Each certification ID card expires at the end of the last day of the month and year stated on the certification ID card.~~

~~(c) Renewal of certification ID Card.~~

~~1. Applications for examination to renew a certification ID card shall be filed in accordance with .04(38)(a).~~

~~2. The examination for renewal of a certification ID card shall be administered in accordance with .04(38)(b).~~

~~3. A renewal identification card shall be issued in accordance with .04(39)(a).~~

~~(d) Revocation or suspension of a certification ID Card.~~

~~1. Any radiographer who violates these regulations, equivalent State or Nuclear Regulatory Commission regulations, or any applicable statutory requirements may be required to show cause at a formal hearing why their certification ID card should not be revoked or suspended in accordance with .04(39)(d)2.~~

~~2. When an order has been issued by the Director for an industrial radiographer to cease and desist from the use of sources of radiation or the Director revokes or suspends their certification ID card, the industrial radiographer shall surrender the certification ID card to the Division until the order is changed or the suspension expires.~~

(40) Reciprocity.

(a) All reciprocal recognition of licenses by the Director will be granted in accordance with Rule 391-3-17-.02(20) of this Chapter.

(b) Reciprocal recognition by the Director of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in .04(3);
2. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by .04(16)(a);
3. The applicant presents the certification to the Division prior to entry into the state; and
4. No escalated enforcement action is pending with the Nuclear Regulatory Commission or in any other state.

(c) Certified individuals who are granted reciprocity by the Director shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of .04(16)(a).

(41) Specific Requirements for Radiographic Personnel Performing Industrial Radiography.

(a) The licensee shall supply the following at the job site:

1. At least one operable, calibrated survey instrument for each exposure device in use;
2. A current whole body personal dosimeter for each individual;

3. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each person performing radiographic operations;
 4. An operable, calibrated alarm ratemeter with preset dose-rate of 500 mr (5 mSv) per hour for each person performing radiographic operations using a radiographic exposure device; and
 5. The appropriate barrier ropes and signs.
- (b) Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.
- (c) Industrial radiographic operations shall not be performed if any of the items in .04(41)(a) or .04(41)(b) are not available at the job site or are inoperable.
- (d) Each licensee shall provide as a minimum two-person crews, i.e., two radiographers or a radiographer assistant who is under the personal supervision of a radiographer, when sources of radiation are used at temporary job sites.
- (e) No individual other than a radiographer or a radiographer assistant who is under the personal supervision of a radiographer shall manipulate controls or operate equipment used in industrial radiographic operations.
- (f) During an inspection by the Division, the Division inspector may terminate an operation if any of the items in .04(41)(a) are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.
- (g) Special Requirements for Enclosed Radiography. Systems for enclosed radiography designed to allow admittance of individuals shall:
1. Comply with all applicable requirements of this Rule and Rule 391-3-17-.03(5)(i); and
 2. Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in .04(41)(g)1. Records of these evaluations shall be maintained for inspection by the Division for a period of two years after the evaluation.
- (h) Prohibitions. Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the Director.

APPENDIX A**I. Requirements for an Independent Certifying Organization.**

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;
2. Make its membership available to the general public nationwide. Membership shall not be restricted because of race, color, religion, sex, age, national origin or disability;
3. Have a certification program open to non-members, as well as members;
4. Be an incorporated, nationally-recognized organization that is involved in setting national standards of practice within its fields of expertise;
5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;
6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;
8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;
9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;
10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;
11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;
12. Exchange information about certified individuals with the Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. Requirements for Certification Programs.

All certification programs must:

1. Require applicants for certification to (a) receive training in the topics set forth in .04(16)(g) or equivalent State or Nuclear Regulatory Commission regulations, and (b) satisfactorily complete a written examination covering these topics;
2. Require applicants for certification to provide documentation that demonstrates that the applicant has:
 - (a) Received training in the topics set forth in .04(16)(g) or equivalent State or Nuclear Regulatory Commission regulations;
 - (b) Satisfactorily completed a minimum period of on-the-job training as specified in .04(16)(a); and
 - (c) Received verification by a State licensee or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer.
3. Include procedures to ensure that all examination questions are protected from disclosure;
4. Include procedures for denying an application and revoking, suspending, and reinstating a certification;
5. Provide a certification period of not less than three years nor more than five years;
6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and
7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for ~~Written~~ Examinations.

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in .04(16)(g) or equivalent State or Nuclear Regulatory Commission requirements;
2. Written in a multiple-choice format;

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in .04(16)(g).

Rule 391-3-17-.05, "Use of Radionuclides in the Healing Arts," is amended to read as follows:

391-3-17-.05 Use of Radionuclides in the Healing Arts

(1) **Purpose and Scope.** This Rule, 391-3-17-.05, 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 this Rule are in addition to, and not in substitution for, others in these regulations unless specifically exempted. All numbered and lettered references within this Rule refer to parts of this Rule, unless stated otherwise.

(2) **Definitions.**

(a) "Accredited institution," means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.

(b) "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.

(c) "Area of use," means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

(d) "Authorized medical physicist," means an individual who:

1. Meets the requirements in Rules .05(23)(a) and .05(27); or
2. Is identified as an authorized medical physicist on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission or Agreement State; or
3. Is identified as an authorized medical physicist on a permit issued by the Director, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.

(e) "Authorized nuclear pharmacist," means a pharmacist who:

1. Meets the requirements in Rules .05(24)(a) and .05(27); or
2. Is identified as an authorized nuclear pharmacist on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission or Agreement State; or
3. Is identified as an authorized nuclear pharmacist on a permit issued by the Director, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.

(f) "Authorized user," means a physician, dentist, or podiatrist who:

1. Meets the requirements in Rule .05(27) and .05(43)(a), .05(47)(a), .05(52)(a), .05(53)(a), .05(54)(a), .05(63)(a), .05(66)(a), or .05(84)(a); or
2. Is identified as an authorized user on a license or equivalent permit issued by the Director, Nuclear Regulatory Commission or Agreement State; or
3. Is identified as an authorized user on a permit issued by the Director, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material.

(g) "Brachytherapy," means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

(h) "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.

(i) "Client's address," means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with Rule .05(38).

(j) "Dedicated check source," means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

(k) "Dentist," means an individual licensed to engage in the practice dentistry under the Authority of O.C.G.A. 43-11-40.

(l) "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 procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

(m) "High dose-rate remote afterloader," (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rad) per hour at the treatment site.

(n) "Low dose-rate remote afterloader," (LDR) means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rad) per hour at the treatment site.

(o) "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.

(p) "Manual brachytherapy," means a type of therapy in which brachytherapy sources are manually applied or inserted.

- (q) "Medical institution," means an organization in which several medical disciplines are practiced.
- (r) "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.
- (s) "Medium dose-rate remote afterloader," (MDR) means a device that remotely delivers a dose rate of greater than 2 gray (200 rad), but less than, or equal to, 12 gray (1200 rad) per hour at the treatment site.
- (t) "Misadministration," means an event that meets the criteria in Rule .05(115)(a).
- (u) "Mobile medical service," means the transportation of radioactive material or its medical use at the client's address.
- (v) "Nuclear medicine technologist," means an individual who meets the requirements of Rule .05(25)(a) and, is under the supervision of an authorized user, to prepare or administers radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purposes.
- (w) "Nuclear medicine technology," means the science and art of *in vivo* and *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.
- (x) "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.
- (y) "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.
- (z) "Pharmacist," means any individual who is licensed to practice Pharmacy in this State by the Georgia State Board of Pharmacy.
- (aa) "Physician," means any person who is licensed to engage in the practice of medicine under the Authority of O.C.G.A. 43-34-20 or the limited practice of medicine under O.C.G.A. 43-35-1.
- (bb) "Podiatrist," means an individual licensed by the appropriate authority to practice podiatry in the state of Georgia.
- (cc) "Positron Emission Tomography (PET) radionuclide production facility" is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

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

(ee) "Prescribed dosage," means the specified activity or range of activity of radioactive drug as documented:

1. In a written directive; or
2. In accordance with the directions of the authorized user for procedures performed pursuant to Rule .05(41), (44) and (48).

(ff) "Prescribed dose," means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, the total dose and dose per fraction as documented in the written directive;
3. For 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.

(gg) "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.

(hh) "Radiation Safety Officer," means an individual who:

1. Meets the requirements in Rule .05(22)(a) or .05(22)(c)1. And .05(27); or
2. Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Division for similar types and uses of radioactive material.

(ii) "Radiation therapist," means an individual who meets the requirements of Rule .05(25)(b) and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

(jj) "Radiation therapy technology," means the science and art of applying radiation emitted from sealed radioactive sources to patients or human research subjects for therapeutic purposes.

(kk) "Radioactive drug," means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

(ll) "Sealed source," means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(mm) "Sealed Source and Device Registry," means the national registry that contains the registration certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(nn) "Stereotactic radiosurgery," means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a treatment site.

(oo) "Structured educational program," means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(pp) "Teletherapy," as used in this Rule, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(qq) "Temporary jobsite," as used in this Rule, means a location where mobile medical services are conducted other than the location(s) of use authorized on the license.

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

(ss) "Therapeutic dose," means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(tt) "Treatment site," means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(uu) "Type of use," means use of radioactive material as specified under Rule .05(41), (44), (48), (55), (65), (67) or (85).

(vv) "Unit dosage," means a dosage that:

1. Is obtained or prepared in accordance with the regulations for uses described in Rule .05(41), (44), (48); and

2. Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(ww) "Written directive," means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Rule .05(19).

(xx) "Associate Radiation Safety Officer," means an individual who:

1. Meets the requirements in 391-3-17-.05(22) and .05(27); and
2. Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:
 - (i) A specific medical use license issued by the Commission or an Agreement State; or
 - (ii) A medical use permit issued by a Commission master material licensee.

(yy) "Ophthalmic physicist," means an individual who:

1. Meets the requirements in 391-3-17-.05(27) and 391-3-17-.05(64)(c)2.; and
2. Is identified as an ophthalmic physicist on a:
 - (i) Specific medical use license issued by the Commission or an Agreement State;
 - (ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;
 - (iii) Medical use permit issued by a Commission master material licensee; or
 - (iv) Permit issued by a Commission master material licensee broad scope medical use permittee.

(3) **Maintenance of Records.** Each record required by Rule .05 must be legible throughout the retention period specified by each Division Rule. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(4) **Provisions for Research Involving Human Subjects.** A licensee may conduct research involving human subjects using radioactive material provided:

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

(b) The research involving human subjects authorized in .05(4)(a) shall be conducted using radioactive material authorized for medical use in the license; and

(c) Nothing in Rule .05(4) relieves licensees from complying with the other requirements in Rule.05.

(5) U.S. Food and Drug Administration, Federal, and State Requirements. Nothing in Rule .05 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

(6) Implementation.

(a) A licensee shall implement the provisions in Rule .05 on July 1, 2003.

(b) When a requirement in Rule .05 differs from the requirement in an existing license condition, the requirement in Rule .05 shall govern.

(c) Any existing license condition that is not affected by a requirement in Rule .05 remains in effect until there is a license amendment or license renewal.

(d) If a license condition exempted a licensee from a provision of Rule .05 on July 1, 2003, it will continue to exempt a licensee from the corresponding provision in Rule .05.

(e) If a license condition cites provisions in Rule .05 that will be deleted on July 1, 2003, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(f) Licensees shall continue to comply with any license condition that requires it to implement procedures required by Rule .05(70), (76), (77) and (78) until there is a license amendment or renewal that modifies the license condition.

(7) License Required.

(a) A person may manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Director, the Nuclear Regulatory Commission or an Agreement State, or as allowed in Rule .05(7)(b) or (7)(c).

(b) An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in Rule .05 under the supervision of an authorized user as provided in Rule .05(18), unless prohibited by license condition.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in Rule .05 under the supervision of an authorized nuclear pharmacist or authorized user as provided in Rule .05(18), unless prohibited by license condition.

(8) Application for License, Amendment, or Renewal.

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

(b) An application for a license for medical use of radioactive material as described in Rule .05(41), (44), (48), (55), (65), (67) or (85) must be made by:

1. Filing an original Application for Radioactive Materials License, and
2. Submitting procedures required by sections Rule .05(70), (76), (77), and (78), as applicable.

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

1. Submitting an original in letter format.
2. Submitting procedures required by sections Rule .05(70), (76), (77) and (78), as applicable.

(d) In addition to the requirements in (8)(b) and (8)(c), an application for a license or amendment for medical use of radioactive material as described in (85) of Rule .05 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Rule .05(1) through Rule .05(40), as well as any specific information on:

1. Radiation safety precautions and instructions;
2. Training and experience of proposed users;
3. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

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

(f) An applicant that satisfies the requirements specified in Rule .02(10)(b) may apply for a Type A specific license of broad scope.

(9) Mobile Medical Service Administrative Requirements.

(a) The Director shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(b) Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the clinic's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

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

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

(e) A licensee providing mobile medical services shall retain the letter required in (9)(b) in accordance with Rule .05(97).

(f) A mobile medical service licensee shall maintain on each mobile unit:

1. The current operating and emergency procedures;
2. A copy of the license;
3. Copies of the letter required by .05(9)(b);
4. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
5. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

(g) A mobile medical service licensee shall maintain records required by Rules .03 and .05 of this Chapter at a location within the Division's jurisdiction that is:

1. A single address of use:

(i) Identified as the records retention location; and

(ii) Staffed at all reasonable hours by individual(s) authorized to provide the Division with access for purposes of inspection; or

2. When no address of use is identified on the license for records retention, the mobile unit:

(i) Identified in the license; and

(ii) Whose current client's address schedule and location schedule is reported to the Division.

(10) **License Amendments.** A licensee shall apply for and must receive a license amendment:

(a) Before it receives, prepares or uses radioactive material for a type of use that is permitted under Rule .05, but that is not authorized on the licensee's current license issued pursuant to Rule .05;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is:

1. For an authorized user, an individual who meets the requirements in Rule .05(27) and (43)(a), Rule .05(47)(a), (52)(a), (53)(a), (54)(a), (63)(a), (64)(a), (66)(a), or (84)(a) or;

2. For an authorized nuclear pharmacist, an individual who meets the requirements in Rule .05(24)(a) and (27);

3. For an authorized medical physicist, an individual who meets the requirements in Rule .05(23)(a) and (27);

4. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Division that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

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

(c) Before it changes Radiation Safety Officers, except as provided in (15)(c);

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

(e) Before it adds to or changes the areas of use identified in the application or on the license, except as specified in (11)(b)4.;

- (f) Before it changes the address(es) of use identified in the application or on the license;
- (g) Before it changes statements, representations, and procedures which are incorporated into the license; and
- (h) Before it releases licensed facilities for unrestricted use.

(11) Notifications.

(a) A licensee shall provide to the Division a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist, pursuant to (10)(b).

(b) A licensee shall notify the Division by letter no later than 30 days after:

1. A Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
2. The licensee's mailing address changes;
3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Rule .02 (13)(b) of these regulations; or
4. The licensee has added to or changed the areas where radioactive material is used in accordance with Rule .05(41) and (44).

(12) Exemptions Regarding Type A Specific Licenses of Broad Scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

- (a) The provisions of (8)(d) of these regulations, regarding the need to file an amendment to the license for medical uses of radioactive material, as described in .05(85);
- (b) The provisions of (10)(b) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;
- (c) The provisions of (10)(e) regarding additions to or changes in the areas of use at the addresses specified in the license;
- (d) The provisions of .05(11)(a) regarding notification to the Division for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists; and
- (e) The provisions of .05(21)(a) regarding suppliers for sealed sources.

(13) License Issuance.

(a) The Director shall issue a license for the medical use of radioactive material if:

1. The applicant has filed Application for Radioactive Materials License in accordance with the instructions in .05(8);
2. The applicant has paid any applicable fee;
3. The applicant meets the requirements of Rule .02 of this Chapter; and
4. The Director finds the applicant equipped and committed to observe the safety standards established by the Division in these Rules for the protection of the public health and safety.

(b) The Director shall issue a license for mobile services if the applicant:

1. Meets the requirements in .05(13)(a); and
2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with .05(37).

(14) Specific Exemptions. The Director may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Rule .05 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

General Administrative Requirements**(15) Authority and Responsibilities for the Radiation Protection Program.**

(a) In addition to the radiation protection program requirements of Rule .03(4), a licensee's management must approve in writing:

1. Requests for license application, renewal, or amendments before submittal to the Division;
2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist, and
3. Radiation protection program changes that do not require a license amendment and are permitted under .05(16);

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

management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(c) For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in .05(15)(e), provided the licensee takes the actions required in .05(15)(b),(d),(e) and (h). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

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

(e) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;
2. Initiate, recommend, or provide corrective actions;
3. Stop unsafe operations; and,
4. Verify implementation of corrective actions.

(f) Licensees that are authorized for two or more different types of radioactive material use under Rule .05(48), (55), (67), and (85), or two or more types of units under Rule .05(67) shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(g) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each required meeting in accordance with Rule .05(86)(c).

(h) A licensee shall retain a record of actions taken pursuant to Rule .05(15)(a), (15)(b) and (15)(d) in accordance with Rule .05(86)(a) and (b).

(16) Radiation Protection Program Changes.

(a) A licensee may revise its radiation protection program without Division approval if:

1. The revision does not require an amendment under Rule .05(10);
2. The revision is in compliance with the regulations and the license;
3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
4. The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with Rule .05(87).

(17) Duties of Authorized User and Authorized Medical Physicist.

(a) A licensee shall assure that only authorized users for the type of radioactive material use:

1. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual;
2. Direct, as specified in Rule .05(18) and (19), or in license conditions, the administration of radioactive material for medical use to patients or human research subjects; and
3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with Rule .05(7)(b) and (7)(c) and (18).

(b) A licensee shall assure that only authorized medical physicists perform, as applicable:

1. Full calibration measurements as described in Rule .05(73), (74), and (75);
2. Periodic spot checks as described in Rule .05(76), (77), and (78);and
3. Radiation surveys as described in Rule 5(80).

(18) Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by Rule .05(7)(b) shall:

1. In addition to the requirements in Rule .07(3) of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Rule .05, and license conditions with respect to the use of radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of Rule .05, and license conditions with respect to the medical use of radioactive material.

(b) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by Rule .05(7)(c), shall:

1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of Rule .05, and license conditions.

(c) Unless physical presence is required in other sections of Rule .05, a licensee who permits supervised activities under Rule .05(18)(a) and (18)(b) shall require an authorized user to be immediately available to communicate with the supervised individual, and when a written directive is required, be able to be physically present within one hour of notification; and

(d) A licensee that permits supervised activities under Rule .05(18)(a) and (18)(b) is responsible for the acts and omissions of the supervised individual.

(19) Written Directives.

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

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

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

3. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as

possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

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

1. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;
 2. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
 3. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;
 4. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;
 5. For all other brachytherapy including LDR, MDR, and PDR:
 - (i) Prior to implantation: treatment site, the radionuclide, and dose; and
 - (ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose), and date; or
 6. For permanent implant brachytherapy:
 - (i) Before implantation: The treatment site, the radionuclide, and the total source strength; and
 - (ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date.
- (c) The licensee shall retain the written directive in accordance with Rule.05 (88).

(20) 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 Rule .05(20)(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;
4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Rule .05(67);
5. Determining if a medical event, as defined in Rule .05(115), has occurred; and
6. Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(c) A licensee shall retain a copy of the procedures required under subparagraph (a) in accordance with 391-3-17-.05(20) and (88).

(21) Suppliers for Sealed Sources or Devices 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 Rule .02 of this Chapter or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(b) Sealed sources or devices non-commercially transferred from Rule .05 licensee or a Nuclear Regulatory Commission or an Agreement State medical use licensee.

(22) Training for Radiation Safety Officer. Except as provided in Rule .05(26), the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in Rule .05(15) to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in Rule .05(22)(d), and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. (i) 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;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be

substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(iii) 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

2. (i) 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;

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

(I) 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

(II) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in Rule .05(26), .05(47) or .05(52); and

(iii) 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:

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Radiation biology; and

(V) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Nuclear Regulatory Commission, Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission, Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of radioactive byproduct material. The full-time radiation safety experience must involve the following;

- (I) Shipping, receiving, and performing related radiation surveys;
- (II) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;
- (III) Securing and controlling radioactive material;
- (IV) Using administrative controls to avoid mistakes in the administration of radioactive material;
- (V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- (VI) Using emergency procedures to control radioactive material; and
- (VII) Disposing of radioactive material; or

2. This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in subparagraphs (b)1. and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(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 Rule .05(23)(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 or Associate Radiation Safety Officer and who meets the requirements in .05(22)(d); or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or an Agreement State license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in subparagraph .05(22)(d); or

3. Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material license. The individual must also meet the requirements in subparagraph .05(22)(d).

(d) 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, an Associate 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.

(23) Training for Authorized Medical Physicist. Except as provided in Rule .05(26) the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in .05(23)(c) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. 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 2 years of full-time practical training and/or supervised experience in medical physics:

(i) 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

(ii) 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 Rule .05(26), .05(63) or .05(84); 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 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

- (ii) Performing decay corrections;
 - (iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
 - (iv) 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 .05(23)(b)1. and .05(23)(c) of this section, 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 Rule .05(23), .05(26), 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.
- (24) Training for an Authorized Nuclear Pharmacist.** Except as provided in Rule .05(26), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:
- (a) Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - 1. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
 - 2. Hold a current, active license to practice pharmacy;
 - 3. Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and
 - 4. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance,

dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

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

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

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

(V) Radiation biology; and

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

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha or beta-emitting radionuclides;

(III) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(IV) Using administrative controls to avoid misadministrations in the administration of radioactive material; and

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

2. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in Rule .05(24)(b)1. and has achieved a level of competency sufficient to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist and operate a nuclear pharmacy, and

(c) Licensed as a Nuclear Pharmacist by the Georgia Board of Pharmacy.

(25) Training and Technical Requirements for Nuclear Medicine Technologists and Radiation Therapists.

(a) The licensee shall require a nuclear medicine technologist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in:
 - (i) Nuclear Medicine by the Nuclear Medicine Technology Certification Board;
 - (ii) Nuclear Medicine by the American Registry of Radiologic Technologists with competency in Nuclear Medicine; or,
2. Is board eligible to take the CNMT or ARRT(N) examinations; or,
3. Has successfully completed a training program in nuclear medicine which has resulted in a certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,
4. Has performed as a full-time nuclear medicine technologist for a minimum of two years during the past five-year period under the supervision of an authorized user who attests the experience in writing; or,
5. Has completed 80 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:
 - (i) Classroom and laboratory training in the following areas:
 - (I) Radiation physics and instrumentation;
 - (II) Radiation protection;
 - (III) Mathematics pertaining to the use and measurement of radioactivity;
 - (IV) Chemistry of radioactive material for medical use; and
 - (V) Radiation biology; and
 - (ii) Work experience, under the supervision of an authorized user involving:
 - (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (II) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (III) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
 - (V) Using procedures to contain spilled radioactive material safely and using proper

decontamination procedures;

(VI) Administering dosages to patients or human research subjects; and

(iii) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of competency sufficient to independently function as a nuclear medicine technologist.

(b) The licensee shall require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:

1. Is certified in Radiation Therapy by the American Registry of Radiologic Technologists (ARRT(T)); or

2. Is board eligible to take the ARRT(T) examination; or,

3. Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology¹; or,

4. Has performed as a full-time radiation therapist for a minimum of two years during the past five-year period under the supervision of an authorized user who attests the experience in writing; or

5. Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user involving:

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

(II) Assisting the authorized user in simulating the patient for treatment;

¹ "Essentials and guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988.

- (III) Preparing the patient for treatment;
- (IV) Implementing treatment plans as prescribed by the authorized user;
- (V) Providing written documentation of treatment setup and patient treatments;
- (VI) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;
- (VII) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;
- (VIII) Delivering doses to patients or human research subjects under the supervision of the authorized user;
- (IX) Preparing, implanting, and removing sealed sources;
- (X) Delivering dose to patients or human research subjects;
- (XI) Maintaining running inventories of material on hand;
- (XII) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,
- (XIII) Properly implementing emergency procedures and
 - (iii) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of competency sufficient to independently function as a radiation therapist.
- (c) Individuals working as nuclear medicine technologists or radiation therapists prior to July 1, 2003 for a facility holding a Division license need not comply with the training requirements of this section.
- (d) The licensee shall maintain records of the above training as specified in Rule .05(100).

(26) Provisions for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

- (a) 1. An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on a Division, Nuclear Regulatory Commission or Agreement State license or on a permit issued by the Division, Nuclear Regulatory commission or Agreement State broad scope licensee or master

material license permit or by a master material license permittee of broad scope before the effective date of this rule, need not comply with the training requirements of Rules .05(22), .05(23), or .05(24), respectively except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in Rule .05(22)(d) or .05(23)(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of Rule .05(22) to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Division, U.S. Nuclear Regulatory Commission or an Agreement State license or U.S. Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Rule .05(23), for those materials and uses that these individuals performed on or before October 24, 2005.

4. A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Rules .05(22), .05(23) or .05(24), respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(b) 1. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive byproduct material on a license issued by the Division, Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Division, Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before March 17, 2020, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63).

.05(64), .05(66), and .05(84), respectively.

2. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive byproduct material on a license issued by the Division, Nuclear Regulatory Commission or Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Division, Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who perform only those medical uses for which they were authorized on or before October 24, 2005, need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63), .05(64), .05(66), and .05(84), as follows:

(i) For uses authorized under Rules .05(41) or .05(44), or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under Rule .05(48), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under Rules .05(55) or .05(67), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under Rules .05(65), a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Rules .05(43), .05(47), .05(52), .05(53), .05(54), .05(54.1), .05(63), .05(64), .05(66), and .05(84) respectively, when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials,

discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on the Division licenses for the same uses for which these individuals are authorized.

(27) **Recentness of Training.** The training and experience specified in Rule .05 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

GENERAL TECHNICAL REQUIREMENTS

(28) **Quality Control of Diagnostic Equipment.** Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures that have been approved by the Division. The licensee shall conduct quality control procedures in accordance with written procedures.

(29) Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.

(a) For direct measurements performed in accordance with Rule .05(31), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(b) A licensee shall test the instrumentation required in Rule .05(29)(a) in accordance with nationally recognized standards or the manufacturer's instructions.

(c) The tests required in Rule .05(29)(b) shall include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.

(d) A licensee shall retain a record of each instrument test required by Rule .05(29) in accordance with Rule .05(91).

(30) Calibration of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with Rule .05 and Rule .03 of this Chapter, have been calibrated before first use, annually, and following any repair that will affect the calibration.

(b) To satisfy the requirements of Rule .05(30)(a), the licensee shall:

1. Calibrate all required scale readings up to 10 millisievert (1,000 mrem) per hour with a radiation source;

2. Have each radiation survey instrument calibrated:

- (i) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;
- (ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisievert (2 and 1,000 mrem) per hour; and
- (iii) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked; and

3. Conspicuously note on the instrument the date of calibration.

- (c) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.
- (d) A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.
- (e) The licensee shall retain a record of each survey instrument calibration in accordance with Rule .05(92).

(31) Determination of Dosages of Radioactive Material for Medical Use.

- (a) A licensee shall determine and record the activity of each dosage prior to medical use.
- (b) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission or Agreement State.
- (c) For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission or Agreement State.
- (d) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.
- (e) A licensee shall retain a record of the dosage determination required by Rule .05(31)(a) through (31)(c) in accordance with Rule .05(93).

(32) Authorization for Calibration, Transmission and Reference Sources. Any person authorized by Rule .05(7) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

(a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the Nuclear Regulatory Commission or Agreement State and that do not exceed 1.11 gigabecquerel (30 mCi) each;

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

(c) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

1. 7.4 megabecquerel (200 μ Ci); or

2. 1,000 times the quantities in Schedule B of Rule .02(21)(b) of this Chapter; and

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

(33) Requirements for Possession of Sealed Sources and Brachytherapy Sources.

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

(b) A licensee in possession of a sealed source shall:

1. Test the source for leakage in accordance with Rule .03 of this Chapter.

2. Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Division, an Agreement State, or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(c) If the leak test reveals the presence of 185 becquerel (0.005 μ Ci) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Rules .02 and .03 of this Chapter; and

2. File a report with the Division within 5 days of receiving the leak test results in accordance with Rule .05(117).

(d) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with Rule .05(94).

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

(35) **Vial Shields.** A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

(36) Surveys for Ambient Radiation Dose Rate and Contamination.

(a) Except as provided in Rule .05(36)(h), a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by Rule .05(36)(a) and (b) so as to be able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by Rule .05(36)(a) and (36)(b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by Rule .05(36)(e) so as to be able to detect contamination on each wipe sample of 33.3 becquerel (2,000 dpm).

(g) A licensee shall establish removable contamination action levels for the surveys required by Rule .05(36)(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee does not need to perform the surveys required by Rule .05(36)(a) in area(s) where patients or human research subjects are confined when they cannot be released pursuant to Rule .05(37).

(i) A licensee shall retain a record of each survey in accordance with Rule .05(95)

(37) Release of Individuals Containing Radioactive Drugs or Implants.

(a) A licensee may authorize the release of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to

exceed 5 mSv (0.5 rem).

(b) For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including oral and written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall also include:

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

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with Rule .05(96).

(d) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with Rule .05(96).

(e) Notwithstanding Rule .05(37)(a), the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

(f) The licensee shall immediately notify the Division in accordance with Rule .05(118) if a patient departs prior to an authorized release.

(g) The licensee shall notify the Division in accordance with Rule .05(119):

1. When they are aware that a patient containing radioactive material and who has been released in accordance with Rule .05(37) dies; and,
2. If it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

(38) Mobile Medical Service Technical Requirements. A licensee providing mobile medical service shall:

(a) Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

(b) Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

- (d) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;
- (e) Check survey instruments for consistent response with a dedicated check source before use at each client's address;
- (f) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Rule .03 of this Chapter;
- (g) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Division for compliance with airborne release standards; and,
- (h) Retain a record of each survey required by Rule .05(38)(f) in accordance with Rule .05(97)(b).

(39) Storage and Control of Volatiles and Gases.

- (a) A licensee shall store volatile radioactive materials and radioactive gases in the shippers' radiation shield and container.
- (b) A licensee shall store and use a multi-dose container in a properly functioning fume hood.
- (c) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Rule .03 of this Chapter.
- (d) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- (e) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.

(40) Decay-in-Storage.

- (a) A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
 1. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
 2. Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and
 3. Separates and monitors each generator column individually with all radiation shielding

removed to ensure that its contents have decayed to background radiation level before disposal.

(b) For radioactive material disposed in accordance with (40)(a) of this section, the licensee shall retain a record of each disposal in accordance with Rule .05(98).

SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL WRITTEN DIRECTIVE NOT REQUIRED

(41) Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required. A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State or the Nuclear Regulatory Commission; or

(b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or an individual under the supervision of either as specified in Rule .05(18); or

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

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

(42) Possession of Survey Instrument. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour. The instrument shall be operable and calibrated in accordance with Rule .05(30).

(43) Training for Uptake, Dilution, and Excretion Studies. Except as provided in Rule .05(26), the licensee shall require an authorized user of a unsealed radioactive material for the uses authorized under Rule .05(41) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and

radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in Rule .05(43)(c)1.(i) through .05(43)(c)1.(ii)(VI); and

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

(b) Is an authorized user under Rule .05(47) or .05(52) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) 1. Has completed 60 hours of training and experience, including a minimum of 8 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 that includes:

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

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

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rules .05(26), (43), (47) or (52) or equivalent Agreement State or Nuclear Regulatory Commission requirements, involving:

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

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

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

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(VI) Administering dosages to patients or human research subjects; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(43)(c)1. and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rule .05(41). The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(43)(c)1.

(44) Use of Unsealed Radioactive 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 (except aerosol or gaseous forms) prepared for medical use, in quantities that do not require a written directive as described in Rule .05(19) that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State or the Nuclear Regulatory Commission; or

(b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or .05(52) and .05(47)(c)1.(ii)(VII), or an individual under the supervision of either as specified in Rule .05(18); or

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

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

(e) Provided the conditions of Rule .05(39) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Division.

(45) Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(a) A licensee shall not administer to humans a radioactive drug containing:

1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μ Ci of Mo-99 per mCi of Tc-99m); or
2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μ Ci of Sr-82 per mCi of Rb-82 chloride); or
3. More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μ Ci of Sr-85 per mCi of Rb-82);

(b) To demonstrate compliance with Rule .05(45)(a), the licensee preparing radioactive drugs from radionuclide generators shall:

1. Measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with subparagraph .05(45)(a);
2. Before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with subparagraph .05(45)(a).

(c) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with Rule .05(99).

(d) A licensee shall report immediately to the Division each occurrence of radionuclide contaminant concentration exceeding the limits specified in Rule .05(45)(a).

(46) Possession of Survey Instruments. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(47) Training for Imaging and Localization Studies. Except as provided in Rule .05(26), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Rule .05(44) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in (c)1.(i) through (c)1.(ii)(VII) of this rule; and

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

(b) Is listed as an authorized user under Rule .05(52) and meets the requirements in .05(47)(c)1.(ii)(VII) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(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 that includes, at a minimum:

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Chemistry of radioactive material for medical use;

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in Rule .05(26), .05(47) or .05(47)(c)1.(ii)(VII) and Rule .05(52), or equivalent Agreement State or Nuclear Regulatory Commission requirements. An authorized nuclear pharmacist who meets the requirements in 391-3-17-.05(24) or 391-3-17-.05(26) may provide the supervised work experience for subparagraph .05(47)(c)1.(ii)(VII). Work experience must involve:

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

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

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

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(VI) Administering dosages to patients or human research subjects; and

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

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(47)(c)1. and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rules .05(41) and .05(44).

The signed attestation must be obtained from either:

- (i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
- (ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(47)(c)1.

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

(48) Use of Unsealed Radioactive Material for Which a Written Directive is Required. A licensee may use any unsealed radioactive material identified in subparagraph (52)(b)1.(ii)(VII) prepared for diagnostic or therapeutic medical use for which a written directive is required that has been:

- (a) Obtained from a manufacturer or preparer licensed pursuant to Rule .02 of this Chapter or equivalent regulations of another Agreement State or the Nuclear Regulatory Commission; or
- (b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(47) or (52), or an individual under the supervision of either as specified in Rule .05(26); or
- (c) Obtained from and prepared by the Division, 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.

(49) Safety Instruction. In addition to the requirements of Rule .07(3) of this Chapter:

(a) A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with Rule .05(37). The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;

2. Visitor control to include the following:

(i) Routine visitation to hospitalized individuals in accordance with Rule .03 of this Chapter;

(ii) Contamination control;

(iii) Waste control; and

(iv) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule .05(101).

(50) Safety Precautions.

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with Rule .05(37), a licensee shall:

1. Quarter the patient or the human research subject either in:

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

(ii) A room, with a private sanitary facility, with another individual who also has received radiopharmaceutical therapy and who cannot be released in accordance with Rule .05(37); and,

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

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

(b) The Radiation Safety Officer, or his designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also

notify the Division in accordance with Rule .05(119) if it is possible that any individual could receive exposures in excess of the limits in Rule .03(5)(i) of this Chapter as a result of the deceased's body.

(51) **Possession of Survey Instruments.** A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(52) **Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.** Except as provided in Rule .05(26), the licensee shall require an authorized user of radioactive material for the uses authorized under Rule .05(48) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State, and who meets the requirements of Rule .05(52)(b)1(ii)(VII). (Specialty boards whose certification processes have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in Rule .05(52)(b)1.(i) through .05(52)(b)1.(ii)(V). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Post-Graduate Training~~Council on Postdoctoral Training of the American Osteopathic Association; and

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

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

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

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

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), .05(52) or equivalent Agreement State, or Nuclear Regulatory Commission requirements. The work experience must involve:

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

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

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

(IV) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.

(VI) Reserved.

(VII) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status. This experience may be obtained concurrently with the supervised work experience required by Rule .05(52)(b)1.(ii):

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

(ii) Oral administration of greater than 1.22 gigabecquerel (33 millicurie) of sodium iodide I-131²;

(iii) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV, for which a written directive is required; and/or

(iv) 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

2 Experience with at least 3 cases in category (VII)(ii) also satisfies the requirement in category (VII)(i).

requirements in Rule .05(52)(b)1., and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rule .05(48).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph .05(52)(b)1.

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

Except as provided in Rule .05(26), 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 gigabecquerel (33 millicurie), 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 .05(53)(c)1. and .05(53)(c)2. and whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user under Rule (52) for uses listed in (52)(b)1.(ii)(VII)(i) or (ii), or (54), 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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), (52), (53) or (54), or equivalent Agreement State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of Rule .05(52)(b) must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(i) or (ii); the work experience must involve:

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

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

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

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

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

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

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(53)(c)1. and (53)(c)2. and is able to independently fulfill the radiation safety-related duties as an authorized user for medical uses authorized under .05(48).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (43), (47), or (52), or equivalent Agreement State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program

director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(53)(c)1. and 2.

(54) Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerel (33 millicurie) for which a Written Directive is Required. Except as provided in Rule .05(26), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerel (33 millicurie), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in Rules .05(54)(c)1. and .05(54)(c)2. and whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user under Rule .05(52) for uses listed in Rule.05(52)(b)1.(ii)(VII)(ii), 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:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), (52), or (54), or equivalent Agreement State or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(ii); the work experience must involve:

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

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

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

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

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

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

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(54)(c)1. and .05(54)(c)2. and is able to independently fulfill the duties as an authorized user for medical uses authorized under Rule .05(48). The written attestation must be signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(52), or .05(54), or equivalent Agreement State or Nuclear Regulatory Commission requirements. The preceptor authorized user, who meets the requirements of Rule .05(52)(b), must have experience in administering dosages as specified in Rule .05(52)(b)1.(ii)(VII)(ii).

(54.1) Except as provided in Rule .05(26) 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 Rule .05(52) for uses listed in 05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(b) Is an authorized user under Rules .05(63), .05(84), or equivalent Agreement State or Nuclear Regulatory Commission requirements and who meets the requirements in .05(54.1)(d); or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Division, Nuclear Regulatory Commission or an Agreement State under Rules .05(63) or .05(84), and who meets the requirements in paragraph .05(54.1)(d).

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rules .05(26), .05(52), .05(54.1) or equivalent Agreement State or Nuclear Regulatory Commission requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Rule .05(52) or .05(54.1) must have experience in administering dosages as specified in 05(52)(b)1.(ii)(VII)(iii) or .05(52)(b)1.(ii)(VII)(iv). The work experience must involve:

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

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

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

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

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

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in .05(54.1)(d)1. and (d)2. and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive.

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26), (52), (54.1) or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (52) or (54.1), or equivalent Agreement State or Nuclear Regulatory Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(54.1)(d)1. and 2.

Manual Brachytherapy

(55) Use of Sealed Sources for Manual Brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(21)(a) are met.

(56) Surveys After Source Implant and Removal.

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

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

(c) A licensee shall retain a record of the surveys in accordance with Rule .05(102).

(57) Brachytherapy Sources Inventory.

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

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

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance

with Rule .05(103).

(58) **Safety Instruction.** In addition to the requirements of Rule .07(3) of this Chapter:

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with Rule .05(37). Instruction must be commensurate with the duties of the personnel and shall include the following:

1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions;
3. Patient or human research subject control;
4. Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with Rule .03(5)(i)1.(i) of this Chapter; and

(ii) Visitation authorized in accordance with Rule .03(5)(i)2. of this Chapter; and

5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Division in accordance with Rule .05(119) if it is possible for any individual to receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule .05(101).

(59) **Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.**

(a) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with Rule .05(37), a licensee shall:

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

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

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

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

(60) Calibration Measurements of Brachytherapy Sealed Sources.

(a) Prior to the first medical use of a brachytherapy sealed source on or after July 1, 2003, a licensee shall perform the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of Rule .05(72)(a);
2. Determine source positioning accuracy within applicators; and
3. Use published protocols accepted by nationally recognized bodies to meet the requirements of Rule .05(60)(a)1. and .05(60)(a)2.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with Rule .05(60)(a).

(c) A licensee shall mathematically correct the outputs or activities determined in Rule .05(60)(a) of this section for physical decay at intervals consistent with 1.0 percent physical decay.

(d) An authorized medical physicist shall perform or review the calculation measurements made pursuant to Rule .05(60)(a), (60)(b), or (60)(c).

(e) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with Rule .05(60)(a), (60)(b), and (60)(c).

(f) A licensee shall retain a record of each calibration in accordance with Rule .05(104).

(g) A licensee shall retain a record of decay calculations required by Rule .05(60)(e) in accordance with Rule .05(105).

(61) Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- (a) The source-specific input parameters required by the dose calculation algorithm;
- (b) The accuracy of dose, dwell time, and treatment time calculations at representative points;
- (c) The accuracy of isodose plots and graphic displays; and
- (d) The accuracy of the software used to determine radioactive source positions from radiographic images.

(62) Possession of Survey Instruments. A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(63) Training for Use of Manual Brachytherapy Sources. Except as provided in Rule .05(26), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under Rule .05(55) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in .05(26), (63) or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution authorized to use byproduct material under Rule .05(55), involving:

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

(II) Checking survey meters for proper operation;

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

(IV) Maintaining running inventories of material on hand;

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

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

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule .05(26), .05(63) 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~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by Rule .05(63)(b)-1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rules .05(63)(b)1. and (63)(b)2. and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under in Rule .05(55).

The signed attestation must be obtained from either:

(i) A preceptor authorized user, who meets the requirements in Rules .05(26) or (63), or equivalent Agreement State or Nuclear Regulatory Commission requirements and has experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26) or (63), or equivalent Agreement State or Nuclear Regulatory

Commission requirements, have experience in administering dosages in the same dosage category or categories (i.e., in Rule .05(52)(b)1.(ii)(VII)) as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(63)(b)1. and 2.

(64) Training for Ophthalmic Use of Strontium-90. Except as provided in Rule .05(26), the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under Rule .05(55) to be a physician who:

(a) Is an authorized user under Rule .05(63) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or,

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

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

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

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

3. Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in Rule .05(26), .05(63) or .05(64) or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in Rule .05(64)(b)1. and 2., and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

(c) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subparagraph .05(64)(d) are performed by either:

1. An authorized medical physicist; or

2. An individual who:

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

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

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

(iv) Has documented training in:

(I) The creation, modification, and completion of written directives;

(II) Procedures for administrations requiring a written directive; and

(III) Performing the calibration measurements of brachytherapy sources as detailed in Rule (.05)(60).

(d) The individuals who are identified in subparagraph .05(64)(c) must:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Rule (.05)(60); and

2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in subparagraph .05(64)(c) will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(e) Licensees must retain a record of the activity of each strontium-90 source in accordance with Rule (.05)(105).

Sealed Sources For Diagnosis

(65) Use of Sealed Sources and Medical Devices for Diagnosis.

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

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

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(20)(a) are met.

(66) Training for Use of Sealed Sources for Diagnosis and Medical Devices for Diagnosis.

Except as provided in Rule .05(26), the licensee shall require the authorized user of a diagnostic sealed source for the use in a device authorized under Rule .05(65) to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in Rules .05(66)(c) and .05(66)(d) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission. (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.); or

(b) Is an authorized user for uses listed in Rule .05(44) or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(c) Has had 8 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

(d) 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**(67) Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.**

(a) A licensee must only use sealed sources:

1. Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or
2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Rule .05(21)(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of Rule .05(21)(a) are met.

(68) Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.

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

(b) A licensee shall retain a record of the surveys in accordance with Rule .05(102).

(69) Installation, Maintenance, Adjustment, and Repair.

(a) Only a person specifically licensed by the Director, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the

source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

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

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

(d) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with Rule .05(106).

(70) Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall:

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

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

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

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

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

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

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

(b) A copy of the procedures required by Rule .05(70)(a)4. must be physically located at the unit console.

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

1. The location of the procedures required by Rule .05(70)(a)4.; and
2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) 1. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

2. A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

(i) The procedures identified in Rule .05(70)(a)4.; and

(ii) The operating procedures for the unit.

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

(f) A licensee shall retain a record of individuals receiving instruction required by Rule .05(70)(d), in accordance with Rule .05(101).

(g) A licensee shall retain a copy of the procedures required by subparagraphs .05(70)(a)4. and (d)2.(ii).

(71) Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

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

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
2. Cause the source(s) to be shielded promptly when an entrance door is opened; and

3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

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

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

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

(f) In addition to the requirements specified in Rule .05(71)(a) through (71)(e), a licensee shall:

1. For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

2. For high dose-rate remote afterloader unit, require:

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

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

(g) A licensee shall have emergency response equipment available near each treatment room, to

respond to a source that inadvertently:

1. Remains in the unshielded position; or
2. Lodges within the patient following completion of the treatment.

(72) Dosimetry Equipment.

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

1. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or
2. The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been inter-compared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the inter-comparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the inter-comparison result to change the calibration factor. When inter-comparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with Rule .05(72)(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in Rule .05(72)(a).

(c) The licensee shall retain a record of each calibration, inter-comparison, and comparison in accordance with Rule .05(107).

(73) Full Calibration Measurements on Teletherapy Units.

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

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:

- (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
3. At intervals not exceeding 1 year.
- (b) To satisfy the requirement of Rule .05(73)(a), full calibration measurements must include determination of:
 - 1. The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;
 - 2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - 3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
 - 4. Timer accuracy and linearity over the range of use;
 - 5. On-off error; and
 - 6. The accuracy of all distance measuring and localization devices in medical use.
 - (c) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(73)(b)1. may be made using a dosimetry system that indicates relative dose rates.
 - (d) A licensee shall make full calibration measurements required by Rule .05(73)(a) in accordance with published protocols accepted by nationally recognized bodies.
 - (e) A licensee shall mathematically correct the outputs determined in Rule .05(73)(b)1. for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.
 - (f) Full calibration measurements required by Rule .05(73)(a) and physical decay corrections required by Rule .05(73)(e) must be performed by the authorized medical physicist.
 - (g) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(74) Full Calibration Measurements on Remote Afterloader Units.

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

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

(b) To satisfy the requirement of Rule .05(74)(a), full calibration measurements must include, as applicable, determination of:

1. The output within +/- 5 percent;
2. Source positioning accuracy to within +/- 1 millimeter;
3. Source retraction with backup battery upon power failure; and
4. Length of the source transfer tubes;
5. Timer accuracy and linearity over the typical range of use;
6. Length of the applicators; and
7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in Rule .05(74)(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(d) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output.

(e) A licensee shall make full calibration measurements required by Rule .05(74)(a) in

accordance with published protocols accepted by nationally recognized bodies.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with Rule .05(74)(a) through (74)(e).

(g) A licensee shall mathematically correct the outputs determined in Rule .05(74)(b)1. of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by Rule .05(74)(a) and physical decay corrections required by Rule .05(74)(g) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(75) Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

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

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

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

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

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

3. At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of Rule .05(75)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent;
2. Relative helmet factors;
3. Isocenter coincidence;
4. Timer accuracy and linearity over the range of use;

5. On-off error;
6. Trunnion centricity;
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches;
9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in Rule .05(72)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(75)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by Rule .05(75)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in Rule .05(75)(b)1. at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by Rule .05(75)(a) and physical decay corrections required by Rule .05(75)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with Rule .05(108).

(76) Periodic Spot-Checks for Teletherapy Units.

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

1. Timer accuracy, and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(72)(b); and

6. The difference between the measurement made in Rule .05(76)(a)5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by Rule .05(76)(a) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

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

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

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in Rule .05(76)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by Rule.05(76)(a) and (76)(d), in accordance with Rule .05(109).

(77) Periodic Spot-Checks for Remote Afterloader Units.

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

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

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

3. After each source installation.

(b) The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in Rule .05(77)(a). The authorized medical physicist need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(d) To satisfy the requirements of Rule .05(77)(a), spot-checks must, at a minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;

4. Emergency response equipment;

5. Radiation monitors used to indicate the source position;

6. Timer accuracy;

7. Clock (date and time) in the unit's computer; and

8. Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in Rule .05(77)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by Rule .05(77)(d) in accordance with Rule .05(110).

(78) Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. At the beginning of each day of use; and
3. After each source installation.

(b) The licensee shall have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in Rule .05(78)(a); and
2. Review the results of each spot-check required by Rule .05(78)(a)1. within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(c) To satisfy the requirements of Rule .05(78)(a)1., spot-checks must, at a minimum:

1. Assure proper operation of:

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

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

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

2. Determine:

(i) The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(72)(b);

(ii) The difference between the measurement made in Rule .05(78)(c)2.(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

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

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of Rule .05(78)(a)2. and (78)(a)3., spot-checks must assure proper operation of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 3. Viewing and intercom systems;
 4. Timer termination;
 5. Radiation monitors used to indicate room exposures; and
 6. Emergency off buttons.
- (e) A licensee shall arrange for prompt repair of any system identified in Rule .05(78)(c) that is not operating properly.
- (f) If the results of the checks required in Rule .05(78)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (g) A licensee shall retain a record of each check required by Rule .05(78)(c) and (78)(d) in accordance with Rule .05(111).

(79) Additional Technical Requirements for Mobile Remote Afterloader Units.

- (a) A licensee providing mobile remote afterloader service shall:
1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
 2. Account for all sources before departure from a client's address of use.
- (b) In addition to the periodic spot-checks required by Rule .05(77), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:
1. Electrical interlocks on treatment area access points;
 2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 3. Viewing and intercom systems;
 4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

5. Radiation monitors used to indicate room exposures;
 6. Source positioning (accuracy); and
 7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.
- (c) In addition to the requirements for checks in Rule .05(79)(b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
- (d) If the results of the checks required in Rule .05(79)(b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (e) A licensee shall retain a record of each check required by Rule .05(79)(b) in accordance with Rule .05(112).

(80) Radiation Surveys.

- (a) In addition to the survey requirements in Rule .03(8) of this Chapter, a person licensed pursuant to Rule .05 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.
- (b) The licensee shall make the survey required by Rule .05(80)(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- (c) A licensee shall retain a record of the radiation surveys required by Rule .05(80)(a) of this section in accordance with Rule .05(113).

(81) Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

- (a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism and other safety components.
- (b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Director, an Agreement State or the Nuclear Regulatory Commission.
- (c) A licensee shall keep a record of the inspection and servicing in accordance with Rule .05(114).

(82) **Therapy-Related Computer Systems.** The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- (a) The source-specific input parameters required by the dose calculation algorithm;
- (b) The accuracy of dose, dwell time, and treatment time calculations at representative points;
- (c) The accuracy of isodose plots and graphic displays;
- (d) The accuracy of the software used to determine radioactive source positions from radiographic images; and
- (e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(83) **Possession of Survey Instruments.** A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsievert (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsievert (1 mrem) per hour to 10 millisievert (1,000 mrem) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(30).

(84) **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.** Except as provided in Rule .05(26), the licensee shall require an authorized user of a sealed source for a use authorized under Rule .05(67) to be a physician who:

(a) Is certified by a medical specialty board whose certification has been recognized by the Division, an Agreement State or the Nuclear Regulatory Commission, and who meets the requirements in .05(84)(c). (The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate Training~~ Council on Postdoctoral Training of the American Osteopathic Association; and
2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external

beam therapy; or

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

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rule .05(26), .05(84) or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution that is authorized to use radioactive materials in Rule .05(67), involving:

(I) Reviewing full calibration measurements and periodic spot checks;

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

(III) Using administrative controls to prevent a mis-administration involving the use of radioactive material;

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

(V) Checking and using survey meters; and

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

2. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rule .05(26), .05(84) 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~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by Rule .05(84)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in Rule .05(84)(b)1. and .05(84)(b)2., and .05(84)(c), and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic

medical unit for which the individual is requesting authorized user status; and

The signed attestation must be obtained from either:

- (i) A preceptor authorized user, who meets the requirements in Rules .05(26), (84), or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
- (ii) A residency program director who affirms in writing that the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rules .05(26), (84), or equivalent Agreement State or Nuclear Regulatory Commission requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraphs .05(63)(b)1. and 2.
- (c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

(85) 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 Rule .05 if:

- (a) The applicant or licensee has submitted the information required by Rule .05(8)(b), (8)(c) and (8)(d); and
- (b) The applicant or licensee has received written approval from the NRC or an Agreement State in a license and uses the material in accordance with the regulations and specific conditions the NRC or Agreement State considers necessary for the medical use of the material.

Records

(86) Records of Authority and Responsibilities for Radiation Protection Programs.

- (a) A licensee shall retain a record of actions taken by the licensee's management in accordance with Rule .05(15)(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.
- (b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the

Radiation Safety Officer as required by Rule .05(15)(d), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by Rule .05(15)(b). The record must include the signature of the Radiation Safety Officer and licensee management.

(c) The minutes of each Radiation Safety Committee meeting held in accordance with Rule .05(15)(g) shall include:

1. The date of the meeting;
2. Members present;
3. Members absent; and
4. Summary of deliberations and discussions.

(87) **Records of Radiation Protection Program Safety Changes.** A licensee shall retain a record of each radiation protection program change made in accordance with Rule .05(16)(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(88) **Records of Written Directives.** A licensee shall retain a copy of each written directive as required by Rule .05(19) for 3 years.

(89) **Records of Misadministrations.** A licensee shall retain a record of misadministrations reported in accordance with Rule .05(115) for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(90) **Record of a Dose to an Embryo/Fetus or a Nursing Child.** A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with Rule .05(116) for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(91) **Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.** A licensee shall maintain a record of instrument calibrations required by Rule .05(29) for 3 years. The records must include the model and serial number of the

instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(92) Records of Survey Instrument Calibrations. A licensee shall maintain a record of instrument calibrations required by Rule .05(30) for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(93) Records of Dosages of Unsealed Radioactive Material for Medical Use. A licensee shall maintain a record of dosage determinations required by Rule .05(31) for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.11 MBq (30 μ Ci); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(94) Records of Possession of Sealed Sources and Brachytherapy Sources. A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by Rule .05(33)(d) for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(95) Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by Rule .05(36) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

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

(a) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release,

(b) A licensee shall retain a record, for 3 years after the date of release, that the instructions required by Rule .05(37)(b) were provided to a breast-feeding woman.

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

(a) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by Rule .05(9)(b), for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by Rule .05(38)(f) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(98) **Records of Decay-in-Storage.** A licensee shall maintain records of the disposal of licensed materials, as required by Rule .05(40), for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(99) **Records of Radionuclide Purity.** A licensee shall maintain a record of the radionuclide contaminant concentration tests required by Rule .05(45) for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcurie/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

(100) **Records of Training.** A licensee shall maintain records of training required by Rule .05(25) for 3 years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.

(101) **Records of Safety Instruction and Training.** A licensee shall maintain a record of safety instructions and training required by Rules .05(49), (58) and (70) for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(102) **Records of Radiation Surveys of Patients and Human Research Subjects.** A licensee shall maintain a record of the surveys required by Rule .05(56) and (68) for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(103) **Records of Brachytherapy Source Inventory.**

(a) A licensee shall maintain a record of brachytherapy source accountability required by Rule .05(57) for 3 years.

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

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use;
2. The number and activity of unused sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of temporarily implanted sources removed from the patient or human research subject, the time and date they were returned to storage, and the name of the individual who returned them to storage.

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

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
2. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of sources permanently implanted in the patient or human research subject.

(104) Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by Rule .05(60) for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(105) Records of Decay of Strontium-90 Sources for Ophthalmic Treatments. The licensee shall maintain a record of the activity of a strontium 90 source required by Rule .05(60) for the life of the source. The record must include the date and initial activity of the source as determined under Rule .05(60), and for each decay calculation, the date, and the source activity and the signature of the authorized medical physicist.

(106) Records of Installation, Maintenance, Adjustment, and Repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by Rule .05(69) for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(107) Records of Dosimetry Equipment.

(a) A licensee shall retain a record of the calibration, inter-comparison, and comparisons of its dosimetry equipment done in accordance with Rule .05(72) for the duration of the license.

(b) For each calibration, inter-comparison, or comparison, the record must include:

1. The date;
2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by Rule .05(72)(a) and (72)(b);
3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an inter-comparison; and

4. The names of the individuals who performed the calibration, inter- comparison, or comparison.

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

(a) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by Rule .05(73), (74) and (75) for 3 years.

(b) The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;
3. The results and assessments of the full calibrations;
4. The results of the autoradiograph required for low dose-rate remote afterloader units; and
5. The signature of the authorized medical physicist who performed the full calibration.

(109) Records of Periodic Spot-Checks for Teletherapy Units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by Rule .05(76) for 3 years.

(b) The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;

8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(110) Records of Periodic Spot-Checks for Remote Afterloader Units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by Rule .05(77) for 3 years.

(b) The record must include, as applicable:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(111) Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by Rule .05(78) for 3 years.

(b) The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;

6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(112) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

- (a) A licensee shall retain a record of each check for mobile remote afterloader units required by Rule .05(79) for 3 years.
- (b) The record must include:
 1. The date of the check;
 2. The manufacturer's name, model number, and serial number of the remote afterloader unit;
 3. Notations accounting for all sources before the licensee departs from a facility;
 4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
 5. The signature of the individual who performed the check.

(113) Records of Surveys of Therapeutic Treatment Units.

- (a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Rule .05(80) for the duration of use of the unit.
- (b) The record must include:
 1. The date of the measurements;
 2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
 3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4. The signature of the individual who performed the test.

(114) Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.

(a) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by Rule .05(81) for the duration of use of the unit.

(b) The record must contain:

1. The inspector's radioactive materials license number;
2. The date of inspection;
3. The manufacturer's name and model number and serial number of both the treatment unit and source;
4. A list of components inspected and serviced, and the type of service; and
5. The signature of the inspector.

Reports

(115) Reports and Notifications of Misadministrations.

(a) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug or the wrong radionuclide for brachytherapy

procedures;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(i) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(ii) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

4. For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following:

(I) The wrong radionuclide;

(II) The wrong individual or human research subject;

(III) Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or

(IV) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

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

system, as determined by a physician.

(c) The licensee shall notify the Division by telephone no later than the next calendar day after discovery of the misadministration.

(d) The licensee shall submit a written report to the Division within 15 days after discovery of the misadministration.

1. The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

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

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

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

(g) A licensee shall retain a record of a misadministration in accordance with Rule .05(89). A copy of the record required under Rule .05(89) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

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

(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (~~500~~ mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

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

1. Is greater than 50 mSv (~~500~~ mrem) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the Division no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in Rule .05(116)(a) or (116)(b).

(d) The licensee shall submit a written report to the Division within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in Rule .05(116)(a) or (116)(b).

1. The written report must include:

- (i) The licensee's name;
- (ii) The name of the prescribing physician;
- (iii) A brief description of the event;
- (iv) Why the event occurred;
- (v) The effect on the embryo/fetus or the nursing child;
- (vi) What actions, if any, have been taken, or are planned, to prevent recurrence; and
- (vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that

could lead to identification of the individual or child.

(e) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require reporting under Rule .05(116)(a) or (116)(b), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with Rule .05(90). A copy of the record required under Rule .05(90) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(117) Reports of Leaking Sources. A licensee shall file a report with the Division within 5 days if a leakage test required by Rule .05(33) reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

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

(a) A licensee shall notify the Division by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under Rule .05(37)(a).

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

1. The licensee's name;
2. The date and time of the unauthorized departure;
3. The projected date and time when release would have occurred;
4. The address of the patient's or human research subject's home or anticipated destination following departure;

5. The radionuclide, chemical and physical form and calculated activity at time of release;
6. The apparent reason(s) for the departure prior to authorized release; and
7. A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

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

(a) The licensee shall notify the Division by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of limits specified in Rule .03(5)(i) of this Chapter as a result of the deceased's body.

(b) The licensee shall submit a written report to the Division within 30 days after discovery that the patient or human research subject referenced in (119)(a) has died. The written report must include:

1. The licensee's name;
2. The date of death;
3. The radionuclide, chemical and physical form and calculated activity at time of death; and,
4. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 millisievert (500 mrem).

(120) Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

(a) The licensee shall notify by telephone the Georgia Department of Natural Resources, Environmental Protection Division and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 391-3-17-.05(45)(a) at the time of generator elution. The telephone report to the Georgia EPD must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(b) By an appropriate method listed in 391-3-17-.01(13), the licensee shall submit a written report to Georgia Department of Natural Resources, Environmental Protection Division within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive

readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subparagraph .05(120)(a).

Rule 391-3-17-.06, "Transportation of Radioactive Material," is amended to read as follows:

391-3-17-.06 Transportation of Radioactive Material

(1) General.

(a) Purpose. The Regulations in this Rule, 391-3-17-.06, establish requirements for packaging, preparation for shipment, and transportation of radioactive material.

(b) Scope. This Rule applies to any licensee authorized by specific or general license issued by the Director, Agreement State, or NRC to receive, possess, use, or transfer licensed material to a carrier for transport of the material outside the site of usage as specified in the license, or transports that material on public highways or public access roads. No provision of this part authorizes possession of licensed material.

(2) **Requirement for License.** No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Director or as exempted in (4).

(3) **Definitions.** As used in this Rule, the following definitions apply:

(a) "A₁" and "A₂" mean, respectively, the maximum activity of special form radioactive material (A₁) and the maximum activity of radioactive material, other than special form material, LSA, and SCO material (A₂), permitted in a Type A package.

(b) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(c) "Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the U.S. Nuclear Regulatory Commission.

(d) "Certificate of Compliance (CoC)" means the certificate issued by the U.S Nuclear Regulatory Commission, which approves the design of a package for the transportation of radioactive material.

(e) "Close reflection by water" means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

(f) "Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

(g) "Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

(h) "Containment system" means the assembly components of the packaging intended to retain the radioactive material during transport.

(i) "Conveyance" means:

1. For transport by public highway or rail any transport vehicle or large freight container;
2. For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and
3. For transport by any aircraft.

(j) "Criticality Safety Index (CSI)" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in 391-3-17-.06(11) and (12) and 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.

(k) "Deuterium" means deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5,000.

(l) "DOT" means the U.S. Department of Transportation.

(m) "Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.¹

(n) "Fissile material" means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Neither natural nor depleted uranium is fissile material.² Unirradiated natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

¹ The term "exclusive use" is used interchangeably with the terms "sole use" or "full load" in other regulations, such as Title 49 of the Code of Federal Regulations.

² Department jurisdiction extends only to special nuclear material if quantities are not sufficient to form a critical mass as defined in Rule .01(2)(ddddd) of these Regulations.

(o) "Graphite" means graphite with a boron equivalent content less than five (5) parts per million and density greater than 1.5 grams per cubic centimeter.

(p) "Indian Tribe" means an Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

(q) "Licensed material" means byproduct, source, or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to the regulations in 10 CFR or this Chapter, respectively.

(r) "Low specific activity material" means radioactive material with limited specific activity which is nonfissile or is excepted under 391-3-17-.06(4)(f), and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. The LSA material must be in one of three groups:

1. LSA-I

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides; or

(ii) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form; or

(iii) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

(iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 391-3-17-.06(23).

2. LSA-II

(i) Water with tritium concentration up to 20.0 Ci/L (0.8 TBq/liter); or

(ii) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed $10^{-4} A_2/g$ for solids and gases, and $10^{-5} A_2/g$ for liquids.

3. LSA-III. Solids (e.g. consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77, in which:

(i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc);

- (ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed $0.1 A_2$; and
- (iii) The estimated average specific activity of the solid, excluding any shielding material, does not exceed $2 \times 10^{-3} A_2/g$.
- (s) "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.
- (t) "Maximum normal operating pressure" means the maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.
- (u) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).
- (v) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material."
- (w) "Nuclear waste" means a quantity of source, byproduct or special nuclear material³ required to be in US Nuclear Regulatory Commission-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.
- (x) "Optimum interspersed hydrogenous moderation" means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.
- (y) "Package" means the packaging together with its radioactive contents as presented for transport.
1. "Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package" means a fissile material packaging together with its fissile material contents.
 2. "Type A package" means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.
 3. "Type B package" means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a

³ The definition of nuclear waste in this Part is used in the same way as in 49 CFR 173.403.

maximum normal operating pressure of more than 700 kPa (100 lb/in²) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR Part 71 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in .06(8).

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

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

(bb) "Regulations of the U.S. Nuclear Regulatory Commission" means the regulations in 10 CFR 71 for purposes of this Rule.

(cc) "Special form radioactive material" means radioactive material that satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 in.); and
3. It satisfies the requirements specified by the Nuclear Regulatory Commission in 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR 71, revised as of January 1, 1983), and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR 71, revised as of January 1, 1996), and constructed prior to April 1, 1998, may continue to be used. A special form material that was successfully tested before September 10, 2015 in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form must meet requirements of this definition applicable at the time of its design or construction.

(dd) "Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(ee) "Spent nuclear fuel or Spent fuel" means fuel that has been withdrawn from a nuclear

reactor following irradiation, has undergone at least one (1) year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

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

1. SCO-I: A solid object on which:

(i) 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 10^{-4} microcurie/ cm^2 ($4 \text{ Bq}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or 10^{-5} microcurie/ cm^2 ($0.4 \text{ Bq}/\text{cm}^2$) for all other alpha emitters;

(ii) 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 1.0 microcurie/ cm^2 ($4 \times 10^4 \text{ Bq}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/ cm^2 ($4 \times 10^3 \text{ Bq}/\text{cm}^2$) for all other alpha emitters; and

(iii) 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 1.0 microcurie/ cm^2 ($4 \times 10^4 \text{ Bq}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/ cm^2 ($4 \times 10^3 \text{ Bq}/\text{cm}^2$) for all other alpha emitters.

2. SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(i) 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 10^{-2} microcurie/ cm^2 ($400 \text{ Bq}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or 10^{-3} microcurie/ cm^2 ($40 \text{ Bq}/\text{cm}^2$) for all other alpha emitters;

(ii) 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 20 microcurie/ cm^2 ($8 \times 10^5 \text{ Bq}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/ cm^2 ($8 \times 10^4 \text{ Bq}/\text{cm}^2$) for all other alpha emitters; and

(iii) 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 20 microcurie/ cm^2 ($8 \times 10^5 \text{ Bq}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/ cm^2 ($8 \times 10^4 \text{ Bq}/\text{cm}^2$) for all other alpha emitters.

(gg) "Transport index" means the dimension-less 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 transportation index is the number expressing the maximum radiation level in

millirem per hour at 1 meter from the external surface of the package.

(hh) "Tribal official" means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

(ii) "Type A package" means a packaging that, together with its radioactive contents limited to A_1 or A_2 as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding required by this Rule under normal conditions of transport as demonstrated by the tests set forth in 49 CFR 173.465 or 173.466, as appropriate.

(jj) "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 Table 4, "A₁ and A₂ Values for Radionuclides" or may be determined by procedures described in (23) of this Rule.

(kk) "Type B package" is defined in Rule 391-3-17-.01(2)(ttt).

(ll) "Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.

(mm) "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

(nn) "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} grams of uranium-236 per gram of uranium-235.

(oo) "Uranium-natural, depleted, enriched" means:

1. Natural uranium means uranium (which may be chemically separated) 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.

(pp) "Contamination" means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm^2 ($1 \times 10^{-5} \text{ } \mu\text{Ci/cm}^2$) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 ($1 \times 10^{-6} \text{ } \mu\text{Ci/cm}^2$) for all other alpha emitters.

1. Fixed contamination means contamination that cannot be removed from a surface during normal conditions of transport

2. Non-fixed contamination means contamination that can be removed from a surface during normal conditions of transport

(4) Exemptions.

(a) Common and contract carriers, freight forwarders, and warehousemen who are subject to the requirements of the U.S. Department of Transportation (DOT) in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section C-023.9.0, and the U.S. Postal Service, are exempt from the requirements of this Rule and as stated in 10 CFR 30.13 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 (2) of this Rule and other applicable requirements of these Regulations.

(b) Any licensee is exempt from the requirements of this Rule to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 0.002 microcurie per gram (70 Bq/gm).

(c) Any physician licensed by Georgia to dispense drugs in the practice of medicine is exempt from Rule .06 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under Rule .05.

(d) A licensee is exempt from the requirements of Rule .06 with respect to shipment or carriage of the following low-level materials:

1. Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in Table 5 and 7.

2. Materials for which the activity concentration is not greater than the activity concentration values specified in Table 5 and 7, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table 5 and 7.

3. Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in 391-3-17-.06(3)(pp).

(e) A licensee is exempt from the requirements of Rule .06, other than .06(5) and .06(17), with respect to shipment or carriage of the following packages, providing the packages do not contain any fissile material, or the material is exempt from classification as fissile material in .06(4)(f):

1. A package that contains no more than a Type A quantity of radioactive material;

2. A package transported within the United States that contains no more than 20 Ci (0.74 TBq) of special form plutonium-244; or

3. A package contains LSA or SCO radioactive material, provided that the LSA or SCO material has an external radiation dose of less than or equal to 1 rem/hr (10 mSv/hr) at a distance of 3 meters from the unshielded material or that the package contains only LSA-I or SCO-I material.

(f) Fissile material meeting the requirements of at least one of the following six paragraphs in this part are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of this part, except as noted.

1. Individual package containing two (2) grams or less of fissile material.

2. Individual or bulk packaging containing fifteen (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. Low concentrations of solid fissile material commingled with solid nonfissile material, provided that (i) there is at least 2,000 grams of solid nonfissile material for every gram of fissile material, and (ii) there is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile 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.

4. Uranium enriched in uranium-235 to a maximum of one (1) percent by weight, and with a total plutonium and uranium-233 content of up to one (1) percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five (5) percent of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

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

6. Packages containing, individually, a total plutonium mass of not more than 1,000 grams, of which not more than twenty (20) percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

(5) Transportation of Licensed Material.

(a) Each licensee who transports licensed material outside the site of usage, as specified in a Division license, or where transport is on public highway, or public access road, or who delivers licensed material to a carrier for transport, shall:

1. Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the US Department of Transportation (DOT).

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

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

(II) Marking and Labeling - 49 CFR Part 172: Subpart D, and §§ 49 CFR 172.400 through 172.407, §§ 172.436 through 172.440 of Subpart E.

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

(IV) Accident Reporting - 49 CFR Part 171: §§ 171.15 and 171.16.

(V) Shipping Papers and Emergency Information – 49 CFR Part 172, Subpart C and Subpart G.

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

(VII) Security Plans – 49 CFR Part 172: Subpart I.

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

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

(I) Rail - 49 CFR Part 174, Subparts A through D and K.

(II) Air - 49 CFR Part 175.

(III) Vessel - 49 CFR Part 176, Subparts A through F and M.

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

2. 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 Rule 391-3-17-.03(12)(f).

(b) If, for any reason, the regulations of the DOT are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 170-189 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.

(6) General Licenses for Carriers.

(a) A general license is hereby issued to any common or contract carrier not exempt under (4) 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 DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.⁴

(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 DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

(c) Persons who transport radioactive material pursuant to the general licenses in (6)(a) or (b) are exempt from the requirements of Rules 391-3-17-.03 and .07 to the extent that they transport radioactive material.

(7) General License: NRC-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 U.S. Nuclear Regulatory Commission (NRC).

(b) Each licensee issued a general license under .06(7)(a) shall:

1. Possess a copy of the specific license, certificate of compliance, or other approval of the package and 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. Comply with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of this Rule;
3. Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.71(a), the licensee's name and license number and the package identification number specified in the package approval.

(c) This general license applies only to a licensee who has a quality assurance program required by the Georgia Department of Natural Resources Radioactive Materials Program satisfying the provisions of (22).

(d) The general license in (7)(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 NRC before April 1, 1996 the general license is subject to additional restrictions of 10 CFR 71.19.

⁴ Notification of an incident shall be filed with, or made to, the Department as prescribed in 49 CFR, regardless of and in addition to notification made to DOT or to other agencies.

(8) **[Reserved]**.

(9) General License: DOT Specification Container.

(a) A general license is issued to any licensee of the Division 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 this Rule; and
3. Has a quality assurance program required by (22).

(c) The general license in (9)(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 DOT regulations at 49 CFR 173.403.

(10) General License: Use of Foreign-Approved Package.

(a) A general license is issued to any licensee of the Division 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 DOT as meeting the applicable requirements of 49 CFR 171.23.

(b) This general license applies only to international shipments.

(c) This general license applies only to a licensee who:

1. 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;
2. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this Rule; and
3. Has a quality assurance program approved by the Georgia Department of Natural Resources, Environmental Protection Division, Radioactive Materials Program satisfying the requirements of (22).

(11) 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 this section. 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) This general license applies only to a licensee who has a quality assurance program required by (22).
- (c) This general license applies only when a package contains no more than a Type A quantity of fissile material and contains less than 500 grams total of beryllium, graphite, or hydrogenous material enriched in deuterium.
- (d) 1. This general license applies only to packages containing fissile material that are labeled with a Criticality Safety Index (CSI), defined as

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

where the values of X, Y, and Z used in the CSI equation must be taken from Tables 1 or 2, as appropriate. If Table 2 is used to obtain the value of X, then the values for the terms for uranium-233 and plutonium must be assumed to be zero. Table 1 values for X, Y, and Z must be used to determine the CSI if:

- i. Uranium-233 is present in the package;
 - ii. The mass of plutonium exceeds one (1) percent of the mass of uranium-235;
 - iii. The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or
 - iv. Substances having a moderating effectiveness (i.e., an average hydrogen density greater than water) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.
2. In all cases, the Criticality Safety Index must be rounded up to one decimal place and may not exceed 10.0.
 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 non-exclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

Table 1

Mass Limits for General License Packages Containing Mixed Quantities Of Fissile Material or Uranium-235 of Unknown Enrichment

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

(a) – When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substances has an average hydrogen density greater than water.

Table 2

Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment

Uranium Enrichment in weight percent of ^{235}U not exceeding	Fissile Material mass of ^{235}U (X) (in 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*

*- Pursuant to the Division's agreement with the USNRC, jurisdiction extends only to 350 grams of uranium-235.

(12) General License: Plutonium-Beryllium Special Form Material.

(a) A general license is hereby 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 this section. 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) This general license applies only when all of the following requirements are met:

1. The package contains no more than a Type A quantity of radioactive material.

2. The package contains less than 1,000 grams of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 grams of the total quantity of plutonium in the package.

(c) 1. This general license applies only to packages that are labeled with a Criticality Safety Index, calculated by:

$$\text{CSI} = (10 / 24) \times (\text{grams } ^{239}\text{Pu} + \text{grams } ^{241}\text{Pu})$$

where the CSI value is less than or equal to 100 and must be rounded up to the first decimal place.

2. 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).

(d) The general license has a quality assurance program required by (22).

(13) Assumptions as to Unknown Properties of Fissile Material. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties had credible values that will cause the maximum neutron multiplication.

(14) External Radiation Standards For All Packages.

(a) Except as provided in (14)(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 200 mrem/hr (2 mSv/hr) at any point on the external surface of the package, and the transport index does not exceed 10.

(b) A package that exceeds the radiation level limits specified in (14)(a) must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

1. 200 mrem/hr (2 mSv/hr) on the external surface of the package, unless the following conditions are met, in which case the limit is 1,000 mrem/hr (10 mSv/hr):

- (i) The shipment is made in a closed transport vehicle;
- (ii) The package is secured within the vehicle so that its position remains fixed during transportation; and
- (iii) There are no loading or unloading operations between the beginning and end of the transportation;

2. 200 mrem/hr (2 mSv/hr) 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. 10 mrem/hr (0.1 mSv/hr) at any point two (2) meters (80 inches) 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 (2) 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

4. 2 mrem/hr (0.02 mSv/hr) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with Rule 391-3-17-.03(8)(b).

(c) For shipments made under the provisions of (14)(b), the shipper will provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

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

(15) Preliminary Determinations. Prior to the first use of any packaging for the shipment of radioactive material:

(a) The licensee shall ascertain that the determinations in 10 CFR 71.85(a) through (c) have been made.

(16) Routine Determinations. Prior to each shipment of licensed material, the licensee shall determine that:

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

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

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

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

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

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

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

condition;

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

(i) The level of non-fixed radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable.

1. The level of non-fixed radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in (16)(i)2., the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 3 at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in Table 3.

2. In the case of packages transported as exclusive use shipments by rail or highway only, the non-fixed radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in (16)(i)1. The levels at the beginning of transport must not exceed the levels in (16)(i)1.;

Table 3
Non-Fixed (Removable) External Radioactive Contamination-Wipe Limits

Contaminant	Maximum Permissible limits		
	$\mu\text{Ci}/\text{cm}^2$	dpm/cm ²	Bq/cm ²
Beta-/gamma-emitting radionuclides; and low toxicity alpha emitters.....	10^{-5}	22	0.4
All other alpha-emitting radionuclides.....	10^{-6}	2.2	0.04

(j) External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirem per hour (2 mSv/hr) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.

(k) For package transported as exclusive use by rail, highway, or water, radiation levels external to the package may exceed the limits specified in (16)(j). but shall not exceed any of the following:

1. 200 millirem per hour (2 mSv/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1,000 millirem per hour (10 mSv/hr):

(i) The shipment is made in a closed transport vehicle,

(ii) Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and

(iii) There are no loading or unloading operations between the beginning and end of the transportation;

2. 200 millirem per hour (2 mSv/hr) 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 with a personnel barrier⁵, 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;

3. 10 millirem per hour (0.1 mSv/hr) at any point 2 meters from the vertical planes represented by the outer lateral surfaces of the vehicle; or in the case of a flat-bed style vehicle, at any point 2 meters from the vertical planes projected from the outer edges of the vehicle; and

⁵ A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier is in place, the package cannot exceed 200 millirem per hour (2 mSv/hr) at any accessible surface.

4. 2 millirem per hour (0.02 mSv/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with 391-3-17-.07(3) of this Chapter; and

(l) A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 185 degrees Fahrenheit (85 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

(m) A package may not incorporate a feature intended to allow continuous venting during transport.

(17) **Air Transport of Plutonium.** Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Rule or included indirectly by citation of the DOT regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

(a) The plutonium is contained in a medical device designed for individual human application;

(b) The plutonium is contained in a material in which the specific activity is not greater than the activity concentration values for plutonium as specified in Table 7, and in which the radioactivity is essentially uniformly distributed;

(c) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with (5); or

(d) The plutonium is shipped in a package specifically authorized, in the certificate of compliance, issued by the Nuclear Regulatory Commission, for the shipment of plutonium by air and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the US Department of Transportation regulations applicable to the air transport of plutonium.

(18) **Opening instructions.** Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with Rule 391-3-17-.03(12)(f).

(19) **Shipment Records.** Each licensee shall maintain for a period of three years after shipment a record of each shipment of licensed material not exempt under (4), showing, where applicable:

(a) Identification of the packaging by model number;

(b) Verification that there were no significant defects in the packaging, as shipped;

- (c) Volume and identification of coolant;
- (d) Type and quantity of licensed material in each package, and the total quantity of each shipment;
- (e) Date of the shipment;
- (f) Name and address of the transferee;
- (g) Address to which the shipment was made; and
- (h) Results of the determinations required by (16) and the conditions of the package approval.
- (i) The licensee shall make available to the Division for inspection, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.
- (j) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by 391-3-17-.06(15) and 10 CFR 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for 3 years after the life of the packaging to which they apply.
- (k) For each item of irradiated fissile material —
 1. Identification by model number and serial number;
 2. Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and
 3. Any abnormal or unusual condition relevant to radiation safety;
- (l) For fissile packages and for Type B packages, any special controls exercised.
- (20) **Reports.** The licensee shall report to the Division within 30 days:
 - (a) Any instance in which there is significant reduction in the effectiveness of any authorized packaging during use; and
 - (b) Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence.

(21) Advance Notification of Transport of Nuclear Waste.

(a) As specified in paragraphs (b), (c), and (d) of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee⁶, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

1. As specified in paragraphs (b), (c), and (d) of this section, after June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph (d)3.(iii) of this section, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b) Advance notification is also required when:

1. The licensed material is required to be in Type B packaging for transportation;
2. The licensed material is being transported into, within, or through, a state en route to a disposal facility or to a collection point for transport to a disposal facility; and
3. The quantity of licensed material in a single package exceeds the least of the following:
 - (i) 3000 times the A_1 value of the radionuclides as specified in Table 7, for special form radioactive material;
 - (ii) 3000 times the A_2 value of the radionuclides as specified in Table 7 for normal form radioactive material; or
 - (iii) 27,000 Ci (1000 TBq);

(c) Each advance notification required by .06(21)(a) shall contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;
2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);
3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;
4. The seven-day period during which arrival of the shipment at state boundaries or Tribal

⁶ A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, State Programs, NRC, Washington, D.C., 20555. The list will be published in the Federal Register on or about June 30 of each year to reflect any changes in information.

reservation boundaries is estimated to occur;

5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

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

(d) Procedures for Submitting Advance Notification:

1. The notification required by .06(21)(a) shall be made in writing to the office of each appropriate governor, or governor's designee, to the office of each appropriate Tribal official or Tribal official's designee, and to the Division.

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

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

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

(ii) The list of governor's designees and Tribal official's designees of participating Tribes will be published annually in the Federal Register on or about June 30th to reflect any changes in information.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes, including telephone and mailing addresses of Tribal official's designees, is available on the NRC Web site at: <https://scp.nrc.gov/special/designee.pdf>.

4. A copy of the notification shall be retained by the licensee for three years.

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

(f) Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and to the Division.

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

(22) Quality Assurance Requirements.

This paragraph 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 paragraph, “quality assurance” comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

(a) Unless otherwise authorized by the Division, each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

(b) The licensee shall identify the material and components to be covered by the quality assurance program.

(c) Each licensee 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 packaging is used.

(d) Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the Division of its quality assurance program.

(e) The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of three years after shipment.

(f) 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 rule 391-3-17-.04(11)(d) and (e) or equivalent NRC or Agreement State requirement, is deemed to satisfy the requirements of 391-3-17-.06(7) and .06(22)(g).

(g) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 391-3-17-.06(22) and satisfying any specific provisions that are applicable to the licensee's activities including procurement of

packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(h) Approval of program.

1. Before the use of any package for the shipment of licensed material subject to this paragraph, each licensee shall obtain Division approval of its quality assurance program. Using an appropriate method listed in 391-3-17-.06(22), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: Georgia Department of Natural Resources/Environmental Protection Division, Radioactive Materials Program, at 4244 International Parkway, Suite 120, Atlanta, Georgia 30354.

(i) Quality Assurance Organization

1. The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee 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.

2. The quality assurance functions are:

(i) Assuring that an appropriate quality assurance program is established and effectively executed; and

(ii) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(j) Changes to Quality Assurance Programs

1. Each quality assurance program approval holder shall submit, in accordance with the requirements of 391-3-17-.01(13) and 391-3-17-.06(19), a description of a proposed change to its Georgia Department of Natural Resources Radioactive Materials Program approved quality assurance program that will reduce commitments in the program description as approved by the Georgia Department of Natural Resources Radioactive Materials Program. The quality assurance program approval holder shall not implement the change before receiving Georgia Department of Natural Resources Radioactive Materials Program approval.

(i) The description of a proposed change to the Georgia Department of Natural Resources Radioactive Materials Program approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of 391-3-17-.06(22).

(ii) [Reserved]

2. Each quality assurance program approval holder may change a previously approved quality assurance program without prior Georgia Department of Natural Resources Radioactive Materials Program approval, if the change does not reduce the commitments in the quality assurance program previously approved by the Georgia Department of Natural Resources Radioactive Materials Program. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the Georgia Department of Natural Resources Radioactive Materials Program every 24 months, in accordance with 391-3-17-.01(13). In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

- (i) The use of a quality assurance standard approved by the Georgia Department of Natural Resources Radioactive Materials Program that is more recent than the quality assurance standard in the applicant's current quality assurance program at the time of the change;
- (ii) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;
- (iii) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;
- (iv) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and
- (v) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

3. Each quality assurance program approval holder shall maintain records of quality assurance program changes.

(k) Quality Assurance Records

1. The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by 391-3-17-.06(22)(j), the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for 3 years beyond the date when the licensee last engage in the activity for which the quality assurance program was developed. If any portion of the quality

assurance program, written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 years after it is superseded.

(23) Determination of A₁ and A₂. -

(a) Values of A₁ and A₂ for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations, are given in Table 4. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A₁ or A₂ are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

(b) 1. For individual radionuclides whose identities are known but are not listed in Table 4, the A₁ and A₂ values contained in Table 5 may be used. Otherwise, the licensee shall obtain prior Division approval of the A₁ and A₂ values for radionuclides not listed in Table 4, before shipping the material

2. For individual radionuclides whose identities are known but are not listed in Table 7, the exempt material activity concentration and exempt consignment activity values contained in Table 5 may be used. Otherwise, the licensee shall obtain prior Division approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table 7, before shipping the material.

(c) In calculations of A₁ and A₂ for a radionuclide not in Table 4, 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 10 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 A₁ and A₂ 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 of the parent nuclide, the parent and those daughters nuclides shall be considered as a mixture of different nuclides.

(d) Mixtures of radionuclides.

1. For mixture of radionuclides whose identities and respective activities are known, following conditions apply:

(i) For a 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 in special form, and A₁(i) is the A₁ value for radionuclide i.

(ii) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i in normal form, and A₂(i) is the A₂ value for radionuclide i.

(iii) If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} + \sum_j \frac{C(j)}{A_2(j)} \leq 1$$

where B(i) is the activity of radionuclide i as special form radioactive material, A₁(i) is the A₁ value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and A₂(j) is the A₂ value for radionuclide j.

(iv) Alternatively, the A₁ value for mixtures of special form material may be determined as follows:

A₁ for mixture =

$$\frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture and A₁(i) is the appropriate A₁ value for radionuclide i.

(v) Alternatively, the A₂ value for mixtures of normal form material may be determined as follows:

A₂ for mixture =

$$\frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture and A₂(i) is the appropriate A₂ value for radionuclide i.

(e) The exempt activity concentration for mixtures of radionuclides may be determined as follows:

Exempt activity concentration for mixture =

$$\frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where $f(i)$ is the fraction activity concentration of radionuclide i in the mixture and $[A](i)$ 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 =

$$\frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

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 .

(g) 1. 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 formulas above. 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.

2. 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 $[A]$ (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph 391-3-17-.06(23). Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest $[A]$ or A values for the alpha emitters and beta/gamma emitters, respectively.

Table 4 – A₁ and A₂ VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity (TBq/g) (Ci/g)	
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	2.7	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)	2.0	5.4X10 ¹	2.0	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		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	5.8X10 ³	1.6X10 ⁵
Al-26	Aluminum (13)	1.0X10 ⁻¹	2.7	1.0X10 ⁻¹	2.7	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	3.4
Am-242m (a)		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	3.6X10 ⁻¹	1.0X10 ¹
Am-243 (a)		5.0	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		4.0X10 ¹	1.1X10 ³	2.0X10 ¹	5.4X10 ²	1.3	3.4X10 ¹
Ar-41		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.5X10 ⁶	4.2X10 ⁷
As-72	Arsenic (33)	3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	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		1.0	2.7X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	3.7X10 ³	9.9X10 ⁴
As-76		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	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
Au-193	Gold (79)	7.0	1.9X10 ²	2.0	5.4X10 ¹	3.4X10 ⁴	9.2X10 ⁵
Au-194		1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.5X10 ⁴	4.1X10 ⁵
Au-195		1.0X10 ¹	2.7X10 ²	6.0	1.6X10 ²	1.4X10 ²	3.7X10 ³
Au-198		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	9.0X10 ³	2.4X10 ⁵
Au-199		1.0X10 ¹	2.7X10 ²	6.0X10 ⁻¹	1.6X10 ¹	7.7X10 ³	2.1X10 ⁵
Ba-131 (a)	Barium (56)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	3.1X10 ³	8.4X10 ⁴
Ba-133		3.0	8.1X10 ¹	3.0	8.1X10 ¹	9.4	2.6X10 ²
Ba-133m		2.0X10 ¹	5.4X10 ²	6.0X10 ⁻¹	1.6X10 ¹	2.2X10 ⁴	6.1X10 ⁵
Ba-140 (a)		5.0X10 ⁻¹	1.4X10 ¹	3.0X10 ⁻¹	8.1	2.7X10 ³	7.3X10 ⁴
Be-7	Beryllium (4)	2.0X10 ¹	5.4X10 ²	2.0X10 ¹	5.4X10 ²	1.3X10 ⁴	3.5X10 ⁵
Be-10		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻¹	1.6X10 ¹	8.3X10 ⁻⁴	2.2X10 ⁻²
Bi-205	Bismuth (83)	7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	1.5X10 ³	4.2X10 ⁴
Bi-206		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	3.8X10 ³	1.0X10 ⁵
Bi-207		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	1.9	5.2X10 ¹
Bi-210		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.6X10 ³	1.2X10 ⁵
Bi-210m (a)		6.0X10 ⁻¹	1.6X10 ¹	2.0X10 ⁻²	5.4X10 ⁻¹	2.1X10 ⁻⁵	5.7X10 ⁻⁴

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
Bi-212 (a)		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	5.4X10 ⁵	1.5X10 ⁷
Bk-247	Berkelium (97)	8.0	2.2X10 ²	8.0X10 ⁻⁴	2.2X10 ⁻²	3.8X10 ⁻²	1.0
Bk-249 (a)		4.0X10 ¹	1.1X10 ³	3.0X10 ⁻¹	8.1	6.1X10 ¹	1.6X10 ³
Br-76	Bromine (35)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	9.4X10 ⁴	2.5X10 ⁶
Br-77		3.0	8.1X10 ¹	3.0	8.1X10 ¹	2.6X10 ⁴	7.1X10 ⁵
Br-82		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁴	1.1X10 ⁶
C-11	Carbon (6)	1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.1X10 ⁷	8.4X10 ⁸
C-14		4.0X10 ¹	1.1X10 ³	3.0	8.1X10 ¹	1.6X10 ⁻¹	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	3.1X10 ⁻³	8.5X10 ⁻²
Ca-45		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	6.6X10 ²	1.8X10 ⁴
Ca-47 (a)		3.0	8.1X10 ¹	3.0X10 ⁻¹	8.1	2.3X10 ⁴	6.1X10 ⁵
Cd-109	Cadmium (48)	3.0X10 ¹	8.1X10 ²	2.0	5.4X10 ¹	9.6X10 ¹	2.6X10 ³
Cd-113m		4.0X10 ¹	1.1X10 ³	5.0X10 ⁻¹	1.4X10 ¹	8.3	2.2X10 ²
Cd-115 (a)		3.0	8.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.9X10 ⁴	5.1X10 ⁵
Cd-115m		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	9.4X10 ²	2.5X10 ⁴
Ce-139	Cerium (58)	7.0	1.9X10 ²	2.0	5.4X10 ¹	2.5X10 ²	6.8X10 ³
Ce-141		2.0X10 ¹	5.4X10 ²	6.0X10 ⁻¹	1.6X10 ¹	1.1X10 ³	2.8X10 ⁴
Ce-143		9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.5X10 ⁴	6.6X10 ⁵
Ce-144 (a)		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	1.2X10 ²	3.2X10 ³
Cf-248	Californium (98)	4.0X10 ¹	1.1X10 ³	6.0X10 ⁻³	1.6X10 ⁻¹	5.8X10 ¹	1.6X10 ³
Cf-249		3.0	8.1X10 ¹	8.0X10 ⁻⁴	2.2X10 ⁻²	1.5X10 ⁻¹	4.1
Cf-250		2.0X10 ¹	5.4X10 ²	2.0X10 ⁻³	5.4X10 ⁻²	4.0	1.1X10 ²
Cf-251		7.0	1.9X10 ²	7.0X10 ⁻⁴	1.9X10 ⁻²	5.9X10 ⁻²	1.6
Cf-252		1.0X10 ⁻¹	2.7	3.0X10 ⁻³	8.1X10 ⁻²	2.0X10 ¹	5.4X10 ²
Cf-253 (a)		4.0X10 ¹	1.1X10 ³	4.0X10 ⁻²	1.1	1.1X10 ³	2.9X10 ⁴
Cf-254		1.0X10 ⁻³	2.7X10 ⁻²	1.0X10 ⁻³	2.7X10 ⁻²	3.1X10 ²	8.5X10 ³
Cl-36	Chlorine (17)	1.0X10 ¹	2.7X10 ²	6.0X10 ⁻¹	1.6X10 ¹	1.2X10 ⁻³	3.3X10 ⁻²
Cl-38		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	4.9X10 ⁶	1.3X10 ⁸
Cm-240	Curium (96)	4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	7.5X10 ²	2.0X10 ⁴
Cm-241		2.0	5.4X10 ¹	1.0	2.7X10 ¹	6.1X10 ²	1.7X10 ⁴
Cm-242		4.0X10 ¹	1.1X10 ³	1.0X10 ⁻²	2.7X10 ⁻¹	1.2X10 ²	3.3X10 ³
Cm-243		9.0	2.4X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	1.9X10 ⁻³	5.2X10 ¹
Cm-244		2.0X10 ¹	5.4X10 ²	2.0X10 ⁻³	5.4X10 ⁻²	3.0	8.1X10 ¹
Cm-245		9.0	2.4X10 ²	9.0X10 ⁻⁴	2.4X10 ⁻²	6.4X10 ⁻³	1.7X10 ⁻¹
Cm-246		9.0	2.4X10 ²	9.0X10 ⁻⁴	2.4X10 ⁻²	1.1X10 ⁻²	3.1X10 ⁻¹
Cm-247 (a)		3.0	8.1X10 ¹	1.0X10 ⁻³	2.7X10 ⁻²	3.4X10 ⁻⁶	9.3X10 ⁻⁵
Cm-248		2.0X10 ⁻²	5.4X10 ⁻¹	3.0X10 ⁻⁴	8.1X10 ⁻³	1.6X10 ⁻⁴	4.2X10 ⁻³
Co-55	Cobalt (27)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	1.1X10 ⁵	3.1X10 ⁶

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
Co-56		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.1X10 ³	3.0X10 ⁴
Co-57		1.0X10 ¹	2.7X10 ²	1.0X10 ¹	2.7X10 ²	3.1X10 ²	8.4X10 ³
Co-58		1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.2X10 ³	3.2X10 ⁴
Co-58m		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	2.2X10 ⁵	5.9X10 ⁶
Co-60		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.2X10 ¹	1.1X10 ³
Cr-51	Chromium (24)	3.0X10 ¹	8.1X10 ²	3.0X10 ¹	8.1X10 ²	3.4X10 ³	9.2X10 ⁴
Cs-129	Cesium (55)	4.0	1.1X10 ²	4.0	1.1X10 ²	2.8X10 ⁴	7.6X10 ⁵
Cs-131		3.0X10 ¹	8.1X10 ²	3.0X10 ¹	8.1X10 ²	3.8X10 ³	1.0X10 ⁵
Cs-132		1.0	2.7X10 ¹	1.0	2.7X10 ¹	5.7X10 ³	1.5X10 ⁵
Cs-134		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	4.8X10 ¹	1.3X10 ³
Cs-134m		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻¹	1.6X10 ¹	3.0X10 ⁵	8.0X10 ⁶
Cs-135		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	4.3X10 ⁻⁵	1.2X10 ⁻³
Cs-136		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	2.7X10 ³	7.3X10 ⁴
Cs-137 (a)		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.2	8.7X10 ¹
Cu-64	Copper (29)	6.0	1.6X10 ²	1.0	2.7X10 ¹	1.4X10 ⁵	3.9X10 ⁶
Cu-67		1.0X10 ¹	2.7X10 ²	7.0X10 ⁻¹	1.9X10 ¹	2.8X10 ⁴	7.6X10 ⁵
Dy-159	Dysprosium (66)	2.0X10 ¹	5.4X10 ²	2.0X10 ¹	5.4X10 ²	2.1X10 ²	5.7X10 ³
Dy-165		9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.0X10 ⁵	8.2X10 ⁶
Dy-166 (a)		9.0X10 ⁻¹	2.4X10 ¹	3.0X10 ⁻¹	8.1	8.6X10 ³	2.3X10 ⁵
Er-169	Erbium (68)	4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	3.1X10 ³	8.3X10 ⁴
Er-171		8.0X10 ⁻¹	2.2X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	9.0X10 ⁴	2.4X10 ⁶
Eu-147	Europium (63)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	1.4X10 ³	3.7X10 ⁴
Eu-148		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.0X10 ²	1.6X10 ⁴
Eu-149		2.0X10 ¹	5.4X10 ²	2.0X10 ¹	5.4X10 ²	3.5X10 ²	9.4X10 ³
Eu-150 (short lived)		2.0	5.4X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	6.1X10 ⁴	1.6X10 ⁶
Eu-150 (long lived)		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	6.1X10 ⁴	1.6X10 ⁶
Eu-152		1.0	2.7X10 ¹	1.0	2.7X10 ¹	6.5	1.8X10 ²
Eu-152m		8.0X10 ⁻¹	2.2X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	8.2X10 ⁴	2.2X10 ⁶
Eu-154		9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	9.8	2.6X10 ²
Eu-155		2.0X10 ¹	5.4X10 ²	3.0	8.1X10 ¹	1.8X10 ¹	4.9X10 ²
Eu-156		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	2.0X10 ³	5.5X10 ⁴
F-18	Fluorine (9)	1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.5X10 ⁶	9.5X10 ⁷
Fe-52 (a)	Iron (26)	3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	2.7X10 ⁵	7.3X10 ⁶
Fe-55		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	8.8X10 ¹	2.4X10 ³
Fe-59		9.0X10 ⁻¹	2.4X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	1.8X10 ³	5.0X10 ⁴
Fe-60 (a)		4.0X10 ¹	1.1X10 ³	2.0X10 ⁻¹	5.4	7.4X10 ⁻⁴	2.0X10 ⁻²
Ga-67	Gallium (31)	7.0	1.9X10 ²	3.0	8.1X10 ¹	2.2X10 ⁴	6.0X10 ⁵

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Ga-68		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	1.5X10 ⁶	4.1X10 ⁷
Ga-72		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.1X10 ⁵	3.1X10 ⁶
Gd-146 (a)	Gadolinium (64)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.9X10 ²	1.9X10 ⁴
Gd-148		2.0X10 ¹	5.4X10 ²	2.0X10 ⁻³	5.4X10 ⁻²	1.2	3.2X10 ¹
Gd-153		1.0X10 ¹	2.7X10 ²	9.0	2.4X10 ²	1.3X10 ²	3.5X10 ³
Gd-159		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.9X10 ⁴	1.1X10 ⁶
Ge-68 (a)	Germanium (32)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	2.6X10 ²	7.1X10 ³
Ge-71		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	5.8X10 ³	1.6X10 ⁵
Ge-77		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.3X10 ⁵	3.6X10 ⁶
Hf-172 (a)	Hafnium (72)	6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.1X10 ¹	1.1X10 ³
Hf-175		3.0	8.1X10 ¹	3.0	8.1X10 ¹	3.9X10 ²	1.1X10 ⁴
Hf-181		2.0	5.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.3X10 ²	1.7X10 ⁴
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	8.1X10 ⁻⁶	2.2X10 ⁻⁴
Hg-194 (a)	Mercury (80)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.3X10 ⁻¹	3.5
Hg-195m (a)		3.0	8.1X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	1.5X10 ⁴	4.0X10 ⁵
Hg-197		2.0X10 ¹	5.4X10 ²	1.0X10 ¹	2.7X10 ²	9.2X10 ³	2.5X10 ⁵
Hg-197m		1.0X10 ¹	2.7X10 ²	4.0X10 ⁻¹	1.1X10 ¹	2.5X10 ⁴	6.7X10 ⁵
Hg-203		5.0	1.4X10 ²	1.0	2.7X10 ¹	5.1X10 ²	1.4X10 ⁴
Ho-166	Holmium (67)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	2.6X10 ⁴	7.0X10 ⁵
Ho-166m		6.0X10 ⁻¹	1.6X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.6X10 ⁻²	1.8
I-123	Iodine (53)	6.0	1.6X10 ²	3.0	8.1X10 ¹	7.1X10 ⁴	1.9X10 ⁶
I-124		1.0	2.7X10 ¹	1.0	2.7X10 ¹	9.3X10 ³	2.5X10 ⁵
I-125		2.0X10 ¹	5.4X10 ²	3.0	8.1X10 ¹	6.4X10 ²	1.7X10 ⁴
I-126		2.0	5.4X10 ¹	1.0	2.7X10 ¹	2.9X10 ³	8.0X10 ⁴
I-129		Unlimited	Unlimited	Unlimited	Unlimited	6.5X10 ⁻⁶	1.8X10 ⁻⁴
I-131		3.0	8.1X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	4.6X10 ³	1.2X10 ⁵
I-132		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	3.8X10 ⁵	1.0X10 ⁷
I-133		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.2X10 ⁴	1.1X10 ⁶
I-134		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	9.9X10 ⁵	2.7X10 ⁷
I-135 (a)		6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.3X10 ⁵	3.5X10 ⁶
In-111	Indium (49)	3.0	8.1X10 ¹	3.0	8.1X10 ¹	1.5X10 ⁴	4.2X10 ⁵
In-113m		4.0	1.1X10 ²	2.0	5.4X10 ¹	6.2X10 ⁵	1.7X10 ⁷
In-114m (a)		1.0X10 ¹	2.7X10 ²	5.0X10 ⁻¹	1.4X10 ¹	8.6X10 ²	2.3X10 ⁴
In-115m		7.0	1.9X10 ²	1.0	2.7X10 ¹	2.2X10 ⁵	6.1X10 ⁶
Ir-189 (a)	Iridium (77)	1.0X10 ¹	2.7X10 ²	1.0X10 ¹	2.7X10 ²	1.9X10 ³	5.2X10 ⁴
Ir-190		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	2.3X10 ³	6.2X10 ⁴
Ir-192		°1.0	°2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.4X10 ²	9.2X10 ³
Ir-194		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	3.1X10 ⁴	8.4X10 ⁵

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K-40	Potassium (19)	9.0X10 ⁻¹	2.4X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	2.4X10 ⁻⁷	6.4X10 ⁻⁶
K-42		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	2.2X10 ⁵	6.0X10 ⁶
K-43		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.2X10 ⁵	3.3X10 ⁶
Kr-79	Krypton (36)	4.0	1.1X10 ²	2.0	5.4X10 ¹	4.2X10 ⁴	1.1X10 ⁶
Kr-81		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	7.8X10 ⁻⁴	2.1X10 ⁻²
Kr-85		1.0X10 ¹	2.7X10 ²	1.0X10 ¹	2.7X10 ²	1.5X10 ¹	3.9X10 ²
Kr-85m		8.0	2.2X10 ²	3.0	8.1X10 ¹	3.0X10 ⁵	8.2X10 ⁶
Kr-87		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	1.0X10 ⁶	2.8X10 ⁷
La-137	Lanthanum (57)	3.0X10 ¹	8.1X10 ²	6.0	1.6X10 ²	1.6X10 ⁻³	4.4X10 ⁻²
La-140		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	2.1X10 ⁴	5.6X10 ⁵
Lu-172	Lutetium (71)	6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.2X10 ³	1.1X10 ⁵
Lu-173		8.0	2.2X10 ²	8.0	2.2X10 ²	5.6X10 ¹	1.5X10 ³
Lu-174		9.0	2.4X10 ²	9.0	2.4X10 ²	2.3X10 ¹	6.2X10 ²
Lu-174m		2.0X10 ¹	5.4X10 ²	1.0X10 ¹	2.7X10 ²	2.0X10 ²	5.3X10 ³
Lu-177		3.0X10 ¹	8.1X10 ²	7.0X10 ⁻¹	1.9X10 ¹	4.1X10 ³	1.1X10 ⁵
Mg-28 (a)	Magnesium (12)	3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	2.0X10 ⁵	5.4X10 ⁶
Mn-52	Manganese (25)	3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.6X10 ⁴	4.4X10 ⁵
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	6.8X10 ⁻⁵	1.8X10 ⁻³
Mn-54		1.0	2.7X10 ¹	1.0	2.7X10 ¹	2.9X10 ²	7.7X10 ³
Mn-56		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	8.0X10 ⁵	2.2X10 ⁷
Mo-93	Molybdenum (42)	4.0X10 ¹	1.1X10 ³	2.0X10 ¹	5.4X10 ²	4.1X10 ⁻²	1.1
Mo-99 (a) (h)		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.8X10 ⁴	4.8X10 ⁵
N-13	Nitrogen (7)	9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	5.4X10 ⁷	1.5X10 ⁹
Na-22	Sodium (11)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	2.3X10 ²	6.3X10 ³
Na-24		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	3.2X10 ⁵	8.7X10 ⁶
Nb-93m	Niobium (41)	4.0X10 ¹	1.1X10 ³	3.0X10 ¹	8.1X10 ²	8.8	2.4X10 ²
Nb-94		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	6.9X10 ⁻³	1.9X10 ⁻¹
Nb-95		1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.5X10 ³	3.9X10 ⁴
Nb-97		9.0X10 ⁻¹	2.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	9.9X10 ⁵	2.7X10 ⁷
Nd-147	Neodymium (60)	6.0	1.6X10 ²	6.0X10 ⁻¹	1.6X10 ¹	3.0X10 ³	8.1X10 ⁴
Nd-149		6.0X10 ⁻¹	1.6X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	4.5X10 ⁵	1.2X10 ⁷
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	3.0X10 ⁻³	8.0X10 ⁻²
Ni-63		4.0X10 ¹	1.1X10 ³	3.0X10 ¹	8.1X10 ²	2.1	5.7X10 ¹
Ni-65		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	7.1X10 ⁵	1.9X10 ⁷
Np-235	Neptunium (93)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	5.2X10 ¹	1.4X10 ³
Np-236 (short-lived)		2.0X10 ¹	5.4X10 ²	2.0	5.4X10 ¹	4.7X10 ⁻⁴	1.3X10 ⁻²
Np-236 (long-lived)		9.0X10 ⁰	2.4X10 ²	2.0X10 ⁻²	5.4X10 ⁻¹	4.7X10 ⁻⁴	1.3X10 ⁻²

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Np-237		2.0X10 ¹	5.4X10 ²	2.0X10 ⁻³	5.4X10 ⁻²	2.6X10 ⁻⁵	7.1X10 ⁻⁴
Np-239		7.0	1.9X10 ²	4.0X10 ⁻¹	1.1X10 ¹	8.6X10 ³	2.3X10 ⁵
Os-185	Osmium (76)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	2.8X10 ²	7.5X10 ³
Os-191		1.0X10 ¹	2.7X10 ²	2.0	5.4X10 ¹	1.6X10 ³	4.4X10 ⁴
Os-191m		4.0X10 ¹	1.1X10 ³	3.0X10 ¹	8.1X10 ²	4.6X10 ⁴	1.3X10 ⁶
Os-193		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.0X10 ⁴	5.3X10 ⁵
Os-194 (a)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.1X10 ¹	3.1X10 ²
P-32	Phosphorus (15)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	1.1X10 ⁴	2.9X10 ⁵
P-33		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	5.8X10 ³	1.6X10 ⁵
Pa-230 (a)	Protactinium (91)	2.0	5.4X10 ¹	7.0X10 ⁻²	1.9	1.2X10 ³	3.3X10 ⁴
Pa-231		4.0	1.1X10 ²	4.0X10 ⁻⁴	1.1X10 ⁻²	1.7X10 ⁻³	4.7X10 ⁻²
Pa-233		5.0	1.4X10 ²	7.0X10 ⁻¹	1.9X10 ¹	7.7X10 ²	2.1X10 ⁴
Pb-201	Lead (82)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	6.2X10 ⁴	1.7X10 ⁶
Pb-202		4.0X10 ¹	1.1X10 ³	2.0X10 ¹	5.4X10 ²	1.2X10 ⁻⁴	3.4X10 ⁻³
Pb-203		4.0	1.1X10 ²	3.0	8.1X10 ¹	1.1X10 ⁴	3.0X10 ⁵
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	4.5X10 ⁻⁶	1.2X10 ⁻⁴
Pb-210 (a)		1.0	2.7X10 ¹	5.0X10 ⁻²	1.4	2.8	7.6X10 ¹
Pb-212 (a)		7.0X10 ⁻¹	1.9X10 ¹	2.0X10 ⁻¹	5.4	5.1X10 ⁴	1.4X10 ⁶
Pd-103 (a)	Palladium (46)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	2.8X10 ³	7.5X10 ⁴
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	1.9X10 ⁻⁵	5.1X10 ⁻⁴
Pd-109		2.0	5.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	7.9X10 ⁴	2.1X10 ⁶
Pm-143	Promethium (61)	3.0	8.1X10 ¹	3.0	8.1X10 ¹	1.3X10 ²	3.4X10 ³
Pm-144		7.0X10 ⁻¹	1.9X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	9.2X10 ¹	2.5X10 ³
Pm-145		3.0X10 ¹	8.1X10 ²	1.0X10 ¹	2.7X10 ²	5.2	1.4X10 ²
Pm-147		4.0X10 ¹	1.1X10 ³	2.0	5.4X10 ¹	3.4X10 ¹	9.3X10 ²
Pm-148m (a)		8.0X10 ⁻¹	2.2X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	7.9X10 ²	2.1X10 ⁴
Pm-149		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.5X10 ⁴	4.0X10 ⁵
Pm-151		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.7X10 ⁴	7.3X10 ⁵
Po-210	Polonium (84)	4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	1.7X10 ²	4.5X10 ³
Pr-142	Praseodymium (59)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.3X10 ⁴	1.2X10 ⁶
Pr-143		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.5X10 ³	6.7X10 ⁴
Pt-188 (a)	Platinum (78)	1.0	2.7X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	2.5X10 ³	6.8X10 ⁴
Pt-191		4.0	1.1X10 ²	3.0	8.1X10 ¹	8.7X10 ³	2.4X10 ⁵
Pt-193		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	1.4	3.7X10 ¹
Pt-193m		4.0X10 ¹	1.1X10 ³	5.0X10 ⁻¹	1.4X10 ¹	5.8X10 ³	1.6X10 ⁵
Pt-195m		1.0X10 ¹	2.7X10 ²	5.0X10 ⁻¹	1.4X10 ¹	6.2X10 ³	1.7X10 ⁵
Pt-197		2.0X10 ¹	5.4X10 ²	6.0X10 ⁻¹	1.6X10 ¹	3.2X10 ⁴	8.7X10 ⁵
Pt-197m		1.0X10 ¹	2.7X10 ²	6.0X10 ⁻¹	1.6X10 ¹	3.7X10 ⁵	1.0X10 ⁷

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
Pu-236	Plutonium (94)	3.0X10 ¹	8.1X10 ²	3.0X10 ⁻³	8.1X10 ⁻²	2.0X10 ¹	5.3X10 ²
Pu-237		2.0X10 ¹	5.4X10 ²	2.0X10 ¹	5.4X10 ²	4.5X10 ²	1.2X10 ⁴
Pu-238		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	6.3X10 ⁻¹	1.7X10 ¹
Pu-239		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	2.3X10 ⁻³	6.2X10 ⁻²
Pu-240		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	8.4X10 ⁻³	2.3X10 ⁻¹
Pu-241 (a)		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻²	1.6	3.8	1.0X10 ²
Pu-242		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	1.5X10 ⁻⁴	3.9X10 ⁻³
Pu-244 (a)		4.0X10 ⁻¹	1.1X10 ¹	1.0X10 ⁻³	2.7X10 ⁻²	6.7X10 ⁻⁷	1.8X10 ⁻⁵
Ra-223 (a)	Radium (88)	4.0X10 ⁻¹	1.1X10 ¹	7.0X10 ⁻³	1.9X10 ⁻¹	1.9X10 ³	5.1X10 ⁴
Ra-224 (a)		4.0X10 ⁻¹	1.1X10 ¹	2.0X10 ⁻²	5.4X10 ⁻¹	5.9X10 ³	1.6X10 ⁵
Ra-225 (a)		2.0X10 ⁻¹	5.4	4.0X10 ⁻³	1.1X10 ⁻¹	1.5X10 ³	3.9X10 ⁴
Ra-226 (a)		2.0X10 ⁻¹	5.4	3.0X10 ⁻³	8.1X10 ⁻²	3.7X10 ⁻²	1.0
Ra-228 (a)		6.0X10 ⁻¹	1.6X10 ¹	2.0X10 ⁻²	5.4X10 ⁻¹	1.0X10 ¹	2.7X10 ²
Rb-81	Rubidium (37)	2.0	5.4X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	3.1X10 ⁵	8.4X10 ⁶
Rb-83 (a)		2.0	5.4X10 ¹	2.0	5.4X10 ¹	6.8X10 ²	1.8X10 ⁴
Rb-84		1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.8X10 ³	4.7X10 ⁴
Rb-86		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	3.0X10 ³	8.1X10 ⁴
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	3.2X10 ⁻⁹	8.6X10 ⁻⁸
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	6.7X10 ⁶	1.8X10 ⁸
Re-184	Rhenium (75)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	6.9X10 ²	1.9X10 ⁴
Re-184m		3.0	8.1X10 ¹	1.0	2.7X10 ¹	1.6X10 ²	4.3X10 ³
Re-186		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	6.9X10 ³	1.9X10 ⁵
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	1.4X10 ⁻⁹	3.8X10 ⁻⁸
Re-188		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	3.6X10 ⁴	9.8X10 ⁵
Re-189 (a)		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.5X10 ⁴	6.8X10 ⁵
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	2.4X10 ⁻⁸
Rh-99	Rhodium (45)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	3.0X10 ³	8.2X10 ⁴
Rh-101		4.0	1.1X10 ²	3.0	8.1X10 ¹	4.1X10 ¹	1.1X10 ³
Rh-102		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	4.5X10 ¹	1.2X10 ³
Rh-102m		2.0	5.4X10 ¹	2.0	5.4X10 ¹	2.3X10 ²	6.2X10 ³
Rh-103m		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	1.2X10 ⁶	3.3X10 ⁷
Rh-105		1.0X10 ¹	2.7X10 ²	8.0X10 ⁻¹	2.2X10 ¹	3.1X10 ⁴	8.4X10 ⁵
Rn-222 (a)	Radon (86)	3.0X10 ⁻¹	8.1	4.0X10 ⁻³	1.1X10 ⁻¹	5.7X10 ³	1.5X10 ⁵
Ru-97	Ruthenium (44)	5.0	1.4X10 ²	5.0	1.4X10 ²	1.7X10 ⁴	4.6X10 ⁵
Ru-103 (a)		2.0	5.4X10 ¹	2.0	5.4X10 ¹	1.2X10 ³	3.2X10 ⁴
Ru-105		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.5X10 ⁵	6.7X10 ⁶
Ru-106 (a)		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	1.2X10 ²	3.3X10 ³
S-35	Sulphur (16)	4.0X10 ¹	1.1X10 ³	3.0	8.1X10 ¹	1.6X10 ³	4.3X10 ⁴

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
Sb-122	Antimony (51)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.5X10 ⁴	4.0X10 ⁵
Sb-124		6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	6.5X10 ²	1.7X10 ⁴
Sb-125		2.0	5.4X10 ¹	1.0	2.7X10 ¹	3.9X10 ¹	1.0X10 ³
Sb-126		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	3.1X10 ³	8.4X10 ⁴
Sc-44	Scandium (21)	5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	6.7X10 ⁵	1.8X10 ⁷
Sc-46		5.0X10 ⁻¹	1.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	1.3X10 ³	3.4X10 ⁴
Sc-47		1.0X10 ¹	2.7X10 ²	7.0X10 ⁻¹	1.9X10 ¹	3.1X10 ⁴	8.3X10 ⁵
Sc-48		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	5.5X10 ⁴	1.5X10 ⁶
Se-75	Selenium (34)	3.0	8.1X10 ¹	3.0	8.1X10 ¹	5.4X10 ²	1.5X10 ⁴
Se-79		4.0X10 ¹	1.1X10 ³	2.0	5.4X10 ¹	2.6X10 ⁻³	7.0X10 ⁻²
Si-31	Silicon (14)	6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.4X10 ⁶	3.9X10 ⁷
Si-32		4.0X10 ¹	1.1X10 ³	5.0X10 ⁻¹	1.4X10 ¹	3.9	1.1X10 ²
Sm-145	Samarium (62)	1.0X10 ¹	2.7X10 ²	1.0X10 ¹	2.7X10 ²	9.8X10 ¹	2.6X10 ³
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	8.5X10 ⁻¹⁰	2.3X10 ⁻⁸
Sm-151		4.0X10 ¹	1.1X10 ³	1.0X10 ¹	2.7X10 ²	9.7X10 ⁻¹	2.6X10 ¹
Sm-153		9.0	2.4X10 ²	6.0X10 ⁻¹	1.6X10 ¹	1.6X10 ⁴	4.4X10 ⁵
Sn-113 (a)	Tin (50)	4.0	1.1X10 ²	2.0	5.4X10 ¹	3.7X10 ²	1.0X10 ⁴
Sn-117m		7.0	1.9X10 ²	4.0X10 ⁻¹	1.1X10 ¹	3.0X10 ³	8.2X10 ⁴
Sn-119m		4.0X10 ¹	1.1X10 ³	3.0X10 ¹	8.1X10 ²	1.4X10 ²	3.7X10 ³
Sn-121m (a)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻¹	2.4X10 ¹	2.0	5.4X10 ¹
Sn-123		8.0X10 ⁻¹	2.2X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	3.0X10 ²	8.2X10 ³
Sn-125		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ³	1.1X10 ⁵
Sn-126 (a)		6.0X10 ⁻¹	1.6X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.0X10 ⁻³	2.8X10 ⁻²
Sr-82 (a)	Strontium (38)	2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	2.3X10 ³	6.2X10 ⁴
Sr-85		2.0	5.4X10 ¹	2.0	5.4X10 ¹	8.8X10 ²	2.4X10 ⁴
Sr-85m		5.0	1.4X10 ²	5.0	1.4X10 ²	1.2X10 ⁶	3.3X10 ⁷
Sr-87m		3.0	8.1X10 ¹	3.0	8.1X10 ¹	4.8X10 ⁵	1.3X10 ⁷
Sr-89		6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.1X10 ³	2.9X10 ⁴
Sr-90 (a)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	5.1	1.4X10 ²
Sr-91 (a)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.3X10 ⁵	3.6X10 ⁶
Sr-92 (a)		1.0	2.7X10 ¹	3.0X10 ⁻¹	8.1	4.7X10 ⁵	1.3X10 ⁷
T (H-3)	Tritium (1)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	3.6X10 ²	9.7X10 ³
Ta-178 (long-lived)	Tantalum (73)	1.0	2.7X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	4.2X10 ⁶	1.1X10 ⁸
Ta-179		3.0X10 ¹	8.1X10 ²	3.0X10 ¹	8.1X10 ²	4.1X10 ¹	1.1X10 ³
Ta-182		9.0X10 ⁻¹	2.4X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	2.3X10 ²	6.2X10 ³
Tb-157	Terbium (65)	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	5.6X10 ⁻¹	1.5X10 ¹
Tb-158		1.0	2.7X10 ¹	1.0	2.7X10 ¹	5.6X10 ⁻¹	1.5X10 ¹

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
Tb-160		1.0	2.7X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	4.2X10 ²	1.1X10 ⁴
Tc-95m (a)	Technetium (43)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	8.3X10 ²	2.2X10 ⁴
Tc-96		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.2X10 ⁴	3.2X10 ⁵
Tc-96m (a)		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.4X10 ⁶	3.8X10 ⁷
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	5.2X10 ⁻⁵	1.4X10 ⁻³
Tc-97m		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	5.6X10 ²	1.5X10 ⁴
Tc-98		8.0X10 ⁻¹	2.2X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	3.2X10 ⁻⁵	8.7X10 ⁻⁴
Tc-99		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻¹	2.4X10 ¹	6.3X10 ⁻⁴	1.7X10 ⁻²
Tc-99m		1.0X10 ¹	2.7X10 ²	4.0	1.1X10 ²	1.9X10 ⁵	5.3X10 ⁶
Te-121	Tellurium (52)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	2.4X10 ³	6.4X10 ⁴
Te-121m		5.0	1.4X10 ²	3.0	8.1X10 ¹	2.6X10 ²	7.0X10 ³
Te-123m		8.0	2.2X10 ²	1.0	2.7X10 ¹	3.3X10 ²	8.9X10 ³
Te-125m		2.0X10 ¹	5.4X10 ²	9.0X10 ⁻¹	2.4X10 ¹	6.7X10 ²	1.8X10 ⁴
Te-127		2.0X10 ¹	5.4X10 ²	7.0X10 ⁻¹	1.9X10 ¹	9.8X10 ⁴	2.6X10 ⁶
Te-127m (a)		2.0X10 ¹	5.4X10 ²	5.0X10 ⁻¹	1.4X10 ¹	3.5X10 ²	9.4X10 ³
Te-129		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	7.7X10 ⁵	2.1X10 ⁷
Te-129m (a)		8.0X10 ⁻¹	2.2X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.1X10 ³	3.0X10 ⁴
Te-131m (a)		7.0X10 ⁻¹	1.9X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	3.0X10 ⁴	8.0X10 ⁵
Te-132 (a)		5.0X10 ⁻¹	1.4X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.1X10 ⁴	3.0X10 ⁵
Th-227	Thorium (90)	1.0X10 ¹	2.7X10 ²	5.0X10 ⁻³	1.4X10 ⁻¹	1.1X10 ³	3.1X10 ⁴
Th-228 (a)		5.0X10 ⁻¹	1.4X10 ¹	1.0X10 ⁻³	2.7X10 ⁻²	3.0X10 ¹	8.2X10 ²
Th-229		5.0	1.4X10 ²	5.0X10 ⁻⁴	1.4X10 ⁻²	7.9X10 ⁻³	2.1X10 ⁻¹
Th-230		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	7.6X10 ⁻⁴	2.1X10 ⁻²
Th-231		4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	2.0X10 ⁴	5.3X10 ⁵
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	4.0X10 ⁻⁹	1.1X10 ⁻⁷
Th-234 (a)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	8.6X10 ²	2.3X10 ⁴
Th (natural)		Unlimited	Unlimited	Unlimited	Unlimited	8.1X10 ⁻⁹	2.2X10 ⁻⁷
Ti-44 (a)	Titanium (22)	5.0X10 ⁻¹	1.4X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	6.4	1.7X10 ²
Tl-200	Thallium (81)	9.0X10 ⁻¹	2.4X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	2.2X10 ⁴	6.0X10 ⁵
Tl-201		1.0X10 ¹	2.7X10 ²	4.0	1.1X10 ²	7.9X10 ³	2.1X10 ⁵
Tl-202		2.0	5.4X10 ¹	2.0	5.4X10 ¹	2.0X10 ³	5.3X10 ⁴
Tl-204		1.0X10 ¹	2.7X10 ²	7.0X10 ⁻¹	1.9X10 ¹	1.7X10 ¹	4.6X10 ²
Tm-167	Thulium (69)	7.0	1.9X10 ²	8.0X10 ⁻¹	2.2X10 ¹	3.1X10 ³	8.5X10 ⁴
Tm-170		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.2X10 ²	6.0X10 ³
Tm-171		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³
U-230 (fast lung absorption) (a)(d)	Uranium (92)	4.0X10 ¹	1.1X10 ³	1.0X10 ⁻¹	2.7	1.0X10 ³	2.7X10 ⁴

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
U-230 (medium lung absorption) (a)(e)		4.0X10 ¹	1.1X10 ³	4.0X10 ⁻³	1.1X10 ⁻¹	1.0X10 ³	2.7X10 ⁴
U-230 (slow lung absorption) (a)(f)		3.0X10 ¹	8.1X10 ²	3.0X10 ⁻³	8.1X10 ⁻²	1.0X10 ³	2.7X10 ⁴
U-232 (fast lung absorption) (d)		4.0X10 ¹	1.1X10 ³	1.0X10 ⁻²	2.7X10 ⁻¹	8.3X10 ⁻¹	2.2X10 ¹
U-232 (medium lung absorption) (e)		4.0X10 ¹	1.1X10 ³	7.0X10 ⁻³	1.9X10 ⁻¹	8.3X10 ⁻¹	2.2X10 ¹
U-232 (slow lung absorption) (f)		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	8.3X10 ⁻¹	2.2X10 ¹
U-233 (fast lung absorption) (d)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻²	2.4	3.6X10 ⁻⁴	9.7X10 ⁻³
U-233 (medium lung absorption) (e)		4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	3.6X10 ⁻⁴	9.7X10 ⁻³
U-233 (slow lung absorption) (f)		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻³	1.6X10 ⁻¹	3.6X10 ⁻⁴	9.7X10 ⁻³
U-234 (fast lung absorption) (d)		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻²	2.4	2.3X10 ⁻⁴	6.2X10 ⁻³
U-234 (medium lung absorption) (e)		4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	2.3X10 ⁻⁴	6.2X10 ⁻³
U-234 (slow lung absorption) (f)		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻³	1.6X10 ⁻¹	2.3X10 ⁻⁴	6.2X10 ⁻³
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	8.0X10 ⁻⁸	2.2X10 ⁻⁶
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	2.4X10 ⁻⁶	6.5X10 ⁻⁵
U-236 (medium lung absorption) (e)		4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	2.4X10 ⁻⁶	6.5X10 ⁻⁵
U-236 (slow lung absorption) (f)		4.0X10 ¹	1.1X10 ³	6.0X10 ⁻³	1.6X10 ⁻¹	2.4X10 ⁻⁶	6.5X10 ⁻⁵
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	1.2X10 ⁻⁸	3.4X10 ⁻⁷

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
U (natural)		Unlimited	Unlimited	Unlimited	Unlimited	2.6X10 ⁻⁸	7.1X10 ⁻⁷
U (enriched to 20% or less) (g)		Unlimited	Unlimited	Unlimited	Unlimited	See Table 6	See Table 6
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table	See Table
V-48	Vanadium (23)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	6.3X10 ³	1.7X10 ⁵
V-49		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	3.0X10 ²	8.1X10 ³
W-178 (a)	Tungsten (74)	9.0	2.4X10 ²	5.0	1.4X10 ²	1.3X10 ³	3.4X10 ⁴
W-181		3.0X10 ¹	8.1X10 ²	3.0X10 ¹	8.1X10 ²	2.2X10 ²	6.0X10 ³
W-185		4.0X10 ¹	1.1X10 ³	8.0X10 ⁻¹	2.2X10 ¹	3.5X10 ²	9.4X10 ³
W-187		2.0	5.4X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	2.6X10 ⁴	7.0X10 ⁵
W-188 (a)		4.0X10 ⁻¹	1.1X10 ¹	3.0X10 ⁻¹	8.1	3.7X10 ²	1.0X10 ⁴
Xe-122 (a)	Xenon (54)	4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	4.8X10 ⁴	1.3X10 ⁶
Xe-123		2.0	5.4X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	4.4X10 ⁵	1.2X10 ⁷
Xe-127		4.0	1.1X10 ²	2.0	5.4X10 ¹	1.0X10 ³	2.8X10 ⁴
Xe-131m		4.0X10 ¹	1.1X10 ³	4.0X10 ¹	1.1X10 ³	3.1X10 ³	8.4X10 ⁴
Xe-133		2.0X10 ¹	5.4X10 ²	1.0X10 ¹	2.7X10 ²	6.9X10 ³	1.9X10 ⁵
Xe-135		3.0	8.1X10 ¹	2.0	5.4X10 ¹	9.5X10 ⁴	2.6X10 ⁶
Y-87 (a)	Yttrium (39)	1.0	2.7X10 ¹	1.0	2.7X10 ¹	1.7X10 ⁴	4.5X10 ⁵
Y-88		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	5.2X10 ²	1.4X10 ⁴
Y-90		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	2.0X10 ⁴	5.4X10 ⁵
Y-91		6.0X10 ⁻¹	1.6X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	9.1X10 ²	2.5X10 ⁴
Y-91m		2.0	5.4X10 ¹	2.0	5.4X10 ¹	1.5X10 ⁶	4.2X10 ⁷
Y-92		2.0X10 ⁻¹	5.4	2.0X10 ⁻¹	5.4	3.6X10 ⁵	9.6X10 ⁶
Y-93		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	1.2X10 ⁵	3.3X10 ⁶
Yb-169	Ytterbium (70)	4.0	1.1X10 ²	1.0	2.7X10 ¹	8.9X10 ²	2.4X10 ⁴
Yb-175		3.0X10 ¹	8.1X10 ²	9.0X10 ⁻¹	2.4X10 ¹	6.6X10 ³	1.8X10 ⁵
Zn-65	Zinc (30)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	3.0X10 ²	8.2X10 ³
Zn-69		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.8X10 ⁶	4.9X10 ⁷
Zn-69m (a)		3.0	8.1X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	1.2X10 ⁵	3.3X10 ⁶
Zr-88	Zirconium (40)	3.0	8.1X10 ¹	3.0	8.1X10 ¹	6.6X10 ²	1.8X10 ⁴
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	9.3X10 ⁻⁵	2.5X10 ⁻³
Zr-95 (a)		2.0	5.4X10 ¹	8.0X10 ⁻¹	2.2X10 ¹	7.9X10 ²	2.1X10 ⁴
Zr-97 (a)		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	7.1X10 ⁴	1.9X10 ⁶

^a A₁ and/or A₂ values include contributions from daughter nuclides with half-lives less than 10 days as listed in Table 4-A.

^b The values of A₁ and A₂ in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq).

^c The activity of Ir-192 in special form may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.

^d These values apply only to compounds of uranium that take the chemical form of UF₆, UO₂F₂ and UO₂(NO₃)₂ in both normal and accident conditions of transport.

^c These values apply only to compounds of uranium that take the chemical form of UO_3 , UF_4 , UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

^f These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

^g These values apply to unirradiated uranium only.

^h $A_2 = 0.74 \text{ TBq (20 Ci)}$ for Mo-99 for domestic use.

TABLE 4-A – DAUGHTER NUCLIDES WITH HALF-LIVES LESS THAN 10 DAYS

Parent Nuclide	Daughter Nuclide(s)
Mg-28	Al-28
Ca-47	Sc-47
Ti-44	Sc-44
Fe-52	Mn-52m
Fe-60	Co-60m
Zn-69m	Zn-69
Ge-68	Ga-68
Rb-83	Kr-83m
Sr-82	Rb-82
Sr-90	Y-90
Sr-91	Y-91m
Sr-92	Y-92
Y-87	Sr-87m
Zr-95	Nb-95m
Zr-97	Nb-97m, Nb-97
Mo-99	Tc-99m
Tc-95m	Tc-95
Tc-96m	Tc-96
Ru-103	Rh-103m
Ru-106	Rh-106
Pd-103	Rh-103m
Ag-108m	Ag-108
Ag-110m	Ag-110
Cd-115	In-115m
In-114m	In-114
Sn-113	In-113m
Sn-121m	Sn-121
Sn-126	Sb-126m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
I-135	Xe-135m
Xe-122	I-122
Cs-137	Ba-137m
Ba-131	Cs-131
Ba-140	La-140
Ce-144	Pr-144m, Pr-144

Parent Nuclide	Daughter Nuclide(s)						
Pm-148m	Pm-148						
Gd-146	Eu-146						
Dy-166	Ho-166						
Hf-172	Lu-172						
W-178	Ta-178						
W-188	Re-188						
Re-189	Os-189m						
Os-194	Ir-194						
Ir-189	Os-189m						
Pt-188	Ir-188						
Hg-194	Au-194						
Hg-195m	Hg-195						
Pb-210	Bi-210						
Pb-212	Bi-212,	Tl-208,	Po-212				
Bi-210m	Tl-206						
Bi-212	Tl-208,	Po-212					
At-211	Po-211						
Rn-222	Po-218,	Pb-214,	At-218,	Bi-214,	Po-214		
Ra-223	Rn-219,	Po-215,	Pb-211,	Bi-211,	Po-211,	Tl-207	
Ra-224	Rn-220,	Po-216,	Pb-212,	Bi-212,	Tl-208,	Po-212	
Ra-225	Ac-225,	Fr-221,	At-217,	Bi-213,	Tl-209,	Po-213,	Pb-209
Ra-226	Rn-222,	Po-218,	Pb-214,	At-218,	Bi-214,	Po-214	
Ra-228	Ac-228						
Ac-225	Fr-221,	At-217,	Bi-213,	Tl-209,	Po-213,	Pb-209	
Ac-227	Fr-223						
Th-228	Ra-224,	Rn-220,	Po-216,	Pb-212,	Bi-212,	Tl-208,	Po-212
Th-234	Pa-234m,	Pa-234					
Pa-230	Ac-226,	Th-226,	Fr-222,	Ra-222,	Rn-218,	Po-214	
U-230	Th-226,	Ra-222,	Rn-218,	Po-214			
U-235	Th-231						
Pu-241	U-237						
Pu-244	U-240,	Np-240m					
Am-242m	Am-242,	Np-238					
Am-243	Np-239						
Cm-247	Pu-243						
Bk-249	Am-245						

TABLE 5 — GENERAL VALUES FOR A₁ AND A₂

Contents	A ₁		A ₂		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	(TBq)	(Ci)	(TBq)	(Ci)				
Only beta or gamma emitting radionuclides are known to be present	1 x 10 ⁻¹	2.7 x 10 ⁰	2 x 10 ⁻²	5.4 x 10 ⁻¹	1 x 10 ¹	2.7 x 10 ⁻¹⁰	1 x 10 ⁴	2.7 x 10 ⁻⁷
Alpha emitting nuclides, but no neutron emitters, are known to be present ^a	2 x 10 ⁻¹	5.4 x 10 ⁰	9 x 10 ⁻⁵	2.4 x 10 ⁻³	1 x 10 ⁻¹	2.7 x 10 ⁻¹²	1 x 10 ³	2.7 x 10 ⁻⁸
Neutron emitting nuclides are known to be present or no relevant data are available	1 x 10 ⁻³	2.7 x 10 ⁻²	9 x 10 ⁻⁵	2.4 x 10 ⁻³	1 x 10 ⁻¹	2.7 x 10 ⁻¹²	1 x 10 ³	2.7 x 10 ⁻⁸

^a If beta or gamma emitting nuclides are known to be present, the A₁ value of 0.1 TBq (2.7 Ci) should be used.

TABLE 6 — ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment ¹ wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.2×10^{-6}	5.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}

¹ The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.

Table 7 — EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225	Actinium (89)	1.0×10^1	2.7×10^{-10}	1.0×10^4	2.7×10^{-7}
Ac-227		1.0×10^{-1}	2.7×10^{-12}	1.0×10^3	2.7×10^{-8}
Ac-228		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ag-105	Silver (47)	1.0×10^2	2.7×10^{-9}	1.0×10^6	2.7×10^{-5}
Ag-108m (b)		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ag-110m		1.0×10^1	2.7×10^{-10}	1.0×10^6	2.7×10^{-5}
Ag-111		1.0×10^3	2.7×10^{-8}	1.0×10^6	2.7×10^{-5}
Al-26	Aluminum (13)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}
Am-241	Americium (95)	1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Am-242m (b)		1.0	2.7×10^{-11}	1.0×10^4	2.7×10^{-7}
Am-243 (b)		1.0	2.7×10^{-11}	1.0×10^3	2.7×10^{-8}
Ar-37	Argon (18)	1.0×10^6	2.7×10^{-5}	1.0×10^8	2.7×10^{-3}
Ar-39		1.0×10^7	2.7×10^{-4}	1.0×10^4	2.7×10^{-7}
Ar-41		1.0×10^2	2.7×10^{-9}	1.0×10^9	2.7×10^{-2}
As-72	Arsenic (33)	1.0×10^1	2.7×10^{-10}	1.0×10^5	2.7×10^{-6}

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
As-73		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
As-74		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
As-76		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
As-77		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
At-211	Astatine (85)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Au-193	Gold (79)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Au-194		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Au-195		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Au-198		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Au-199		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ba-131	Barium (56)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ba-133		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ba-133m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ba-140 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Be-7	Beryllium (4)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Be-10		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁶	2.7X10 ⁻⁵
Bi-205	Bismuth (83)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Bi-206		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Bi-207		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Bi-210		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Bi-210m		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Bi-212 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Bk-247	Berkelium (97)	1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Bk-249		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Br-76	Bromine (35)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Br-77		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Br-82		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
C-11	Carbon (6)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
C-14		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Ca-41	Calcium (20)	1.0X10 ⁵	2.7X10 ⁻⁶	1.0X10 ⁷	2.7X10 ⁻⁴
Ca-45		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Ca-47		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Cd-109	Cadmium (48)	1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁶	2.7X10 ⁻⁵
Cd-113m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Cd-115		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Cd-115m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ce-139	Cerium (58)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ce-141		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Ce-143		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ce-144 (b)		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Cf-248	Californium (98)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Cf-249		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Cf-250		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Cf-251		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Cf-252		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Cf-253		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Cf-254		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Cl-36	Chlorine (17)	1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁶	2.7X10 ⁻⁵
Cl-38		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Cm-240	Curium (96)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Cm-241		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Cm-242		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Cm-243		1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Cm-244		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Cm-245		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Cm-246		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Cm-247		1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Cm-248		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Co-55	Cobalt (27)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Co-56		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Co-57		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Co-58		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Co-58m		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Co-60		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Cr-51	Chromium (24)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Cs-129	Cesium (55)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Cs-131		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Cs-132		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Cs-134		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Cs-134m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁵	2.7X10 ⁻⁶
Cs-135		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Cs-136		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Cs-137 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cu-64	Copper (29)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Cu-67		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Dy-159	Dysprosium (66)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Dy-165		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Dy-166		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Er-169	Erbium (68)	1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Er-171		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Eu-147	Europium (63)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Eu-148		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Eu-149		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Eu-150 (short lived)		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Eu-150 (long lived)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Eu-152		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Eu-152m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Eu-154		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Eu-155		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Eu-156		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
F-18	Fluorine (9)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Fe-52	Iron (26)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Fe-55		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁶	2.7X10 ⁻⁵
Fe-59		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Fe-60		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Ga-67	Gallium (31)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ga-68		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Ga-72		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Gd-146	Gadolinium (64)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Gd-148		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Gd-153		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Gd-159		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Ge-68	Germanium (32)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Ge-71		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁸	2.7X10 ⁻³
Ge-77		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Hf-172	Hafnium (72)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Hf-175		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Hf-181		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Hf-182		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Hg-194	Mercury (80)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Hg-195m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Hg-197		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Hg-197m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Hg-203		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Ho-166	Holmium (67)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁵	2.7X10 ⁻⁶
Ho-166m		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
I-123	Iodine (53)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
I-124		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
I-125		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
I-126		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
I-129		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
I-131		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
I-132		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
I-133		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
I-134		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
I-135		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
In-111	Indium (49)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
In-113m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
In-114m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
In-115m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ir-189	Iridium (77)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Ir-190		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Ir-192		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Ir-194		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
K-40	Potassium (19)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
K-42		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
K-43		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Kr-79	Krypton (36)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁵	2.7X10 ⁻⁶
Kr-81		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Kr-85		1.0X10 ⁵	2.7X10 ⁻⁶	1.0X10 ⁴	2.7X10 ⁻⁷
Kr-85m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ¹⁰	2.7X10 ⁻¹
Kr-87		1.0X10 ¹	2.7X10 ⁻⁹	1.0X10 ⁹	2.7X10 ⁻²
La-137	Lanthanum (57)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
La-140		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Lu-172	Lutetium (71)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Lu-173		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Lu-174		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Lu-174m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Lu-177		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Mg-28	Magnesium (12)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Mn-52	Manganese (25)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Mn-53		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁹	2.7X10 ⁻²
Mn-54		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Mn-56		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Mo-93	Molybdenum (42)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁸	2.7X10 ⁻³
Mo-99		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
N-13	Nitrogen (7)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁹	2.7X10 ⁻²
Na-22	Sodium (11)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Na-24		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Nb-93m	Niobium (41)	1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Nb-94		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Nb-95		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Nb-97		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Nd-147	Neodymium (60)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Nd-149		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ni-59	Nickel (28)	1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁸	2.7X10 ⁻³
Ni-63		1.0X10 ⁵	2.7X10 ⁻⁶	1.0X10 ⁸	2.7X10 ⁻³
Ni-65		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Np-235	Neptunium (93)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Np-236 (short-lived)		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Np-236 (long-lived)		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Np-237 (b)		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Np-239		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Os-185	Osmium (76)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Os-191		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Os-191m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Os-193		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Os-194		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
P-32	Phosphorus (15)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁵	2.7X10 ⁻⁶
P-33		1.0X10 ⁵	2.7X10 ⁻⁶	1.0X10 ⁸	2.7X10 ⁻³
Pa-230	Protactinium (91)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Pa-231		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Pa-233		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Pb-201	Lead (82)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pb-202		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Pb-203		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Pb-205		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Pb-210 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Pb-212 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Pd-103	Palladium (46)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁸	2.7X10 ⁻³
Pd-107		1.0X10 ⁵	2.7X10 ⁻⁶	1.0X10 ⁸	2.7X10 ⁻³
Pd-109		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Pm-143	Promethium (61)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Pm-144		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Pm-145		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Pm-147		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Pm-148m		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Pm-149		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Pm-151		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Po-210	Polonium (84)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Pr-142	Praseodymium (59)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Pr-143		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁶	2.7X10 ⁻⁵
Pt-188	Platinum (78)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Pt-191		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Pt-193		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Pt-193m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Pt-195m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Pt-197		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Pt-197m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Pu-236	Plutonium (94)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Pu-237		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Pu-238		1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Pu-239		1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Pu-240		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Pu-241		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Pu-242		1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Pu-244		1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Ra-223 (b)	Radium (88)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Ra-224 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Ra-225		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Ra-226 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ra-228 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Rb-81	Rubidium (37)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Rb-83		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Rb-84		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Rb-86		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Rb-87		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Rb(nat)		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Re-184	Rhenium (75)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Re-184m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Re-186		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Re-187		1.0X10 ⁶	2.7X10 ⁻⁵	1.0X10 ⁹	2.7X10 ⁻²
Re-188		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Re-189		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Re(nat)		1.0X10 ⁶	2.7X10 ⁻⁵	1.0X10 ⁹	2.7X10 ⁻²
Rh-99	Rhodium (45)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Rh-101		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Rh-102		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Rh-102m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Rh-103m		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁸	2.7X10 ⁻³
Rh-105		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Rn-222 (b)	Radon (86)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁸	2.7X10 ⁻³
Ru-97	Ruthenium (44)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Ru-103		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Ru-105		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Ru-106 (b)		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
S-35	Sulphur (16)	1.0X10 ⁵	2.7X10 ⁻⁶	1.0X10 ⁸	2.7X10 ⁻³
Sb-122	Antimony (51)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁴	2.7X10 ⁻⁷
Sb-124		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Sb-125		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Sb-126		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Sc-44	Scandium (21)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Sc-46		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Sc-47		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Sc-48		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Se-75	Selenium (34)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Se-79		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Si-31	Silicon (14)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Si-32		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Sm-145	Samarium (62)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Sm-147		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Sm-151		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁸	2.7X10 ⁻³
Sm-153		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Sn-113	Tin (50)	1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Sn-117m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Sn-119m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Sn-121m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Sn-123		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Sn-125		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Sn-126		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Sr-82	Strontium (38)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Sr-85		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Sr-85m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Sr-87m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Sr-89		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Sr-90 (b)		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁴	2.7X10 ⁻⁷
Sr-91		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Sr-92		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
T (H-3)	Tritium (1)	1.0X10 ⁶	2.7X10 ⁻⁵	1.0X10 ⁹	2.7X10 ⁻²
Ta-178 (long-lived)	Tantalum (73)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Ta-179		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Ta-182		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Tb-157	Terbium (65)	1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Tb-158		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Tb-160		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Tc-95m	Technetium (43)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Tc-96		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Tc-96m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Tc-97		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁸	2.7X10 ⁻³
Tc-97m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Tc-98		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Tc-99		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
Tc-99m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Te-121	Tellurium (52)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Te-121m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Te-123m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Te-125m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Te-127		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Te-127m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Te-129		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Te-129m		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Te-131m		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Te-132		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Th-227	Thorium (90)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Th-228 (b)		1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Th-229 (b)		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Th-230		1.0	2.7X10 ⁻¹¹	1.0X10 ⁴	2.7X10 ⁻⁷
Th-231		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Th-232		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
Th-234 (b)		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁵	2.7X10 ⁻⁶
Th (nat) (b)		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
Ti-44	Titanium (22)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
Tl-200	Thallium (81)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Tl-201		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Tl-202		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Tl-204		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁴	2.7X10 ⁻⁷
Tm-167	Thulium (69)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Tm-170		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Tm-171		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁸	2.7X10 ⁻³
U-230 (fast lung absorption) (b),(d)	Uranium (92)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
U-230 (medium lung absorption) (e)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U-230 (slow lung absorption) (f)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U-232 (fast lung absorption) (b),(d)		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
U-232 (medium lung absorption) (e)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U-232 (slow lung absorption) (f)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U-233 (fast lung absorption) (d)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U-233 (medium lung absorption) (e)		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
U-233 (slow lung absorption) (f)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
U-234 (fast lung absorption) (d)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U-234 (medium lung absorption) (e)		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
U-234 (slow lung absorption) (f)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
U-235 (all lung absorption types) (b),(d),(e),(f)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U-236 (fast lung absorption) (d)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U-236 (medium lung absorption) (e)		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
U-236 (slow lung absorption) (f)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U-238 (all lung absorption types) (b),(d),(e),(f)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁴	2.7X10 ⁻⁷
U (natural) (b)		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
U (enriched to 20% or less) (g)		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
U (dep)		1.0	2.7X10 ⁻¹¹	1.0X10 ³	2.7X10 ⁻⁸
V-48	Vanadium (23)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶
V-49		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
W-178	Tungsten (74)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
W-181		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
W-185		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁷	2.7X10 ⁻⁴
W-187		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
W-188		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Xe-122	Xenon (54)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁹	2.7X10 ⁻²
Xe-123		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁹	2.7X10 ⁻²
Xe-127		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁵	2.7X10 ⁻⁶
Xe-131m		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁴	2.7X10 ⁻⁷
Xe-133		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁴	2.7X10 ⁻⁷
Xe-135		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ¹⁰	2.7X10 ⁻¹
Y-87	Yttrium (39)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Y-88		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Y-90		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁵	2.7X10 ⁻⁶
Y-91		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁶	2.7X10 ⁻⁵
Y-91m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Y-92		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Y-93		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁵	2.7X10 ⁻⁶
Yb-169	Ytterbium (70)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁷	2.7X10 ⁻⁴
Yb-175		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Zn-65	Zinc (30)	1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Zn-69		1.0X10 ⁴	2.7X10 ⁻⁷	1.0X10 ⁶	2.7X10 ⁻⁵
Zn-69m		1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Zr-88	Zirconium (40)	1.0X10 ²	2.7X10 ⁻⁹	1.0X10 ⁶	2.7X10 ⁻⁵
Zr-93 (b)		1.0X10 ³	2.7X10 ⁻⁸	1.0X10 ⁷	2.7X10 ⁻⁴
Zr-95		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁶	2.7X10 ⁻⁵
Zr-97 (b)		1.0X10 ¹	2.7X10 ⁻¹⁰	1.0X10 ⁵	2.7X10 ⁻⁶

^a [Reserved]

^b Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214

U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

^c [Reserved]

^d These values apply only to compounds of uranium that take the chemical form of UF₆, UO₂F₂ and UO₂(NO₃)₂ in both normal and accident conditions of transport.

^e These values apply only to compounds of uranium that take the chemical form of UO₃, UF₄, UCl₄ and hexavalent compounds in both normal and accident conditions of transport.

^f These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

^g These values apply to unirradiated uranium only.

Rule 391-3-17-.09, “Licensing and Radiation Safety Requirements for Irradiators,” is amended to read as follows:

391-3-17-.09 Licensing and Radiation Safety Requirements for Irradiators

(1) Purpose and scope.

(a) This Rule, 391-3-17-.09, contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This Rule also contains radiation safety requirements for operating irradiators. The requirements of this Rule are in addition to other requirements of this Chapter. In particular, the provisions of Rules 391-3-17-.02, .03, and .07 apply to applications and licenses subject to this Rule. Nothing in this Rule relieves the licensee from complying with other applicable Federal, State, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) The Regulations in this Rule apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 500 rads (5 Grays) per hour at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Rule.

(c) This Rule does not apply to self-contained dry-source-storage irradiators (those in which both the source and the areas subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

(d) Any sealed source licensed pursuant to this Rule shall have a solubility equal to or less than the solubility of cobalt-60 metal in water.

(2) Definitions.

(a) "Annually" means once every 12 calendar months or no later than the last day of the same calendar month of the following year.

(b) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

(c) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials.

(d) "Irradiator operator" means an individual who has successfully completed the training and testing described in (5)(a) of this Rule and is authorized by the terms of the license to operate the irradiator without a supervisor present.

(e) "Large irradiator" means an irradiator where radiation dose rates exceeding 500 rads (5

Grays) per hour exist at one meter from the sealed radioactive sources in air or in water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(f) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

(g) "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

(h) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(i) "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

(j) "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

(k) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(l) "Radiation Safety Officer" means an individual with responsibility for the overall Radiation Safety Program at the facility.

(m) "Sealed source" means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

(n) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than ten percent, as designated by the U.S. Geological Survey.

(o) "Solubility of one liquid or solid in another" means the mass of a substance contained in the solution which is in equilibrium with an excess of the substance.

(p) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

(3) Specific Licensing Requirements.

(a) Application for a specific license.

1. A person, as defined in Rule 391-3-17-.01 may file an application for a specific license authorizing the use of sealed sources in large irradiators in accordance with Rule .02 of this Chapter.
2. A separate license is required for each large irradiator, radiation room, or underwater irradiator.
 - (b) Specific licenses for large irradiators. The Director will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.
 1. The applicant shall satisfy the general requirements specified in Rule 391-3-17-.02 and the requirements contained in this Rule.
 2. The applicant shall describe its training for irradiator operators that shall include, at a minimum, the following:
 - (i) A minimum of 40 hours of classroom training;
 - (ii) A minimum of 160 hours of on-the-job training;
 - (iii) Safety reviews;
 - (iv) The means the applicant will use to test each operator's understanding of and ability to comply with the Division's Rules and licensing requirements and the irradiator operating and emergency procedures; and
 - (v) Minimum training and experience of personnel who may provide training.
3. The applicant shall submit an outline or summary of the written operating and emergency procedures listed in this Rule that describes the radiation safety aspects of the procedures.
4. The application shall describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The applicant shall also describe the training and experience required for the position of Radiation Safety Officer.
5. The application must include a description of the access control system required by (4)(b) of this Rule, the radiation monitors required by (4)(e) of this Rule, the method of detecting leaking sources required by (5)(e) of this Rule including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.
6. The applicant shall provide assurance that any radioactive source not used in the irradiation process shall be removed from the irradiator pool and disposed of or returned to the

manufacturer.

7. If the applicant intends to perform leak testing of dry-source storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Division for approval. The procedures must include the following:

- (i) Instruments to be used;
- (ii) Methods of performing the analysis; and
- (iii) Pertinent experience of the individual who analyzes the samples.

8. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at his facility, the loading or unloading must be done by an organization specifically licensed by the Director, an Agreement State, or the U.S. Nuclear Regulatory Commission to load or unload irradiator sources.

9. The applicant shall perform the following operational tests to ensure proper functioning of all equipment and safety devices before the irradiator is loaded with sources:

- (i) Interlock and radiation safety systems;
- (ii) Pool integrity and plumbing;
- (iii) Source rack mechanical positioning system;
- (iv) Source rack movement and position sensing systems;
- (v) Source rack electrical control system;
- (vi) Uninterruptible electrical power supply for radiation monitoring warning systems;
- (vii) Fire protection system;
- (viii) Emergency systems for returning a stuck source rack into the pool;
- (ix) Systems used for transferring sources to and from transport vehicles; and
- (x) Product conveyor system.

10. The applicant shall describe the operational inspection and maintenance program, including the frequency of the checks required by (5)(f) of this Rule.

11. The roof plug opening or removable shielding providing access for the loading and removal of sources shall be large enough to accommodate the largest applicable transportation cask.

(c) The applicant shall not begin construction of a new irradiator facility prior to the issuance of a license by the Director. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of site, site surveys or soil testing, site preparation, site excavation, and other similar tasks. Any activities undertaken prior to the issuance of license with respect to the requirements of this Chapter shall be at the risk of the applicant and have no bearing on the issuance of a license in accordance with this Chapter.

(d) Applications for exemptions.

1. The Director may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this Rule that it determines are authorized by law and will not endanger public health, safety, or property.

2. Any application for a license or for an amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this Rule. The Division will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

(e) Request for written statements.

1. After the filing of the original application, the Division may request further information necessary to enable the Director to determine whether the application should be granted or denied.

2. Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Division's request, submit written statements or other sufficient information to enable the Director to determine whether the license should be modified, suspended, or revoked.

(4) Design and Performance Requirements for Irradiators.

(a) Performance criteria for sealed sources.

1. Requirements. Sealed sources installed after January 1, 1994:

(i) Must have a certificate of registration issued under 10 CFR 32.210;

(ii) Must be doubly encapsulated;

(iii) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(iv) Must be encapsulated in a material resistant to general corrosion and to localized corrosion,

such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(v) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the following tests:

2. Temperature. The test source must be held at 40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.
3. Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.
4. Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from height of 1 meter onto the test source.
5. Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.
6. Puncture. A 50-gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.
7. Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

(b) Access control.

1. Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they are reliable and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.
2. Each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their full shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained in how to respond to the alarm and prepared to promptly render or summon assistance.

3. A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in (4)(b)2. of this Rule. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.
4. Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.
5. Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.
6. Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed with a present time after activation of the control.
7. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "Very High radiation area," but the sign may be removed, covered, or otherwise made inoperable when the sources are fully shielded.
8. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if the shield is not placed properly or by an operating procedure requiring inspection including documentation of inspection, of shielding before operation.
9. Panoramic irradiators shall not operate if the requirements in (4)(b) of this Rule are not met.
10. Underwater irradiators must have a personnel access barrier around the pool, which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

(c) Shielding.

1. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 millirems (0.02 millisievert) per hour at any location 30 centimeters

or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 millirems (0.02 millisievert) per hour must be locked, roped off, or posted and not entered without written approval or in the physical presence of the Radiation Safety Officer.

2. The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 2 millirems (0.02 millisievert) per hour when the sources are in the fully shielded position.
3. The radiation dose rate at 1 meter from the shield of a drysource- storage panoramic irradiator when the source is shielded may not exceed 2 millirems (0.02 millisievert) per hour and at 5 centimeters from the shield must not exceed 20 millirems (0.02 millisievert) per hour.

(d) Fire protection.

1. The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.
2. The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

(e) Radiation monitors.

1. Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.
2. For pool irradiators, the licensee shall provide a means to detect radioactive contamination in pool water each day the irradiator operates. The means may be either an on-line radiation monitor on the pool water purification system or an analysis of pool water. If the licensee uses an on-line radiation monitor, the detection of above normal background radiation levels must activate the alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. If a false alarm due to background radiation occurs, the alarm set-point must be increased. Activation of the alarm must automatically cause the water purification system to shut off. However, the licensee may reset the alarm set-point to a higher level if necessary to operate the pool purification system to clean up contamination in the pool as specifically provided in written emergency procedures.
3. Underwater irradiators that are not in a shielded radiation room must have a radiation monitor

over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

(f) Control of source movement.

1. The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.
2. The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.
3. The control console of a panoramic irradiator must have an emergency control that promptly returns the sources to the shielded position.
4. Each control for a panoramic irradiator must be clearly marked as to its function.

(g) Irradiator pools.

1. For licenses initially issued after January 1, 1994, irradiator pools must either:
 - (i) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or
 - (ii) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.
2. For licenses initially issued after January 1, 1994, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.
3. A means must be provided to replenish water losses from the pool.
4. A visible indicator must be provided in a clearly visible location to indicate the pool water level is below the normal low water level or above the normal high water level.
5. Irradiator pools must be equipped with a purification system designed to be capable of

maintaining the water during normal operation at a conductivity of 20 micromhos per centimeter or less and with a clarity so that the sources can be seen clearly.

6. A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

7. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 2 millirems (0.02 millisievert) per hour.

(h) Source rack protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

(i) Power failures.

1. If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

2. The lock on the door of the radiation room of a panoramic irradiator shall not be deactivated by a power failure.

3. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

(j) Design requirements.

Irradiators whose construction begins after January 1, 1994, must meet the design requirements of this section.

1. Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of (4)(c) of this Rule. If the irradiator will use more than 5 million Curies (1.85×10^{17} becquerels) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

2. Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure that it is adequate to support the weight of the facility shield walls.

3. Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of (4)(c)2. of this Rule, and that metal components are metallurgically compatible with other

components in the pool.

4. Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of (4)(g) of this Rule. The system must be designed so that water leading from the system does not drain to unrestricted areas without being monitored.

5. Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by (4)(e)1. of this Rule. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under (5)(e)2. of this Rule, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

6. Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

7. Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of (4)(b) of this Rule.

8. Fire protection. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

9. Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

10. Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

11. Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and

electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

12. Product carriers. For irradiators utilizing product carriers, the basic design of the carrier shall prevent the carrier from opening or coming into contact with the source rack or protective barrier. The basic design shall be submitted to the Division for approval.

13. Floor penetrations. All floor penetrations, including expansion joints, floor joints, and drains, shall not allow the uncontrolled release of water, which has not been analyzed for its radioactive content, from the radiation room.

14. Lift mechanisms. The lift mechanisms for the source rack and source transport cask must be designed for working and breaking strength to safely lift a source transport cask and sources into and out of the irradiator pool.

15. Ventilation. All radiation rooms in a panoramic irradiator shall be maintained under negative pressure. Any exhaust from radiation rooms shall be through a high-efficiency nuclear air cleaning system. This system shall consist of standard roughing and absolute (HEPA) filters that have been tested in line in accordance with and has met the requirements of ANSI N510.

(k) Construction monitoring and acceptance testing.

The requirements of (4)(k) of this Rule must be met for irradiators whose construction begins after January 1, 1994. Additionally, the requirements for shielding, (4)(k)1., foundations, (4)(k)2., pool integrity, (4)(k)3., and wiring, (4)(k)11. of this Rule must be certified by a registered professional engineer. The requirements must be met prior to loading sources.

1. Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

2. Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

3. Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of (4)(f)2. of this Rule.

4. Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

5. Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by (4)(e)1. of this Rule. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm, if used, to meet (4)(e)2. of this Rule. For underwater irradiators, the licensee shall verify the proper operation of the over-the-

pool monitor, alarms, and interlocks required by (4)(e)2. of this Rule.

6. Source racks. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in (4)(h) of this Rule are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

7. Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

8. Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

9. Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

10. Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

11. Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

(5) Operation of Irradiators.

(a) Training.

1. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in the following:

(i) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Division's dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

(ii) The requirements of this Rule and Rule 391-3-17-.07 that are applicable to the irradiator;

- (iii) The operation of the irradiator;
 - (iv) Those operating and emergency procedures listed in (5)(b) of this Rule that the individual is responsible for performing; and
 - (v) Case histories of accidents or problems involving irradiators.
2. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received, consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.
 3. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.
 4. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:
 - (i) Changes in operating and emergency procedures since the last review, if any;
 - (ii) Changes in Regulations and license conditions since the last review, if any;
 - (iii) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
 - (iv) Relevant results of inspections of operator safety performance;
 - (v) Relevant results of the facility's inspection and maintenance checks; and
 - (vi) A drill to practice an emergency or abnormal event procedure.
 5. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that the Regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.
 6. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the Radiation Safety Officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, and procedures or parts of procedures listed in (5)8. of this Rule that they are expected to perform or comply with, and their proper response to alarms required in this Rule. Tests may be oral.
 7. Individual who must be prepared to respond to alarms required by (4)(b)2., (4)(b)10., (4)(d)1.,

(4)(e)1., and (5)(e)2. of this Rule shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

(b) Operating and emergency procedures.

1. The licensee shall have and follow written operating procedures for the following:

(i) Operation of the irradiator, including entering and leaving the radiation room;

(ii) Use of personnel dosimeters;

(iii) Surveying the shielding of panoramic irradiators;

(iv) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(v) Leak testing of sources;

(vi) Inspection and maintenance checks required by (5)(f) of this Rule;

(vii) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(viii) Inspection of movable shielding required by (4)(b)8. of this Rule, if applicable.

2. The licensee shall have and follow emergency or abnormal event procedures, appropriate to the irradiator type, for the following:

(i) Source stuck in the unshielded position;

(ii) Personnel overexposures;

(iii) A radiation alarm from the product exit portal monitor or pool monitor;

(iv) Detection of leaking sources, pool contamination, or alarm cause by contamination of pool water;

(v) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(vi) A prolonged loss of electrical power;

(vii) A fire alarm or explosion in the radiation room;

(viii) An alarm indicating unauthorized entry into the radiation room, area around the pool, or another alarm area;

(ix) Natural phenomena, including an earthquake, tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(x) The jamming of the automatic conveyor system.

3. The licensee may revise operating and emergency procedures without Division approval only if all of the following conditions are met:

(i) The revisions do not reduce the safety of the facility,

(ii) The revisions are consistent with the outline or summary of procedures submitted with the license application,

(iii) The revisions have been reviewed and approved by the Radiation Safety Officer, and

(iv) The users or operators are instructed and tested on the revised procedures before they are put into use.

(c) Personnel monitoring.

1. Irradiator operators shall wear a personnel monitoring device while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel monitoring device processor must be ~~accredited by the National Voluntary Laboratory Accreditation Program~~ capable of detecting high energy photons in the normal and accident dose ranges. Each personnel monitoring device must be assigned to and worn only by one individual. Film Badges must be replaced at least monthly and all other personnel monitoring devices must be processed at least quarterly.

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

(d) Radiation surveys.

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

2. If the radiation levels specified in (4)(c) of this Rule are exceeded, the facility must be modified to comply with the requirements of (4)(c) of this Rule.
3. Portable radiation survey meters must be calibrated at least annually to an accuracy of ± 20 percent of the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.
4. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 10 CFR Part 20, Table 2, Column 2 or Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage".
5. Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level of less than 0.5 millirem (0.005 millisievert) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 millirem (0.005 millisievert) per hour.

(e) Detection of leaking sources.

1. Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Division, an Agreement State, or the U.S. Nuclear Regulatory Commission. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 0.005 microcurie (200 becquerels) of radioactive material and must be performed by a person approved by the Division, an Agreement State, or the U.S. Nuclear Regulatory Commission to perform the test.
2. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.
3. If a leaking source is detected, the licensee shall arrange to remove the leaking source from

service and have it decontaminated, repaired, or disposed of by the Division, Agreement State, or U.S. Nuclear Regulatory Commission licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by the Division, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B to 20.1001 to 20.2401 of 10 CFR 20.

(f) Inspection and maintenance.

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

(i) Operability of each aspect of the access control system required by (4)(b) of this Rule.

(ii) Functioning of the source position indicator required by (4)(f) of this Rule.

(iii) Operability of the radiation monitor for radioactive contamination in pool water required by (5)(e)2. of this Rule using a radiation check source, if applicable.

(iv) Operability of the over-the-pool radiation monitor at underwater irradiators as required by (4)(e)3. of this Rule.

(v) Operability of the product exit monitor required by (4)(e)1. of this Rule.

(vi) Operability of the emergency source return control required by (4)(e)3. of this Rule.

(vii) Leak-tightness of systems through which pool water circulates (visual inspection).

(viii) Operability of the heat and smoke detectors and extinguisher system required by (4)(d) of this Rule (but without turning extinguishers on).

(ix) Operability of the means of pool water replenishment required by (4)(g)3. of this Rule.

(x) Operability of the indicators of high and low pool water levels required by (4)(g)4. of this Rule.

(xi) Operability of the intrusion alarm required by (4)(b)10. of this Rule, if applicable.

(xii) Functioning and wear of the system, mechanism, and cables used to raise and lower

sources.

(xiii) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by (4)(h) of this Rule.

(xiv) Amount of water added to the pool to determine if the pool is leaking.

(xv) Electrical wiring on required safety systems for radiation damage.

(xvi) Pool water conductivity measurements and analysis as required by (5)(g)2. of this Rule.

2. Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

(g) Pool water purity.

1. The pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 micromhos per centimeter under normal circumstances. If pool water conductivity rises above 20 micromhos per centimeter, the licensee shall take prompt actions to lower the pool water conductivity, and shall take corrective actions to prevent future recurrences.

2. The licensee shall measure the pool water conductivity frequently enough, but not less than weekly, to assure that the conductivity remains below 20 micromhos per centimeter. Conductivity meters must be calibrated at least annually.

(h) Attendance during operation.

1. Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:

(i) Whenever the irradiator is operated using an automatic product conveyor system; and

(ii) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

2. At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in (5)(a)7. of this Rule must be onsite.

3. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in (5)(a)6. and 7. of this Rule. Static irradiations may be performed without a person present at the facility.

4. Irradiator operators shall not be on duty more than 12 hours in any 24-hour period without at least 8 hours uninterrupted rest, unless an emergency exists and prior authorization has been given by the Division.

(i) Entering and leaving the radiation room.

1. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source while entering the radiation room. The survey meter must be of a type that does not saturate and read zero at high radiation dose rates.

2. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(i) Visually inspect the entire radiation room to verify that no one else is in it; and

(ii) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

3. During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by (4)(e)3. of this Rule is operating with backup power.

(j) Irradiation of explosive or flammable materials.

1. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Division. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

2. Irradiation of more than small quantities of flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Division. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

(6) Records.

(a) Records and retention periods.

The licensee shall maintain the following records at the irradiator for the periods specified:

1. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Director terminates the

license for documents not superseded.

2. Records of each individual's training, tests, and safety reviews provided to meet the requirements of (5)(a)1., 2., 3., 4., 5., and 7. of this Rule for 3 years after the evaluation.
3. Records of the annual evaluations of the safety performance of irradiator operators required by (5)(a)5. of this Rule for 3 years after the evaluation.
4. A copy of the current operating and emergency procedures required by (5)(b) of this Rule until superseded or the Director terminates the license. Records of the Radiation Safety Officer's review and approval of changes in procedures as required by (5)(b)3.iii of this Rule are to be retained for 3 years from the date of the change.
5. Personnel monitoring results required by (5)(c) of this Rule shall be retained until the Director terminates each pertinent license requiring the record. Upon termination of the license, the licensee shall permanently store records on Division Form, "Occupational Radiation Exposure History", or equivalent, or shall make provisions with the Division for transfer to the Division.
6. Records of radiation surveys required by (5)(d) of this Rule for three years from the date of the survey.
7. Records of radiation survey meter calibrations required by (5)(d) of this Rule and pool water conductivity meter calibrations required by (5)(g)2. of this Rule until three years from the date of calibration.
8. Records of the results of leak tests required by (5)(e)1. of this Rule and the results of contamination checks required by (5)(e)2. of this Rule for three years from the date of each test.
9. Records of inspection and maintenance checks required by (5)(f) of this Rule for three years.
10. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.
11. Records of the receipt, transfer, and disposal of all licensed sealed sources for three years after the transfer or disposal of the sealed source.
12. Records of the design checks required by (4)(j) of this Rule and the construction control checks as required by (4)(k) of this Rule until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.
13. Records related to decommissioning of the irradiator as required by Rule 391-3-17-.02(8)(g)8.

(b) Reports.

1. In addition to the reporting requirements in other Rules of this Chapter, the licensee shall report the following events if not reported under other Rules of this Chapter:

- (i) Source stuck in an unshielded position.
- (ii) Any fire or explosion in a radiation room.
- (iii) Damage to the source racks.
- (iv) Failure of the cable or drive mechanism used to move the source racks.
- (v) Inoperability of the access control system.
- (vi) Detection of a radiation source by the product exit monitor.
- (vii) Detection of radioactive contamination attributable to licensed radioactive material.
- (viii) Structural damage to the pool liner or walls.
- (ix) Abnormal water loss or leakage from the source storage pool.
- (x) Pool water conductivity exceeding 100 micromhos (100 μ S) per centimeter.

2. The report must include a telephone report within 24 hours and a written report within 30 days as described in Rule 391-3-17-.03(14)(b).

Authority: O.C.G.A. Section 31-13-1 et seq., as amended.