

APA-1
11/96

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-3-26-.07

Rule Title Use of Radionuclides in the Healing Arts

New Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? n/a

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer Jahricc Shie Date 2/20/2014

FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-3-26-.07, Use of Radionuclides in the Healing Arts

INTENDED ACTION: Revision of Rule 420-3-26-.07.

SUBSTANCE OF PROPOSED ACTION: To amend the current rules to be compatible with those of the U.S. Nuclear Regulatory Commission.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held at 9:00 a.m. March 26, 2014, at the Alabama Department of Public Health, RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on May 29, 2014. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: David Walter, Director of the Office of Radiation Control, Department of Public Health, 201 Monroe Street, Suite 700, Montgomery, Alabama 36104. Telephone number (334) 206-5391.


Patricia E. Ivie, Agency Secretary

420-3-26-.07 Use of Radionuclides in the Healing Arts

(1) Purpose and Scope.

This rule establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of these rules are in addition to, and not in substitution for, others in these rules. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

(2) Definitions.

(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 an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

(c) "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

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

1. Meets the requirements in 420-3-26-.07(27) and 420-3-26-.07(30); or
2. Is identified as an authorized medical physicist or teletherapy physicist on:

(i) A U.S. Nuclear Regulatory Commission or Agreement State specific license that authorizes the medical use of radioactive material; or,

(ii) A U.S. Nuclear Regulatory ~~commission~~Commission or Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material; or,

(iii) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee; and,

3. Is identified as an authorized medical physicist or teletherapy physicist on a specific medical use license issued by the Agency; or,

4. Is identified as an authorized medical physicist or teletherapy physicist on a permit issued by an Agency specific medical use license of broad scope that is authorized to permit the use of radioactive material.

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

1. Meets the requirements in 420-3-26-.07(28) and 420-3-26-.07(30); or

2. Is identified as an authorized nuclear pharmacist on—:

(i) A U.S. Nuclear Regulatory Commission or Agreement State specific license that authorizes medical use or the practice of nuclear pharmacy; or,

(ii) A U.S. Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit medical use or the practice of nuclear pharmacy; or,

(iii) A permit issued by a U.S. Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; and,

3. Has been approved to practice nuclear pharmacy by the Alabama State Board of Pharmacy; and

4. Is identified as an authorized nuclear pharmacist on a specific license that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Agency; or

5. Is identified as an authorized nuclear pharmacist on a permit issued by an Agency specific license of broad scope that is authorized to permit the use of radioactive material.

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

1. Meets the requirements in 420-3-26-.07(30) and 420-3-26-.07(47), 420-3-26-.07(51), 420-3-26-.07(56), 420-3-26-.07(57), 420-3-26-.07(58), 420-3-26-.07(68), 420-3-26-.07(69), 420-3-26-.07(71), or 420-3-26-.07(89); or

2. Is identified as an authorized user on:

(i) A U.S. Nuclear Regulatory Commission or Agreement State specific license that authorized the medical use of radioactive material; or

(ii) A U.S. Nuclear Regulatory Commission or Agreement State specific license of broad scope, or a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, that is authorized to permit the medical use of radioactive material; and,

3. Is identified as an authorized user on a license issued by the Agency; or

4. Is identified as an authorized user on a permit issued by an Agency specific license of broad scope that is authorized to permit the medical use of radioactive material.

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

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

(i) "Client's address" means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with 420-3-26-.07(42).

(j) "Cyclotron" means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

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

(l) "Dentist" means an individual licensed to practice dentistry by the Alabama Board of Dental Examiners.

(m) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

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

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

treatment site.

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

(q) "Manual brachytherapy" means a type of therapy in which brachytherapy sources are manually placed topically on, or inserted into, either the body cavities that are in close proximity to a treatment site, or directly into the tissue volume.

(r) "Medical institution" means an organization in which more than one medical discipline is practiced.

(s) "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(t) "Medium dose-rate remote afterloader" (MDR) means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the prescribed treatment site.

(u) "Misadministration" means an event that meets the criteria in 420-3-26-.07(120)(a) or (b).

(v) "Mobile medical service" means the transportation of radioactive material to, and its medical use at, the client's address.

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

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

(y) "Pharmacist" means an individual licensed by the Alabama Board of Pharmacy.

(z) "Physician" means a doctor of medicine or doctor of osteopathy licensed by the Alabama State Board of Medical Examiners to prescribe drugs in the practice of medicine.

(aa) "Podiatrist" means an individual licensed by the Alabama State Board of Podiatry.

(bb) "Positron Emission Tomography (PET) radionuclide production facility" is a

facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

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

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

1. In a written directive as specified in 420-3-26-.07(23); or
2. In accordance with the directions of the authorized user for procedures as specified in 420-3-26-.07(45) and 420-3-26-.07(48).

(ee) "Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, the total dose and dose per fraction as documented in the written directive;
3. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

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

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
2. Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(gg) "Radiation Safety Officer" means an individual who:

1. ~~meets~~ Meets the requirements in 420-3-26-.07(26) and 420-3-26-.07(30);
- or,

2. Is named as a Radiation Safety Officer on a specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State, or a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; and,

3. ~~is~~ Is named as a Radiation Safety Officer on an Agency license.

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

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

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

(kk) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.

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

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

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

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

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

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

(rr) "Type of use" means use of radioactive material as specified under

420-3-26-.07(45), (48), (52), (60), (70), (72) or (90).

(ss) "Unit dosage" means a dosage prepared for medical use, to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(tt) "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 420-3-26-.07(23).

(3) Maintenance of Records.

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

(4) Provisions for Research Involving Human Subjects.

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

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

(b) The research involving human subjects authorized in 420-3-26-.07(4)(a) shall be conducted using radioactive material authorized for medical use in the license; and

(c) Nothing in 420-3-26-.07(4) relieves licensees from complying with the other requirements in this rule.

(5) U.S. Food and Drug Administration, Federal, and State Requirements.

Nothing in this rule relieves the licensee from complying with applicable U.S. Food and

Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

(6) Implementation.

~~(a)~~ A licensee shall implement the provisions in this rule on June 23, 2006.

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

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

~~(d)~~ If a license condition exempted a licensee from a provision of this Rule on ~~June 23, 2006~~ its effective date, it will continue to exempt a licensee from the corresponding provision in this Rule.

~~(e)~~ If a license condition cites provisions in this rule that ~~will be~~ were deleted on ~~June 23, 2006~~ the effective date of this rule, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

~~(f)~~ Licensees shall continue to comply with any license condition that requires it to implement procedures required by 420-3-26-.07(75), 420-3-26-.07(81), 420-3-26-.07(82) and 420-3-26-.07(83) until there is a license amendment or renewal that modifies the license condition.

(7) License Required.

(a) A person shall only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Agency, or as allowed in 420-3-26-.07(7)(b) or 420-3-26-.07(7)(c).

(b) An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in this rule under the supervision of an authorized user as provided in 420-3-26-.07(22), unless prohibited by license condition.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in this rule under the supervision of an authorized nuclear pharmacist or authorized user as provided in 420-3-26-.07(22), unless prohibited by license condition.

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

- (a) An application must be signed by the applicant's or licensee's management.
- (b) An application for a license for medical use of radioactive material as described in 420-3-26-.07(45), (48), (52), (60), (70), (72) or (90) must be made by:
 - i. Filing an original of Agency Form RM; and
 - ii. Submitting procedures required by sections 420-3-26-.07(75), 420-3-26-.07(81), 420-3-26-.07(82) and 420-3-26-.07(83), as applicable.
- (c) A request for a license amendment or renewal must be made by:
 - i. Submitting an original request in letter format.
 - ii. Submitting procedures required by sections 420-3-26-.07(75), 420-3-26-.07(81), 420-3-26-.07(82) and 420-3-26-.07(83), as applicable.
- (d) In addition to the requirements in 420-3-26-.07(8)(b) and 420-3-26-.07(8)(c), an application for a license or amendment for medical use of radioactive material as described in 420-3-26-.07(90) of this rule must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 420-3-26-.07(1) through 420-3-26-.07(44), as well as any specific information on:
 - i. Radiation safety precautions and instructions;
 - ii. Training and experience of proposed users;
 - iii. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
 - iv. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.
- (e) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.
- (f) An applicant that satisfies the requirements specified in 420-3-26-.02(10)(e) may apply for a Type A specific license of broad scope.

(9) Mobile Medical Service Administrative Requirements.

- (a) The Agency shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive

material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

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

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

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

(e) A licensee providing mobile medical services shall retain the letter required in (9)(b) in accordance with 420-3-26-.07(102).

(f) A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:

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

(g) A mobile medical service licensee shall maintain all records required by rules 420-3-26-.03 and 420-3-26-.07 of these regulations at a location within the Agency's jurisdiction that is:

1. A single address of use:
- (i) Identified as the records retention location; and

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

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

(i) Identified in the license; and

(ii) Whose current client's address schedule and location schedule is reported to the Agency at a frequency specified by the Agency.

(10) License Amendments.

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

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

(b) Before it permits anyone, except a visiting authorized user described in 420-3-26-.07(12), a visiting authorized medical physicist as described in 420-3-26-.07(13), or a visiting authorized nuclear pharmacist as described in 420-3-26-.07(14) to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license.

(c) Before it changes Radiation Safety Officers, except as provided in 420-3-26-.07(19)(c);

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

(e) Before it adds to or changes the areas of use identified in the application or on the license;

(f) Before it changes the address(es) of use identified in the application or on the license;

(g) Before it changes statements, representations, and procedures which are incorporated into the license; and

(h) Before it releases licensed facilities for unrestricted use.

(11) Notifications.

A licensee shall notify the Agency by letter no later than 30 days after:

(a) A Radiation Safety Officer, authorized user, authorized medical physicist or authorized nuclear pharmacist permanently discontinues performance of duties under the license, or has a name change;

(b) The licensee's mailing address changes;

(c) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 420-3-26-.02(12)(b); or

(d) The licensee has added to or changed the areas where radioactive material is used in accordance with 420-3-26-.07(45), 420-3-26-.07(48), 420-3-26-.07(52) and 420-3-26-.07(70).

(12) Visiting Authorized User.

(a) A licensee may permit a physician to act as a visiting authorized user and use licensed material for medical use under the terms and conditions of the licensee's license for 60 days each calendar year if:

1. The visiting authorized user has the prior written permission of the licensee's management, and the Radiation Safety Committee if one is required;

2. The licensee has a copy of:

(i) An Agency license that identifies the visiting authorized user, by name, as an authorized user for medical use; or

(ii) A permit issued by an Agency specific license of broad scope that identifies the visiting authorized user, by name, as an authorized user for medical use; and;

3. The visiting authorized user performs only those procedures:

(i) For which they are specifically authorized to perform on an Agency license; and;

(ii) Which are specifically approved on the licensee's license.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in 420-3-26-.07(12)(a).

(c) A licensee shall retain copies of the records specified in 420-3-26-.07(12)(a) for three years from the date of the last visit.

(13) Visiting Authorized Medical Physicist.

(a) A licensee may permit a medical physicist to act as a visiting authorized medical physicist and perform the duties of a medical physicist under the terms and conditions of the licensee's license for 60 days each calendar year if:

1. The visiting authorized medical physicist has the prior written permission of the licensee's management, and the Radiation Safety Committee if one is required; and,

2. The licensee has a copy of:

(i) An Agency license that identifies the visiting authorized medical physicist, by name, as an authorized medical physicist; or

(ii) A permit issued by an Agency specific license of broad scope that identifies the visiting authorized medical physicist, by name, as an authorized medical physicist.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized medical physicist to perform licensed duties as described in 420-3-26-.07(13)(a).

(c) A licensee shall retain copies of the records specified in 420-3-26-.07(13)(a) for three years from the date of the last visit.

(14) Visiting Authorized Nuclear Pharmacist.

(a) A licensee may permit a nuclear pharmacist to act as a visiting authorized nuclear pharmacist and perform the duties of a nuclear pharmacist under the terms and conditions of the licensee's license for 60 days each calendar year if:

1. The visiting authorized nuclear pharmacist has the prior written permission of the licensee's management, and the Radiation Safety Committee if one is required;

2. The licensee has a copy of:

(i) An Agency license that identifies the visiting authorized nuclear pharmacist, by name, as an authorized nuclear pharmacist; or

(ii) A permit issued by an Agency specific license of broad scope that identifies the nuclear pharmacist, by name, as an authorized nuclear pharmacist.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized nuclear pharmacist to perform licensed duties as described in 420-3-26-.07(14)(a).

(c) A licensee shall retain copies of the records specified in 420-3-26-.07(14)(a) for ~~three~~ years from the date of the last visit.

(15) Exemptions Regarding Type A Specific Licenses of Broad Scope.

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

(a) The provisions of 420-3-26-.07(8)(d), regarding the need to file an amendment to the license for medical uses of radioactive material, as described in 420-3-26-.07(90);

(b) The provisions of 420-3-26-.07(10)(b);

(c) The provisions of 420-3-26-.07(10)(e) regarding additions to or changes in the areas of use at the addresses specified in the license;

(d) The provisions of 420-3-26-.07(11)(a) regarding notification to the Agency for authorized users, authorized medical physicists and authorized nuclear pharmacists;

(e) The provisions of 420-3-26-.07(11)(c) and (d); and

(f) The provisions of 420-3-26-.07(25)(a).

(16) License Issuance.

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

1. The applicant has filed an Agency Form RM in accordance with the instructions in 420-3-26-.07(8);

2. The applicant has paid any applicable fee;

3. The applicant meets the requirements of 420-3-26-.02 of these regulations; and

4. The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.

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

1. Meets the requirements in 420-3-26-.07(16)(a); and

2. Assures that individuals to whom radioactive drugs or radiation from implants

containing radioactive material will be administered, may be released following treatment in accordance with 420-3-26-.07(41).

(17) Specific Exemptions.

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

(18) ALARA Program.

(a) 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 accordance with 420-3-26-.03(5)(b) of these rules.

(b) To satisfy the requirement of 420-3-26-.07(18)(a):

1. The management, Radiation Safety Officer and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or required by the Radiation Safety Committee.

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

(c) 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.

(d) 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.

(e) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description must include:

1. A commitment by management to keep occupational doses as low as reasonably achievable;

2. A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

3. Personnel exposure action levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

4. 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.

(19) Authority and Responsibilities for the Radiation Protection Program.

(a) In addition to the radiation protection program requirements of 420-3-26-.03(5) of these regulations, a licensee's management must approve in writing:

1. Requests for license application, renewal, or amendments before submittal to the Agency;

2. Radiation protection program changes that do not require a license amendment and are permitted under 420-3-26-.07(20); and

3. Any individual before allowing that individual to act as a visiting authorized user, visiting authorized medical physicist or a visiting authorized nuclear pharmacist.

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

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 420-3-26-.07(19)(e), provided the licensee takes the actions required in 420-3-26-.07(19)(b),(d),(e) and (h). A licensee may simultaneously appoint more than one temporary Radiation Safety Officer, if needed, to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different uses of radioactive material permitted by the license.

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

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

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

(f) Licensees that are authorized for two or more different types of radioactive material use under 420-3-26-.07(52), 420-3-26-.07(60), 420-3-26-.07(72) and 420-3-26-.07(90), or two or more types of units under 420-3-26-.07(72) shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(g) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 6 months. The Licensee shall maintain minutes of each meeting in accordance with 420-3-26-.07(91).

(h) For record requirements, see 420-3-26-.07(91). ~~A licensee shall retain a record of actions taken pursuant to 420-3-26-.07(91)(a), (b), and (d) in accordance with 420-3-26-.07(91).~~

(20) Radiation Protection Program Changes.

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

1. The revision does not require an amendment under 420-3-26-.07(10);
2. The revision is in compliance with the regulations and the license;
3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
4. The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with 420-3-26-.07(92).

(21) Duties of Authorized Users and Authorized Medical Physicists.

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

1. Select the patients to receive radiopharmaceuticals or radiation from radioactive materials;
2. Prescribe the radiopharmaceutical dosage and/or dose to be administered, in writing, through the issuance of a written directive as described in 420-3-26-.07(23) or by written reference to the diagnostic clinical procedures manual;
3. Direct, as specified in 420-3-26-.07(22) and 420-3-26-.07(23), or in license conditions, the administration of radiopharmaceuticals or radioactive material for medical use to patients or human research subjects;
4. Prepare and administer, or supervise the preparation and administration of radiopharmaceuticals or radioactive material for medical use, in accordance with 420-3-26-.07(7)(b), 420-3-26-.07(7) (c) and 420-3-26-.07(22); and
5. Perform the final interpretation of the results of tests, studies, or treatments.

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

1. Full calibration measurements as described in 420-3-26-.07(78), 420-3-26-.07(79) and 420-3-26-.07(80);
2. Periodic spot checks as described in 420-3-26-.07(81), 420-3-26-.07(82) and 420-3-26-.07(83); and
3. Radiation surveys as described in 420-3-26-.07(85).

(22) Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by 420-3-26-.07(7)(b) shall:

1. In addition to the requirements in 420-3-26-.10(3) of these regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this rule, and license conditions with respect to the use of radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising

authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of this rule, and license conditions with respect to the medical use of radioactive material.

(b) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 420-3-26-.07(7)(c), shall:

1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of this rule, and license conditions.

(c) Unless physical presence as described in other sections of this rule is required, a licensee who permits supervised activities under 420-3-26-.07(22)(a) and 420-3-26-.07(22)(b) shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification; and

(d) A licensee that permits supervised activities under 420-3-26-.07(22)(a) and 420-3-26-.07(22)(b) is responsible for the acts and omissions of the supervised individual.

(23) Written Directives.

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

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

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

1. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of

administration;

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

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

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

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

(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).

(c) For all other medical uses of radioactive material that do not require a specific written directive, an authorized user shall prescribe the radiopharmaceutical dosage and/or dose from radioactive material to be administered in writing, or by written reference to the diagnostic clinical procedures manual.

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

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

(e) The licensee shall retain the written directive in accordance with 420-3-26-.07(93).

(24) Procedures for Administrations Requiring a Written Directive.

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

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

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

(b) The procedures required by 420-3-26-.07(24)(a) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;

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

3. Checking both manual and computer-generated dose calculations; and

4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 420-3-26-.07(72).

(25) Suppliers for Sealed Sources or Devices for Medical Use.

For medical use, a licensee may only use:

(a) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 420-3-26-.02 of these regulations or the equivalent requirements of the U.S. Nuclear Regulatory Commission or an Agreement State;

(b) Sealed sources or devices noncommercially transferred from an Agency, U.S. Nuclear Regulatory Commission or Agreement State licensee: or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 420-3-26-.02 of these regulations or the equivalent requirements of the U.S. Nuclear Regulatory Commission or an Agreement State.

(26) Training for Radiation Safety Officer.

Except as provided in 420-3-26-.07(29), the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in 420-3-26-.07(19) to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements of paragraphs (d) and (e) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(ii) Have ~~five~~5 or more years of professional experience in health physics (graduate training may be substituted for no more than ~~two~~2 years of the required experience), including at least 3 years in applied health physics; and

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

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

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

(I) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State; or

(II) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in 420-3-26-.07(29), 420-3-26-.07(51) or 420-3-26-.07(56); and

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

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

1. 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(v) Radiation dosimetry; and

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

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

(ii) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

(iii) Securing and controlling radioactive material;

(iv) Using administrative controls to avoid mistakes in the administration of radioactive material;

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

(vi) Using emergency procedures to control radioactive material;

(vii) Disposing of radioactive material; or

(c) 1. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State under 420-3-26-.07(27)(a) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs 420-3-26-.07(26)(d) and (e); or

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

(d) Has obtained written ~~certification~~ attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph 420-3-26-.07(26)(e) and in paragraphs 420-3-26-.07(26)(a)1.(i) and (a)1.(ii) or 420-3-26-.07(26)(a)2.(i) and (a)2.(ii) or 420-3-26-.07(26)(b)(1) or 420-3-26-.07(26)(c)(1) or 420-3-26-.07(26)(c)(2), and has achieved a level of radiation safety knowledge sufficient to independently function as an Radiation Safety Officer for a medical use licensee; and

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

(27) Training for Authorized Medical Physicist.

Except as provided in 420-3-26-.07(29), the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 420-3-26-.07(27)(b)(2) and (c). To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 420-3-26-.07(29), 420-3-26-.07(68) or 420-3-26-.07(89); and

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

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

- (i) Performing sealed source leak tests and inventories;
- (ii) Performing decay corrections;
- (iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(27)(c) and 420-3-26-.07(27)(a)1. and 2., or 420-3-26-.07(27)(b)1. and (c), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 420-3-26-.07(27), 420-3-26-.07(29) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

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

(28) Training for an Authorized Nuclear Pharmacist.

Except as provided in 420-3-26-.07(29), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph 420-3-26-.07(28)(b)(2). To have its certification process recognized, a specialty board shall require all candidates for certification to:

- 1. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
- 2. Hold a current, active license to practice pharmacy;
- 3. Provide evidence of having acquired at least 4000 hours of training/experience in

nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

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

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

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

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

(V) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving

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

(II) Using and performing checks for proper operation of instruments used to determine the activity of dosages, 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 medical events in the administration of radioactive material; and

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

2. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(28)(a)1., (a)2., and (a)3. or 420-3-26-.07(28)(b)1., and has achieved a level of

competency sufficient to function independently as an authorized nuclear pharmacist.

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

(a) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on an Agency license or a permit issued by an Agency broad scope licensee before June 23, 2006, need not comply with the training requirements of 420-3-26-.07(26), 420-3-26-.07(27), or 420-3-26-.07(28), respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Agency or a permit issued by an Agency broad scope licensee before June 23, 2006, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of this rule.

(c) Individuals who meet the provisions for experienced Radiation Safety Officer, Authorized Medical Physicist, Authorized User or Authorized Nuclear Pharmacist may serve as a preceptor for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which the preceptoring individual is authorized.

(30) Recentness of Training.

The training and experience specified in this rule must have been obtained within the seven (7) years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

(31) 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, in writing, by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

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

(a) For direct measurements performed in accordance with 420-3-26-.07(34), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(b) A licensee shall:

1. 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 must be done on a frequently used setting with a sealed source of not less than 3700 kilobecquerel (100 microcuries) for any photon-emitting radio- nuclide with a half-life greater than 90 days;

2. Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least ~~two~~2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 3700 kilobecquerel (100 microcuries) for any photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

3. Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 1.1 Megabecquerel (30 μ Ci) and the highest dosage that will be administered; and

4. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 1.1 Megabecquerel (30 μ Ci) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(d) A licensee shall also perform checks and tests required by 420-3-26-.07(32) following adjustment or repair of the dose calibrator.

(e) A licensee shall retain a record of each instrument test required by 420-3-26-.07(32) in accordance with 420-3-26-.07(96).

(33) Calibration of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with 420-3-26-.07 and 420-3-26-.03 of these regulations have been calibrated before first use, annually, and following any repair that will affect the calibration.

(b) To satisfy the requirements of 420-3-26-.07(33)(a), the licensee shall:

1. Calibrate all required scale readings up to 10 millisieverts (1000 millirem) per hour with a radiation source;

2. Have each radiation survey instrument calibrated:

(i) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at ~~three~~ three points between 0.02 and 10 millisieverts (2 and 1000 millirem) per hour; and

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

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

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

(d) A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each survey instrument calibration in accordance with 420-3-26-.07(97).

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

(a) A licensee shall determine and record the activity of each dosage prior to medical use. For photon-emitting radioactive material, this determination shall be within 30 minutes prior to medical use. For all other radioactive material, this determination shall be within the period before medical use that is no greater than 10 percent of the physical half-life of the radioactive material.

(b) This determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 420-3-26-.02 of these regulations, or equivalent provisions of the U.S. Nuclear Regulatory Commission or an Agreement State.

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

(d) A licensee shall retain a record of the dosage determination required by this rule in accordance with 420-3-26-.07(98).

(35) Authorization for Calibration, Transmission and Reference Sources.

Any person authorized by 420-3-26-.07(7) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

(a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 420-3-26-.02 or equivalent provisions of the U.S. Nuclear Regulatory Commission or an Agreement State and that do not exceed 1.11 gigabecquerels (30 millicurie) each;

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

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

1. 7.4 megabecquerels (200 μCi); or
2. 1000 times the quantities in Appendix B of 420-3-26-.02; and

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

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

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

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

1. Test the source for leakage in accordance with 420-3-26-.03.
2. Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

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

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of 420-3-26-.02 and 420-3-26-.03;
2. File a report with the Agency within ~~five~~ 5 days of receiving the leak tests results

in accordance with 420-3-26-.07(122).

(d) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with 420-3-26-.07(99).

(37) Syringe Shields.

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

(b) A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient.

(38) Vial Shields.

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

(39) Labels.

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

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

(a) Except as provided in 420-3-26-.07(40)(b) of this section, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs were prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument once each week, or at other intervals authorized by the Agency, all areas where radioactive drugs, sealed sources or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by 420-3-26-.07(40)(a) and (b) so as to be able to measure dose rates as low as 1 microsievert (0.1 millirem) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by 420-3-26-.07(40)(a) and (b) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination at the end of each day of use, or at other intervals authorized by the Agency, all areas where radioactive drugs were prepared for use or administered. The licensee shall also survey for removable contamination each week all areas where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by 420-3-26-.07(40)(e) so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).

(g) A licensee shall establish removable contamination action levels for the surveys required by 420-3-26-.07(40)(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee does not need to perform the surveys required by 420-3-26-.07(40)(a) in area(s) where patients or human research subjects are confined when they cannot be released pursuant to 420-3-26.07(41).

(i) A licensee shall retain a record of each survey in accordance with 420-3-26-.07(100).

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

(a) A licensee may authorize the release from its control of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).

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

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

(c) Release of the patient must be approved by an individual listed as an authorized user on the Agency license, and who is approved for the type of radioactive material use for which the patient being released has received.

(d) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 420-3-26-.07(101).

(e) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 420-3-26-.07(101).

(f) Notwithstanding 420-3-26-.07(41)(a), the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

(g) The licensee shall immediately notify the Agency in accordance with 420-3-26-.07(123) if a patient departs prior to an authorized release.

(h) The licensee shall notify the Agency in accordance with 420-3-26-.07(124):

1. When they are aware that a patient containing radioactive material and who has been released in accordance with 420-3-26-.07(41) dies; and,

2. If it is possible that any individual could receive exposures in excess of 5 millisieverts (500 millirem) as a result of the deceased's body.

(42) Mobile Medical Service Technical Requirements.

A licensee providing mobile medical service shall:

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

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

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

(d) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check.

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

(f) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with 420-3-26-.03;

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

(h). Retain a record of each survey required by 420-3-26-.07(42)(f) in accordance with 420-3-26-.07(102).

(43) Storage of Volatiles and Gases.

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

(b) A licensee shall store and use a multi-dose container in a properly functioning fume hood.

(c) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in 420-3-26-.03.

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

(e) A licensee shall only administer radioactive gases in rooms that are at negative pressure with respect to surrounding rooms.

(f) 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 420-3-26-.03. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(g) A licensee shall post the time calculated in 420-3-26-.07(43)(f) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(h) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for ~~three~~ years.

(i) A copy of the calculations required in 420-3-26-.07(43)(f) shall be recorded and retained for the duration of the license.

(44) Decay-in-Storage.

(a) A licensee may hold radioactive material with a physical half-life of less than or

equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

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

(b) For radioactive material disposed in accordance with 420-3-26-.07(44)(a), the licensee shall retain a record of each disposal in accordance with 420-3-26-.07(103).

Specific Requirements for the Use of Radioactive Material for Uptake, Dilution, or Excretion Studies

(45) Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for Which a Written Directive is Not Required.

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

(a) Obtained from a manufacturer or preparer licensed pursuant to 420-3-26-.02 or equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 420-3-26-.07(47) or (51), or an individual under the supervision of either as specified in 420-3-26-.07(22); or

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

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

U.S. Food and Drug Administration for use in research.

(46) Possession of Survey Instrument.

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirem) per hour. The instrument shall be operable and calibrated in accordance with 420-3-26-.07(33).

(47) Training for Uptake, Dilution, and Excretion Studies.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(45) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph 420-3-26-.07(47)(c)(2). To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs 420-3-26-.07(47)(c)(1)(i) and (c)(1)(ii); and

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

(b) Is an authorized user under 420-3-26-.07(51) or (56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(c) 1. Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

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

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(47), 420-3-26-.07(51), 420-3-26-.07(56) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving:

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

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

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

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

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

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

2. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(47), 420-3-26-.07(51), 420-3-26-.07(56) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph 420-3-26-.07(47)(a)(1) or (c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 420-3-26-.07(45).

Specific Requirements for the Use of Radioactive Material for Imaging and Localization Studies

(48) Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required.

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

420-3-26-.07(23) that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to 420-3-26-.02 or equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 420-3-26-.07(51), or 420-3-26-.07(56) and 420-3-26-.07(51)(c)(ii)(VII), or an individual under the supervision of either as specified in 420-3-26-.07(22); or

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

(d) Provided the conditions of 420-3-26-.07(43) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

(49) **Radionuclide Contaminants.**

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

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

(b) To demonstrate compliance with 420-3-26-.07(49)(a), the licensee preparing radioactive drugs from radionuclide generators shall:

1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;
2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

(c) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with 420-3-26-.07(104).

(d) A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in 420-3-26-.07(49)(a).

(50) Possession of Survey Instruments.

A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 millirem) per hour to 10 millisieverts (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(33).

(51) Training for Imaging and Localization Studies.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(48) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 420-3-26-.07(51)(c)(1)(i) and (c)(1)(ii); and

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

(b) Is an authorized user under 420-3-26-.07(56) and meets the requirements in 420-3-26-.07(51)(c)(1)(ii)(VII), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

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

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

- (I) Radiation physics and instrumentation;
- (II) Radiation protection;
- (III) Mathematics pertaining to the use and measurement of radioactivity;
- (IV) Chemistry of radioactive material for medical use;
- (V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(51), or 420-3-26-.07(51)(c)(1)(ii)(VII) and 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving:

- (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (III) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- (V) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- (VI) Administering dosages of radioactive drugs to patients or human research subjects; and
- (VII) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(51) or 420-3-26-.07(56) and 420-3-26-.07(51)(c)(1)(ii)(VII), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in 420-3-26-.07(51)(a)(1) or 420-3-26-.07(51)(c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under

420-3-26-.07(45) and (48).

Radioactive Material - Written Directive Required

(52) Use of Unsealed Radioactive Material for Which a Written Directive is Required.

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

(a) Obtained from a manufacturer or preparer licensed in accordance with 420-3-26-.02 or equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 420-3-26-.07(51) or 420-3-26-.07(56), or an individual under the supervision of either as specified in 420-3-26-.07(22); or

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

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by U.S. Food and Drug Administration for use in research.

(53) Safety Instruction.

In addition to the requirements of 420-3-26-.10(3):

(a) A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with 420-3-26-.07(41). The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;
2. Visitor control to include the following:
 - (i) Routine visitation to hospitalized individuals in accordance with 420-3-26-.03;

- (ii) Contamination control;
- (iii) Waste control; and
- (iv) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with 420-3-26-.07(105).

(54) Safety Precautions.

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 420-3-26-.07(41), a licensee shall:

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

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

(ii) A room, with a private sanitary facility, with another individual who also has received radiopharmaceutical therapy and who cannot be released in accordance with 420-3-26-.07(41); and,

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

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

(b) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Agency in accordance with 420-3-26-.07(124) if it is possible that any individual could receive exposures in excess of 420-3-26-.03(14) as a result of the deceased's body.

(55) Possession of Survey Instruments.

A licensee authorized to use radioactive material for which a written directive is required

shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 millirem) per hour to 10 millisieverts (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(33).

(56) Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(52) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 420-3-26-.07(56)(b)1.(ii)(VII) and (b)2. To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs 420-3-26-.07(56)(b)1.(i) through (b)1.(ii)(V). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

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

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

- (i) Classroom and laboratory training in the following areas
- (I) Radiation physics and instrumentation;
- (II) Radiation protection;
- (III) Mathematics pertaining to the use and measurement of radioactivity;

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

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 420-3-26-.07(56)(b) must also have experience in administering dosages in the same dosage category or categories (i.e., 420-3-26-.07(56)(b)1.(ii)(VII)) as the individual requesting authorized user status. The work experience must involve:

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

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

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

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

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

(VI) [Reserved]

(VII) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status

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

(B) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131¹;

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

¹ Experience with at least 3 cases in (56)(b)1.(ii)(VII)(B) also satisfies the requirement in (56)(b)1.(ii)(VII)(A).

(D) Parenteral administration of any other radionuclide, for which a written directive is required; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(56)(a)1. and (b)1.(ii)(VII) or (b)1., and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 420-3-26-.07(52). The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements in 420-3-26-.07(56)(b) must have experience in administering dosages in the same dosage category or categories (i.e., 420-3-26-.07(56)(b)1.(ii)(VII)) as the individual requesting authorized user status.

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

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 420-3-26-.07(57)(c)1. and (c)2. and whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph 420-3-26-.07(57)(c)3.; or

(b) Is an authorized user under 420-3-26-.07(56)(a), 420-3-26-.07(56)(b) for uses listed in 420-3-26-.07(56)(b)1(ii)(VII)(A) or (B), 420-3-26-.07(58) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

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

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(57), 420-3-26-.07(58) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii)(VII)(A) or (B). The work experience must involve:

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

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

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

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

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

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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(57)(c)1. and (c)2., and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 420-3-26-.07(52). The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(57) or 420-3-26-.07(58) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii)(VII)(A) or (B).

(58) Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user for

the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 420-3-26-.07(58)(c)1. and (c)2., and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in paragraph 420-3-26-.07(58)(c)3.; or

(b) Is an authorized user under 420-3-26-.07(56)(a), 420-3-26-.07(56)(b) for uses listed in 420-3-26-.07(56)(b)1.(ii)(VII)(B), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

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

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of radioactive material for medical use; and
- (v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(58), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)(1)(ii)(VII)(B). The work experience must involve:

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

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

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

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

radioactive material;

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

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

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(58)(c)1. and (c)2. and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 420-3-26-.07(52). The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56) or 420-3-26-.07(58), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)(1)(ii)(VII)(B).

(59) Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an authorized user under 420-3-26-.07(56) for uses listed in 420-3-26-.07(56)(b)1.(ii)(VII)(C) or 420-3-26-.07(56)(b)1.(ii)(VII)(D), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(b) Is an authorized user under 420-3-26-.07(68) or 420-3-26-.07(89), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and who meets the requirements in paragraph 420-3-26-.07(59)(d) of this section; or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under 420-3-26-.07(68) or 420-3-26-.07(89) and who meets the requirements in paragraph 420-3-26-.07(59)(d) of this section.

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

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of radioactive material for medical use; and
- (v) Radiation biology; and

(2) Has work experience under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(59), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 420-3-26-.07(56) must have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii)(VII)(C) and/or 420-3-26-.07(56)(b)1.(ii)(VII)(D). The work experience must involve:

- (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- (v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
- (vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

- (3) Has obtained written attestation that the individual has satisfactorily completed

the requirements in paragraph 420-3-26-.07(59)(b) or (c), and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(59), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in 420-3-26-.07(56) must have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii)(VII)(C) and/or 420-3-26-.07(56)(b)1.(ii)(VII)(D).

Manual Brachytherapy

(60) Use of Sealed Sources for Manual Brachytherapy

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

- (a) As approved in the Sealed Source and Device Registry; or
- (b) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 420-3-26-.07(25)(a) are met.

(61) Surveys After Source Implant and Removal.

- (a) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.
- (b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys in accordance with 420-3-26-.07(106).

(62) Brachytherapy Sources Inventory.

- (a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.
- (b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with 420-3-26-.07(107).

(63) Safety Instruction.

In addition to the requirements of 420-3-26-.10(3):

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with 420-3-26-.07(41). Instruction must be commensurate with the duties of the personnel and shall include the following:

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

(i) Routine visitation of hospitalized individuals in accordance with 420-3-26-.03(14)(a)1.; and

(ii) Visitation authorized in accordance with 420-3-26-.03(14)(b); and

5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Agency in accordance with 420-3-26-.07(124) if it is possible that any individual could receive exposures in excess of 420-3-26-.03(14) as a result of the deceased's body.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with 420-3-26-.07(105).

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

(a) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with 420-3-26-.07(41), a licensee shall:

1. Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

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

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

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

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

(65) Calibration Measurements of Brachytherapy Sealed Sources.

(a) Prior to the first medical use of a brachytherapy sealed source on or after June 23, 2006, a licensee shall perform the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of 420-3-26-.07(77);
2. Determine source positioning accuracy within applicators; and
3. Use published protocols accepted by nationally recognized bodies to meet the requirements of 420-3-26-.07(65)(a)1. and (a)2.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 420-3-26-.07(65)(a).

(c) A licensee shall mathematically correct the outputs or activities determined in 420-3-26-.07(65)(a) of this section for physical decay at intervals consistent with 1.0 percent physical decay.

(d) An authorized medical physicist shall perform or review the calculation measurements made pursuant to 420-3-26-.07(65)(a), (b) and (c).

(e) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs 420-3-26-.07(65)(a), (b) and (c).

(f) A licensee shall retain a record of each calibration in accordance with 420-3-26-.07(108).

(g) A licensee shall retain a record of decay calculations required by 420-3-26-.07(65)(e) in accordance with 420-3-26-.07(109).

(66) Therapy-related Computer Systems.

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

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

(67) Possession of Survey Instruments.

A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 millirem) per hour to 10 millisieverts (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(33).

(68) Training for Use of Manual Brachytherapy Sources.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 420-3-26-.07(60) to be a physician who:

- (a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in paragraph 420-3-26-.07(68)(b)3. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation

oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

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

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

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving

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

(II) Checking survey meters for proper operation;

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

(IV) Maintaining running inventories of radioactive material on hand;

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

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

2. Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology

of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph 420-3-26-.07(68)(b)1.(ii); and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(68)(a)1., or 420-3-26-.07(68)(b)1. and (b)2. of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 420-3-26-.07(60).

(69) Training for Ophthalmic Use of Strontium-90.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under 420-3-26-.07(60) to be a physician who:

(a) Is an authorized user under 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

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

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
- (iv) Radiation biology; and

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

- (i) Examination of each individual to be treated;
- (ii) Calculation of the dose to be administered;
- (iii) Administration of the dose; and

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

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68) or 420-3-26-.07(69), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(69)(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Sealed Sources For Diagnosis

(70) Use of Sealed Sources for Diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

(71) Training for Use of Sealed Sources for Diagnosis.

Except as provided in 420-3-26-.07(29), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 420-3-26-.07(70) to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in 420-3-26-.07(71)(b) and (c) and whose certification has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:

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

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

Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

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

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

- (a) As approved in the Sealed Source and Device Registry; or
- (b) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 420-3-26-.07(25)(a) are met.

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

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

(b) A licensee shall retain a record of the surveys in accordance with 420-3-26-.07(106).

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

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

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

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

(d) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 420-3-26-.07(110).

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

(a) A licensee shall:

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

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

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

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

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

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

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

(b) A copy of the procedures required by 420-3-26-.07(75)(a)4. must be physically located at the unit console.

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

1. The location of the procedures required by 420-3-26-.07(75)(a)4.; and

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

abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

1. The procedures identified in 420-3-26-.07(75)(a)4. of this section; and
2. The operating procedures for the unit.

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

(f) A licensee shall retain a record of individuals receiving instruction required by 420-3-26-.07(75)(d), in accordance with 420-3-26-.07(105).

(g) A licensee shall maintain a record of the procedures required by 420-3-26-.07(75)(a)4. and (d)2. in accordance with 420-3-26-.07(111).

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

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

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

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

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

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

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

(f) In addition to the requirements specified in 420-3-26-.07(76)(a) through (e), a licensee shall:

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

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

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

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

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

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

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

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

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

1. Remains in the unshielded position; or

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

(77) Dosimetry Equipment.

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

1. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

2. The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 420-3-26-.07(77)(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 420-3-26-.07(77)(a).

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with 420-3-26-.07(112).

(78) Full Calibration Measurements on Teletherapy Units.

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

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

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

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

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

3. At intervals not exceeding one year.

(b) To satisfy the requirement of 420-3-26-.07(78)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

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

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in 420-3-26-.07(77)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 420-3-26-.07(78)(b)1 may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by 420-3-26-.07(78)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in 420-3-26-.07(78)(b)1. for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by 420-3-26-.07(78)(a) and physical decay corrections required by 420-3-26-.07(78)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with 420-3-26-.07(113).

(79) Full Calibration Measurements on Remote Afterloader Units.

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

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

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

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

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

4. At intervals not exceeding one year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of 420-3-26-.07(79)(a), full calibration measurements must include, as applicable, determination of:

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

interfaces.

(c) A licensee shall use the dosimetry system described in 420-3-26-.07(77)(a) to measure the output.

(d) A licensee shall make full calibration measurements required by 420-3-26-.07(79)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 420-3-26-.07(79)(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 420-3-26-.07(79)(a) through (e).

(g) A licensee shall mathematically correct the outputs determined in 420-3-26-.07(79)(b)1. for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by 420-3-26-.07(79)(a) and physical decay corrections required by 420-3-26-.07(79)(VII) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with 420-3-26-.07(113)(80).

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

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

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

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

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

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

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

(b) To satisfy the requirement of 420-3-26-.07(80)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent;
2. Relative helmet factors;
3. Isocenter coincidence;
4. Timer accuracy and linearity over the range of use;
5. On-off error;
6. Trunnion centricity;
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches;
9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in 420-3-26-.07(77)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 420-3-26-.07(80)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by 420-3-26-.07(80)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in 420-3-26-.07(80)(b)1. at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by 420-3-26-.07(80)(a) and physical decay corrections required by 420-3-26-.07(80)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with 420-3-26-.07(113).

(81) Periodic Spot-Checks for Teletherapy Units.

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

1. Timer accuracy, and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in 420-3-26-.07(77)(b); and
6. The difference between the measurement made in 420-3-26-.07(81)(a)5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by 420-3-26-.07(81)(a) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

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

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

1. Electrical interlocks at each teletherapy room entrance;

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

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

4. Viewing and intercom systems;

5. Treatment room doors from inside and outside the treatment room; and

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

(e) If the results of the checks required in 420-3-26-.07(81)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by 420-3-26-.07(81)(a) and (d), in accordance with 420-3-26-.07(114).

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

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

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

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

3. After each source installation.

(b) The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in 420-3-26-.07(82)(a). The authorized medical physicist need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(d) To satisfy the requirements of 420-3-26-.07(82)(a), spot-checks must, at a

minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit's computer; and
8. Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in 420-3-26-.07(82)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by 420-3-26-.07(82)(d) in accordance with 420-3-26-.07(115).

(83) Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

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

1. Monthly;
2. At the beginning of each day of use; and
3. After each source installation.

(b) The licensee shall have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in 420-3-26-.07(83)(a); and

2. Review the results of each spot-check required by 420-3-26-.07(83)(a) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spotcheck.

(c) To satisfy the requirements of 420-3-26-.07(83)(a)1., spot-checks must, at a minimum:

1. Assure proper operation of:

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

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

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

2. Determine:

(i) The output for one typical set of operating conditions measured with the dosimetry system described in 420-3-26-.07(77)(b);

(ii) The difference between the measurement made in 420-3-26-.07(83)(c)2.(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);

(iii) Source output against computer calculation;

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

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of 420-3-26-.07(83)(a)2. and 3., spot-checks must assure proper operation of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

(e) A licensee shall arrange for prompt repair of any system identified in 420-3-26-.07(83)(c) that is not operating properly.

(f) If the results of the checks required in 420-3-26-.07(83)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by 420-3-26-.07(83)(c) and (d) in accordance with 420-3-26-.07(116).

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

(a) A licensee providing mobile remote afterloader service shall:

1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
2. Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by 420-3-26-.07(82), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
5. Radiation monitors used to indicate room exposures;

6. Source positioning (accuracy); and

7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in 420-3-26-.07(84)(b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in 420-3-26-.07(84)(b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by 420-3-26-.07(84)(b) in accordance with 420-3-26-.07(117).

(85) Radiation Surveys.

(a) In addition to the survey requirements in 420-3-26-.03 of these regulations, a person licensed pursuant to this rule shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by 420-3-26-.07(85)(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by 420-3-26-.07(85)(a) of this section in accordance with 420-3-26-.07(118).

(86) Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

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

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

(c) A licensee shall keep a record of the inspection and servicing in accordance with 420-3-26-.07(119).

(87) Therapy-Related Computer Systems.

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

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

(88) Possession of Survey Instruments.

_____A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 millirem) per hour to 10 millisieverts (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(33).

(89) Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a sealed source for a use authorized under 420-3-26-.07(72) to be a physician who:

- (a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 420-3-26-.07(89)(b)3. and 420-3-26-.07(89)(c). To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(89), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

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

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

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

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

(V) Checking and using survey meters; and

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

2. Has completed three3 years of supervised clinical experience in radiation therapy,

under an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(89), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph 420-3-26-.07(89)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(89)(a)1. and (c), or 420-3-26-.07(89)(b)1., (b)2., and (c), and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(89), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

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

Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

(90) 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 this rule if:

(a) The applicant or licensee has submitted the information required by 420-3-26-.07(8)(b), 420-3-26-.07(8)(c) and 420-3-26-.07(8)(d); and

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

Records

(91) Records of Authority and Responsibilities for Radiation Protection

Programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with 420-3-26-.07(19)(a) for ~~five~~5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 420-3-26-.07(19)(d), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 420-3-26-.07(19)(b). The record must include the signature of the Radiation Safety Officer and licensee management.

(c) The minutes of each Radiation Safety Committee meeting held in accordance with 420-3-26-.07(19)(VII). shall include:

1. The date of the meeting;
2. Members present;
3. Members absent; and
4. Summary of deliberations and discussions.

(92) Records of Radiation Protection Program Safety Changes.

A licensee shall retain a record of each radiation protection program change made in accordance with 420-3-26-.07(20)(a) for ~~five~~5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(93) Records of Written Directives.

A licensee shall retain a copy of each written directive as required by 420-3-26-.07(23) for ~~three~~3 years.

(94) Records of Misadministrations.

A licensee shall retain a record of misadministrations reported in accordance with 420-3-26-.07(120) for ~~three~~3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's

responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(95) Record of a Dose to an Embryo/Fetus or a Nursing Child.

A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 420-3-26-.07(121) for three years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(96) Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

A licensee shall maintain a record of instrument tests required by 420-3-26-.07(32) for 3 years. The records must include the model and serial number of the instrument, the date of the test, the results of the test, and the name of the individual who performed the test.

(97) Records of Survey Instrument Calibrations.

A licensee shall maintain a record of survey instrument calibrations required by 420-3-26-.07(33) for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(98) Records of Dosages of Unsealed Radioactive Material for Medical Use.

A licensee shall maintain a record of dosage determinations required by 420-3-26-.07(34) for three years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30 microcuries); the date and time of the dosage determination; and the name of the individual who determined the dosage.

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

A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 420-3-26-.07(36)(d) for three years. The inventory record must contain the model number of each source, and serial number if one has been

assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(100) Records of Surveys for Ambient Radiation Exposure Rate.

A licensee shall retain a record of each survey required by 420-3-26-.07(40) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

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

(a) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for three years after the date of release.

(b) A licensee shall retain a record, for three years after the date of release, that the instructions required by 420-3-26-.07(41)(b) were provided to a breast-feeding woman.

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

(a) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by 420-3-26-.07(9)(b), for three years after the last provision of service.

(b) A licensee shall retain the record of each survey required by 420-3-26-.07(42)(f) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(103) Records of Decay-in-Storage.

A licensee shall maintain records of the disposal of licensed materials, as required by 420-3-26-.07(44), for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(104) Records of Radionuclide Purity.

A licensee shall maintain a record of the radionuclide contaminant concentration tests required by 420-3-26-.07(49) for three years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as microcuries of contaminant per millicurie of desired radionuclide (kilobecquerel/megabecquerel), or microgram of contaminant per millicurie of desired radionuclide (microgram/megabecquerel),

the time and date of the measurement, and the name of the individual who made the measurement.

(105) Records of Safety Instruction and Training.

A licensee shall maintain a record of safety instructions and training required by 420-3-26-.07(53), 420-3-26-.07(63) and 420-3-26-.07(75)(d) 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.

(106) Records of Radiation Surveys of Patients and Human Research Subjects.

A licensee shall maintain a record of the surveys required by 420-3-26-.07(61) and 420-3-26-.07(73) for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(107) Records of Brachytherapy Source Inventory.

(a) A licensee shall maintain a record of brachytherapy source accountability required by 420-326-.07(62) for three years.

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

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

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

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

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

2. The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

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

(108) Records of Calibration Measurements on Brachytherapy Sources.

A licensee shall maintain a record of the calibrations on brachytherapy sources required by 420-3-26-.07(65) for ~~three~~ years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(109) Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

The licensee shall maintain a record of the activity of a strontium-90 source required by 420-3-26-.07(65) for the life of the source. The record must include the date and initial activity of the source as determined under 420-3-26-.07(65), and for each decay calculation, the date, the source activity and the signature of the authorized medical physicist.

(110) Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units and Gamma Stereotatic Radiosurgery Units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 420-3-26-.07(74) 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.

(111) Records of Safety Procedures.

A licensee shall retain a copy of the procedures required by 420-3-26-.07(75)(a)4. and 420-3-26-.07(75)(d)2. until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

(112) Records of Dosimetry Equipment.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 420-3-26-.07(77) for the duration of the license.

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

1. The date;
2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 420-3-26-.07(77)(a) and (b);
3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

4. The names of the individuals who performed the calibration, intercomparison, or comparison.

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

(a) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by 420-3-26-.07(78), 420-3-26-.07(79) and 420-3-26-.07(80) for 3 years.

(b) The record must include:

1. The date of the calibration;

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

3. The results and assessments of the full calibrations;

4. The results of the autoradiograph required for low dose-rate remote afterloader units; and

5. The signature of the authorized medical physicist who performed the full calibration.

(114) Records of Periodic Spot-Checks for Teletherapy Units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by 420-3-26-.07(81) for three3 years.

(b) The record must include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

3. An assessment of timer linearity and constancy;

4. The calculated on-off error;

5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(115) Records of Periodic Spot-Checks for Remote Afterloader Units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by 420-3-26-.07(82) for three years.

(b) The record must include, as applicable:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(116) Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 420-3-26-.07(83) for three years.

(b) The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(117) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

- (a) A licensee shall retain a record of each check for mobile remote afterloader units required by 420-3-26-.07(84) for ~~three~~ years.
- (b) The record must include:
 1. The date of the check;
 2. The manufacturer's name, model number, and serial number of the remote afterloader unit;
 3. Notations accounting for all sources before the licensee departs from a facility;
 4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
 5. The signature of the individual who performed the check and the signature of the

authorized medical physicist who reviewed the record of the spot-check.

(118) Records of Surveys of Therapeutic Treatment Units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 420-3-26-.07(85) for the duration of use of the unit.

(b) The record must include:

1. The date of the measurements;
2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
4. The signature of the individual who performed the test.

(119) Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by 420-3-26-.07(86) for the duration of use of the unit.

(b) The record must contain:

1. The inspector's radioactive materials license number;
2. The date of inspection;
3. The manufacturer's name and model number and serial number of both the treatment unit and source;
4. A list of components inspected and serviced, and the type of service; and
5. The signature of the inspector.

Reports

(120) Reports and Notifications of Misadministrations.

(a) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:

1. A dose that differs from the prescribed dose by more than 5 millisieverts (500 millirem) effective dose equivalent, 0.05 sieverts (5 rem) to an organ or tissue, or 0.05 sieverts (5 rem) shallow dose equivalent to the skin; and either

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 5 millisieverts (500 millirem) effective dose equivalent, 0.05 sieverts (5 rem) to an organ or tissue, or 0.05 sieverts (5 rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment;
or

(v) A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.05 sieverts (5 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

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

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

(d) The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration.

1. The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(iv) The effect, if any, on the individual(s) who received the administration;

(v) Actions, if any, that have been taken, or are planned, to prevent recurrence;

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

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

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

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the

misadministration, or to that individual's responsible relatives or guardians.

(g) A licensee shall retain a record of a misadministration in accordance with 420-3-26-.07(94). A copy of the record required under 420-3-26-.07(94) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.

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

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 millisieverts (500 millirem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

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

1. Is greater than 5 millisieverts (500 millirem) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 420-3-26-.07(121)(a) or (b).

(d) The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 420-3-26-.07(121)(a) or (b).

1. The written report must include:
 - (i) The licensee's name;
 - (ii) The name of the prescribing physician;
 - (iii) A brief description of the event;
 - (iv) Why the event occurred;
 - (v) The effect, if any, on the embryo/fetus or the nursing child;

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

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

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

(e) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 420-3-26-.07(121)(a) or (b), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with 420-3-26-.07(95). A copy of the record required under 420-3-26-.07(95) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(122) Reports of Leaking Sources.

A licensee shall file a report with the Agency within 5 days if a leakage test required by 420-3-26-.07(36) reveals the presence of 185 becquerel (0.005 microcuries) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

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

(a) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 420-3-26-.07(41)(a).

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

1. The licensee's name;
2. The date and time of the unauthorized departure;
3. The projected date and time when release would have occurred;
4. The address of the patient's or human research subject's home or anticipated destination following departure;
5. The radionuclide, chemical and physical form and calculated activity at time of departure;
6. The apparent reason(s) for the departure prior to authorized release; and
7. A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

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

(a) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 5 millisieverts (500 millirem) as a result of the deceased's body.

(b) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in 420-3-26-.07(124)(a) has died. The written report must include:

1. The licensee's name;
2. The date of death;
3. The radionuclide, chemical and physical form and calculated activity at time of death; and,
4. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 millisieverts (500 millirem).

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