391-3-17-.05 USE OF RADIONUCLIDES IN THE HEALING ARTS. AMENDED.

(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 the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this Rule are in addition to, and not in substitution for, others in these Regulations. The requirements and provisions of these Regulations apply to applicants and licensees subject to this Rule unless specifically exempted. All numbered and lettered references within this Rule refer to parts of this Rule, unless stated otherwise.

(2) Definitions. As used in this Rule, the following definitions apply:

(a) "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.

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

(c) "Authorized Medical Physicist" means an individual who:

1. Meets the requirements in Rule .05(16)(j) or (16)(o); or

2. Is identified as an authorized medical physicist on a license or equivalent permit issued by the Department, another Agreement State, Licensing State or the Nuclear Regulatory Commission; or

3. Is identified as an authorized medical physicist on a permit issued by a Department, Agreement State, Licensing State or Nuclear Regulatory Commission specific license of broad scope that is authorized to permit the use of radioactive material.

(ed) "Authorized nuclear pharmacist" means a pharmacist who is:

1. Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialist; ~~and~~ or

2. Identified as an authorized nuclear pharmacist on a Department, NRC, or Agreement State license that authorizes the use of radioactive

Rule .05(2)(d)2.

material in the practice of nuclear pharmacy; or

3. Identified as an authorized nuclear pharmacist on a permit issued by the Department, NRC, or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

(~~d~~e) "Authorized user" means a physician who is:

1. Board certified by at least one of the boards listed in (16) (c)1., (16)(d)1., (16)(e)1., (16)(f)1., (16)(g)1., (16)(h)1., or (16)(i)1.; or

2. Identified as an authorized user on a Department, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission (NRC) license that authorizes the medical use of radioactive material; or

3. Identified as an authorized user on a permit issued by a Department, Agreement State, or NRC specific license of broad scope that permit the medical use of radioactive material.

(e~~f~~) "Brachytherapy" means a method of radiation therapy in which ~~sealed sources~~ radioactive isotopes are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

(f~~g~~) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

(g~~h~~) "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.

(i) "High dose-rate remote afterloader" (HDR) means a device that remotely delivers a dose rate in excess of 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

(j) "Low dose-rate remote afterloader" (LDR) means a device that remotely delivers a dose rate of less than or equal to 200 rads (2 gray) per hour at the

Rule .05(2)(j)

point or surface where the dose is prescribed.

~~(h) "Management" means the chief executive officer or that individual's designee.~~

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

(il) "Medical institution" means an organization in which several medical disciplines are practiced.

(jm) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user in the practice of the healing arts.

(n) "Medium dose-rate remote afterloader" (MDR) means a device that remotely delivers a dose rate of greater than 200 rad (2 gray), but less than, or equal to, 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

(ko) "Misadministration" means the administration of:

1. A radiopharmaceutical dosage greater than 30 microcuries (1.11 MBq) of either sodium iodine I-125 or I-131:

   (i) Involving the wrong individual or the wrong radiopharmaceutical, or

   (ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and the prescribed dosage exceeds 30 microcuries (1.11 Mbq).

2. A therapeutic radiopharmaceutical dosage:

   (i) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration, or

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

Rule .05(2)(o)3.

3. A ~~gamma~~ stereotactic radiosurgery radiation dose:

(i) Involving the wrong individual or wrong treatment site, or

(ii) When the calculated total administered dose differs from the total prescribed dose by more than ~~10~~ ten percent of the total prescribed dose.

4. A teletherapy radiation dose:

(i) Involving the wrong individual, wrong mode of treatment, or wrong treatment site, or

(ii) When the treatment consists of ~~3~~ three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ~~10~~ ten percent of the total prescribed dose, or

(iii) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose, or

(iv) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

5. A brachytherapy radiation dose:

(i) Involving the wrong individual, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or

(ii) Involving a sealed source that is leaking; or

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure, or

(iv) When the calculated administered dose to the treatment site differs from the prescribed dose by more than 20 percent of the prescribed dose.

6. A diagnostic radiopharmaceutical dosage, both:

(i) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs by more than 20 percent of the prescribed dosage, and

Rule .05(2)(o)6.(ii)

(ii) When the dose to the patient exceeds ~~5~~ five rem (50 millisieverts) effective dose equivalent or 50 rem (500 millisieverts) dose equivalent to any individual organ.

(~~l~~p) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

(~~m~~q) "Nuclear Pharmacist" means an individual who is licensed to engage in the practice of pharmacy with regard to radiopharmaceuticals by the Georgia State Board of Pharmacy.

(~~n~~r) "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 stereotactic radiosurgery unit for a specified set of exposure conditions.

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

(~~o~~t) "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

1. In a written directive;

2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

(~~p~~u) "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; or

3. For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.

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

(v) "Pulsed dose-rate remote afterloader" (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates

Rule .05(2)(v)

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.

(qw) "Recordable Event" means the administration of :

1. A radiopharmaceutical or radiation without a written directive where a written directive is required;

2. A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

3. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodine I-125 or I-131 when both:

   (i) The administered dosage differs from the prescribed dosage by more than ~~10~~ ten percent of the prescribed dosage, and

   (ii) The difference between the administered dosage and prescribed dosage exceed 15 microcuries.

4. A therapeutic radiopharmaceutical dosage, other than sodium iodine I-125 or I-131 when the administered dosage differs from the prescribed dosage by more than ~~10~~ ten percent of the prescribed dosage;

5. A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

6. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ~~10~~ ten percent of the prescribed dose.

(x) "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.

~~(r) "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a Department license.~~

Rule .05(2)(y)

(~~s~~y) "Teletherapy" means ~~therapeutic irradiation in which the source of radiation is at a distance from the body.~~ a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject

~~(t) "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.~~

(~~u~~z) "Written directive" means an order in writing for a specific patient, or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in 6. of this definition, containing the following information:

1. For any administration of quantities greater than 30 ~~µCi~~ microcuries (1.11 megabecquerels) of sodium iodide I-125 or I-131: the radionuclide and dosage;

2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

3. For ~~gamma~~ stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

5. For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, and total dose; or

6. For all other brachytherapy,

   (i) Prior to implantation: the radionuclide, number of sources, and source strengths; and

   (ii) After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

(3) License Required.

(a) No person shall manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to this Chapter.

(b) Unless prohibited by license condition, an individual may receive, possess, use,

Rule .05(3)(b)

or transfer radioactive material in accordance with the Regulations in this Rule under the supervision of an authorized user as provided in (6)(~~h~~i).

(c) Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with regulations in this Rule under the supervision of an authorized nuclear pharmacist or authorized user as provided in 6(~~h~~i).

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

(a) Before using radioactive material for a method or type of medical use not permitted by the license issued under this Rule;

(b) Before permitting anyone, ~~except a visiting authorized user described in (6)(i)~~, to work as an authorized user, authorized medical physicist, or nuclear pharmacist under the license except an individual who is:

1. An authorized user certified by the organizations specified in paragraph 1. of (16) (c), (d), (e), (f), (g), (h), or (i); or

2. An authorized medical physicist who meets the requirements in (16)(j)

~~2~~3. An authorized nuclear pharmacist certified by the organization specified in (16)(n)1.; or

~~3~~4. Identified as an authorized user, an authorized medical physicist or an authorized nuclear pharmacist on a Department, Agreement State, or NRC license that authorizes the use of radioactive material in medical use, medical physics or in the practice of nuclear pharmacy, respectively; or

4. Identified as an authorized user, an authorized medical physicist or an authorized nuclear pharmacist on a permit issued by ~~a~~ the Department, Agreement State, Licensing State or NRC specific license of broad scope that is authorized to permit the use of radioactive materials in medical use or in the practice of nuclear

pharmacy, respectively.

(c) Before changing a Radiation Safety Officer or Medical Physicist;

(d) Before receiving radioactive material in excess of the amount authorized on the license;

(e) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

Rule .05(4)(f)

(f) Before changing statements, representations, and procedures which are incorporated into the license.

(5) Notifications.

(a) A licensee shall notify the Department in writing within 30 days when:

1. An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or Medical Physicist permanently discontinues performance of duties under the license or has a name change; or

2. The licensee's mailing address changes.

(b) A licensee shall provide to the Department a copy of either the board certification;~~,~~ the Department, Agreement State, Licensing State or NRC license;~~,~~ or permit issued by a ~~license of~~ broad scope licensee, for each individual within 30 days of permitting the individual to work as an authorized user, authorized medical physicist or an authorized nuclear pharmacist pursuant to (4)(b)1. ~~thru~~ through 4.

(6) General Requirements.

(a) Provisions for Research Involving Human Subjects.

A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise a licensee shall apply for and receive approval of a specific amendment to its Department issued license before conducting such research. Both types of licenses shall, at a minimum, obtain informed consent from the human subject and obtain prior review and approval of the research activities by an "Institutional Review Board" in terms as defined and described in the Federal Policy for the Protection of Human Subjects.

(b) FDA and other State of Georgia Agency and Federal Requirements. Nothing in this Rule relieves the licensee from complying with applicable FDA, other ~~State~~ Georgia agency and Federal requirements governing radioactive drugs or devices.

Rule .05(6)(c)

(c) 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 the following:

1. The provisions of (4)(b);

2. The provisions of (4)(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;

3. The provisions of (5)(a)1. for an authorized user or an authorized nuclear pharmacist; and

4. The provisions of (5)(b).

(d) ALARA Program.

1. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in (ALARA) as defined in Rule .01 of this Chapter.

2. To satisfy the requirement of (6)(d)1.:

(i) The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by this Chapter or the Radiation Safety Committee; or

(ii) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

Rule .05(6)(d)3.

3. The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

4. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

   (i) A commitment by management to keep occupational doses as low as reasonably achievable;

   (ii) A requirement that the Radiation Safety Officer brief management once each year on the Radiation Safety Program;

   (iii) Personnel exposure investigational levels, in accordance with (6)(f)2.(vii), that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

   (iv) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

Rule .05(6)(e)

(e) Radiation Safety Officer.

1. A licensee's management shall appoint a Radiation Safety Officer responsible for implementing the Radiation Safety Program. The licensee's management, through 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 radioactive material program.

2. The Radiation Safety Officer shall:

(i) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(ii) Implement written policy and procedures for:

(I) Authorizing the purchase of radioactive material;

(II) Receiving and opening packages of radioactive material;

(III) Storing radioactive material;

(IV) Keeping an inventory record of radioactive material;

(V) Using radioactive material safely;

(VI) Taking emergency action if control of radioactive material is lost;

(VII) Performing periodic radiation surveys;

(VIII) Performing checks and calibrations of survey instruments and other safety equipment;

(IX) Disposing of radioactive material;

Rule .05(6)(e)2.(ii)(X)

(X) Training personnel who work in or frequent areas where radioactive material is used or stored; and

(XI) Keeping a copy of all records and reports required by the Regulations, a copy of this Chapter, a copy of each licensing request and license and amendments, and the written policy and procedures required by this Chapter; and

(iii) For medical use not sited at a medical institution, approve or disapprove Radiation Safety Program changes with the advice and consent of management prior to submittal to the Department for licensing action; or

(iv) For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

(f) Radiation Safety Committee. Each medical institution licensee, except those medical institution licensees authorized to use only radiopharmaceuticals described in Rule .05(8) and .05(9), shall establish a Radiation Safety Committee to oversee the use of radioactive material.

1. The Committee shall meet the following administrative requirements:

(i) Membership must consist of at least ~~3~~ three individuals and shall 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. Other members may be included as the licensee deems appropriate.

(ii) The Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. ~~at least once each calendar quarter~~.

(iii) To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative.

Rule .05(6)(f)1.(iv)

(iv) The minutes of each Radiation Safety Committee meeting shall include:

(I) The date of the meeting;

(II) Members present;

(III) Members absent;

(IV) Summary of deliberations and discussions;

(V) Recommended actions and the numerical results of all ballots; and

(VI) Document any reviews required in (6)(d)3. and (6)(f)2.

(v) The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the Department authorizes its disposition.

2. To oversee the use of licensed material, the Committee shall:

(i) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(ii) Review, on the basis of safety and with regard to the training and experience standards of this Rule, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or Medical Physicist before submitting a license application or request for amendment or renewal;

Rule .05(6)(f)2.(iii)

(iii) Review, pursuant to (4)(b)1. and 4., on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual before allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(iv) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(iv) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and Radiation Safety Program changes prior to submittal to the Department for licensing action;

(vi) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

(vii) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(viii) Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and

(ix) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

(g) Statement of Authorities and Responsibilities.

1. A licensee shall provide sufficient authority and organizational freedom to the Radiation Safety Officer and the Radiation Safety Committee to:

(i) Identify radiation safety problems;

(ii) Initiate, recommend, or provide solutions; and

Rule .05(6)(g)1.(iii)

(iii) Verify implementation of corrective actions.

2. A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee. The Radiation Safety Officer must agree in writing to be responsible for implementing the radiation protection program.

(h) Duties of Authorized User, Authorized Medical Physicist, and Authorized Nuclear Pharmacist.

1. A licensee shall assure that only authorized users for the type of radioactive material use;

(i) 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; and

(ii) Direct, as specified in (6)(i) and (6)(k), or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;

(iii) Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with (3)(b), and (3)(c), and (6)(i);

2. A licensee shall assure that only authorized medical physicists perform, as applicable:

(i) Full calibration measurements as described in (15)(j), (15)(k) and (15)(l)

(ii) Periodic spot checks as described in (15)(m), (15)(n), and (15)(o); and

(iii) Radiation surveys as described in (15)(q).

(~~h~~i) Supervision.

1. A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by (3)(b) shall:

(i) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and the licensee's quality management program;

Rule .05(6)(i)1.(ii)

(ii) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the rules of this chapter and the license conditions with respect to the use of radioactive material.

(iii) Review the supervised individual's use of radioactive material, provide re-instruction as needed, and review records kept to reflect this use;

(iv) Require an authorized user to be immediately available to communicate with the supervised individual; and

(v) Require that only those individuals permitted under State and local regulations and specifically trained, and designated in writing by the authorized user, shall be permitted to administer radionuclides or radiation to patients.

Rule .05(6)(i)2.

2. A licensee that permits the production, preparation, compounding, of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or an authorized user, as allowed by (3)(c), shall:

(i) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and the licensee's quality management program, as appropriate to that individual's use of radioactive material;

(ii) Require the supervised individual to follow the instructions given pursuant to (i) above and to comply with the regulations of this Chapter and license conditions; and

(iii) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to review the work of supervised individuals as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

~~(i) Visiting Authorized User.~~

~~1. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:~~

~~(i) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;~~

~~(ii) The licensee has a copy of a Department or Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user by name as an authorized user for medical use; and~~

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

Rule .05(6)(j)

~~2. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in (6)(i)1.~~

~~3. A licensee shall retain copies of the records specified in (6)(i)1. for 3 years from the date of the last visit.~~

(j) Mobile ~~Nuclear Medicine~~ Medical Service Administrative Requirements.

1. The Department shall license mobile ~~nuclear medicine~~ medical services or clients of such services. The mobile ~~nuclear medicine~~ medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile ~~nuclear medicine~~ medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

2. Mobile ~~nuclear medicine~~ medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material. 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 ~~nuclear medicine~~ medical service.

3. A mobile ~~nuclear medicine~~ medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a license—allowing possession of the radioactive material. Radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's license.

4. A mobile ~~nuclear medicine~~ medical service shall inform the client's management ~~a responsible individual,~~ on site at each client's address of use at the time radiopharmaceuticals are administered.

5. A licensee providing mobile medical services shall retain the letter required in .05(6)(j)2. in accordance with .05(6)(j)7.

6. A mobile medical service licensee shall maintain on each mobile unit:

(i) The current operating and emergency procedures;

(ii) A copy of the license;

(iii) Copies of the letter required by .05(6)(j)2.;

Rule .05(6)(j)6(iv).

(iv) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

(v) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

7. The 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 .05(6)(j)2., for three years after the last provision of service.

8. A mobile medical service licensee shall maintain records required by Section .03 and Section .05 of these regulations at a location within the Department's jurisdiction that is a single address of use which is identified as the records retention location; and staffed at all reasonable hours by individual(s) authorized to provide the Department with access for purposes of inspection.

(k) Quality Management Program. Each licensee shall establish a written quality management program to provide documentation that radioactive material or radiation therefrom is administered as directed by the authorized user.

1. ~~Each licensee shall establish a written quality management program to provide documentation that radioactive material or radiation therefrom is administered as directed by the authorized user.~~ The Quality Management program must include written policies and procedures to meet the following specific objectives:

(i) That, prior to administration, ~~a written directive is~~ prepared a written directive that must contain the patient or human research subject's name and the following: ~~for:~~

~~(I)~~ ~~Any teletherapy dose,~~ For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;

(II) ~~Any gamma stereotactic radiosurgery radiation dose,~~ For stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct

treatment site;

(III) ~~Any brachytherapy radiation dose,~~ For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

Rule .05(6)(k)1.(i)(IV)

(IV) ~~Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131,~~ For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(V) ~~Any therapeutic administration of a radio-pharmaceutical, other than sodium iodide I-125 or I-131;~~ 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).

(ii) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(iii) That final plans of treatment and related calculations for brachytherapy, teletherapy, and ~~gamma~~ stereotactic radiosurgery are in accordance with the respective written directives;

(iv) That each administration is in accordance with the written directive; and

(v) That any unintended deviation from the written directive is identified and evaluated, and that appropriate action is taken.

Rule .05(6)(k)2.

2. The licensee shall:

   (i) Develop procedures for, and conduct a review of, the quality management program, including, since the last review, an evaluation of a representative sample of patient and human research subject administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program, such reviews being conducted at intervals of no greater than 12 months;

   (ii) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make ~~modifictaions~~ modifications to meet the objectives of (6)(k)1; and

   (iii) Retain records of each review, including the evaluations and findings of the review for three years.

3. The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

   (i) Assembling the relevant facts, including the cause;

   (ii) Identifying what, if any, corrective action is required to prevent recurrence; and

   (iii) Retaining a record, for three years, of the relevant facts and what corrective action, if any, ~~was~~ were taken.

4. The licensee shall retain each written directive.

5. The licensee shall retain a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required for three years after the administration.

6. The licensee may make modifications to the quality management program to increase the program's efficiency, provided that the program's effectiveness is not decreased. The licensee shall furnish the modification to the Department within 30 days after the modification has been made.

Rule .05(6)(l)

(l) Records, Notifications, and Reports of Misadministration.

1. For a diagnostic misadministration: the licensee shall make and keep a record of the diagnostic misadministration, which shall be made available for review by the Department during the next inspection of the facility.

2. For a therapeutic misadministration:

(i) The license shall notify the Department by telephone no later than the next calendar day after discovery of the misadministration.

(ii) The licensee shall submit a written report to the Department within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(iii) The licensee shall notify the referring physician and also notify the patient of the misadministration not later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the patient or that, based on medical judgement, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

Rule .05(6)(l)2.(iv)

(iv) If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(I) A copy of the report that was submitted to the Department, or

(II) A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the Department can be obtained from the licensee.

3. Each licensee shall retain a record of each misadministration, diagnostic and therapeutic, for ~~5~~ five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

4. Aside from the notification requirement, nothing in (6)(l)2. and (6)(l)3. shall affect any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

(m) Suppliers. A licensee shall use for medical use only:

1. Radioactive material manufactured, produced, labeled, prepared, compounded, packaged, and distributed in accordance with a license issued pursuant to this Chapter or the equivalent regulations of another Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission; and

2. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration (FDA); or

3. Radiopharmaceuticals compounded from a prescription in accordance with the regulations of the Georgia State Board of Pharmacy.

Rule .05(6)(m)4.

4. 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, an Agreement State or a Licensing State; or

45. Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to this Chapter, or the equivalent regulations of another Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

(7) General Technical Requirements.

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

(b) Possession, Use, Calibration, and Check of Dose Calibrators.

1. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity of dosages of photon-emitting radionuclides administered to each patient or human research subject.

2. Each licensee shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient. As a minimum, quality control procedures and frequencies shall be those recommended by the American National Standards Institute; or the licensee shall:

(i) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently-used setting with a sealed source of not less than ~~10~~ ten ~~μCi~~ microcuries (370 kilobecquerels) of radium-226 or 50 ~~μCi~~ microcuries (1.85 megabecquerels) of any other photon-emitting radionuclide with a half-life greater than 90 days;

Rule .05(7)(b)2.(ii)

(ii) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least ~~2~~ two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within ~~5~~ five percent of the stated activity, with minimum activity of 50 ~~μCi~~ microcuries (1.85 megabecquerels) and energies representative of the radionuclides in clinical use at the facility;

(iii) Test each dose calibrator for linearity upon installation and at intervals not to exceed ~~3~~ three months thereafter over the range of use between ~~10 μCi (370 kilobecquerels)~~ the lowest and the highest dosage that will be administered; and

(iv) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

3. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds ~~10~~ ten percent if the dosage is greater than ~~10~~ ten ~~μCi~~ microcuries (370 kilobecquerels) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ~~10~~ ten percent.

4. A licensee shall also perform checks and tests required by (7)(b)2. following adjustment or repair of the dose calibrator.

5. A licensee shall retain a record of each check and test required by (7) for ~~3~~ three years. The records required by (7)(b)2. shall include:

(i) For (7)(b)2.(i), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(ii) For (7)(b)2.(ii), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, the identity of the person performing the test and the signature of the Radiation Safety Officer;

Rule .05(7)(b)5.(iii)

(iii) For (7)(b)2.(iii), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, the identity of the person performing the test, and the signature of the Radiation Safety Officer; and

(iv) For (7)(b)2.(iv), the model and serial number of the dose calibrator, the configuration of the source measured, the decay corrected activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, the identity of the individual performing the test and the signature of the Radiation Safety Officer. Not withstanding the record retention requirements of this rule, geometry dependence records will be maintained from installation or repair until the next installation or repair, or three years, whichever is longer.

6. A licensee shall use dose calibrator reference and calibration sources traceable to the National Institute of Standards and Technology (NIST) or other standards recognized as being equivalent by the NIST.

(c) Calibration and Check of Survey Instruments.

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

2. ~~To satisfy the requirements of (7)(c)1., the licensee shall:~~ Have each radiation survey instrument calibrated:

(i) ~~Calibrate all required scale readings up to 1000 mrem (10 millisieverts) per hour with a radiation source;~~ At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(ii) ~~For each scale that shall be calibrated, calibrate 2 separate readings at 1/3 and 2/3 of full scale rating;~~ 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 three points between two and 1000 millirem (0.02 and ten millisieverts) per hour; and

(iii) ~~Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.~~ For dose rate

Rule .05(7)(c)2.(iii)

instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

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

~~3~~4. ~~To satisfy the requirements of (7)(c)2., the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.~~ 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.

~~4~~5. A licensee shall check each survey instrument for ~~proper operation~~ consistent response with ~~the~~ a dedicated check source before each use. The licensee is not required to keep records of these checks.

~~5~~6. The licensee shall retain a record of each calibration required in (7)(c)1. for ~~3~~ three years. The record shall include:

(i) A description of the calibration procedures; and

(ii) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

~~6~~7. To meet the requirements of (7)(c)1., 2., and 3., the licensee may obtain the services of individuals licensed by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by (7)(c)~~5~~6. shall be maintained by the licensee.

(d) Assay of Radiopharmaceutical Dosages. A licensee shall:

1. Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than ~~10~~ ten ~~µCi~~ microcuries (370 kilobecquerels) of a photon-emitting radionuclide if its half-life is less than ~~8~~ eight days, or assay within one hour if its half-life is equal to or greater than ~~8~~ eight days;

2. Measure by direct measurement or by combination of measurements and calculations, the activity of each dosage of alpha- or beta- emitting

Rule .05(7)(d)2.

radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licenced pursuant to .02(11)(i) or equivalent Agreement State or NRC requirements.

3. Assay, before medical use, the activity of each radiopharmaceutical dosage with a desired activity of ~~10~~ ten ~~μCi~~ microcuries (370 kilobecquerels) or less of a photon-emitting radionuclide to verify that the dosage does not exceed ~~10~~ ten ~~μCi~~ microcuries (370 kilobecquerels); and

4. Retain a record of the assays required by (7)(d)1. and 3. for ~~3~~ three years. To satisfy this requirement, the record shall contain the:

(i) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, expiration dates, and the radionuclide;

(ii) Patient's or human research subject's name, and identification number if one has been assigned;

(iii) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than ~~10~~ ten ~~μCi~~ microcuries (370 kilobecquerels);

(iv) Date and time of the assay and administration; and

(v) Initials of the individual who performed the assay.

(e) Possession, Use, Calibration, and Check of Instruments to Measure Dosages of Alpha- or Beta- Emitting Radionuclides.

1. This section does not apply to unit dosages of ~~alaha~~ alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to .02(11)(i) or equivalent Agreement state or NRC requirements.

2. For other than unit dosages obtained pursuant to (7)(e)1., a licensee shall possess and use instrumentation to measure the radioactivity of the alpha- or beta- emitting radiopharmaceutical. The licensee shall have procedures for use of the instrumentation.

The licensee shall measure, by direct measurement or by calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radiopharmaceutical prior to administration to each patient or human research subject.

Rule .05(7)(e)3.

3. In addition, the licensee shall:

(i) Perform test before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for use of the instrument; and make adjustments when necessary; and

(ii) Check each instrument for constancy and proper operation at the beginning of each day of use.

(f) Authorization for Calibration and Reference Sources. Any person authorized by (3) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

1. Sealed sources manufactured and distributed by persons specifically licensed pursuant to Rule .02 of this Chapter or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State and that do not exceed 15 ~~mCi~~ millicuries (555 megabecquerels) each;

2. Any radioactive material authorized in (8)(a) or (9) with a half-life of 100 days or less in individual amounts not to exceed 15 ~~mCi~~ millicuries (555 megabecquerels);

3. Any radioactive material authorized in (8)(a) or (9) with a half-life greater than 100 days in individual amounts not to exceed 200 ~~μCi~~ microcuries (7.4 megabecquerels) each; and

4. Technetium-99m in individual amounts not to exceed 50 ~~mCi~~ millicuries (1.85 gigabecquerels).

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

1. 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 Department and shall maintain the instructions for the duration of source use in a legible form convenient to users.

Rule .05(7)(g)2.

2. A licensee in possession of a sealed source shall assure that:

   (i) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within ~~6~~ six months before transfer to the licensee; and

   (ii) The source is tested for leakage at intervals not to exceed ~~6~~ six months or at intervals approved by the Department, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission.

3. To satisfy the leak test requirements of (7)(g)2., the licensee shall assure that:

   (i) Leak tests are capable of detecting the presence of 0.005 ~~µCi~~ microcuries (185 becquerels) of radioactive material on the test sample, or in the case of radium, ~~the escape of radon at the rate of 0.001 µCi (37 becquerels) per 24 hours;~~ shall be capable of detecting an absolute leakage rate of 0.001 microcuries (37 Bq) of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume, and time.

   (ii) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

   (iii) Test samples are taken when the source is in the "off" position.

4. A licensee shall retain leak test records for ~~5~~ three years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide ~~and its estimated activity,~~ the measured activity of each test sample expressed in ~~µCi~~ microcuries (becquerels), ~~a description of the method used to measure each test sample,~~ and the date of the test~~, and the signature of the Radiation Safety Officer~~.

Rule .05(7)(g)5.

5. If the leak test reveals the presence of 0.005 ~~μCi~~ microcuries (185 becquerels) or more of removable contamination, the licensee shall:

   (i) Immediately withdraw the sealed source from use and store, repair, or dispose of it in accordance with the requirements of Rule .03 of this Chapter; and

   (ii) File a report with the Department within ~~5~~ five days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

6. A licensee need not perform a leak test on the following sources:

   (i) Sources containing only radioactive material with a half-life of less than 30 days;

   (ii) Sources containing only radioactive material as a gas;

   (iii) Sources containing 100 ~~μCi~~ microcuries (3.7 megabecquerels) or less of beta- or photon-emitting material or ~~10~~ ten ~~μCi~~ microcuries (370 kilobecquerels) or less of alpha-emitting material;

   (iv) Seeds of iridium-192 encased in nylon ribbon; and

   (v) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within ~~6~~ six months before the date of use or transfer.

7. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record for ~~5~~ three years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide ~~and its estimated activity~~, the location of each source, and date of the inventory~~, and the signature of the Radiation Safety Officer~~.

Rule .05(7)(g)8.

8. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed ~~3~~ three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

9. A licensee shall retain a record of each survey required in (7)(g)8. for ~~3~~ three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem(microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

(h) Syringe and Vial Shields and Labels.

1. ~~A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield~~. 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.

2. A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.

~~3.~~ ~~A licensee shall conspicuously label each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's or the human research subject's name.~~

(i) Vial Shields ~~and Labels.~~

1. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

~~2.~~ ~~A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.~~

Rule .05(7)(j)

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

1. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

2. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

3. A licensee shall conduct the surveys required by (7)(j)1. and 2. so as to be able to measure dose rates as low as 0.1 ~~mrem~~ millirem (1 microsievert) per hour.

4. A licensee shall establish dose rate action levels for the surveys required by (7)(j)1. and 2. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

5. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

6. A licensee shall conduct the surveys required by (7)(j)5. so as to be able to detect contamination on each wipe sample of 2000 dpm (33.3 becquerels).

7. A licensee shall establish removable contamination action levels for the surveys required by (7)(j)5. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

8. A licensee shall retain a record of each survey required by (7)(j)1., 2., and 5. for ~~3~~ three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in ~~mrem~~ millirem (microsieverts) per hour or the removable contamination in each area expressed in dpm (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

Rule .05(7)(k)

(k) Release of Patients Containing Radiopharmaceuticals or ~~Permanent~~ Implants.

1. A licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

   (i) The dose rate from the patient is less than ~~5~~ five ~~mrem~~ millirem (50 microsieverts) per hour at a distance of ~~1~~ one meter; or

   (ii) The activity in the patient is less than 30 ~~mCi~~ millicuries (1.11 gigabequerels).

2. A licensee shall not authorize release from confinement for medical care any patient administered a ~~permanent~~ implant until the dose rate from the patient is less than ~~5~~ five ~~mrem~~ millirem (50 microsieverts) per hour at a distance of ~~1~~ one meter.

(l) Mobile Nuclear Medicine Service Technical Requirements. A licensee providing mobile nuclear medicine service shall:

1. Transport to each Client's address ~~of use~~ only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

2. Bring into each Client's address ~~area of use~~ all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

3. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at ~~an~~ a client's address ~~area of use~~;

4. ~~Check survey instruments and dose calibrators as required in (7)(b)2.(i), (7)(b)4., and (7)(c)4., and check all other transported equipment for proper function before medical use at each area of use~~; 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.

5. Check survey instruments for consistent response with a dedicated check source before use at each client's address;

~~56.~~ ~~Carry a survey meter calibrated in accordance with (7)(c) in each vehicle that is being used to transport radioactive material, and,~~ ~~before~~ Prior to leaving a client's address ~~area of use~~, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste

Rule .05(7)(l)6.

have been removed and to ensure compliance with Rule .03 of this Chapter;

7. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Department for compliance with airborne release standards; and Rule .05(7)(l)6.

~~68.~~ Retain a record of each survey required by (7)(l)~~56~~. for ~~3~~ three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in ~~mrem~~ millirem (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey;

~~8.~~ ~~Remove all radioactive material from the mobile vehicle and monitor the vehicle for contamination at the end of each day of use.~~

(m) Storage of Volatiles and Gases.

1. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container.

2. A licensee shall store and use a multidose container in a properly functioning fume hood.

(n) Decay-In-Storage.

1. A licensee ~~shall~~ may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash and is exempt from the waste disposal requirements in Rule .03 of this Chapter if the licensee:

(i) Holds radioactive material for decay a minimum of ~~10~~ ten half-lives;

(ii) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(iii) Removes and destroys or makes illegible all radiation labels; and

(iv) 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.

Rule .05(7)(n)2.

2. For radioactive material disposed in accordance with (7)(n)1., the licensee shall retain a record of each disposal for ~~3~~ three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

(8) Specific Requirements for the Use of Radiopharmaceuticals, for Uptake, Dilution, or Excretion Studies.

(a) Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies.

A licensee may use any unsealed radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion that is either:

1. Obtained from a manufacturer or preparer licensed pursuant to .02 (11)(i) or equivalent Agreement State, licensing state or NRC requirements; or

2. Prepared and compounded by an authorized nuclear pharmacist or an authorized user and who meets the requirements specified in (16)(n) or an individual under the supervision of either as specified in (6)(h), from a prescription, in accordance with the regulations of the Georgia State Board of Pharmacy.

(b) 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 of 0.1 ~~mrem~~ millirem (1 microsievert) per hour to 100 ~~mrem~~ millirem (1 millisievert) per hour. The instrument shall be operable and calibrated in accordance with (7)(c).

(9) Specific Requirements for the Use of Reagent Kits for Imaging and Localization Studies.

(a) A licensee may use any unsealed radioactive material in a non-gaseous or non-aerosol diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use involving imaging and localization studies prepared for medical use that is either:

Rule .05(9)(a)1.

1. Obtained from a manufacturer or preparer licensed pursuant to .02 (11)(i) or equivalent Agreement State licensing state or NRC requirements; or

2. Prepared and compounded by an authorized nuclear pharmacist or an authorized user and who meets the requirements specified in (16)(n) or an individual under the supervision of either as specified in (6)(h), from a prescription, in accordance with the regulations of the Georgia State Board of Pharmacy.

(b) A licensee shall elute generators in compliance with (10).

(c) A licensee shall use radioactive aerosols or gases in compliance with (11).

(d) 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 0.1 ~~mrem~~ millirem (1 microsievert) per hour to 100 ~~mrem~~ millirem (1 millisievert) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ~~1~~ one ~~mrem~~ millirem (10 microsieverts) per hour to 1000 ~~mrem~~ millirem (10 millisieverts) per hour. The instruments shall be operable and calibrated in accordance with (7)(c).

(10) Radionuclide Contaminants.

(a) A licensee shall not administer a radiopharmaceutical containing:

1. More than 0.15 ~~μCi~~ microcuries of Mo-99 per mCi of Tc-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m);

2. More than 0.02 ~~μCi~~ microcuries of Sr-82 per mCi of Rb-82 chloride (0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection);

3. More than 0.2 ~~μCi~~ microcuries of Sr-85 per mCi of Rb-82 (0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection).

(b) A licensee preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for the generator system, to determine compliance with the limits specified in (10)(a).

Rule .05(10)(c)

(c) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement for ~~3~~ three years. The record shall include, for each elution or extraction tested, the measured activity of the radiopharmaceutical expressed in ~~mCi~~ millicuries (megabecquerels), the measured activity of contaminant expressed in ~~µCi~~ microcuries (kilobecquerels), the ratio of the measures expressed as ~~µCi~~ microcuries (kilobecquerels) of contaminant per ~~mCi~~ millicuries (megabecquerel) of radiopharmaceutical, the date of the test, and the initials of the individual who performed the test.

(d) A licensee shall report immediately to the Department each occurrence of radionuclide contaminant concentration exceeding the limits specified in (10)(a).

(11) Control of Aerosols and Gases.

(a) 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.

(b) 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.

(c) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(d) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 10 CFR 20.1001-20.2401, effective January 1, 1994. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(e) A licensee shall post the time calculated in (11)(d) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(f) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for ~~3~~ three years.

(g) A copy of the calculations required in (11)(d) shall be recorded and retained for the duration of the license.

Rule .05(12)

(12) Specific Requirements for the Use of Radiopharmaceuticals for Therapy.

(a) A licensee may use for therapeutic administration any unsealed radioactive material prepared for medical use that is either:

1. Obtained from a manufacturer or preparer licensed pursuant to .02 (11)(i) or equivalent Agreement State or NRC requirements; or

2. Prepared and compounded by an authorized nuclear pharmacist or an authorized user and who meets the requirements specified in (16)(n) or an individual under the supervision of either as specified in (6)(h), from a prescription in accordance with the regulations of the Georgia State Board of Pharmacy.

(b) Safety Instruction.

1. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.

2. To satisfy (12)(b)1., the instruction shall describe the licensee's procedures for:

(i) Patient or human research subject control;

(ii) Visitor control;

(iii) Contamination control;

(iv) Waste control;

(v) Notification of the Radiation Safety Officer or authorized user in case of the patient's or human research subject's death or medical emergency; and

(vi) Training for workers as required by Rule .07 of this Chapter.

Rule .05(12)(b)3.

3. A licensee shall keep a record of individuals receiving instruction required by (12)(b)1., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the Department for ~~3~~ three years.

(c) Safety Precautions.

1. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with (7)(k), a licensee shall:

(i) Provide a private room with a private sanitary facility;

(ii) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room;

(iii) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(iv) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Rule .03 of this Chapter and retain for ~~3~~ three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in ~~mrem~~ millirem (microsieverts) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

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

Rule .05(12)(c)1.(vi)

(vi) Instruct the patient or human research subject in radiation safety precautions that will help to keep radiation doses to household members and the public as low as reasonably achievable before authorizing release of the patient;

(vii) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 dpm (3.33 becquerels) per 100 square centimeters; and

(viii) Measure the thyroid burden of each individual who helped prepare or administer a dosage of I-131 within ~~3~~ three days after administering the dosage, and retain for a period required by Rule .03 of this Chapter a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Other procedures acceptable to the Department may be used for individuals who only prepare, but do not administer, doses of stabilized I-131.

2. For each non-hospitalized patient or human research subject receiving radiopharmaceutical therapy, the licensee shall instruct the patient or human research subject in radiation safety precautions that will help to keep radiation doses to the household members and the public as low as reasonably achievable.

3. A licensee shall notify the Radiation Safety Officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

(d) Possession of Survey Instruments. A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 ~~mrem~~ millirem (1 microsievert) per hour to 100 ~~mrem~~ millirem (1 millisieverts) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ~~1~~ one ~~mrem~~ millirem (10 microsieverts) per hour to 1000 ~~mrem~~ millirem (10 millisieverts) per hour. The instruments shall be operable and calibrated in accordance with (7)(c).

Rule .05(13)

(13) Specific Requirements for the Use of Sealed Sources for Diagnosis.

(a) ~~A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:~~ A licensee shall use only sealed sources for diagnostic medical uses:

1. ~~Iodine-125 as a sealed source in a device for bone mineral analysis;~~ Approved in the Sealed Source and Device Registry; and

2. ~~Americium-241 as a sealed source in a device for bone mineral analysis;~~ Handled in accordance with the manufacturer's radiation safety instructions.

~~3. Gadolinium-153 as a sealed source in a device for bone mineral analysis; and~~

~~4. Iodine-125 as a sealed source in a portable device for imaging.~~

(b) Availability of Survey Instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 ~~mrem~~ millirem (1 microsievert) per hour to 100 ~~mrem~~ millirem (1 millisievert) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ~~1~~ one ~~mrem~~ millirem (10 microsieverts) per hour to 1000 ~~mrem~~ millirem (10 millisieverts) per hour. The instrument shall be operable and calibrated in accordance with (7)(c).

(14) ~~Specific Requirements for the Use of Sources for Brachytherapy.~~ Use of Sealed Sources for Manual Brachytherapy.

~~(a) A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:~~

~~1. Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

~~2. Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

~~3. Gold-198 as a sealed source in seeds for interstitial treatment of cancer;~~

~~4. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer; Rule .05(14)(a)5.~~

Rule .05(14)(a)

~~5. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;~~

~~6. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and~~

~~7. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer~~.

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

1. As approved in the Sealed Source and Device Registry; or

2. In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of Rule .05(6)(m)4. are met.

(b) Safety Instruction.

1. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy. Refresher training shall be provided at intervals not to exceed one year.

2. To satisfy (14)(b)1., the instruction shall describe:

(i) Size and appearance of the brachytherapy sources;

(ii) Safe handling and shielding instructions in case of a dislodged source;

(iii) Procedures for patient or human research subject control;

(iv) Procedures for visitor control;

(v) Procedures for notification of the Radiation Safety Officer or authorized user if the patient or human research subject dies or has a medical emergency; and

(vi) Training for workers as required by Rule .07 of this Chapter.

3. A licensee shall maintain a record of individuals receiving instruction required by (14)(b)1., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for ~~3~~ three years.

Rule .05(14)(c)

(c) Safety Precautions.

1. For each patient or human research subject receiving implant therapy a licensee shall:

(i) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the radiation dose limits for individual members of the public as specified in Rule .03 of this Chapter at a distance of ~~1~~ one meter from the implant;

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

(iii) Authorize visits by individuals under 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(iv) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with Rule .03 of this Chapter and retain for ~~3~~ three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in ~~mrem~~ millirem (microsieverts) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

(v) Provide the patient or human research subject with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient or human research subject if the patient or human research subject was administered a permanent implant.

2. A licensee shall notify the Radiation Safety Officer or authorized user immediately if the patient or human research subject dies or has a

medical emergency.

Rule .05(14)(d)

(d) Manual Brachytherapy Sources Inventory.

1. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

2. A licensee shall make a record of brachytherapy source utilization which includes:

(i) The names of the individuals permitted to handle the sources;

(ii) The number and activity of sources removed from storage, the room number of use and patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(iii) The number and activity of sources returned to storage, the room number of use and patient's or human research subject 's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

3. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall ~~make~~ retain a record of each survey in accordance with Rule .05(17)(b).

~~(e) Release of Patients Treated With Temporary Implants.~~

~~1. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.~~

Rule .05(14)(e)

~~2. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with (14)(e)1. for 3 years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient or human research subject expressed as mrem (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.~~

~~(f)~~(e) Possession of Survey Instruments. A licensee authorized to use radioactive material for implant therapy shall have in its possession possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 ~~mrem~~ millirem (1 microsievert) per hour to 50 ~~mrem~~ millirem (500 microsieverts) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ~~1~~ one ~~mrem~~ millirem (10 microsieverts) per hour to 1000 ~~mrem~~ millirem (10 millisieverts) per hour. The instruments shall be operable and calibrated in accordance with (7)(c).

(15) ~~Specific Requirements for the Use of a Sealed Source in Teletherapy.~~Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Stereotactic Radiosurgery Unit.

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

~~(a) Use of a Sealed Source in a Teletherapy Unit. A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.~~

1. As approved in the Sealed Source and Device Registry; or

2. In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of Rule .05(6)(m)5. are met.

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

1. 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.

Rule .05(15)(b)2.

2. A licensee shall retain a record of the surveys in accordance with Rule .05(17)(b).

(~~b~~c) Installation, Maintenance, Adjustment, and Repair. ~~Maintenance and Repair Restrictions. Only a person specifically licensed by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.~~

1. Only a person specifically licensed by the Department, the Nuclear Regulatory Commission, an Agreement State, or Licensing State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or 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).

2. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Department, an Agreement State, Licensing 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 stereotactic units.

3. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department, an Agreement State, Licensing 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.

4. A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and stereotactic radiosurgery units in accordance with Rule .05(17)(c).

(~~c~~d) Amendments. In addition to the requirements specified in (4), a licensee shall apply for and receive a license amendment before:

1. Making any change in the treatment room shielding;

2. Making any change in the location of the teletherapy unit or stereotactic radiosurgery unit within the treatment room;

Rule .05(15)(d)3.

3. Using the ~~tele~~therapy unit in a manner that could result in increased radiation levels in areas outside the ~~teletherapy~~ treatment room;

4. Relocating the teletherapy unit; or

5. Allowing an individual not listed on the licensee's license to perform the duties of the medical physicist.

(~~de~~) ~~Safety Instruction.~~ Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units.

~~1. A licensee shall conspicuously post written instructions at the teletherapy unit console. These instructions shall inform the operator of:~~

~~(i) The procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;~~

~~(ii) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and~~

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

~~2. A licensee shall provide instruction in the topics identified in (15)(d)1. to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed 1 year.~~

~~3. A licensee shall maintain a record of individuals receiving instruction required by (15)(d)2., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 3 years.~~

1. A licensee shall:

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

(ii) 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);

Rule .05(15)(e)1.(iii)

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

(iv) 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.

2. A copy of the procedures required by Rule .05(15)(e)1.(iv) must be physically located at the unit console.

3. A licensee shall post instructions at the unit console to inform the operator of:

(i) The location of the procedures required by Rule .05(15)(e)1.(iv); and

(ii) 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.

4. A licensee shall provide instruction, initially and at least annually, to all

individuals who operate the unit, as appropriate to the individual's assigned duties, in:

(i) The procedures identified in Rule .05(15)(e)1.(iv); and

(ii) The operating procedures for the unit.

5. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially

Rule .05(15)(e)5.

and at least annually.

6. A licensee shall retain a record of individuals receiving instruction required by Rule .05 .05(15)(e)4., in accordance with Rule .05(17)(a).

(ef) ~~Doors, Interlocks, and Warning Systems.~~ Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units.

~~1. A licensee shall control access to the teletherapy room by a door at each entrance.~~

~~2. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:~~

~~(i) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;~~

~~(ii) Turn the beam of radiation "off" immediately when an entrance door is opened; and~~

~~(iii) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.~~

~~3. A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.~~

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

2. A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(i) Prevent the operator from initiating the treatment cycle unless

each treatment room entrance door is closed;

(ii) Cause the source(s) to be shielded promptly when an entrance door is opened; and

(iii) 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.

Rule .05(15)(f)3.

3. 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.

4. 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.

5. 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.

6. In addition to the requirements specified in Rule .05(15)(f)1. through (15)(f)5., a licensee shall:

(i) 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.

(ii) 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.

Rule .05(15)(f)6.(iii)

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

(iv) Notify the Radiation Safety Officer, or his 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.

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

(i) Remains in the unshielded position; or

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

(~~f~~g) Possession of Survey Instrument. A licensee authorized to use radioactive material in a ~~tele~~therapy unit shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 ~~mrem~~ millirem (1 microsievert) per hour to 50 ~~mrem~~ millirem (500 microsieverts) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ~~1~~ one ~~mrem~~ millirem (10 microsieverts) per hour to 1000 ~~mrem~~ millirem (10 millisieverts) per hour. The instruments shall be operable and calibrated in accordance with Rule .05(7)(c).

(~~g~~h) Radiation Monitoring Device.

1. A licensee shall have in each ~~tele~~therapy room a permanent radiation

monitor capable of continuously monitoring beam status.

2. Each radiation monitor shall be capable of providing visible notice of a ~~tele~~therapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the ~~tele~~therapy room.

3. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the ~~tele~~therapy unit. This backup power supply may be a battery system.

4. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the ~~tele~~therapy unit is used for treatment of patients or human research subjects.

5. A licensee shall maintain a record of the check required by (15)(~~g~~h)4. for

Rule .05(15)(h)5.

~~3~~ three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

6. If a radiation monitor is inoperable, the licensee shall require any individual entering the ~~tele~~therapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record of this as described in (15)(~~g~~h)5.

7. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

~~(h) Viewing System. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.~~

(i) Dosimetry Equipment.

~~1. A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, 1 of the following 2 conditions shall be met:~~

~~(i) The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in~~

Medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(ii) The system shall have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-

Rule .05(15)(i)1.

60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

2. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with (15)(i)1. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in (15)(i)1.

3. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers, and serial numbers of the instruments that were calibrated, intercompared, or compared as required by (15)(i)1. and 2., the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or

~~radiologic physics center accredited by the American Association of Physicists in Medicine.~~

1. 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.

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

   (ii) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the

Rule .05(15)(i)1.(ii)

   calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

2. 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(15)(i)1. 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(15)(i)1.

3. The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with Rule .05(17)(d)(2).

(j) Calibration Measurements of Brachytherapy Sealed sources.

1. Prior to the first medical use of a brachytherapy sealed source on of after the effective date of this rule, a licensee shall perform the following:

(i) Determine the source output or activity using a dosimetry system that meets the requirements of (15)(i);

(ii) Determine source positioning accuracy within applicators; and

(iii) Use published protocols accepted by nationally recognized bodies to meet the requirements of (15)(j)1.(i) and (ii).

2. 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 (15)(j)1.

3. A licensee shall mathematically correct the outputs or activities determined in (15)(j)1. for physical decay at intervals consistent with 1.0 percent physical decay.

4. An authorized medical physicist shall perform or review the calculation measurements made pursuant to (15)(j)1., (j)2. and (j)3.

5. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for

Rule .05(15)(j)5.

ophthalmic treatment. The decay must be based on the activity determined in accordance with (15)(j)1., (j)2., and (j)3.

6. A licensee shall retain a record of each calibration in accordance with (17)(l).

7. A licensee shall retain a record of decay calculations required by (15)(j)5. in accordance with (17)(m).

(jk) Full Calibration Measurements on Teletherapy Units.

~~1. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:~~

(i) Before the first medical use of the unit;

(ii) 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; and

(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

(iii) At intervals not exceeding 1 year.

2. To satisfy the requirement of (15)(j)1., full calibration measurements shall include determination of:

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

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

(iii) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(iv) Timer accuracy, constancy, and linearity;

(v) "On-off" error; and

(vi) The accuracy of all distance measuring and localization devices in medical use.

3. A licensee shall use the dosimetry system described in (15)(i) to measure the output for 1 set of exposure conditions. The remaining radiation measurements required in (15)(j)2.(i) may then be made using a dosimetry system that indicates relative dose rates.

4. A licensee shall make full calibration measurements required by (15)(j)1. in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in

~~Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics, Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213.~~

~~5. A licensee shall correct mathematically the outputs determined in (15)(j)2. for physical decay for intervals not exceeding 1 month for cobalt-60 and intervals not exceeding 6 months for cesium-137.~~

~~6. Full calibration measurements required by (15)(j)2.(i) and physical decay corrections required by (15)(j)5. shall be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.~~

~~7. A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.~~

Rule .05(15)(k)1.

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

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

   (ii) Before medical use under the following conditions:

      (I) Whenever spot-check measurements indicate that the output differs by more than five 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

(iii) At intervals not exceeding one year.

2. To satisfy the requirement of Rule .05(15)(k)1., full calibration measurements must include determination of:

(i) The output within +/- three percent for the range of field sizes and for the distance or range of distances used for medical use;

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

(iii) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

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

(v) On-off error; and

(vi) The accuracy of all distance measuring and localization devices in medical use.

3. A licensee shall use the dosimetry system described in Rule .05(15)(i)1. to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(15)(k)2.(i) may be made using a dosimetry system that indicates relative dose rates.

Rule .05(15)(k)4.

4. A licensee shall make full calibration measurements required by Rule .05(15)(k)1. in accordance with published protocols accepted by nationally recognized bodies.

5. A licensee shall mathematically correct the outputs determined in Rule .05(15)(k)2(i) for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

6. Full calibration measurements required by Rule .05(15)(k)1. and physical decay corrections required by Rule .05(15)(k)5. must be

performed by the authorized medical physicist.

7. A licensee shall retain a record of each calibration in accordance with Rule .05(17)(e).

(l) Full Calibration Measurements on Remote Afterloader Units.

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

(i) Before the first medical use of the unit;

(ii) 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; and

(iii) At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(iv) At intervals not exceeding one year for low dose-rate remote afterloader units.

2. To satisfy the requirement of Rule .05(15)(l)1., full calibration measurements must include, as applicable, determination of:

(i) The output within +/- five percent;

Rule .05(15)(l)2.(ii)

(ii) Source positioning accuracy to within +/- one millimeter;

(iii) Source retraction with backup battery upon power failure; and

(iv) Length of the source transfer tubes;

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

(vi) Length of the applicators; and

(vii) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

3. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in Rule .05(l)2., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

4. A licensee shall use the dosimetry system described in Rule .05(15)(i)1. to measure the output.

5. A licensee shall make full calibration measurements required by Rule .05(15)(l)1. in accordance with published protocols accepted by nationally recognized bodies.

6. 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(15)(l)1. through (l)5.

7. A licensee shall mathematically correct the outputs determined in Rule .05(15)(l)2.(i) for physical decay at intervals consistent with one percent physical decay.

8. Full calibration measurements required by Rule .05(15)(l)1. and physical decay corrections required by Rule .05(15)(l)7. must be performed by the authorized medical physicist.

9. A licensee shall retain a record of each calibration in accordance with Rule .05(17)(e).

(m) Full Calibration Measurements on Stereotactic Radiosurgery Units.

1. A licensee authorized to use a stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

Rule .05(15)(m)1.(i)

(i) Before the first medical use of the unit;

(ii) Before medical use under the following conditions:

(I) Whenever spot-check measurements indicate that the output differs by more than five 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 stereotactic radiosurgery unit in a new location; and

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

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

2. To satisfy the requirement of Rule .05(15)(m)1., full calibration measurements must include determination of:

(i) The output within +/- three percent;

(ii) Relative helmet factors;

(iii) Isocenter coincidence;

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

(v) On-off error;

(vi) Trunnion centricity;

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

(viii) Helmet microswitchs;

(ix) Emergency timing circuits; and

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

Rule .05(15)(m)3.

3. A licensee shall use the dosimetry system described in Rule .05(15)(i)1. to measure the output for one set of exposure conditions. The remaining radiation measurements required in Rule .05(15)(m)2.(i) may be made using a dosimetry system that indicates relative dose rates.

4. A licensee shall make full calibration measurements required by Rule .05(15)(m)1. in accordance with published protocols accepted by nationally recognized bodies.

5. A licensee shall mathematically correct the outputs determined in Rule .05(15)(m)2.(i) at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

6. Full calibration measurements required by Rule .05(15)(m)1. and physical decay corrections required by Rule .05(15)(m)5. must be performed by the authorized medical physicist.

7. A licensee shall retain a record of each calibration in accordance with Rule .05(17)(e).

(kn) Periodic Spot-Checks for Teletherapy Units.

~~1. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed 1 month.~~

~~2. To satisfy the requirement of (15)(k)1., spot checks shall include determination of:~~

~~(i) Timer constancy and timer linearity over the range of use;~~

~~(ii) "On-off" error;~~

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

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

~~(v) The output for 1 typical set of operating conditions; and~~

~~(vi) The difference between the measurement made in (15)(k)2.(v) 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).~~

~~3. A licensee shall use the dosimetry system described in (15)(i) to make the spot check required in (15)(k)2.(v).~~

~~4. A licensee shall perform spot checks required by (18)(k)1. in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output~~

~~spot check measurements.~~

~~5. A licensee shall have the teletherapy physicist review the results of each output spot check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for 2 years.~~

~~6. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed 1 month.~~

~~7. To satisfy the requirement of (15)(k)6., safety spot checks shall assure proper operation of:~~

~~(i) Electrical interlocks at each teletherapy room entrance;~~

~~(ii) 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;~~

~~(iii) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;~~

~~(iv) Viewing systems;~~

~~(v) Treatment room doors from inside and outside the treatment room; and~~

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

~~8. A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the Department.~~

~~9. A licensee shall promptly repair any system identified in (15)(k)7. that is not~~

Rule .05(15)(n)1.

~~operating properly. The teletherapy unit shall not be used until all repairs are completed.~~

~~10. A licensee shall maintain a record of each spot check required by (15)(k)1. and (15)(k)6. for 3 years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial~~

~~number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the timer constancy and linearity, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.~~

1. 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:

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

   (ii) On-off error;

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

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

   (v) The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(15)(i)2.; and

   (vi) The difference between the measurement made in Rule .05(15)(n)1.(v) 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).

2. A licensee shall perform measurements required by Rule .05(15)(n)1. in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

Rule .05(15)(n)3.

3. 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.

4. 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 :

(i) Electrical interlocks at each teletherapy room entrance;

(ii) 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);

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

(iv) Viewing and intercom systems;

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

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

5. If the results of the checks required in Rule .05(15)(n)4. 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.

6. A licensee shall retain a record of each spot-check required by Rule .05(15)(n)1. and (n)4., in accordance with Rule .05(17)(f).

(o) Periodic Spot-Checks for Remote Afterloader Units.

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

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

(ii) Prior to each patient treatment with a low dose-rate remote

Rule .05(15)(o)1.(ii)

afterloader unit; and

(iii) After each source installation.

2. The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in Rule .05(15)(o)1. The authorized medical physicist need not actually perform the spot-check measurements.

3. 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)(within 30 days) in writing of the results of each spot check.

4. To satisfy the requirements of Rule .05(15)(o)1., spot-checks must, at a minimum, assure proper operation of:

(i) Electrical interlocks at each remote afterloader unit room entrance;

(ii) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(iii) Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;

(iv) Emergency response equipment;

(v) Radiation monitors used to indicate the source position;

(vi) Timer accuracy;

(vii) Clock (date and time) in the unit's computer; and

(viii) Decayed source(s) activity in the unit's computer.

5. If the results of the checks required in Rule .05(15)(o)4. 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.

6. A licensee shall retain a record of each check required by Rule .05(15)(o)4. in accordance with Rule .05(17)(g).

(p) Periodic Spot-Checks for Stereotactic Radiosurgery Units. Rule .05(15)(p)1.

1. A licensee authorized to use a stereotactic radiosurgery unit for medical use shall perform spot-checks of each stereotactic radiosurgery facility and on each unit:

   (i) Monthly;

   (ii) At the beginning of each day of use; and

   (iii) After each source installation.

2. The licensee shall have the authorized medical physicist:

   (i) Establish written procedures for performing the spot-checks required in Rule .05(15)(p)1.; and

   (ii) Review the results of each spot-check required by Rule .05(15)(p)1.(i) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

3. To satisfy the requirements of Rule .05(15)(p)1.(i)., spot-checks must, at a minimum:

   (i) Assure proper operation of:

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

      (II) Helmet microswitchs;

      (III) Emergency timing circuits; and

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

   (ii) Determine :

      (I) The output for one typical set of operating conditions measured with the dosimetry system described in Rule .05(15)(i)2.;

      (II) The difference between the measurement made in Rule .05(15)(p)3.(ii)(I) 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);

Rule .05(15)(p)3.(ii)(III)

(III) Source output against computer calculation;

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

(V) On-off error; and

(VI) Trunnion centricity.

4. To satisfy the requirements of Rule .05(15)(p)1.(ii) and (p)1.(iii), spot-checks must assure proper operation of:

(i) Electrical interlocks at each stereotactic radiosurgery room entrance;

(ii) Source exposure indicator lights on the stereotactic radiosurgery unit, on the control console, and in the facility;

(iii) Viewing and intercom systems;

(iv) Timer termination;

(v) Radiation monitors used to indicate room exposures; and

(vi) Emergency off buttons.

5. A licensee shall arrange for prompt repair of any system identified in Rule .05(15)(p)3. that is not operating properly.

6. If the results of the checks required in Rule .05(15)(p)4. 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.

7. A licensee shall retain a record of each check required by Rule .05(15)(p)3. and (p)4. in accordance with Rule .05(17)(h).

(q) Additional Technical Requirements for Mobile Remote Afterloader Units.

1. A licensee providing mobile remote afterloader service shall:

(i) Check survey instruments before medical use at each address of use or on each day of use, which ever is more frequent; and

(ii) Account for all sources before departure from a client's

address of

Rule .05(15)(q)1.(ii)

use.

2. In addition to the periodic spot-checks required by Rule .05(15)(o), 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 :

   (i) Electrical interlocks on treatment area access points;

   (ii) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

   (iii) Viewing and intercom systems;

   (iv) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

   (v) Radiation monitors used to indicate room exposures;

   (vi) Source positioning (accuracy); and

   (vii) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

3. In addition to the requirements for checks in Rule .05(15)(q)2., 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.

4. If the results of the checks required in Rule .05(15)(q)2. 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.

5. A licensee shall retain a record of each check required by Rule .05(15)(q)2. in accordance with Rule .05(17)(i).

(Ir) Radiation Surveys ~~for Teletherapy Facilities.~~

~~1. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by~~

~~(15)(c), the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with (7)(c) to~~

Rule .05(15)(r)1.

~~verify that:~~

~~(i) The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 mrem (100 microsieverts) per hour and 2 mrem (20 microsieverts) per hour, respectively; and~~

~~(ii) With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:~~

~~(I) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Rule .03 of this Chapter; and~~

~~(II) Radiation levels in unrestricted areas do not exceed the limits specified in Rule .03 of this Chapter.~~

~~2. If the results of the surveys required in (18)(l)1. indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:~~

~~(i) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or~~

~~(ii) Until the licensee has received a specific exemption from the Department.~~

~~3. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in mrem (microsieverts) per hour, the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area, and the signature of the Radiation Safety~~

~~Officer.~~

1. In addition to the survey requirements in Rule .03(8) of these regulations,

Rule .05(15)(r)1.

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.

2. The licensee shall make the survey required by Rule .05(15)(r)1. 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).

3. A licensee shall retain a record of the radiation surveys required by Rule .05(15)(r)1. of this section in accordance with Rule .05(17)(j).

~~(m)~~ ~~Safety Spot Checks for Teletherapy Facilities.~~

~~1.~~ ~~A licensee shall promptly check all systems listed in (15)(k)7. for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by (15)(c).~~

~~2.~~ ~~If the results of the safety spot checks required in (15)(m)1. indicate the malfunction of any system specified in (15)(k), the 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.~~

~~3.~~ ~~A licensee shall maintain a record of the safety spot checks following installation of a source for 3 years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the Radiation Safety Officer.~~

(~~n~~s) Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If the survey required by (15)(~~l~~)(r) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those

permitted by Rule .03 of this Chapter, before beginning the treatment program the licensee shall:

1. Either equip the unit with stops or add additional radiation shielding to ensure compliance with Rule .03 of this Chapter;

2. Perform the survey required by (15)~~(l)~~(r) again; and

3. Include in the report required by (15)~~(o)~~(t)the results of the initial survey, a description of the modification made to comply with (15)~~(n)~~(s)1., and the results of the second survey; or

Rule .05(15)(s)4

.

4. Request and receive a license amendment under Rule .03 of this Chapter that authorizes radiation levels in unrestricted areas greater than those permitted by Rule .03 of this Chapter.

(~~o~~t) Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A licensee shall furnish a copy of the records required in (15)~~(l)~~(r), ~~(m),~~ and ~~(n)~~(s) and the output from the teletherapy source expressed as rad (Grays) per hour at ~~1~~ one meter from the source as determined during the full calibration required in (15)(jk) to the Department within 30 days following completion of the action that initiated the record requirement.

(~~p~~u) Five-Year Inspection for Teletherapy and Stereotactic Radiosurgery Units.

~~1. A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.~~

~~2. This inspection and servicing shall only be performed by persons specifically licensed to do so by the Department, an Agreement State, or the U.S. Nuclear Regulatory Commission.~~

~~3. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.~~

1. A licensee shall have each teletherapy unit and stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

2. This inspection and servicing may only be performed by persons specifically licensed to do so by the Department, an Agreement State, a Licensing State or the Nuclear Regulatory Commission.

3. A licensee shall keep a record of the inspection and servicing in accordance with Rule .05(17)(k).

(v) Therapy-Related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols

Rule .05(15)(v)

accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;

2. The accuracy of dose, dwell time, and treatment time calculations at representative points;

3. The accuracy of isodose plots and graphic displays;

4. The accuracy of the software used to determine radioactive source positions from radiographic images; and

5. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(w) 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:

1. The applicant or licensee has submitted the information required by Rule .05(3)(a), and Rule .02(8); and

2. The applicant or licensee has received written approval from the NRC, an agreement state, or licensing state in a license and uses the material in accordance with the regulations and specific conditions the NRC, agreement state, or licensing state considers necessary for the medical use of the material.

(16) Specific Requirements for Training.

(a) Radiation Safety Officer. Except as provided in (16)(b), an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in (6)(e) shall:

1. Be certified by the:

(i) American Board of Health Physics in Comprehensive Health Physics;

(ii) American Board of Radiology in Radiological Physics, Diagnostic Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics;

Rule .05(16)(a)1.(iii)

(iii) American Board of Nuclear Medicine;

(iv) American Board of Science in Nuclear Medicine;

(v) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science;

(vi) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine;

(vii) American Board of Medical Physics in Radiation Oncology Physics;

(viii) American Osteopathic Board of Radiology; ~~or~~

(ix) American Osteopathic Board of Nuclear Medicine; or

2. Have had 200 hours of classroom and laboratory training as follows:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology;

(v) Radiopharmaceutical chemistry; and

(vi) One year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Department, Agreement

State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

3. Be an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of ~~for those~~ radioactive material for which the individual has ~~uses that come within the~~ Radiation Safety Officer's responsibilities ~~and have had a minimum of 80 hours of instruction in basic radionuclide handling techniques~~.
Note: It is permissible to have more than one Radiation Safety Officer to see that all requirements of the license are met.

Rule .05(16)(b)

(b) ~~Training~~ Provisions for experienced Radiation Safety Officer, Medical Physicist, Authorized User, and Nuclear Pharmacist.

1. An individual identified as a Radiation Safety Officer, medical physicist, or a nuclear pharmacist on a Department, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license ~~on May 22, 1991~~ prior to September 1, 2001 who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of (16)(a), (16)(j), and (16)(n) respectively. ~~until renewal of the license.~~

2. ~~For renewal of the license, the licensee shall name a Radiation Safety Officer who meets the requirements of (16)(a).~~ Physicians, dentist, or podiatrists identified as authorized users for the medica, dental, or podiatric use of radioactive material on a Department, Agreement State, Licensing State or Nuclear Regulatory Commission license issued before September 1, 2001 who performs only those medical uses for which they were authorized on that date need not comply with the training requirements of (16)(c), (16)(d), (16)(e), (16)(f), (16)(g), (16)(h), and (16)(i).

Note: It is permissible to have more than one RSO to see that all requirements of the license are met.

(c) Training for Uptake, Dilution, or Excretion Studies. Except as provided in (16)(k) and (16)(l), the licensee shall require the authorized user of a radiopharmaceutical listed in (8)(a) to be a physician who:

1. Is certified in:

(i) Nuclear medicine by the American Board of Nuclear Medicine;

(ii) Diagnostic radiology by the American Board of Radiology;
(iii) Radiology if certified by the American Board of Radiology prior to 1979;

(iv) Diagnostic radiology (or radiology if certified prior to 1979) by the American Osteopathic Board of Radiology; ~~or~~

(v) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;

(vi) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

Rule .05(16)(c)2.

2. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience.

(d) Training for Imaging and Localization Studies. Except as provided in (16)(k) or (16)(l), the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in (9) to be a physician who:

1. Is certified in:

(i) Nuclear medicine by the American Board of Nuclear Medicine;

(ii) Diagnostic radiology by the American Board of Radiology;

(iii) Radiology, if certified by the American Board of Radiology prior to 1979;

(iv) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; ~~or~~

(v) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; ~~or~~

(vi) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

2. Has successfully completed a ~~6~~ six months training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience.

(e) Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in (16)(k), the licensee shall require the authorized user of a radiopharmaceutical listed in (12)(a) for therapy to be a physician who:

1. Is certified in:

(i) Nuclear medicine by the American Board of Nuclear Medicine;

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

Rule .05(16)(e)1.(iii)

(iii) Radiology if certified by the American Board of Radiology prior to 1979;

(iv) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;

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

(vi) Nuclear medicine by the Canadian Board of Nuclear Medicine;

(vii) Therapeutic radiology by the Royal College of Physicians and Surgeons of Canada; ~~or~~

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

(ix) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

2. Has successfully completed a ~~6~~ six months training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in therapy using unsealed radioactive material.

(f) Training for Therapeutic Use of Brachytherapy Sources. Except as provided in (16)(k), the licensee shall require the authorized user using a brachytherapy source specified in (14)(a) for therapy to be a physician who:

1. Is certified in:

(i) Radiation oncology or therapeutic radiology by the American Board of Radiology;

(ii) Radiology if certified by the American Board of Radiology prior to 1979;

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

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

Rule .05(16)(f)1.(v)

(v) Therapeutic radiology by the Royal College of Physicians and Surgeons of Canada; or

2. Has successfully completed a ~~6~~ six months training program in radiation oncology or therapeutic radiology that has been approved

by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience.

(g) Training for Ophthalmic Use of Strontium-90. Except as provided in (16)(k), the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

1. Is certified in radiation oncology or therapeutic radiology by the American Board of Radiology;

2. Is certified in radiology by the American Board of Radiology prior to 1979; or

3. Is in the active practice of radiation oncology, therapeutic radiology, or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology.

(h) Training for Use of Sealed Sources for Diagnosis. Except as provided in (16)(k), the licensee shall require the authorized user using a sealed source in a device specified in (13)(a) to be a physician, dentist, or podiatrist who:

Rule .05(16)(h)1.

1. Is certified in:

   (i) Diagnostic radiology with special competence in nuclear radiology, radiation oncology, or therapeutic radiology by the American Board of Radiology;

   (ii) Radiology by the American Board of Radiology if certified prior to 1979;

   (iii) Nuclear medicine by the American Board of Nuclear Medicine; ~~or~~

   (iv) Diagnostic radiology by the American Osteopathic Board of Radiology; ~~or~~

   (v) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada.; or

2. Has completed ~~8~~ eight hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training shall include:

   (i) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

   (ii) Radiation biology; and

   (iii) Radiation protection and training in the use of the device for the purposes authorized by the license.

(i) Training for Teletherapy. Except as provided in (16)(k), the licensee shall require the authorized user of a sealed source specified in (15)(a) in a teletherapy unit to be a physician who:

1. Is certified in:

   (i) Radiation oncology or therapeutic radiology by the American Board of Radiology;

   (ii) Radiology if certified by the American Board of Radiology prior to 1979;

Rule .05(16)(i)1.(iii)

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

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

(v) Therapeutic radiology by the Royal College of Physicians and Surgeons of Canada; or

2. Is in the active practice of radiation oncology or therapeutic radiology and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of ~~3~~ three years of supervised clinical experience.

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Radiation biology.

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

(I) Review of the full calibration measurements and periodic spot checks;

(II) Preparing treatment plans and calculating treatment times;

(III) Using administrative controls to prevent misadministrations;

Rule .05(16)(i)2.(ii)(IV)

(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(V) Checking and using survey meters.

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

(j) Training for Authorized Medical ~~Teletherapy~~ Physicist. The licensee shall require the authorized medical ~~Teletherapy~~ physicist to:

1. Be certified by the American Board of Radiology in:

(i) Therapeutic radiological physics;

(ii) Roentgen-ray and gamma-ray physics;

(iii) X-ray and radium physics; or

(iv) Radiological physics~~.~~; or

2. Is certified by the American Board of Medical Physics in Radiation Oncology; or

3. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, or an equivalent training program approved by the Department, another Agreement State , Licensing State or the Nuclear Regulatory Commission and ~~have~~ has completed ~~1~~ one year of full-time training in therapeutic radiological physics and ~~also~~ an additional ~~1~~ one year of full-time work experience under the supervision of a ~~teletherapy~~ medical physicist at a medical institution that includes the task listed~~. To meet this requirement, the individual shall have performed the tasks listed~~ in (7)(f), (15)(j), (15)(k), (15)(l), (15)(m),(15)(n), (15)(o), (15)(p) and (15)(r) ~~under the supervision of a teletherapy physicist during the year of work experience~~.

Rule .05(16)(k)

(k) Training for Experienced Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on a Department [or U.S. Nuclear Regulatory Commission or Agreement State or Licensing State] license on May 22, 1991 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of (16)(a) through (16)(m).

(l) Physician Training in a ~~3~~ three-Month Program. A physician who, before July 1, 1984, began a ~~3~~ three-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of (16)(c) and (16)(d).

(m) Recentness of Training. The training and experience specified in paragraphs (16)(a) through (16)(j) shall have been obtained within the ~~5~~ seven years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

(n) Training for an Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a licensed pharmacist who:

1. Is currently board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

2. Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

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

(V) Radiation biology;

Rule .05(16)(n)2.(ii)

(ii) Didactic training in the following areas:

(I) Shipping, receiving and preforming 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 mistakes in the administration of radioactive material;

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

3. Has obtained written certification signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

(o) Training for Experienced Nuclear Pharmacists.

A licensee may apply for and must receive, except as provided for in .05(4)(b), a license amendment identifying an experienced nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in (16)(n)2. before January 1, 1997, and who is working in nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement and recentness of training to qualify as an authorized nuclear pharmacist.

(17) Records Retention Requirements

(a) Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by Rules .05(14)(b) and (15)(e) for three years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the

name(s) of the individual(s) who provided the instruction.

(b) Records of Radiation Surveys of Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by Rule .05(14)(d)3. and (15)(b) for three years. Each record must include the date and results of Rule .05(17)(b)

the survey, the survey instrument used, and the name of the individual who made the survey.

(c) 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 stereotactic radiosurgery units as required by Rule .05(15)(c) for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(d) Records of Dosimetry Equipment.

1. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with Rule .05(15)(i) for the duration of the license.

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

(i) The date;

(ii) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by Rule .05(15)(i)1. and (i)2.;

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

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

(e) Records of Teletherapy, Remote Afterloader, and Stereotactic Radiosurgery Full Calibrations

1. A licensee shall maintain a record of the teletherapy, remote afterloader, and stereotactic radiosurgery full calibrations required by Rule .05(15)(k), (l) and (m) for three years.

2. The record must include:

(i) The date of the calibration;

(ii) The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and stereotactic radiosurgery

Rule .05(17)(e)2.(ii)

unit(s), the source(s), and instruments used to calibrate the unit;

(iii) The results and assessments of the full calibrations;

(iv) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(v) The signature of the authorized medical physicist who performed the full calibration.

(f) Records of Periodic Spot-Checks for Teletherapy Units.

1. A licensee shall retain a record of each periodic spot-check for teletherapy units required by Rule .05(15)(n) for three years.

2. The record must include:

(i) The date of the spot-check;

(ii) 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;

(iii) An assessment of timer linearity and constancy;

(iv) The calculated on-off error;

(v) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(vi) The determined accuracy of each distance measuring and localization device;

(vii) The difference between the anticipated output and the measured output;

(viii) 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

(ix) 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.

Rule .05(17)(g)

(g) Records of Periodic Spot-Checks for Remote Afterloader Units

1. A licensee shall retain a record of each spot-check for remote afterloader units required by Rule .05(15)(o) for three years.

2. The record must include, as applicable:

(i) The date of the spot-check;

(ii) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(iii) An assessment of timer accuracy;

(iv) 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

(v) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(h) Records of Periodic Spot-Checks for Stereotactic Radiosurgery Units

1. A licensee shall retain a record of each spot-check for stereotactic radiosurgery units required by Rule .05(15)(p) for three years.

2. The record must include:

(i) The date of the spot-check;

(ii) The manufacturer's name, model number, and serial number for the stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(iii) An assessment of timer linearity and accuracy;

(iv) The calculated on-off error;

(v) A determination of trunnion centricity;

(vi) The difference between the anticipated output and the measured output;

(vii) An assessment of source output against computer calculations;
Rule .05(17)(h)2.(viii)

(viii) Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(ix) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(i) Records of Additional Technical Requirements for Mobile Remote Afterloader Units

1. A licensee shall retain a record of each check for mobile remote afterloader units required by Rule .05(15)(q) for three years.

2. The record must include:

(i) The date of the check;

(ii) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(iii) Notations accounting for all sources before the licensee departs from a facility;

(iv) 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

(v) The signature of the individual who performed the check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(j) Records of Surveys of Therapeutic Treatment Units

1. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Rule .05(15)(r) for the duration of use of the unit.

2. The record must include:

(i) The date of the measurements;

Rule .05(17)(j)2.(ii)

(ii) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(iii) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(iv) The signature of the individual who performed the test.

(k) Records of Five-Year Inspection for Teletherapy and Stereotactic Surgery Units

1. A licensee shall maintain a record of the five-year inspections for teletherapy and stereotactic radiosurgery units required by Rule .05(15)(u) for the duration of use of the unit.

(l) Records of Calibration Measurements on Brachytherapy Sources.

1. A licensee shall maintain a record of the calibrations on brachytherapy sources required by (15)(j) for three years after the last use of the source. The record must include the date of the calibration; the manufacturer's mane, model number, and serial number for the source and the instrument used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(m) Records of Decay of Strontium-90 Opthalmic Treatments.

1. The record must include the date and initial activity of the source as determined under (15)(j) and for each decay calculation the date , the source activity and the signature of the authorized medical physicist.

Authority Ga. L 1964, pp. 499, 507, 566-575, as amended (Georgia Radiation Control Act).

391-3-17-.06 TRANSPORTATION OF RADIOACTIVE MATERIAL. AMENDED.

(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 Department, 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 Department or as exempted in (4).

(3) Definitions. As used in this Rule, the following definitions apply:

(a) "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.

(b) "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.

(c) "Containment system" means the assembly components of the packaging intended to retain the radioactive material during transport.

(d) "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.

Rule .06(3)(e)

(e) "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]

(f) "Fissile material" Mean plutonium-238, plutonium-239, plutonium-241, uranium-233, and uranium-235. 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 71.53.

(g) "Low specific activity material" means radioactive material with limited specific activity that 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. LSA material must be in one of three groups:

1. LSA-I

(i) Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and Uranium or thorium concentrates of those ores or;

(ii) Solid unirradiated natural or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

(iii) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

(iv) Mill tailings, contaminated earth, concrete, rubble, other debris, and activated material in which the radioactive material is essentially uniformly distributed and, the average specific activity does not exceed 10^{-6} A_2/g.

---

[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)(xxxx) of these Regulations.

Rule .06(3)(g)2.

2. LSA-II

(i) Water with tritium concentration up to 20.0 Ci/L (0.8 TBq/liter); or

(ii) Material in which the radioactivity is essentially uniformly distributed; and the 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) in which:

(i) The radioactive material is essentially uniformly 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 $_{0.1\ A2;}$ and

(iii) The average specific activity of the solid does not exceed 2 X 10^{-3} A_2/g.

(h) "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.

(i) "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.

(j) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(k) "Normal form radioactive material" means radioactive material which has not been demonstrated to qualify as "special form radioactive material."

Rule .06(3)(l)

(l) "Nuclear waste" means a quantity of source, byproduct or special nuclear material[2] 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.

(m) "Package" means the packaging together with its radioactive contents as presented for transport.

1. "Fissile material package" means a fissile material packaging together with its fissile material contents.

2. "Type B package" means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lb/in^2) 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).

(n) "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.

(o) "Regulations of the US Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.

---

[2] *The definition of nuclear waste in this Part is used in the same way as in 49 CFR 173.403.*

(p) "Regulations of the US Nuclear Regulatory Commission" means the regulations in 10 CFR 71 for purposes of this Rule.

(q) "Special form radioactive material" means radioactive material that satisfies the following conditions:

Rule .06(3)(q)1.

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 test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

(r) "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.

(s) "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 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-5} microcurie/cm^2 (0.4 Bq/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 X 10^4 Bq/cm^2) for beta and gamma
and low toxicity alpha emitters, or 0.1 microcurie/cm^2 (4 X 10^3 Bq/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 x 10^4 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 (4 X 10^3 Bq/cm^2) for all other alpha emitters; and

Rule .06(3)(s)2.

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 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-3} microcurie/cm^2 (40 Bq/$cm^{2)}$ 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 X 10^5 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/cm^2 (8 X 10^4 Bq/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 X 10^5 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/cm^2 (8 X 10^4 Bq/cm^2) for all other alpha emitters.

(t) "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.

(u) "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 A-1 for A_1 and A_2 values for radionuclides" of 10 CFR 71 or may be determined by procedures described in Appendix A of 10 CFR 71.

(v) "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.

(w) "Type B package" is defined in Rule 391-3-17-.01(2)(qqq).

(x) "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.

Rule .06(3)(y)

(y) "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

(z) "Uranium-natural, depleted, enriched" means

1. Natural uranium means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

2. Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

3. Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(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 ~~124.3 incorporated by reference, 39 CFR 111.11 (1974)~~, and the U.S. Postal Service, are exempt from the requirements of this Rule 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 ~~DOT~~ 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) With the exception of (5) and (16), a licensee is exempt from all requirements of this Rule, with respect to shipment or carriage of the following:~~

~~1. A package containing no more than a Type A quantity of radioactive material if the package contains no fissile material; or~~

~~Packages transported between locations within the United States which contain only americium or plutonium in special form with an aggregate radioactivity not to exceed 20 Curies (740 Gbq); or~~

~~3. A package in which the only radioactive material is low specific activity (LSA) material or surface contaminated objects (SCO), provided the external radiation level at 3 m from the unshielded material or objects does not exceed 1 rem/h (10 mSv/h);~~

~~(d) Any physician licensed to dispense drugs in the practice of medicine is exempt from (5) with respect to transport by physician of licensed material for use in the practice of medicine. However any physician operating under this exemption must be licensed under 391-3-17-.05 of these Regulations.~~

~~(e) A licensee is exempt from all requirements of this part, other than (5) and (16) with respect to shipment or carriage of low-specific activity (LSA) material in group LSA-I, or surface contaminated objects (SCOs) in group SCO-I.~~

Rule .06(5)

(5) Transportation of Licensed Material.

(a) Each licensee who transports licensed material outside ~~of~~ the site ~~confines of the licensee's plant or other place~~ of usage, as specified in a Department's 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) ~~in 49 CFR Parts 170 through 189~~.

(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 §§ ~~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) 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~~, Subparts A-D and M.~~

Rule .06(5)(a)1.(ii)(III)

(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 ~~those regulations~~ 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.[3]

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the 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 ~~of the Department~~ 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).

---

[3] ~~Any~~ nNotification of an incidents shall be filed with, or made to, the Department as prescribed in 49 CFR, regardless of and in addition to notification ~~referred to~~ ~~in those~~ made to DOT ~~requirements shall be filed with,~~ or ~~made~~ to other~~, the Department.~~ agencies.

Rule .06(7)(b)

(b) This general license applies only to a licensee who:

1. Has a copy of the specific license, certificate of compliance, or other approval of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

2. Complies with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of this Rule;

3. Prior to the licensee's first use of the package, has registered with the U.S. Nuclear Regulatory Commission; and

4. Has a quality assurance program required by (21).

(c) The general license in (7)(a) applies only when the package approval authorizes use of the package under this general license.

(d) For ~~previously approved~~ a Type B or fissile material package~~s, for which~~ the design of which was approved by NRC before April 1, 1995~~6 and are not designated as either B(U) or B(M) in the NRC Certificate of Compliance, this~~ the general license is subject to additional restrictions of (8).

(8) General License: Previously Approved Type B Packages.

(a) A Type B package previously approved by the NRC, but not designated as B(U) or B(M) in the identification number of the NRC Certificate of Compliance, may be used under the general license of (7) with the following additional limitations:

1 Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with NRC regulations at 10 CFR 71.85(c);

2 A package used for shipment to a location outside the United States is subject to multilateral approval, as defined in DOT regulations at 49 CFR 173.403; and

3. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

Rule .06(8)(b)

(b) A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC certificate of compliance, may be used under the general license of (7) with the following additional conditions:

1. Fabrication of the package is satisfactory completed by April 1, 1999 as demonstrated by application of its model number in accordance with ~~(14)(c)~~ NRC regulations at 10 CFR 71.85(c).;

2. A package used for shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations at 49 CFR 173.403 and

3. A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(9) General License: DOT Specification Container.

(a) A general license is issued to any licensee of the Department 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 has a quality assurance program required by (20) and approved by the Department.~~

~~(c)~~(b) This general license applies only to a licensee who:

1. Has a copy of the specification; and

2. Complies with the terms and conditions of the specification and the applicable requirements of this Rule.

3. Has a quality assurance program required by (21)

~~(d)~~(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.

Rule .06(10)

(10) General License: Use of Foreign-Approved Package.

(a) A general license is issued to any licensee of the Department 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 171.12.

(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; ~~and~~

2. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this Rule; and.– ~~With respect to the quality assurance provisions of (20), the licensee is exempt from design, construction, and fabrication considerations.~~

3. The licensee has a quality assurance program approved by the NRC.

~~(d) This general license applies only to a licensee who has a quality assurance program required by (20) and approved by the Department.~~

(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.

~~(b) This general license applies only to a licensee who has a quality assurance program required by (20) and approved by the Department.~~

(c)(b) This general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

1. Up to 40 grams of uranium-235;

2. Up to 30 grams of uranium-233;

3. Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or

Rule .06(11)(c)4.

4. A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in (11)(b)1., 2., and 3. does not exceed unity.

~~(d)~~(c) 1. Except as specified in (11)(~~c~~b)2., this general license applies only when a package containing more than 15 grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:

```
BOLD
{Minimum.Transport.Index =
(0.4x + 0.67y + z)[1 -15
OVER{(x+y+z)}]}
```

where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium.

2. For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of 15 grams

3. In all cases, the transport index must be rounded up to one decimal place and may not exceed 10.0.

4. The licensee has a quality assurance program required by (21).

(12) General License: Fissile Material, Limited Moderator 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.

~~(b) This general license applies only to a licensee who has a quality assurance program required by (20) and approved by the Department.~~

~~(c)~~(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. Neither beryllium nor hydrogenous material enriched in deuterium is present.

Rule .06(12)(b)3.

3. The total mass of graphite present does not exceed 7.7 times the total mass of uranium-235 plus plutonium.

4. Substances having a higher hydrogen density than water, ~~(e.g.~~ for example certain hydrocarbons oils~~)~~, are not present, except that polyethylene may be used for packing or wrapping.

5. Uranium-233 is not present, and the amount of plutonium does not exceed 1 percent of the amount of uranium-235.

CONTINUED NEXT PAGE

Rule .06(12)(b)6.

6. The amount of uranium-235 is limited as follows:

(i) If the fissile radionuclides are not uniformly distributed, the maximum amount of uranium-235 per package may not exceed the value given in Table 1: or

---

Table 1
Permissible Mass of Uranium-235 per Fissile Material Package
[Nonuniform Distribution]

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272
1.35	320
1	680*
0.92	1200*

*Pursuant to the Department's agreement with the NRC, jurisdiction extends only to 350 grams of uranium-235.

Rule .06(12)(b)6.(ii)

(ii) If the fissile radionuclides are distributed uniformly ~~(i.e.~~, for example cannot form a lattice arrangement within the packaging~~)~~, the maximum amount of uranium-235 per package may not exceed the value given in Table 2: and

---

Table 2
Permissible Mass of Uranium-235 Per Fissile Material Package
[Uniform Distribution]

Uranium enrichment in weight percent of Uranium-235 not exceeding	Permissible maximum grams of Uranium-235 per package
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560*
1.35	800*

*Pursuant to the Department's agreement with the NRC, jurisdiction extends only to 350 grams of uranium-235.

---

7. The transport index of each package based on criticality considerations is taken as 10 times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with either Table 1 or 2 as applicable.

(c) The general license has a quality assurance program required by (21).

(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 ~~would~~ will cause the maximum neutron multiplication.

(14) Preliminary Determinations. Prior to the first use of any packaging for the shipment of radioactive material:

(a) The licensee shall ascertain that there are no ~~cracks, pinholes, uncontrolled~~

~~voids, or other~~ defects which could significantly reduce the effectiveness of the packaging;

Rule .06(14)(b)

(b) Where the maximum normal operating pressure will exceed 35 kilopascal (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

(c) The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC; and

(d) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the NRC.

(15) 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) 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 ~~the NRC~~ 10 CFR 71.45;

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

Rule .06(15)(h)

~~(i)~~(h) ~~Contamination control:~~ 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 ~~removable~~ 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.

~~2.~~ Except as provided in (15)(h~~i~~)~~3~~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.

~~3~~2. In the case of packages transported as exclusive use shipments by rail or highway only, the ~~removable~~ non-fixed radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in (15)(~~i~~h)~~2~~1. The levels at the beginning of transport must not exceed the levels in (15)(~~i~~h)~~2~~1.;

Table 3
Non-Fixed (Removable) External Radioactive Contamination-Wipe Limits

		Maximum Permissible limits	
Contaminant	~~μ~~Ci/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

~~*To convert microcuries (μCi) to SI units of megabecquerels, multiply the values by .037.~~

Rule .06(15)(i)

~~(j)~~(i) ~~Radiation level limitations:~~

~~1.~~ ~~Except as provided in paragraph (2) of this section, each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the~~ Eexternal radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirems per hour (2 mSv/h) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10~~;~~.

(j)~~2.~~ For package transported as exclusive use by rail, highway, or water, radiation levels external to the package may exceed the limits specified in (15)(ji)1. but shall not exceed any of the following:

(i) 200 millirems per hour (2 mSv/h) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1000 millirems per hour (10 mSv/h):

(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;

(ii) 200 millirems per hour (2 mSv/h) at any point on the outer surface of the vehicle, including the ~~upper and lower surfaces~~ top and underside of the vehicle, or, in the case of a flat-bed style vehicle with a personnel barrier[4], 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;

(iii) 10 millirems per hour (0.1 mSv/h) at any point 2 meters from the vertical planes represented by 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 2 meters from the vertical planes projected from the outer edges of the

[4] 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 millirems per hour (2 mSv/h) at ~~the~~ any accessible surface.

vehicle ~~(excluding the top and underside of the vehicle)~~; and

Rule .06(15)(j)2.(iv)

(iv) 2 millirems per hour (0.02 mSv/h) 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

~~3. For shipments made under the provisions of paragraph 2 of this section, the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.~~

~~4. 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 unnecessary delay delivery or unnecessary result in increased radiation levels or radiation exposures to transport workers or members of the general public.~~

(k) 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 (825 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

(l) A package may not incorporate a feature intended to allow continuous venting during transport.

(16) 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 0.002 microcuries per gram (70 Bq/gm) of material 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

Rule .06(16)(d)

(d) The plutonium is shipped in a package specifically authorized, ~~for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC.~~ 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.

(17) 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).

(18) 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 (145)~~;~~ and the conditions of the package approval.

(19) Reports. The licensee shall report to the Department 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.

Rule .06(20)

(20) Advance Notification of Transport of ~~Irradiated Reactor Fuel and~~ Nuclear Waste.

(a) Prior to the transport of any ~~licensed material~~ nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any ~~licensed material~~ nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee,[5] of each state within or through which the ~~licensed material~~ waste will be transported.

(b) Advance notification is required ~~for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required for licensed material, other than irradiated fuel~~ only when:

1. The ~~licensed material~~ nuclear waste is required to be in Type B packaging for transportation;

2. The ~~licensed material~~ nuclear waste is being transported into, within, or through, ~~or across~~ a state ~~boundaries~~ en route to a disposal facility ~~site~~ or to a collection point for transport to a disposal ~~site~~ 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 Appendix A, Table ~~A-14, A_1 and A_2 Values for Radionuclides 10 CFR 71,~~ for special form radioactive material;

---

[5] A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, State Programs, ~~Office of Governmental and Public Affairs,~~ 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.

Rule .06(20)(b)(3)(ii)

(ii) 3000 times the A_2 value of the radionuclides as specified in ~~Appendix A,~~ Table ~~A-1~~ 4 ~~, A_1 and A_2 Values for Radionuclides of 10 CFR 71,~~ for normal form radioactive material; or

(iii) 27,000 Ci (1000 TBq);

(c) Each advance notification required by (~~19~~ 20)(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 irradiated reactor fuel or 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 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 (~~19~~ 20)(a) shall be made in writing to the office of each appropriate governor, or governor's designee, and to the Department.

Rule .06(20)(d)2.

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 messenger must reach the office of the governor, or governor's designee, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

4. A copy of the notification shall be retained by the licensee for three years.

(e) The licensee shall notify each appropriate governor, or governor's designee, and the Department of any changes to schedule information provided pursuant to (~~19~~ 20)(a). Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for three year a record of the name of the individual contacted.

(f) Each licensee who cancels a ~~irradiator reactor fuel or~~ nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the Department. A copy of the notice shall be retained by the licensee for three years.

(21) Quality Assurance Requirements.

(a) Unless otherwise authorized by the Department, e~~E~~ach 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 Department of its quality assurance program.

Rule .06(21)(e)

(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 ~~two~~ 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 Agreement State requirement, is deemed to satisfy the requirements of 10 CFR 71.12(b) and .06 (21).

(22) Determination of A_1 and A_2.

(a) ~~Individual radionuclides.~~ Values of A_1 and A_2

~~1.~~ ~~F~~for individual radionuclides, ~~whose identities and respective activities are known, the following conditions apply:~~ 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) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

~~(i) For an individual radionuclides of known identity, the values for A_1 and A_2 are taken from Appendix A, Table A-1, A_1 and A_2 Values for Radionuclides of 10 CFR 71. The values for A_1 and A_2 in Table 2, General Values For A_1 and A_2 of Appendix A of 10 CFR 71 are also applicable for radionuclides contained in (alpha, n) or (gamma, n) neutron sources. Where values of A_1 and A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.~~

(b)~~(ii)~~ For ~~any~~ individual radionuclides whose identities are known but are not listed in Table ~~A-1~~ 4, the determination of the values of A_1 and A_2 requires prior Department approval ~~from the NRC~~, except that the values of A_1 and A_2 in Table ~~A-2~~ 5 may be used without obtaining the ~~NRC~~ Department approval.

(c)~~(iii)~~ In calculations of A_1 and A_2 for a radionuclide not in Table ~~A-1~~ 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 A_1 and

Rule.06(22)(c)

A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten days, or greater than of the parent nuclide, the parent and those daughters nuclides shall be considered as a mixture of different nuclides.

(~~b~~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:

```
Sum FROM I { { B(i) } OVER
{ A SUB 1 (i) } } <= 1
```

(ii) For normal form radioactive material, maximum quantity transported in a Type A package:

```
sum FROM I { { B(i) } OVER
{ A SUB 2(i) } } <=1
```

~~W~~where B(i) is the activity of radionuclide ~~i~~i and $A_1(i)$ and $A_2(i)$ are the ~~and~~ A_1 and A_2 values for radionuclide ~~i~~i, respectively.

Alternatively an A_1 value for mixtures of special form material may be as follows:

A_1 for mixture =

```
1 OVER { sum FROM I { f(i)
} OVER  { A SUB 1 (i) } }
```

~~W~~where f(i) is the fraction of activity of nuclide ~~i~~i in the mixture and A_1 (i) is the appropriate A_1 value for nuclide ~~i~~i.

Rule .06(22)(d)1.(ii)

An A_2 value for mixtures of normal form material may be determined as follows:

A2 for mixture =

```
1 OVER { sum FROM I { f(i)
} OVER {A SUB 2 (i) } }
```

~~W~~where f(i) is the fraction of activity of nuclide ~~i~~i in the mixture A_2(i) is the appropriate A_2 value for nuclide ~~i~~i.

(~~e~~e) 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 and A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in ~~paragraph~~ (22)(~~b~~d). 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 for the alpha emitters and beta/gamma emitters.

~~All the radionuclides whose individual activities are not known (their total activity will, however, be known) are classed in a single group and the most restrictive value of A_1 and A_2 applicable to any one of them is used as the value of A_1 or A_2 in the denominator of the fraction.~~

Rule .06(22)(e)

Table 4

ACTIVITY LIMITS FOR LIMITED QUANTITIES, INSTRUMENTS AND ARTICLES

Nature of Contents[1/]	Instruments and Articles Limits for each instrument or article[1/]	Package Limits	Materials Package limits
Solids:			
Special form	$10^{-2}A_1$	A_1	$10^{-3}A_1$
Normal forms	$10^{-2}A_2$	A_2	$10^{-3}A_2$
Liquids			
Tritiated water			
0.1 Ci/liter (<0.0037 Tbq/liter)			1000 Curies (37TBq)
0.1 - 1.0 Ci/liter (0.0037 TBq to 0.037 TBq/L)			100 Curies (3.7 TBq)
1.0 Ci/liter (>0.037 Tbq/L)			1 Curie (0.037 TBq)
Other liquids	$10^{-3}A_2$	$10^{-1}A_2$	$10^{-4}A_2$
Gases			
Tritium[2/]	$2 \times 10^{-2}A_2$	$2 \times 10^{-1}A_2$	$2 \times 10^{-2}A_2$
Special form	$10^{-3}A_1$	$10^{-2}A_1$	$10^{-3}A_1$
Other forms	$10^{-3}A_2$	$10^{-2}A_2$	$10^{-3}A_2$

1/ For mixture of radionuclides see (22)(b) of this Rule.

2/ These values also apply to tritium in activated luminous paint and tritium absorbed on solid carriers.

(22) Limited Quantities, Instruments, and Articles. The A_1 and A_2 values are also used as a basis for defining the package quantity limits for limited quantities and both the item and package limits for instruments, as illustrated in Table 4. Packages containing materials within these quantity limits are excepted from some of the requirements which apply to Type A packages. These exceptions include not having to provide specification packaging, shipping papers, certification, marking or labeling. However, there are a number of conditions which the limited quantity, instrument, or article must meet.

Refer to 40 CFR 173.421 through 173.424 for the complete requirements.

Rule .06(22)(e) Table 4
A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Ac-225	Actinium(89)	0.6	16.2	$1x10^{-2}$	0.270	$2.1x10^{3}$	
	$5.8x10^{4}$						
Ac-227		40	1080	$2x10^{-5}$	$5.41x10^{-4}$	2.7	
	$7.2x10^{1}$						
Ac-228		0.6	16.2	0.4	10.8	$8.4x10^{4}$	
	$2.2x10^{6}$						
Ag-105	Silver(47)	2	54.1	2	54.1	$1.1x10^{3}$	
	$3.0x10^{4}$						
Ag-108m		0.6	16.2	0.6	16.2	$9.7x10^{-1}$	
	$2.6x10^{1}$						
Ag-110m		0.4	10.8	0.4	10.8	$1.8x10^{2}$	
	$4.7x10^{3}$						
Ag-111		0.6	16.2	0.5	13.5	$5.8x10^{3}$	
	$1.6x10^{5}$						
Al-26	Aluminum(13)	0.4	10.8	0.4	10.8	$7.0x10^{-4}$	
	$1.9x10^{-2}$						
Am-241	Mericium(95)	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.3x10^{-1}$	3.4
Am-242m		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.6x10^{-1}$	
	$1.0x10^{1}$						
Am-243		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$7.4x10^{-3}$	
	$2.0x10^{-1}$						
Ar-37	Argon(18)	40	1080	40	1080	$3.7x10^{3}$	
	$9.9x10^{4}$						
Ar-39		20	541	20	541	1.3	
	$3.4x10^{1}$						
Ar-41		0.6	16.2	0.6	16.2	$1.5x10^{6}$	
	$4.2x10^{7}$						
Ar-42		0.2	5.41	0.2	5.41	9.6	
	$2.6x10^{2}$						
As-72	Arsenic(33)	0.2	5.41	0.2	5.41	$6.2x10^{4}$	
	$1.7x10^{6}$						
As-73		40	1080	40	1080	$8.2x10^{2}$	
	$2.2x10^{4}$						
As-74		1	27.0	0.5	13.5	$3.7x10^{3}$	
	$9.9x10^{4}$						
As-76		0.2	5.41	0.2	5.41	$5.8x10^{4}$	
	$1.6x10^{6}$						
As-77		20	541	0.5	13.5	$3.9x10^{4}$	
	$1.0x10^{6}$						

At-211	Astatine(85)	30	811	2	54.1	7.6×10^{4}
	2.1×10^{6}					
Au-193	Gold(79)	6	162	6	162	3.4×10^{4}
	9.2×10^{5}					
Au-194		1	27.0	1	27.0	1.5×10^{4}
	4.1×10^{5}					
Au-195		10	270	10	270	1.4×10^{2}
	3.7×10^{3}					
Au-196		2	54.1	2	54.1	4.0×10^{3}
	1.1×10^{5}					
Au-198		3	81.1	0.5	13.5	9.0×10^{3}
	2.4×10^{5}					
Au-199		10	270	0.9	24.3	7.7×10^{3}
	2.1×10^{5}					
Ba-131	Barium(56)	2	54.1	2	54.1	3.1×10^{3}
	8.4×10^{4}					
Ba-133m		10	270	0.9	24.3	2.2×10^{4}
	6.1×10^{5}					
Ba-133		3	81.1	3	81.1	9.4
	2.6×10^{2}					
Ba-140		0.4	10.8	0.4	10.8	2.7×10^{3}
	7.3×10^{4}					
Be-7	Beryllium(4)	20	541	20	541	1.3×10^{4}
	3.5×10^{5}					
Be-10		20	541	0.5	13.5	8.3×10^{-4}
	2.2×10^{-2}					
Bi-205	Bismuth(83)	0.6	16.2	0.6	16.2	1.5×10^{3}
	4.2×10^{4}					
Bi-206		0.3	8.11	0.3	8.11	3.8×10^{3}
	1.0×10^{5}					

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Bi-207		0.7	18.9	0.7	18.9	1.9	
	$5.2x10^{1}$						
Bi-210m		0.3	8.11	$3x10^{-2}$	0.811	$2.1x10^{-5}$	
	$5.7x10^{-4}$						
Bi-210		0.6	16.2	0.5	13.5	$4.6x10^{3}$	
	$1.2x10^{5}$						
Bi-212		0.3	8.11	0.3	8.11	$5.4x10^{5}$	
	$1.5x10^{7}$						
Bk-247	Berkelium(97)	2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.8x10^{-2}$	1.0
Bk-249		40	1080	$8x10^{-2}$	2.16	$6.1x10^{1}$	
	$1.6x10^{3}$						
Br-76	Bromine(35)	0.3	8.11	0.3	8.11	$9.4x10^{4}$	
	$2.5x10^{6}$						
Br-77		3	81.1	3	81.1	$2.6x10^{4}$	
	$7.1x10^{5}$						
Br-82		0.4	10.8	0.4	10.8	$4.0x10^{4}$	
	$1.1x10^{6}$						
C-11	Carbon(6)	1	27	0.5	13.5	$3.1x10^{7}$	
	$8.4x10^{8}$						
C-14		40	1080	2	54.1	$1.6x10^{-1}$	4.5
Ca-41	Calcium(20)	40	1080	40	1080	$3.1x10^{-3}$	
	$8.5x10^{-2}$						
Ca-45		40	1080	0.9	24.3	$6.6x10^{2}$	
	$1.8x10^{4}$						
Ca-47		0.9	24.3	0.5	13.5	$2.3x10^{4}$	
	$6.1x10^{5}$						
Cd-109	Cadmium(48)	40	1080	1	27.0	$9.6x10^{1}$	
	$2.6x10^{3}$						
Cd-113m		20	541	$9x10^{-2}$	2.43	$8.3x10^{4}$	
	$2.2x10^{2}$						
Cd-115m		0.3	8.11	0.3	8.11	$9.4x10^{2}$	
	$2.5x10^{4}$						
Cd-115		4	108	0.5	13.5	$1.9x10^{4}$	
	$5.1x10^{5}$						
Ce-139	Cerium(58)	6	162	6	162	$2.5x10^{2}$	
	$6.8x10^{3}$						
Ce-141		10	270	0.5	13.5	$1.1x10^{3}$	
	$2.8x10^{4}$						
Ce-143		0.6	16.2	0.5	13.5	$2.5x10^{4}$	
	$6.6x10^{5}$						

Ce-144		0.2	5.41	0.2	5.41	$1.2x10^{2}$	
	$3.2x10^{3}$						
Cf-248	Californium(98)	30	811	$3x10^{-3}$	$8.11x10^{-2}$	$5.8x10^{1}$	
	$1.6x10^{3}$						
Cf-249		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.5x10^{-1}$	4.1
Cf-250		5	135	$5x10^{-4}$	$1.35x10^{-2}$	4.0	
	$1.1x10^{2}$						
Cf-251		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$5.9x10^{-2}$	1.6
Cf-252		0.1	2.70	$1x10^{-3}$	$2.70x10^{-2}$	$2.0x10^{1}$	
	$5.4x10^{2}$						
Cf-253		40	1080	$6x10^{-2}$	1.62	$1.1x10^{3}$	
	$2.9x10^{4}$						
Cf-254		$3x10^{-3}$	$8.11x10^{-2}$	$6x10^{-4}$	$1.62x10^{-2}$	$3.1x10^{2}$	
	$8.5x10^{3}$						
Cl-36	Chlorine(17)	20	541	0.5	13.5	$1.2x10^{-3}$	
	$3.3x10^{-2}$						
Cl-38		0.2	5.41	0.2	5.41	$4.9x10^{6}$	
	$1.3x10^{8}$						
Cm-240	Curium(96)	40	1080	$2x10^{-2}$	0.541	$7.5x10^{2}$	
	$2.0x10^{4}$						
Cm-241		2	54.1	0.9	24.3	$6.1x10^{2}$	
	$1.7x10^{4}$						
Cm-242		40	1080	$1x10^{-2}$	0.270	$1.2x10^{2}$	
	$3.3x10^{3}$						
Cm-243		3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	1.9	
	$5.2x10^{1}$						

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Cm-244		4	108	$4x10^{-4}$	$1.08x10^{-2}$	3.0	
	$8.1x10^{1}$						
Cm-245		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$6.4x10^{-3}$	
	$1.7x10^{-1}$						
Cm-246		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.1x10^{-2}$	
	$3.1x10^{-1}$						
Cm-247		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$3.4x10^{-6}$	
	$9.3x10^{-5}$						
Cm-248		$4x10^{-2}$	1.08	$5x10^{-5}$	$1.35x10^{-3}$	$1.6x10^{-4}$	
	$4.2x10^{-3}$						
Co-55	Cobalt(27)	0.5	13.5	0.5	13.5	$1.1x10^{5}$	
	$3.1x10^{6}$						
Co-56		0.3	8.11	0.3	8.11	$1.1x10^{3}$	
	$3.0x10^{4}$						
Co-57		8	216	8	216	$3.1x10^{2}$	
	$8.4x10^{3}$						
Co-58m		40	1080	40	1080	$2.2x10^{5}$	
	$5.9x10^{6}$						
Co-58		1	27.0	1	27.0	$1.2x10^{3}$	
	$3.2x10^{4}$						
Co-60		0.4	10.8	0.4	10.8	$4.2x10^{1}$	
	$1.1x10^{3}$						
Cr-51	Chromium(24)	30	811	30	811	$3.4x10^{3}$	
	$9.2x10^{4}$						
Cs-129	Cesium(55)	4	108	4	108	$2.8x10^{4}$	
	$7.6x10^{5}$						
Cs-131		40	1080	40	1080	$3.8x10^{3}$	
	$1.0x10^{5}$						
Cs-132		1	27.0	1	27.0	$5.7x10^{3}$	
	$1.5x10^{5}$						
Cs-134m		40	1080	9	243	$3.0x10^{5}$	
	$8.0x10^{6}$						
Cs-134		0.6	16.2	0.5	13.5	$4.8x10^{1}$	
	$1.3x10^{3}$						
Cs-135		40	1080	0.9	24.3	$4.3x10^{-5}$	
	$1.2x10^{-3}$						
Cs-136		0.5	13.5	0.5	13.5	$2.7x10^{3}$	
	$7.3x10^{4}$						
Cs-137		2	54.1	0.5	13.5	3.2	
	$8.7x10^{1}$						
Cu-64	Copper(29)	5	135	0.9	24.3	$1.4x10^{5}$	

	$3.9x10^6$					
Cu-67		9	243	0.9	24.3	$2.8x10^4$
	$7.6x10^5$					
Dy-159	Dysprosium(66)	20	541	20	541	$2.1x10^2$
	$5.7x10^3$					
Dy-165		0.6	16.2	0.5	13.5	$3.0x10^5$
	$8.2x10^6$					
Dy-166		0.3	8.11	0.3	8.11	$8.6x10^3$
	$2.3x10^5$					
Er-169	Erbium(68)	40	1080	0.9	24.3	$3.1x10^3$
	$8.3x10^4$					
Er-171		0.6	16.2	0.5	13.5	$9.0x10^4$
	$2.4x10^6$					
Es-253	Einsteinium(99)[a/]	200	5400	$2.1x10^{-2}$	$5.4x10^{-1}$	-- --
Es-254		30	811	$3x10^{-3}$	$8.11x10^{-2}$	-- --
Es-254m		0.6	16.2	0.4	10.8	-- --
Es-255		--	--	--	--	-- --
Eu-147	Europium(63)	2	54.1	2	54.1	$1.4x10^3$
	$3.7x10^4$					
Eu-148		0.5	13.5	0.5	13.5	$6.0x10^2$
	$1.6x10^4$					
Eu-149		20	541	20	541	$3.5x10^2$
	$9.4x10^3$					
Eu-150		0.7	18.9	0.7	18.9	$6.1x10^4$
	$1.6x10^6$					
Eu-152m		0.6	16.2	0.5	13.5	$8.2x10^4$
	$2.2x10^6$					
Eu-152		0.9	24.3	0.9	24.3	6.5
	$1.8x10^2$					
Eu-154		0.8	21.6	0.5	13.5	9.8
	$2.6x10^2$					
Eu-155		20	541	2	54.1	$1.8x10^1$
	$4.9x10^2$					
Eu-156		0.6	16.2	0.5	13.5	$2.0x10^3$
	$5.5x10^4$					

[a/] *International shipments of Einsteinium require multilateral approval of A_1 and A_2 values.*

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
F-18	Fluorine(9)	1	27.0	0.5	13.5	$3.5x10^6$	$9.5x10^7$
Fe-52	Iron(26)	0.2	5.41	0.2	5.41	$2.7x10^5$	$7.3x10^6$
Fe-55		40	1080	40	1080	$8.8x10^1$	$2.4x10^3$
Fe-59		0.8	21.6	0.8	21.6	$1.8x10^3$	$5.0x10^4$
Fe-60		40	1080	0.2	5.41	$7.4x10^{-4}$	$2.0x10^{-2}$
Fm-255	Fermium(100)[b/]	40	1080	0.8	21.6	--	--
Fm-257		10	270	$8x10^{-3}$	$21.6x10^{-1}$	--	--
Ga-67	Gallium(31)	6	162	6	162	$2.2x10^4$	$6.0x10^5$
Ga-68		0.3	8.11	0.3	8.11	$1.5x10^6$	$4.1x10^7$
Ga-72		0.4	10.8	0.4	10.8	$1.1x10^5$	$3.1x10^6$
Gd-146	Gadolinium(64)	0.4	10.8	0.4	10.8	$6.9x10^2$	$1.9x10^4$
Gd-148		3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	1.2	$3.2x10^1$
Gd-153		10	270	5	135	$1.3x10^2$	$3.5x10^3$
Gd-159		4	108	0.5	13.5	$3.9x10^4$	$1.1x10^6$
Ge-68	Germanium(32)	0.3	8.11	0.3	8.11	$2.6x10^2$	$7.1x10^3$
Ge-71		40	1080	40	1080	$5.8x10^3$	$1.6x10^5$
Ge-77		0.3	8.11	0.3	8.11	$1.3x10^5$	$3.6x10^6$
H-3	Hydrogen(1)	See T-Tritium					
Hf-172	Hafnium(72)	0.5	13.5	0.3	8.11	$4.1x10^1$	$1.1x10^3$
Hf-175		3	81.1	3	81.1	$3.9x10^2$	$1.1x10^4$
Hf-181		2	54.1	0.9	24.3	$6.3x10^2$	$1.7x10^4$

Hf-182		4	108	$3x10^{-2}$	0.811	$8.1x10^{-6}$	
	$2.2x10^{-4}$						
Hg-194	Mercury(80)	1	27.0	1	27.0	$1.3x10^{-1}$	3.5
Hg-195m		5	135	5	135	$1.5x10^{4}$	
	$4.0x10^{5}$						
Hg-197m		10	270	0.9	24.3	$2.5x10^{4}$	
	$6.7x10^{5}$						
Hg-197		10	270	10	270	$9.2x10^{3}$	
	$2.5x10^{5}$						
Hg-203		4	108	0.9	24.3	$5.1x10^{2}$	
	$1.4x10^{4}$						
Ho-163	Holmium(67)	40	1080	40	1080	2.7	
	$7.6x10^{1}$						
Ho-166m		0.6	16.2	0.3	8.11	$6.6x10^{-2}$	1.8
Ho-166		0.3	8.11	0.3	8.11	$2.6x10^{4}$	
	$7.0x10^{5}$						
I-123	Iodine(53)	6	162	6	162	$7.1x10^{4}$	
	$1.9x10^{6}$						
I-124		0.9	24.3	0.9	24.3	$9.3x10^{3}$	
	$2.5x10^{5}$						
I-125		20	541	2	54.1	$6.4x10^{2}$	
	$1.7x10^{4}$						
I-126		2	54.1	0.9	24.3	$2.9x10^{3}$	
	$8.0x10^{4}$						
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5x10^{-6}$	
	$1.8x10^{-4}$						

[b] *International shipments of Fermium require multilateral approval of A_1 and A_2 values.*

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
I-131		3	81.1	0.5	13.5	$4.6x10^3$	$1.2x10^5$
I-132		0.4	10.8	0.4	10.8	$3.8x10^5$	$1.0x10^7$
I-133		0.6	16.2	0.5	13.5	$4.2x10^4$	$1.1x10^6$
I-134		0.3	8.11	0.3	8.11	$9.9x10^5$	$2.7x10^7$
I-135		0.6	16.2	0.5	13.5	$1.3x10^5$	$3.5x10^6$
In-111	Indium(49)	2	54.1	2	54.1	$1.5x10^4$	$4.2x10^5$
In-113m		4	108	4	108	$6.2x10^5$	$1.7x10^7$
In-114m		0.3	8.11	0.3	8.11	$8.6x10^2$	$2.3x10^4$
In-115m		6	162	0.9	24.3	$2.2x10^5$	$6.1x10^6$
Ir-189	Iridium(77)	10	270	10	270	$1.9x10^3$	$5.2x10^4$
Ir-190		0.7	18.9	0.7	18.9	$2.3x10^3$	$6.2x10^4$
Ir-192		1	27.0	0.5	13.5	$3.4x10^2$	$9.2x10^3$
Ir-193m		10	270	10	270	$2.4x10^3$	$6.4x10^4$
Ir-194		0.2	5.41	0.2	5.41	$3.1x10^4$	$8.4x10^5$
K-40	Potassium(19)	0.6	16.2	0.6	16.2	$2.4x10^{-7}$	$6.4x10^{-6}$
K-42		0.2	5.41	0.2	5.41	$2.2x10^5$	$6.0x10^6$
K-43		1.0	27.0	0.5	13.5	$1.2x10^5$	$3.3x10^6$
Kr-81	Krypton(36)	40	1080	40	1080	$7.8x10^{-4}$	$2.1x10^{-2}$
Kr-85m		6	162	6	162	$3.0x10^5$	$8.2x10^6$
Kr-85		20	541	10	270	$1.5x10^1$	$3.9x10^2$

Kr-87		0.2	5.41	0.2	5.41	$1.0x10^{6}$
	$2.8x10^{7}$					
La-137	Lanthanum(57)	40	1080	2	54.1	$1.6x10^{-3}$
	$4.4x10^{-2}$					
La-140		0.4	10.8	0.4	10.8	$2.1x10^{4}$
	$5.6x10^{5}$					
Lu-172	Lutetium(71)	0.5	13.5	0.5	13.5	$4.2x10^{3}$
	$1.1x10^{5}$					
Lu-173		8	216	8	216	$5.6x10^{1}$
	$1.5x10^{3}$					
Lu-174m		20	541	8	216	$2.0x10^{2}$
	$5.3x10^{3}$					
Lu-174		8	216	4	108	$2.3x10^{1}$
	$6.2x10^{2}$					
Lu-177		30	811	0.9	24.3	$4.1x10^{3}$
	$1.1x10^{5}$					
MFP	For mixed fission products, use formula for mixtures or TABLE V.					
Mg-28	Magnesium(12)	0.2	5.41	0.2	5.41	$2.0x10^{5}$
	$5.4x10^{6}$					
Mn-52	Manganese(25)	0.3	8.11	0.3	8.11	$1.6x10^{4}$
	$4.4x10^{5}$					
Mn-53	Unlimited	Unlimited	Unlimited	Unlimited	$6.8x10^{-5}$	$1.8x10^{-3}$
Mn-54		1	27.0	1	27.0	$2.9x10^{2}$
	$7.7x10^{3}$					
Mn-56		0.2	5.41	0.2	5.41	$8.0x10^{5}$
	$2.2x10^{7}$					
Mo-93	Molybdenum(42)40	1080	7	189	$4.1x10^{-2}$	1.1
Mo-99		0.6	16.2	0.5	13.5[c/]	$1.8x10^{4}$
	$4.8x10^{5}$					

[c/] 20 Ci for Mo^{99} for domestic use.

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
N-13	Nitrogen(7)	0.6	16.2	0.5	13.5	$5.4x10^7$	$1.5x10^9$
Na-22	Sodium(11)	0.5	13.5	0.5	13.5	$2.3x10^2$	$6.3x10^3$
Na-24		0.2	5.41	0.2	5.41	$3.2x10^5$	$8.7x10^6$
Nb-92m	Niobium(41)	0.7	18.9	0.7	18.9	$5.2x10^3$	$1.4x10^5$
Nb-93m		40	1080	6	162	8.8	$2.4x10^2$
Nb-94		0.6	16.2	0.6	16.2	$6.9x10^{-3}$	$1.9x10^{-1}$
Nb-95		1	27.0	1	27.0	$1.5x10^3$	$3.9x10^4$
Nb-97		0.6	16.2	0.5	13.5	$9.9x10^5$	$2.7x10^7$
Nd-147	Neodymium(60)	4	108	0.5	13.5	$3.0x10^3$	$8.1x10^4$
Nd-149		0.6	16.2	0.5	13.5	$4.5x10^5$	$1.2x10^7$
Ni-59	Nickel(28)	40	1080	40	1080	$3.0x10^{-3}$	$8.0x10^{-2}$
Ni-63		40	1080	30	811	2.1	$5.7x10^1$
Ni-65		0.3	8.11	0.3	8.11	$7.1x10^5$	$1.9x10^7$
Np-235	Neptunium(93)	40	1080	40	1080	$5.2x10^1$	$1.4x10^3$
Np-236		7	189	$1x10^{-3}$	$2.70x10^{-2}$	$4.7x10^{-4}$	$1.3x10^{-2}$
Np-237		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$2.6x10^{-5}$	$7.1x10^{-4}$
Np-239		6	162	0.5	13.5	$8.6x10^3$	$2.3x10^5$
Os-185	Osmium(76)	1	27.0	1	27.0	$2.8x10^2$	$7.5x10^3$
Os-191m		40	1080	40	1080	$4.6x10^4$	$1.3x10^6$
Os-191		10	270	0.9	24.3	$1.6x10^3$	$4.4x10^4$

Os-193		0.6	16.2	0.5	13.5	$2.0x10^{4}$
	$5.3x10^{5}$					
Os-194		0.2	5.41	0.2	5.41	$1.1x10^{1}$
	$3.1x10^{2}$					
P-32	Phosphorus(15)	0.3	8.11	0.3	8.11	$1.1x10^{4}$
	$2.9x10^{5}$					
P-33		40	1080	0.9	24.3	$5.8x10^{3}$
	$1.6x10^{5}$					
Pa-230	Protactinium(91)	2	54.1	0.1	2.70	$1.2x10^{3}$
	$3.3x10^{4}$					
Pa-231		0.6	16.2	$6x10^{-5}$	$1.62x10^{-3}$	$1.7x10^{-3}$
	$4.7x10^{-2}$					
Pa-233		5	135	0.9	24.3	$7.7x10^{2}$
	$2.1x10^{4}$					
Pb-201	Lead(82)	1	27.0	1	27.0	$6.2x10^{4}$
	$1.7x10^{6}$					
Pb-202		40	1080	2	54.1	$1.2x10^{-4}$
	$3.4x10^{-3}$					
Pb-203		3	81.1	3	81.1	$1.1x10^{4}$
	$3.0x10^{5}$					
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5x10^{-6}$
	$1.2x10^{-4}$					
Pb-210		0.6	16.2	$9x10^{-3}$	0.243	2.8
	$7.6x10^{1}$					
Pb-212		0.3	8.11	0.3	8.11	$5.1x10^{4}$
	$1.4x10^{6}$					
Pd-103	Palladium(46)	40	1080	40	1080	$2.8x10^{3}$
	$7.5x10^{4}$					
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9x10^{-5}$
	$5.1x10^{-4}$					
Pd-109		0.6	16.2	0.5	13.5	$7.9x10^{4}$
	$2.1x10^{6}$					
Pm-143	Promethium(61)	3	81.1	3	81.1	$1.3x10^{2}$
	$3.4x10^{3}$					
Pm-144		0.6	16.2	0.6	16.2	$9.2x10^{1}$
	$2.5x10^{3}$					
Pm-145		30	811	7	189	5.2
	$1.4x10^{2}$					
Pm-147		40	1080	0.9	24.3	$3.4x10^{1}$
	$9.3x10^{2}$					

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Pm-148m		0.5	13.5	0.5	13.5	$7.9x10^{2}$	$2.1x10^{4}$
Pm-149		0.6	16.2	0.5	13.5	$1.5x10^{4}$	$4.0x10^{5}$
Pm-151		3	81.1	0.5	13.5	$2.7x10^{4}$	$7.3x10^{5}$
Po-208	Polonium(84)	40	1080	$2x10^{-2}$	0.541	$2.2x10^{1}$	$5.9x10^{2}$
Po-209		40	1080	$2x10^{-2}$	0.541	$6.2x10^{-1}$	$1.7x10^{1}$
Po-210		40	1080	$2x10^{-2}$	0.541	$1.7x10^{2}$	$4.5x10^{3}$
Pr-142	Praseodymium(59)	0.2	5.41	0.2	5.41	$4.3x10^{4}$	$1.2x10^{6}$
Pr-143		4	108	0.5	13.5	$2.5x10^{3}$	$6.7x10^{4}$
Pt-188	Platinum(78)	0.6	16.2	0.6	16.2	$2.5x10^{3}$	$6.8x10^{4}$
Pt-191		3	81.1	3	81.1	$8.7x10^{3}$	$2.4x10^{5}$
Pt-193m		40	1080	9	243	$5.8x10^{3}$	$1.6x10^{5}$
Pt-193		40	1080	40	1080	1.4	$3.7x10^{1}$
Pt-195m		10	270	2	54.1	$6.2x10^{3}$	$1.7x10^{5}$
Pt-197m		10	270	0.9	24.3	$3.7x10^{5}$	$1.0x10^{7}$
Pt-197		20	541	0.5	13.5	$3.2x10^{4}$	$8.7x10^{5}$
Pu-236	Plutonium(94)	7	189	$7x10^{-4}$	$1.89x10^{-2}$	$2.0x10^{1}$	$5.3x10^{2}$
Pu-237		20	541	20	541	$4.5x10^{2}$	$1.2x10^{4}$
Pu-238		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$6.3x10^{-1}$	$1.7x10^{1}$
Pu-239		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$2.3x10^{-3}$	$6.2x10^{-2}$
Pu-240		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$8.4x10^{-3}$	$2.3x10^{-1}$

Pu-241		40	1080	$1x10^{-2}$	0.270	3.8	
	$1.0x10^{2}$						
Pu-242		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$1.5x10^{-4}$	
	$3.9x10^{-3}$						
Pu-244		0.3	8.11	$2x10^{-4}$	$5.41x10^{-3}$	$6.7x10^{-7}$	
	$1.8x10^{-5}$						
Ra-223	Radium(88)	0.6	16.2	$3x10^{-2}$	0.811	$1.9x10^{3}$	
	$5.1x10^{4}$						
Ra-224		0.3	8.11	$6x10^{-2}$	1.62	$5.9x10^{3}$	
	$1.6x10^{5}$						
Ra-225		0.6	16.2	$2x10^{-2}$	0.541	$1.5x10^{3}$	
	$3.9x10^{4}$						
Ra-226		0.3	8.11	$2x10^{-2}$	0.541	$3.7x10^{-2}$	1.0
Ra-228		0.6	16.2	$4x10^{-2}$	1.08	$1.0x10^{1}$	
	$2.7x10^{2}$						
Rb-81	Rubidium(37)	2	54.1	0.9	24.3	$3.1x10^{5}$	
	$8.4x10^{6}$						
Rb-83		2	54.1	2	54.1	$6.8x10^{2}$	
	$1.8x10^{4}$						
Rb-84		1	27.0	0.9	24.3	$1.8x10^{3}$	
	$4.7x10^{4}$						
Rb-86		0.3	8.11	0.3	8.11	$3.0x10^{3}$	
	$8.1x10^{4}$						
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2x10^{-9}$	
	$8.6x10^{-8}$						
Rb (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7x10^{6}$	
	$1.8x10^{8}$						
Re-183	Rhenium(75)	5	135	5	135	$3.8x10^{2}$	
	$1.0x10^{4}$						
Re-184m		3	81.1	3	81.1	$1.6x10^{2}$	
	$4.3x10^{3}$						
Re-184		1	27.0	1	27.0	$6.9x10^{2}$	
	$1.9x10^{4}$						
Re-186		4	108	0.5	13.5	$6.9x10^{3}$	
	$1.9x10^{5}$						
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4x10^{-9}$	
	$3.8x10^{-8}$						
Re-188		0.2	5.41	0.2	5.41	$3.6x10^{4}$	
	$9.8x10^{5}$						

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Re-189		4	108	0.5	13.5	$2.5x10^4$	$6.8x10^5$
Re (natural)		Unlimited	Unlimited	Unlimited	Unlimited	--	$2.4x10^{-8}$
Rh-99	Rhodium(45)	2	54.1	2	54.1	$3.0x10^3$	$8.2x10^4$
Rh-101		4	108	4	108	$4.1x10^1$	$1.1x10^3$
Rh-102m		2	54.1	0.9	24.3	$2.3x10^2$	$6.2x10^3$
Rh-102		0.5	13.5	0.5	13.5	$4.5x10^1$	$1.2x10^3$
Rh-103m		40	1080	40	1080	$1.2x10^6$	$3.3x10^7$
Rh-105		10	270	0.9	24.3	$3.1x10^4$	$8.4x10^5$
Rn-222	Radon(86)	0.2	5.41	$4x10^{-3}$	0.108	$5.7x10^3$	$1.5x10^5$
Ru-97	Ruthenium(44)	4	108	4	108	$1.7x10^4$	$4.6x10^5$
Ru-103		2	54.1	0.9	24.3	$1.2x10^3$	$3.2x10^4$
Ru-105		0.6	16.2	0.5	13.5	$2.5x10^5$	$6.7x10^6$
Ru-106		0.2	5.41	0.2	5.41	$1.2x10^2$	$3.3x10^3$
S-35	Sulfur(16)	40	1080	2	54.1	$1.6x10^3$	$4.3x10^4$
Sb-122	Antimony(51)	0.3	8.11	0.3	8.11	$1.5x10^4$	$4.0x10^5$
Sb-124		0.6	16.2	0.5	13.5	$6.5x10^2$	$1.7x10^4$
Sb-125		2	54.1	0.9	24.3	$3.9x10^1$	$1.0x10^3$
Sb-126		0.4	10.8	0.4	10.8	$3.1x10^3$	$8.4x10^4$
Sc-44	Scandium(21)	0.5	13.5	0.5	13.5	$6.7x10^5$	$1.8x10^7$
Sc-46		0.5	13.5	0.5	13.5	$1.3x10^3$	$3.4x10^4$
Sc-47		9	243	0.9	24.3	$3.1x10^4$	

	$8.3x10^{5}$					
Sc-48		0.3	8.11	0.3	8.11	$5.5x10^{4}$
	$1.5x10^{6}$					
Se-75	Selenium(34)	3	81.1	3	81.1	$5.4x10^{2}$
	$1.5x10^{4}$					
Se-79		40	1080	2	54.1	$2.6x10^{-3}$
	$7.0x10^{-2}$					
Si-31	Silicon(14)	0.6	16.2	0.5	13.5	$1.4x10^{6}$
	$3.9x10^{7}$					
Si-32		40	1080	0.2	5.41	3.9
	$1.1x10^{2}$					
Sm-145	Samarium(62)	20	541	20	541	$9.8x10^{1}$
	$2.6x10^{3}$					
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5x10^{-1}0$
	$2.3x10^{-8}$					
Sm-151		40	1080	4	108	$9.7x10^{-1}$
	$2.6x10^{1}$					
Sm-153		4	108	0.5	13.5	$1.6x10^{4}$
	$4.4x10^{5}$					
Sn-113	Tin(50)	4	108	4	108	$3.7x10^{2}$
	$1.0x10^{4}$					
Sn-117m		6	162	2	54.1	$3.0x10^{3}$
	$8.2x10^{4}$					
Sn-119m		40	1080	40	1080	$1.4x10^{2}$
	$3.7x10^{3}$					
Sn-121m		40	1080	0.9	24.3	2.0
	$5.4x10^{1}$					
Sn-123		0.6	16.2	0.5	13.5	$3.0x10^{2}$
	$8.2x10^{3}$					
Sn-125		0.2	5.41	0.2	5.41	$4.0x10^{3}$
	$1.1x10^{5}$					
Sn-126		0.3	8.11	0.3	8.11	$1.0x10^{-3}$
	$2.8x10^{-2}$					
Sr-82	Strontium(38)	0.2	5.41	0.2	5.41	$2.3x10^{3}$
	$6.2x10^{4}$					
Sr-85m		5	135	5	135	$1.2x10^{6}$
	$3.3x10^{7}$					
Sr-85		2	54.1	2	54.1	$8.8x10^{2}$
	$2.4x10^{4}$					

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Sr-87m		3	81.1	3	81.1	$4.8x10^5$	$1.3x10^7$
Sr-89		0.6	16.2	0.5	13.5	$1.1x10^3$	$2.9x10^4$
Sr-90		0.2	5.41	0.1	2.70	5.1	$1.4x10^2$
Sr-91		0.3	8.11	0.3	8.11	$1.3x10^5$	$3.6x10^6$
Sr-92		0.8	21.6	0.5	13.5	$4.7x10^5$	$1.3x10^7$
T	Tritium(1)	40	1080	40	1080	$3.6x10^2$	$9.7x10^3$
Ta-178	Tantalum(73)	1	27.0	1	27.0	$4.2x10^6$	$1.1x10^8$
Ta-179		30	811	30	811	$4.1x10^1$	$1.1x10^3$
Ta-182		0.8	21.6	0.5	13.5	$2.3x10^2$	$6.2x10^3$
Tb-157	Terbium(65)	40	1080	10	270	$5.6x10^{-1}$	$1.5x10^1$
Tb-158		1	27.0	0.7	18.9	$5.6x10^{-1}$	$1.5x10^1$
Tb-160		0.9	24.3	0.5	13.5	$4.2x10^2$	$1.1x10^4$
Tc-95m	Technetium(43)	2	54.1	2	54.1	$8.3x10^2$	$2.2x10^4$
Tc-96m		0.4	10.8	0.4	10.8	$1.4x10^6$	$3.8x10^7$
Tc-96		0.4	10.8	0.4	10.8	$1.2x10^4$	$3.2x10^5$
Tc-97m		40	1080	40	1080	$5.6x10^2$	$1.5x10^4$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2x10^{-5}$	$1.4x10^{-3}$
Tc-98		0.7	18.9	0.7	18.9	$3.2x10^{-5}$	$8.7x10^{-4}$
Tc-99m		8	216	8	216	$1.9x10^5$	$5.3x10^6$
Tc-99		40	1080	0.9	24.3	$6.3x10^{-4}$	$1.7x10^{-2}$

Te-118	Tellurium(52)	0.2	5.41	0.2	5.41	$6.8x10^{3}$
	$1.8x10^{5}$					
Te-121m		5	135	5	135	$2.6x10^{2}$
	$7.0x10^{3}$					
Te-121		2	54.1	2	54.1	$2.4x10^{3}$
	$6.4x10^{4}$					
Te-123m		7	189	7	189	$3.3x10^{2}$
	$8.9x10^{3}$					
Te-125m		30	811	9	243	$6.7x10^{2}$
	$1.8x10^{4}$					
Te-127m		20	541	0.5	13.5	$3.5x10^{2}$
	$9.4x10^{3}$					
Te-127		20	541	0.5	13.5	$9.8x10^{4}$
	$2.6x10^{6}$					
Te-129m		0.6	16.2	0.5	13.5	$1.1x10^{3}$
	$3.0x10^{4}$					
Te-129		0.6	16.2	0.5	13.5	$7.7x10^{5}$
	$2.1x10^{7}$					
Te-131m		0.7	18.9	0.5	13.5	$3.0x10^{4}$
	$8.0x10^{5}$					
Te-132		0.4	10.8	0.4	10.8	$1.1x10^{4}$
	$3.0x10^{5}$					
Th-227	Thorium(90)	9	243	$1x10^{-2}$	0.270	$1.1x10^{3}$
	$3.1x10^{4}$					
Th-228		0.3	8.11	$4x10^{-4}$	$1.08x10^{-2}$	$3.0x10^{1}$
	$8.2x10^{2}$					
Th-229		0.3	8.11	$3x10^{-5}$	$8.11x10^{-4}$	$7.9x10^{-3}$
	$2.1x10^{-1}$					
Th-230		2	54.1	$2x10^{-4}$	$5.41x10^{-3}$	$7.6x10^{-4}$
	$2.1x10^{-2}$					
Th-231		40	1080	0.9	24.3	$2.0x10^{4}$
	$5.3x10^{5}$					
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0x10^{-9}$
	$1.1x10^{-7}$					
Th-234		0.2	5.41	0.2	5.41	$8.6x10^{2}$
	$2.3x10^{4}$					
Th (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1x10^{-9}$
	$2.2x10^{-7}$					
Ti-44	Titanium(22)	0.5	13.5	0.2	5.41	6.4
	$1.7x10^{2}$					

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Tl-200	Thallium(81.1)	0.8	21.6	0.8	21.6	$2.2x10^4$	$6.0x10^5$
Tl-201		10	270	10	270	$7.9x10^3$	$2.1x10^5$
Tl-202		2	54.1	2	54.1	$2.0x10^3$	$5.3x10^4$
Tl-204		4	108	0.5	13.5	$1.7x10^1$	$4.6x10^2$
Tm-167	Thulium(69)	7	189	7	189	$3.1x10^3$	$8.5x10^4$
Tm-168		0.8	21.6	0.8	21.6	$3.1x10^2$	$8.3x10^3$
Tm-170		4	108	0.5	13.5	$2.2x10^2$	$6.0x10^3$
Tm-171		40	1080	10	270	$4.0x10^1$	$1.1x10^3$
U-230	Uranium(92)	40	1080	$1x10^{-2}$	0.270	$1.0x10^3$	$2.7x10^4$
U-232		3	81.1	$3x10^{-4}$	$8.11x10^{-3}$	$8.3x10^{-1}$	$2.2x10^1$
U-233		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$3.6x10^{-4}$	$9.7x10^{-3}$
U-234		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$2.3x10^{-4}$	$6.2x10^{-3}$
U-235		Unlimited	Unlimited	Unlimited	Unlimited	$8.0x10^{-8}$	$2.2x10^{-6}$
U-236		10	270	$1x10^{-3}$	$2.70x10^{-2}$	$2.4x10^{-6}$	$6.5x10^{-5}$
U-238		Unlimited	Unlimited	Unlimited	Unlimited	$1.2x10^{-8}$	$3.4x10^{-7}$
U (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6x10^{-8}$	$7.1x10^{-7}$
U (enriched 5% or less)		Unlimited	Unlimited	Unlimited	Unlimited	--(Table 6)	
U (enriched > 5%)		10	270	$1x10^{-3}$	$2.70x10^{-2}$	--(Table 6)	
U (depleted)		Unlimited	Unlimited	Unlimited	Unlimited	--(Table 6)	
V-48	Vanadium(23)	0.3	8.11	0.3	8.11	$6.3x10^3$	$1.7x10^5$
V-49		40	1080	40	1080	$3.0x10^2$	$8.1x10^3$

W-178	Tungsten(74)	1	27.0	1	27.0	$1.3x10^3$
	$3.4x10^4$					
W-181		30	811	30	811	$2.2x10^2$
	$6.0x10^3$					
W-185		40	1080	0.9	24.3	$3.5x10^2$
	$9.4x10^3$					
W-187		2	54.1	0.5	13.5	$2.6x10^4$
	$7.0x10^5$					
W-188		0.2	5.41	0.2	5.41	$3.7x10^2$
	$1.0x10^4$					
Xe-122	Xenon(54)	0.2	5.41	0.2	5.41	$4.8x10^4$
	$1.3x10^6$					
Xe-123		0.2	5.41	0.2	5.41	$4.4x10^5$
	$1.2x10^7$					
Xe-127		4	108	4	108	$1.0x10^3$
	$2.8x10^4$					
Xe-131m		40	1080	40	1080	$3.1x10^3$
	$8.4x10^4$					
Xe-133		20	541	20	541	$6.9x10^3$
	$1.9x10^5$					
Xe-135		4	108	4	108	$9.5x10^4$
	$2.6x10^6$					
Y-87	Yttrium(39)	2	54.1	2	54.1	$1.7x10^4$
	$4.5x10^5$					
Y-88		0.4	10.8	0.4	10.8	$5.2x10^2$
	$1.4x10^4$					
Y-90		0.2	5.41	0.2	5.41	$2.0x10^4$
	$5.4x10^5$					
Y-91m		2	54.1	2	54.1	$1.5x10^6$
	$4.2x10^7$					
Y-91		0.3	8.11	0.3	8.11	$9.1x10^2$
	$2.5x10^4$					
Y-92		0.2	5.41	0.2	5.41	$3.6x10^5$
	$9.6x10^6$					
Y-93		0.2	5.41	0.2	5.41	$1.2x10^5$
	$3.3x10^6$					

Rule .06(22)(e) Table 4

A_1 AND A_2 VALUES FOR RADIONUCLIDES *(Continued)*

Symbol of Radionuclide	Element and Atomic No.	A_1 (TBq)	A_1 (Ci)	A_2 (TBq)	A_2 (Ci)	Specific Activity (TBq/g)	(Ci/g)
Yb-169	Ytterbium(70)	3	81.1	3	81.1	$8.9x10^2$	$2.4X10^4$
Yb-175		30	811	0.9	24.3	$6.6x10^3$	$1.8x10^5$
Zn-65	Zinc(30)	2	54.1	2	54.1	$3.0x10^2$	$8.2x10^3$
Zn-69m		2	54.1	0.5	13.5	$1.2x10^5$	$3.3x10^6$
Zn-69		4	108	0.5	13.5	$1.8x10^6$	$4.9x10^7$
Zr-88	Zirconium(40)	3	81.1	3	81.1	$6.6x10^2$	$1.8x10^4$
Zr-93		40	1080	0.2	5.41	$9.3x10^{-5}$	$2.5x10^{-3}$
Zr-95		1	27.0	0.9	24.3	$7.9x10^2$	$2.1x10^4$
Zr-97		0.3	8.11	0.3	8.11	$7.1x10^4$	$1.9x10^6$

Rule .06(22)(e)

Table 5
GENERAL VALUES FOR A_1 AND A_2

Contents	A_1		A_2	
	TBq	Ci	TBq	Ci
Only beta- or gamma-emitting nuclides are known to be present.	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available.	0.10	2.70	$2x10^{-5}$	$5.41x10^{-4}$

Table ~~5~~ 6
ACTIVITY-MASS RELATIONSHIPS FOR URANIUM/THORIUM

Uranium Enrichment* wt% ^{235}U present	Specific Activity Ci/g	g/Ci
0.45	$5.0x10^{-7}$	$2.0x10^{6}$
0.72	$7.06x10^{-7}$	$1.42x10^{6}$
1.0	$7.6x10^{-7}$	$1.3x10^{6}$
1.5	$1.0x10^{-6}$	$1.0x10^{6}$
5.0	$2.7x10^{-6}$	$3.7x10^{5}$
10.0	$4.8x10^{-6}$	$2.1x10^{5}$
20.0	$1.0x10^{-5}$	$1.0x10^{5}$
35.0	$2.0x10^{-5}$	$5.0x10^{4}$
50.0	$2.5x10^{-5}$	$4.0x10^{4}$
90.0	$5.8x10^{-5}$	$1.7x10^{4}$
93.0	$7.0x10^{-5}$	$1.4x10^{4}$
95.0	$9.1x10^{-5}$	$1.1x10^{4}$
Natural Thorium	$2.2x10^{-7}$	$4.6x10^{6}$

* The figures for uranium include representative values for the activity of the uranium-234 which is concentrated during the enrichment process. The activity for thorium includes the equilibrium concentration of thorium-228.

Authority Ga. L. 1964, pp. 499, 507, 566-575, as amended (Georgia Radiation Control Act).