Subchapter VI — Medical Use of Radioactive Material

DHS 157.59 **General requirements. (1)** MAINTENANCE OF RECORDS. A record required by this subchapter shall be legible throughout the specified retention period. The record may be the original, a reproduced copy or a microform, provided 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 electronically with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings and specifications, shall include all pertinent information such as stamps, initials and signatures. A licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) PROVISIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS. A licensee may conduct research involving human subjects using radioactive material provided all of the following requirements are met:

(a) A licensee shall apply for and receive approval of a specific amendment to its radioactive materials license before conducting the research. A licensee shall obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" or equivalent under the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Note: The definition and responsibilities of an Institutional Review Board are described on 45 CFR Part 46 which may be downloaded from the following website: http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html.

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

(c) Nothing in this subsection relieves a licensee from complying with the other requirements in this subchapter or from complying with applicable FDA or other federal requirements governing radioactive drugs or devices.

(3) IMPLEMENTATION. (a) If the requirements of this subchapter are more restrictive than the existing license condition, a licensee shall comply with this subchapter unless exempted by par. (c).

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

(c) If a license condition exempted a licensee from a provision of this subchapter on the effective date of August 1, 2002, the exemption shall continue until the department amends, suspends or revokes the license.

(d) If a license condition cites provisions in this subchapter that are later deleted, the license condition remains in effect until a license amendment or renewal modifies or removes the license condition.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter.

DHS 157.61 **Administrative requirements. (1)** AUTHORITY AND RESPONSIBILITIES FOR THE RADIATION PROTECTION PROGRAM. (a) In addition to the radiation protection program requirements of s. DHS 157.21, a licensee's management shall approve in writing any of the following:

1. A request for license application, renewal or amendment before submittal to the department.

2. Authorization prior to using licensed materials for any individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist.

3. A radiation protection program change that does not require a license amendment and is permitted under sub. (2).

(b) A licensee's management shall appoint a radiation safety officer who agrees in writing to be responsible for implementing the radiation protection program. A licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed under licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(c) For up to 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 par. (f), provided the licensee takes the actions required in pars. (b), (d), (f) and (g) and notifies the department in accordance with s. DHS 157.13 (5) (c) 2. e. 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 an 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 that is authorized for 2 or more different types of uses of radioactive material under ss. DHS 157.64, 157.65 and 157.67 or 2 or more types of units under s. DHS 157.67 shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The committee shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service and a representative of management who is neither an authorized user nor a radiation safety officer, and may include other members as the licensee deems appropriate.

(f) A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources and management prerogative to perform all the following functions:

1. Identify radiation safety problems.

2. Initiate, recommend or provide corrective actions.

3. Stop unsafe operations.

4. Verify implementation of corrective actions.

(g) A licensee shall retain a record of actions taken under pars. (a), (b) and (d) according to the record retention requirements of s. DHS 157.71 (1).

(2) RADIATION PROTECTION PROGRAM CHANGES. (a) A licensee may revise its radiation protection program without department approval if the revision meets all the following criteria:

1. The revision does not require a license amendment.

2. The revision complies with the requirements of this chapter and the license.

3. The revision has been reviewed and approved by the radiation safety officer and licensee management.

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 under s. DHS 157.71 (2).

(3) SUPERVISION. (a) A licensee who permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user shall do all the following:

1. Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, requirements of this chapter and license conditions regarding the use of radioactive material.

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, requirements of this chapter and license conditions regarding the medical use of radioactive material.

(b) A licensee who 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 shall do all of the following:

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

2. Require the supervised person 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 established by the licensee and the regulations of this chapter, and license conditions.

(c) A licensee who permits supervised activities under pars. (a) and (b) is responsible for the acts and omissions of the supervised individual.

(4) WRITTEN DIRECTIVES. (a) 1. A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabequerels (30 microcuries), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

2. If, because of the emergent nature of the patient's condition, a delay in providing a written directive would jeopardize the patient's health, an oral directive from an authorized user is acceptable provided the information contained in the oral directive is documented immediately in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

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

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

(b) The written directive shall contain the patient or human research subject's name and all of the following information:

1. For the administration of a dosage of a radioactive drug, the name, dosage and administration route of the radioactive drug.

2. For each anatomically distinct treatment site exposed to gamma stereotactic radiosurgery, total dose, treatment site and number of target settings per treatment.

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

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

5. For permanent implant brachytherapy:

a. Before implantation, the written directive shall include the treatment site, the radionuclide, and the total source strength.

b. After implantation but before the patient leaves the post-treatment recovery area, the written directive shall include the treatment site, the number of sources implanted, the total source strength implanted, and the date.

~~5~~6. For all other brachytherapy including low dose rate, medium dose rate and pulsed dose rate afterloading~~, both of the following~~:

a. Before implantation, the written directive shall include~~:~~ the treatment site, radionuclide, and dose.~~Prior to implantation, treatment site, the radionuclide and dose.~~

b. After temporary implantation, but prior to completion of the procedure, the written directive shall include the ~~radioisotope~~radionuclide, treatment site, number of sources, and total source strength and exposure time ~~or, instead of total source strength and exposure time, the total dose~~(or the total dose), and date.

~~c. For permanent implantation, the radioisotope, treatment site, number of sources, total source strength, total dose and method of implantation.~~

(c) A licensee shall retain the written directive under s. DHS 157.71 (3).

(5) PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE. (a) For any administration requiring a written directive, a licensee shall develop, implement and maintain written procedures to help ensure both of the following:

1. The patient's or human research subject's identity is verified by more than one method before each administration.
2. Each administration is performed according to the provisions of a written directive.

(b) The procedures required by par. (a) shall address all of the following items that are applicable for the licensee's use of radioactive material:

1. Verifying the identity by more than one method of the patient or human research subject.
2. Verifying that the specific details of the administration are under the treatment plan, if applicable, and the written directive.
3. Checking both manual and computer-generated dose calculations~~, if performed~~.
4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by ~~s~~s. DHS 157.67 ~~and~~or ~~DHS 157.~~70.Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic ~~remote afterloader, teletherapy or gamma stereotactic radiosurgery~~ units medical units authorized by s. DHS 157.67 or 70.
5. Determining if a medical event, under s. DHS 157.72 (1), has occurred.
6. Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(6) SUPPLIERS FOR SEALED SOURCES OR DEVICES FOR MEDICAL USE. For medical use, a licensee may only use the following:

(a) Sealed sources or devices manufactured, labeled, packaged and distributed under a license issued under subch. II or the equivalent requirements of the NRC or another agreement state.

(b) Teletherapy sources manufactured and distributed under a license issued under subch. II or the equivalent requirements of the NRC or another agreement state.

(c) Sealed sources or devices non-commercially transferred from a medical licensee.

(7) TRAINING FOR RADIATION SAFETY OFFICER AND ASSOCIATE RADIATION SAFETY OFFICER. Except as provided in sub. (10), a licensee shall ensure that an individual fulfilling the responsibilities of the radiation safety officer, or an individual assigned duties and tasks as an associate radiation safety officer as provided in s. DHS 157.61 is an indivual who has training in radiation safety, regulatory issues and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, an associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist or authorized user, as appropriate, who is authorized for the type of use for which the licensee is seeking approval. A licensee shall also require the radiation safety officer or an associate radiation safety officer to be a person who ~~has obtained written attestation under sub. (12) (a) and~~ meets any of the following requirements:

(a) Is certified by a specialty board whose certification process has been recognized by the department, the NRC or another agreement state. To have its certification process ~~be~~ recognized, a specialty board shall require all candidates for certification to have either of the following:

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

b. Five or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics.

c. Passed 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.

2. a. Master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

b. Two years of full-time practical training and/or supervised experience in medical physics either under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the department, the NRC, or another agreement state or in clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in s. DHS 157.61 (10), 157.63 (5) or 157.64 (4).

c. 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.

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

(b) Has completed a structured educational program consisting of all the following:

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

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Radiation biology.

e. Radiation dosimetry.

2. One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a department, NRC or another agreement state license, or a permit issued by a NRC master material licensee that authorizes similar types of uses of radioactive material. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on a department, NRC, or an agreement state license or permit issued by a NRC master material licensee. The full-time radiation safety experience must involve all of ~~involving all~~ the following:

a. Shipping, receiving, and performing related radiation surveys.

b. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters and instruments used to measure radionuclides.

c. Securing and controlling radioactive material.

d. Using administrative controls to avoid mistakes in the administration of radioactive material.

e. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures.

f. Using emergency procedures to control radioactive material.

g. Disposing of radioactive material.

3. Has obtained written attestation under sub. (12) (a).

(c) Is any one of the following:

1. A medical physicist who has been certified by a specialty board whose certification process has been recognized by the department, NRC, or another agreement state under sub. (8) (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 or an associate radiation safety officer.

2. An authorized user, authorized medical physicist or authorized nuclear pharmacist identified on ~~the licensee's license~~ a department, NRC, or an agreement state license, or other equivalent permit or 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~~ the licensee seeks the approval of the individual as the radiation safety officer or associate radiation safety officer.

3. An individual who has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license.

(8) TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST. Except as provided in sub. (10), a licensee shall require the authorized medical physicist to have training for the type 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~~ successfully completing either a training program provided by the vendor of the applicable system, or by training supervised by an authorized medical physicist authorized for the type of use for which the individual is seeking authorization. A licensee shall also require the authorized medical physicist to be an individual who ~~has obtained written attestation under sub. (12) (b) and~~ meets either of the following requirements:

(a) Is ~~C~~certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state. To have its certification process~~be~~ recognized, a specialty board shall require all candidates for certification to have all of the following:

1. ~~a.~~ 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. ~~b.~~ Attained two years full-time practical training or supervised experience in medical physics that meets either of the following requirements:

a. Completed under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized under this section by the department, the NRC, or an agreement state.

b. Completed 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 s. DHS 157.61 (10), 157.65 (8) or 157.67 (17). ~~Attained two years full-time practical training and/or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the department, the NRC or an agreement state or 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 s. DHS 157.61 (10), 157.65 (8) or 157.67 (17).~~

~~c.~~3. Passed 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.

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

(b)

1.~~.~~ Holds a master's or doctorate degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university~~;~~ and completetion of d one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type of use for which the individual is seeking authorization. This training and work experience shall 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 shall include all of the following:

a~~1~~. Performing sealed source leak tests and inventories.

b~~2~~. Performing decay corrections.

c~~3~~. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable.

d~~4~~. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable.

2. Has obtained written attestation under sub. (12) (b).

(9) TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST. Except as provided in sub. (10), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who ~~has obtained written attestation under sub. (12) (c) and~~ meets either of the following requirements:

(a) Is certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state. ~~and who has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in sub. (12) (c) and has achieved a level of competency sufficient to independently operate a nuclear pharmacy~~ To have its certification process be recognized, a specialty board shall require all candidates for certification to have all of the following:

1. Graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education ~~American council on pharmaceutical education~~ or have passed the foreign pharmacy graduate examination committee examination.

2. A current, active license to practice pharmacy.

3. Evidence of having acquired at least 4000 hours of training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience.

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

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

(b) Has completed 700 hours in a structured educational program including all of the following requirements:

1. Two hundred hours of classroom and laboratory training covering all of the following areas:

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Chemistry of radioactive material for medical use.

e. Radiation biology.

2. Supervised practical experience in a nuclear pharmacy involving all the following:

a. Shipping, receiving and performing related radiation surveys.

b. 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-emitting or beta-emitting radionuclides.

c. Calculating, assaying and safely preparing dosages for patients or human research subjects.

d. Using administrative controls to avoid medical events in the administration of radioactive material.

e. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures.

3. Has obtained written attestation under sub. (12) (c).

(10) TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST, AND AUTHORIZED NUCLEAR PHARMACIST. (a) ~~Any of the following experienced individuals:~~

1. An individual identified as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist, or an authorized nuclear pharmacist on a department, NRC or another agreement state license, or other equivalent permit on or before January 14, 2019, is exempt from the training requirements of subs. (7) to (9), respectively, except the radiation safety officers and authorized medical physicists identified in this paragraph must meet the training requirements of subs. (7) or (8), as appropriate, for any material uses for which they were not authorized prior to this date.~~An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a department, NRC or another agreement state license, the permit issued by a licensee of broad scope or the permit issued by an NRC master material licensee before October 24, 2002 need not comply with the training requirements of subs. (7) to (9), respectively.~~

2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, is exempt from the training requirements of subs. (7) to be identified as a radiation safety officer or as an associate radiation safety officer on a department, NRC, or an agreement state license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, is exempt from the training requirements for an authorized medical physicist described in subs. (8), for those materials and uses that these individuals performed on or before October 24, 2005.

4. A radiation safety officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the department, need not comply with the training requirements of subs. (7) to (9), respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(b) An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on a department, NRC or another agreement state license, the permit issued by a licensee of broad scope or the permit issued by NRC master material licensee between October 24, 2002 and April 29, 2005 need not comply with the training requirements of s. DHS 157.61 (7), (8) or (9).

(c) ~~Physicians, dentists, or podiatrists who:~~

1. Physicians, dentists, or podiatrists who are identified as authorized users for the medical use of radioactive material on a license issued by the department, the NRC, an agreement state, a permit issued by a NRC master material licensee, a permit issued by a NRC or an agreement state broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date is exempt from the training requirements of ss. DHS 157.63 to 157.67.

2. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the department, the NRC, an agreement state, a permit issued by a NRC master material licensee, a permit issued by a NRC or an agreement a state broad scope licensee, or a permit issued in accordance with a NRC master material broad scope license on or before October 24, 2005, is exempt from the training requirements of ss. DHS 157.63 to 157.67 for any of the following materials and uses that these individuals performed on or before October 24, 2005:

a. For uses authorized under ss. DHS 157.63 (1) or DHS 157.63 (2), or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine in nuclear medicine, the American Board of Radiology in diagnostic radiology, the American Osteopathic Board of Radiology in diagnostic radiology or radiology the Royal College of Physicians and Surgeons of Canada in nuclear medicine, or American Osteopathic Board of Nuclear Medicine in nuclear medicine.

b. For uses authorized under s. DHS 157.64 (1), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine, the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology, the Royal College of Physicians and Surgeons of Canada in nuclear medicine, or the American Osteopathic Board of Radiology after 1984.

c. For uses authorized under ss. DHS 157.65 (1) or DHS 157.67 (1), a physician who was certified on or before October 24, 2005, by the American Board of Radiology in radiology, therapeutic radiology or radiation oncology, the American Osteopathic Board of Radiology in radiation oncology;, by the Canadian Royal College of Physicians and Surgeons in therapeutic radiology, or as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology" in radiology, with specialization in radiotherapy.

d. For uses authorized under s. DHS 157.66 (1), a physician who was certified on or before October 24, 2005, by the American Board of Radiology, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology, the American Board of Nuclear Medicine in nuclear medicine, the American Osteopathic Board of Radiology in diagnostic radiology or radiology, or the Royal College of Physicians and Surgeons of Canada in nuclear medicine.

1. Are identified as authorized users for the medical use of radioactive material on a license issued by the department, the NRC, or an agreement state, or an equivalent permit on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of ss. DHS 157.63 to 157.67.A physician, dentist or podiatrist identified as an authorized user for the medical, dental or podiatric use of radioactive material on a department, NRC or another agreement state license, the permit issued by a licensee of broad scope or the permit issued by an NRC master material licensee before October 24, 2002 who performs only those medical uses for which they are authorized need not comply with the training requirements of ss. DHS 157.63 to 157.67.

2. Are not identified as authorized users for the medical use of radioactive material on a license issued by the department, the NRC, or an agreement state, or an equivalent permit on or before October 24, 2005, need not comply with the training requirements of ss. DHS 157.63 to 157.67 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

a. For uses authorized under ss. DHS 157.63 (1) or DHS 157.63 (2), or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine.

b. For uses authorized under s. DHS 157.64 (1), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984.

c. For uses authorized under ss. DHS 157.65 (1) or DHS 157.67 (1), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.

d. For uses authorized under s. DHS 157.66 (1), a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the department, is exempt from the training requirements of ss. DHS 157.63 to 157.67 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

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

(11) RECENTNESS OF TRAINING. The training and experience specified in this section and ss. DHS 157.63 to 157.67 shall have been completed within 7 years preceding the date of license application. If the training and experience specified in this section and ss. DHS 157.63 to 157.67 have no)t been completed within 7 years preceding the date of license application, additional related continuing education and experience shall be required.

(12) WRITTEN ATTESTATION. (a) *Radiation safety officer or associate radiation safety officer.* As required by sub. (7) (b) 3., tThe licensee shall ensure that an individual fulfilling the responsibilities of the radiation safety officer or associate radiation safety officer has obtained written attestation, signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of the similar types of use of byproduct material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state, that the individual has satisfactorily successfully completed the requirements in sub. (7) (a) 1. a. and b., 2. a. and b., (b), or (c), has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval has achieved a level of radiation safety knowledge sufficient to independently function as a radiation safety officer for a medial use of radioactive material and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license.

(b) *Authorized medical physicist.* As required by sub. (8) (b) 2., the A licensee shall ensure that the individual has obtained written attestation that the individual has satisfactorily successfully completed the requirements in sub. (8) (a) 1. a. and b. or (b), has training for the type 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, and is able to independently fulfill the radiation safety-related duties 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 shall be signed by a preceptor authorized medical physicist who meets the requirements in sub. (8) or (10), or equivalent NRC 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.

(c) *Authorized nuclear pharmacist.* As required by sub. (9) (b) 3., the ~~A~~ licensee shall ensure that the individual has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has ~~satisfactorily~~ successfully completed the requirements in sub. (9) ~~(a) or~~ (b) and is able to independently flfill the radiation safety-related duties ~~has achieved a level of competency sufficient to function independently~~ as an authorized nuclear pharmacist.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: am. (1) (g), r. and recr. (7) to (10), cr. (12) Register October 2006 No. 610, eff. 11-1-06; CR 09-062: am. (10) (a) and (12) (b), renum. (10) (b) to be (10) (c), cr. (10) (b) Register April 2010 No. 652, eff. 5-1-10; **CR 16-078: am. (7) (a) 2. b., (8) (a) 1. b., (10) (a), (c), cr. (10) (d) Register January 2018 No. 745, eff. 2-1-18.**

DHS 157.62 **Technical requirements. (1)** POSSESSION, USE AND CALIBRATION OF INSTRUMENTS TO MEASURE THE ACTIVITY OF UNSEALED RADIOACTIVE MATERIALS. (a) For direct measurements performed under sub. (3), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration of unsealed radioactive materials to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in par. (a) according to nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration required by this subsection under s. DHS 157.71 (6).

(2) CALIBRATION OF SURVEY INSTRUMENTS. (a) A licensee shall calibrate the survey instruments used to show compliance with this subchapter and subch. III before first use, at a frequency not to exceed 13 months and following any repair that will affect the calibration.

(b) A licensee shall do all the following:

1. Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source.

2. Calibrate each scale used to show compliance at a sufficient number of readings to determine the response characteristics of the instrument.

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

Note: Two separated readings on each scale or decade are typically used ~~used~~ for linear scale instruments.

(c) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%.

(d) A licensee shall retain a record of each survey instrument calibration under s. DHS 157.71 (7).

(3) DETERMINATION OF DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE. (a) A licensee shall determine and record the activity of each dosage prior to medical use.

(b) For a unit dosage, this determination shall be made by using one of the following methods:

1. Direct measurement of radioactivity.

2. A decay correction, based on the measurement made by either of the following:

a. A manufacturer or preparer licensed under s. DHS 157.13 (4) (i) or by NRC or another agreement state.

b. An NRC or other agreement state licensee only for use in research in accordance with an RDRC protocol or and IND protocol accepted by FDA.

c. A PET radioactive drug producer licensed under s. DHS 157.13 (1) (j) or by NRC or another agreement state.

(c) For other than unit dosages, the determination of dosages of unsealed radioactive material shall be made through one of the following methods:

1. Direct measurement of radioactivity.

2. A combination of direct measurements of radioactivity and mathematical calculations.

3. A combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under s. DHS 157.13 (4) (i), a PET radioactive drug producer licensed under s. DHS 157.13 (1) (j), or equivalent NRC or other agreement state requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage differs from the prescribed dosage by more than 20% or if the dosage does not fall within the prescribed dosage range.

(e) A licensee shall retain a record of the dosage determination required by this subsection under s. DHS 157.71 (8).

(4) AUTHORIZATION FOR CALIBRATION, TRANSMISSION AND REFERENCE SOURCES. (a) Any person authorized by s. DHS 157.13 (5) for medical use of radioactive material may receive, possess and use any of the following radioactive material for check, calibration, transmission and reference use:

1. ~~(a)~~ A sealed source that does not exceed 1.11 GBq (30 mCi) that is manufactured and distributed by a person licensed under s. DHS 157.13 (4) (j) or equivalent NRC or agreement state regulations or redistributed by a person authorized to redistribute sealed sources, provided that the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

~~(~~2. ~~b)~~ Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.555 GBq (15 mCi).

3. ~~(c)~~ Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 ~~μCi~~microcuries) or 1000 times the quantities in ch. DHS 157 Appendix F.

~~(~~4. ~~d)~~ Technetium-99m in amounts as needed.

5. Flourine-18 in amounts as needed.

~~(c)~~ (b) Radioactive material in sealed sources authorized by this subsection shall not be used in either of the following:

1. For medical use as defined in s. DHS 157.03 (211) except in accordance with the requirements in s. DHS 157.66(1).

2. Bundled or aggregated to create activity greater than the maximum activity of any single sealed source authorization under this section.

(cf) A licensee using calibration, transmission, and reference sources in accordance with the requirements in this subsection~~pars. (a) to (e)~~ need not list these sources on a specific medical use license.

(5) 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.

(b) A licensee in possession of a sealed source shall do both the following:

1. Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee.

2. Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the department, NRC or another agreement state in the sealed source and device registry.

3. Test the source for leakage at any time there is reason to suspect that the sealed source might have been damaged or might be leaking.

(c) To satisfy the leak test requirements of this section, a licensee shall measure the sample so that the leakage test may detect the presence of 185 Bq (0.005 μCi) of radioactive material on the sample.

(d) A licensee shall retain leakage test records under s. DHS 157.71 (9).

(e) If the leakage test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, a licensee shall do both the following:

1. Immediately withdraw the sealed source from use and store, dispose or cause it to be repaired under the requirements in subchs. II and III.

2. File a report to the department within 5 working days of the leakage test as specified under s. DHS 157.72 (3).

(f) A licensee need not perform a leakage test on any of the following sources:

1. A source containing only radioactive material with a half-life of less than 30 days.

2. A source containing only radioactive material as a gas.

3. A source containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material.

4. A source stored and not being used. A licensee shall, however, test each source for leakage before any use or transfer unless it has been leakage-tested within 6 months before the date of use or transfer.

5. Seeds of iridium-192 encased in intact nylon ribbon.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. A licensee shall retain each inventory record under s. DHS 157.71 (9).

(6) LABELLING OF VIALS AND SYRINGES. Each syringe and vial that contains a radioactive drug containing radioactive material 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.

(7) SURVEYS FOR AMBIENT RADIATION EXPOSURE RATE. (a) Except as provided in par. (b), a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.

(b) A licensee need not perform the surveys required under par. (a) in an area where patients or human research subjects are confined when the patients or human research subjects cannot be released under sub. (8).

(c) A licensee shall retain a record of each survey under s. DHS 157.71 (10).

(8) RELEASE OF INDIVIDUALS CONTAINING RADIOACTIVE DRUGS OR IMPLANTS CONTAINING RADIOACTIVE MATERIAL. (a) A licensee may authorize the release from its control of any person who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other person from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Note: WISREG 1556, Vol. 9, Guidance for Medical Use of Radioactive Material describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 Rem). It is available from the following website: http://dhs.wisconsin.gov/radiation/radioactivematerials/index.htm.

(b) A licensee shall provide the released person or the person's parent or guardian with instructions, including written instructions, on actions recommended to maintain doses to other persons as low as is reasonably achievable if the total effective dose equivalent to any other person is likely to exceed one mSv (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed one mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include all the following:

1. Guidance on the interruption or discontinuation of breast-feeding.

2. Any information on the potential consequences of failure to follow the guidance.

(c) A licensee shall maintain a record, as required by s. DHS 157.71 (11), of the basis for authorizing the release of an individual, under par. (a).

(d) A licensee shall maintain a record of instructions provided to breast-feeding women under par. (b) according to record retention requirements of s. DHS 157.71 (11) (b).

(9) PROVISION OF MOBILE MEDICAL SERVICE. (a) A licensee providing mobile medical service shall do all of the following:

1. Obtain a letter signed by the management of each client for which services are rendered by the licensee that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client.

2. Check instruments used to measure the activity of unsealed radioactive materials for proper function before medical use at each client's address or on each day of use, whichever is more frequent. The check for proper function shall include a test to verify accurate calibration using a known radioactive source.

3. Check survey instruments for proper operation with a dedicated check source before use at each client's address.

4. Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in subch. III.

(b) A mobile medical service may not have radioactive material delivered 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.

(c) A licensee providing mobile medical services shall retain the letter required in par. (a) 1. and the record of each survey required in s. DHS 157.71 (12) (b).

(10) DECAY-IN-STORAGE. (a) A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee does both the following:

1. Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter 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 it has been released.

(b) A licensee shall retain a record of each disposal permitted under s. DHS 157.71 (13).

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; corrections in (9) (c) and (10) (b) made under s. 13.93 (2m) (b) 7., Stats., Register July 2002 No. 559; CR 06-021: am. (2) (a), (3) (b) 2. a., (4) (intro.) and (8) (d) Register October 2006 No. 610, eff. 11-1-06; CR 09-062: am. (1) (b) and (3) (c) 3., cr. (3) (b) 2. c. Register April 2010 No. 652, eff. 5-1-10; **correction in (4) (b) made under s. 35.17, Stats., Register January 2018 No. 745.**

DHS 157.63 Unsealed radioactive material — written directive not required.

(1) USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION AND EXCRETION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED. A licensee may use for uptake, dilution or excretion studies any unsealed radioactive material, except in quantities that require a written directive under s. DHS 157.61 (4), prepared for medical use that meets any of the following requirements:

Note: Uptake, dilution and excretion studies determine the amount of radioactive material absorbed by a patient and the patient's ability to excrete the remainder of the radioactive material.

(a) Is obtained from any of the following:

1. A manufacturer or preparer licensed under s. DHS 157.13 (4) (i), or equivalent NRC or other agreement state requirements.

2. A PET radioactive drug producer licensed under s. DHS 157.13 (1) (j), or equivalent NRC or other agreement state requirements.

(b) Excluding production of PET radionuclides, is prepared by any of the following:

1. An authorized nuclear pharmacist.

2. A physician who is an authorized user and who meets the requirements in sub. (5), or sub. (5) (c) 2. g. and s. DHS 157.64 (4).

3. An individual under the supervision, as specified in s. DHS 157.61 (10), of the authorized nuclear pharmacist in subd.1. or the physician in subd. 2.

(c) Is obtained from an NRC or agreement state licensee for use in research under a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the FDA.

(d) Is prepared by the licensee for use in research under a radioactive drug research committee-approved application or an investigational new drug protocol accepted by the FDA.

Note: Information on radioactive drugs or investigational new drug protocols may be obtained from the following FDA website: http://www.fda.gov/Radiation-EmittingProducts/default.htm.

(2) 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 unsealed radioactive material, except in quantities that require a written directive under s. DHS 157.61 (4), prepared for medical use that meets any of the following requirements:

(a) Is obtained from any of the following:

1. A manufacturer or preparer licensed under s. DHS 157.13 (4) (i), or equivalent NRC or other agreement state requirements.

2. A PET radioactive drug producer licensed under s. DHS 157.13 (1) (j), or equivalent NRC or other agreement state requirements.

(b) Is prepared by, excluding production of PET radionuclides, any of the following:

1. An authorized nuclear pharmacist.

2. A physician who is an authorized user and who meets the requirements in sub. (5), or s. DHS 157.64 (4) and sub. (5) (c) 2. g.

3. An individual under the supervision, as specified in s. DHS 157.61 (3), of the authorized nuclear pharmacist in subd.1., or the physician in subd. 2.

(c) Is obtained from a NRC or agreement state licensee for use in research under a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the FDA.

(d) Is prepared by the licensee for use in research under a radioactive drug research committee-approved application or an investigational new drug protocol accepted by the FDA.

(3) PERMISSIBLE RADIONUCLIDE CONTAMINANTS. (a) A licensee may not administer to humans a radioactive drug containing more than the following:

1. 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per 1 millicurie of technetium 99m).

2. 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per 1 millicurie of rubidium-82 chloride injection).

3. 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per 1 millicurie of rubidium-82 chloride injection).

(b) A licensee that prepares radioactive drugs from radionuclide generators shall do all the following:

1. If using a molybdenum-99/technetium-99m generator for preparing a technetium-99m radiopharmaceutical, measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with par. (a). ~~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.

3. If using a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with par. (a).

(c) A licensee that must measure radionuclide contaminant concentration shall retain a record of each measurement under s. DHS 157.71 (14).

(d) The licensee shall report any measurement that exceeds the limits in par. (a) at the time of generator elution, in accordance with s. DHS 157.72 (4).

(4) TRAINING FOR UPTAKE, DILUTION AND EXCRETION STUDIES. Except as provided in s. DHS 157.61 (10), a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) ~~to have obtained written attestation under sub. (6) (a) and to~~ to be a physician who meets any of the following requirements:

(a) Is certified by a medical specialty board whose certification process has been recognized by the department, the NRC, or an agreement state. To ~~be~~ have its certification process recognized, a specialty board shall require all candidates for certification to do all of the following:

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 par. (c).

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

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

(b) Is an authorized user under sub. (5), s. DHS 157.64 (4), or NRC or equivalent NRC or agreement state requirements.

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

1. Classroom and laboratory training in all the following areas:

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Chemistry of radioactive material for medical use.

e. Radiation biology.

2. Work experience, under the supervision of an authorized user who meets the requirements in this subsection, sub. (4) or (5), s. DHS 157.61 (10) or 157.64 (4), or equivalent NRC or agreement state requirements, involving all the following:

a. Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys.

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.

c. Calculating, measuring and safely preparing patient or human research subject dosages.

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material.

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.

f. Administering dosages of radioactive drugs to patients or human research subjects.

3. A written attestation under sub. (6) (a).

(5) TRAINING FOR IMAGING AND LOCALIZATION STUDIES. Except as provided in s. DHS 157.61 (10), a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (2) ~~to have obtained written attestation under sub. (6) (b) and~~ to be a physician who meets any of the following requirements:

(a) Is certified by a medical special board whose certification process has been recognized by the department, the NRC, or an agreement state. To ~~be~~ have its certification process recognized, a specialty board shall require all candidates for certification to do both of the following:

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 that includes the topics listed in par. (c) 1. and 2.

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

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

(b) Is an authorized user under s. DHS 157.64 (4) and meets the requirements in par. (c) 2. g., or equivalent NRC or agreement state requirements.

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

1. Classroom and laboratory training in all the following areas:

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Chemistry of radioactive material for medical use.

e. Radiation biology.

2. Work experience, under the supervision of an authorized user, who meets the requirements in this subsection, s. DHS 157.61 (10), or subd. 2. g. and s. DHS 157.64 (4) or equivalent NRC or agreement state requirements~~, involving all the~~ . An authorized nuclear pharmacist who meets the requirements in s. DHS 157.61(9) or (10) may provide the supervised work experience under subd. 2. g.. Work experience must include all of the following:

a. Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys.

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.

c. Calculating, measuring and safely preparing patient or human research subject dosages.

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material.

e. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures.

f. Administering dosages of radioactive drugs to patients or human research subjects.

g. 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.

3. A written attestation under sub. (6) (b).

Note: Eluting generator systems are a family of radioactive material devices used to extract useful radioactive materials by passing sterile fluid through a column of the parent material. The resulting mixture of fluid and radioactive material, known as the eluate, is used in the diagnostic procedures. These generators are used to produce Tc-99m, Ga-67 or Rb-82.

(6) WRITTEN ATTESTATION.

(a) *Unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.* As required by sub. (4) (c) 3., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) to have obtained written attestation that the individual has successfully completed the requirements of sub. (4) (c) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under sub. (1). The attestation must be obtained from either of the following:

1. A preceptor authorized user who meets the requirements of sub. (4) or (5), s. DHS 157.61 (10), s. DHS 157.64 (4), or equivalent NRC or agreement state requirements.

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements sub. (4) or (5), s. DHS 157.61 (10), s. DHS 157.64 (4), or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. (4) (c).

(b) *Unsealed radioactive material for imaging and localization studies for which a written directive is not required.* As required by sub. (5) (c) 3., the licensee shall require an authorized user of unsealed radioactive material for uses under sub. (2) to have written attestation that the individual has successfully completed the requirements in sub. (5) (c) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under subs. (1) and (2). The attestation must be obtained from either of the following:

1. A preceptor authorized user who meets the requirements in sub. (5), s. DHS 157.61 (10), or ss. 157.64 (4) and 157.63 (5) (c) 2. g, or equivalent NRC or agreement state requirements.

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements sub. (5), s. DHS 157.61 (10), or ss. DHS 157.64 (4) and 157.63 (5) (c) 2. g,, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. (5) (c).

~~(a) *Unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.* A licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) to have obtained written attestation, signed by a preceptor authorized user who meets the requirements of sub. (4) or (5), s. DHS 157.61 (10), 157.64 (4), or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of sub. (4) (a) 1. or (c) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under sub. (1). The attestation must be obtained from either:A licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) to have obtained written attestation, signed by a preceptor authorized user who meets the requirements of sub. (4) or (5), s. DHS 157.61 (10), 157.64 (4), or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements of sub. (4) (a) 1. or (c) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under sub. (1).~~

~~1. A preceptor authorized user who meets the requirements in sub. (4) or (5), s. DHS 157.61 (10), 157.64 (4), or equivalent NRC or agreement state requirements.~~

~~2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements sub. (4) or (5), s. DHS 157.61 (10), 157.64 (4), or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. (4) (c).~~

~~(b) *Unsealed radioactive material for imaging and localization studies for which a written directive is not required.* A licensee shall require an authorized user of unsealed radioactive material for uses under sub. (2) to have written attestation, signed by a preceptor authorized user who meets the requirements in sub. (5), or s. DHS 157.61 (10), 157.64 (4), or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in sub. (5) (a) 1. or (c) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under subs. (1) and (2). The attestation must be obtained from either:A licensee shall require an authorized user of unsealed radioactive material for uses under sub. (2) to have written attestation, signed by a preceptor authorized user who meets the requirements in sub. (5), or s. DHS 157.61 (10), 157.64 (4), or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in sub. (5) (a) 1. or (c) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under subs. (1) and (2).~~

~~1. A preceptor authorized user who meets the requirements in sub. (4) or (5), s. DHS 157.61 (10), 157.64 (4), or equivalent NRC or agreement state requirements.~~

~~2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements sub. (4) or (5), s. DHS 157.61 (10), 157.64 (4), or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. (5) (c).~~

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; correction in (2) (a) made under s. 13.93 (2m) (b) 7., Stats., Register July 2002 No. 559; CR 06-021: r. and recr. (1) (b), (2) (b), (3) to (5), cr. (6) Register October 2006 No. 610, eff. 11-1-06; CR 09-062: renum. (1) (a) and (2) (a) to be (1) (a) (intro.) and (2) (a) (intro.) and am., cr. (1) (a) 1., 2., (2) (a) 1. and 2., am. (1) (b) (intro.), (2) (b) (intro.), (3) (a) 1. to 3., (4) (c) 2. (intro.), (5) (a) 1., (c) 2. (intro.), (6) (a) and (b) Register April 2010 No. 652, eff. 5-1-10; **CR 16-078: am. (2) (b) 3., (4) (c) 2. Register January 2018 No. 745, eff. 2-1-18.**

DHS 157.64 **Unsealed radioactive material — written directive required. (1)** USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED. A licensee may use any unsealed radioactive material identified in DHS 157.64(4)(b)2.g., prepared for medical use and for which a written directive is required that is any of the following:

(a) Obtained from a manufacturer or preparer licensed under s. DHS 157.13 (4) (i), a PET radioactive drug producer licensed under s. DHS 157.13 (1) (j), or equivalent NRC or other agreement state requirements.

(b) Excluding production of PET radionuclides, is prepared by any of the following:

1. An authorized nuclear pharmacist.

2. A physician who is an authorized user and who meets the requirements specified in sub. (4) or s. DHS 157.63 (5).

3. An individual under the supervision of either an authorized nuclear pharmacist or physician who is an authorized user as specified in s. DHS 157.61 (3).

(c) Obtained from an NRC or agreement state licensee for use in research under an investigational new drug application accepted by FDA.

(d) Prepared by the licensee for use under an investigational new drug protocol accepted by FDA.

(2) SAFETY INSTRUCTION. In addition to the requirements of subch. X, a licensee shall do all the following:

(a) Provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who have received therapy with a drug containing radioactive material and cannot be released under s. DHS 157.62 (8). The instruction shall be commensurate with the duties of the personnel and include all the following:

1. Patient or human research subject control.

2. Visitor control, including both the following:

a. Routine visitation to hospitalized individuals under s. DHS 157.23 (1) (a) 1.

b. Visitation authorized under s. DHS 157.23 (1) (b).

3. Contamination control.

4. Waste control.

5. Notification of the radiation safety officer or his or her designee and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) Retain a record of individuals receiving instruction under s. DHS 157.71 (15).

(3) SAFETY PRECAUTIONS. (a) For each patient or human research subject who cannot be released under s. DHS 157.62 (8), a licensee shall do all the following:

1. Quarter the patient or the human research subject in one of the following:

a. A private room with a bathroom.

b. A room, with a bathroom, with another person who also has received therapy with a radioactive drug containing radioactive material and who cannot be released under s. DHS 157.62 (8).

2. Visibly post a “Radioactive Materials" sign on the door of a patient’s or the human research subject’s room 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.

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) A licensee shall notify the radiation safety officer or his or her designee and the authorized user as soon as possible if the patient or human research subject has a medical emergency and immediately if the patient dies.

(4) TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED. Except as provided in s. DHS 157.61 (10), a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) ~~to have obtained written attestation under sub. (8) (a) and~~ to be a physician who meets either of the following requirements:

(a) Is certified by a medical specialty board whose certification process is recognized by the department, the NRC or an agreement state and who meets the requirements of par. (b) 2. g. To be recognized, a specialty board shall require all candidates for certification to do all of the following:

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 shall include 700 hours of training and experience as described in par. (b) 1. and (b) 2. a., b., c., d., and e. Eligible training programs shall be approved by the Residency R~~r~~eview C~~e~~ommittee of the A~~a~~ccreditation C~~e~~ouncil for G~~g~~raduate M~~m~~edical E~~e~~ducation, the R~~r~~oyal C~~e~~ollege of P~~p~~hysicians and S~~s~~urgeons of Canada, or the Council on Postdo~~cse~~toral Training~~committee on post-graduate training~~ of the American O~~o~~steopathic A~~a~~ssociation.

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.

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC’s web site at www.nrc.gov.

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

1. Classroom and laboratory training in all the following areas:

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Chemistry of radioactive material for medical use.

e. Radiation biology.

2. Work experience under the supervision of an authorized user who meets the requirements in this subsection, s. DHS 157.61 (10), or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements of this paragraph shall also have experience under subd. 2. g. in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience shall involve all of the following:

a. Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys.

b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters.

c. Calculating, measuring, and safely preparing patient or human research subject dosages.

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material.

e. Using procedures to contain spilled radioactive material safely.

f. Using proper decontamination procedures.

g. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status: oral administration of less than or equal to 1.22 GBq (33 millicurie) of sodium iodide I-131 for which a written directive is required; oral administration of greater than 1.22 GBq (33 millicuries) of sodium iodide I-131; ~~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 parenteral administration of any other radionuclide for which a written directive is required~~ and parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required. Experience with at least 3 cases of oral administration of greater than 1.22 GBq (33 millicuries) of I-131 also satisfies the requirement for experience with 3 cases of oral administration of less than or equal to 1.22 GBq (33 millicuries) of I-131.

3. A written attestation under sub. (8) (a).

(5) TRAINING 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). Except as provided in s. DHS 157.61 (10), a 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 have obtained written attestation under sub. (8) (b) and~~ to be a physician who meets any of the following requirements:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in par. (c) and whose certification process has been recognized by the department, the NRC or an agreement state.

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

(b) Is an authorized user under sub. (4) (a) or (b) for specified uses of I-131 listed in subs. (4) (b) 2. g. and (6), or equivalent NRC or agreement state requirements.

(c) Has successfully completed training and work experience, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive that includes ~~both~~ all of the following:

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

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Chemistry of radioactive material for medical use.

e. Radiation biology.

2. Work experience, under the supervision of an authorized user who meets the requirements in sub. (4) (a) or (b), (5) or (6), s. DHS 157.61 (10), or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in sub. (4) (b) or s. DHS 157.61 (10), shall also have experience in administering the same category of sodium iodide I-131 use as specified in sub. (4) (b) 2. g. The work experience shall involve all of the following:

a. Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys.

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.

c. Calculating, measuring, and safely preparing patient or human research subject dosages.

d. Using administrative controls to prevent a medical event involving the use of radioactive material.

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.

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

3. A written attestation under sub. (8) (b).

(6) TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES GREATER THAN 1.22 GIGABECQUERELS (33 MILLICURIES). Except as provided in s. DHS 157.61 (10), a licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) ~~to have obtained written attestation under sub. (8) (c) and~~ to be a physician who meets any of the following requirements:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in par. (c) and whose certification has been recognized by the department, the NRC or agreement state.

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

(b) Is an authorized user under sub. (4) (a) or (b) for use of I-131 greater than 1.22 Gigabecquerel (33 millicuries) under sub. (4) (b) 2. g., or equivalent NRC or agreement state requirements.

(c) Has successfully completed training and experience, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive, that includes ~~both~~ all of the following:

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

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Chemistry of radioactive material for medical use.

e. Radiation biology.

2. Work experience, under the supervision of an authorized user who meets the requirements in sub. (4) (a) or (b), this subsection, s. DHS 157.61 (10), or equivalent NRC or agreement state requirements. A supervising authorized user, who meets the requirements in sub. (4) (b), or s. DHS 157.61 (10), shall also have experience in administering dosages of I-131 greater than 1.22 Gigabecquerels (33 millicuries) as specified in sub. (4) (b) 2. g. The work experience shall involve all the following:

a. Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys.

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.

c. Calculating, measuring and safely preparing patient or human research subject dosages.

d. Using administrative controls to prevent a medical event involving the use of radioactive material.

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures.

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

3. A written attestation under sub. (8) (c).

(7) TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE. Except as provided in s. DHS 157.61 (10), a licensee shall require an authorized user for the parenteral administration requiring a written directive ~~to have obtained written attestation under sub. (8) (d) and~~ to be a physician who meets any of the following requirements:

(a) Is an authorized user under sub. (4) for the specific parenteral uses listed in sub. (4) (b) 2. g., or equivalent NRC or agreement state requirements.

(b) Is an authorized user under s. DHS 157.65 (8) or 157.67 (17), or equivalent NRC or agreement state requirements and who meets the requirements in par. (c) 1. and 2.

(c) Is certified by a medical specialty board whose certification process has been recognized by the department under s. DHS 157.65 (8) or 157.67 (17) or equivalent NRC or agreement state requirements; and who meets the following requirements:

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~~ of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, which a written directive is required. The training shall include all of the following:

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Chemistry of radioactive material for medical use.

e. Radiation biology.

2. Has work experience with any ~~beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide~~ radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keVfor which a written directive is required. This work experience shall be under the supervision of an authorized user with experience in parenteral administration under sub. (4) (b) 2. g., for which a written directive is required, and who meets the requirements in sub. (4), s. DHS 157.61 (10), this subsection, or equivalent NRC or agreement state requirements. The work experience shall involve all the following:

a. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys.

b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters.

c. Calculating, measuring, and safely preparing patient or human research subject dosages.

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material.

e. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures.

f. 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.

3. Has obtained written attestation under sub. (8) (d).

(8) WRITTEN ATTESTATION. (a) *Unsealed radioactive material for which a written directive is required.* As required by sub. (4) (b) 3., the~~A~~ licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) to have obtained written attestation that the individual has successfully ~~satisfactorily~~ completed the requirements in sub. (4) ~~(a) 1. and~~ (b) ~~2. g., or sub. (4) (b)~~ and is able to independently fulfill the radiation safety-related duties as an authorized user for the

medical uses authorized under sub. ~~DHS 157.64~~(1) for which the individual is requesting authorized user status. The attestation must be obtained from either of the following:~~A licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) to have obtained written attestation that the individual has satisfactorily completed the requirements in sub. (4) (a) 1. and (b) 2. g., or sub. (4) (b) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under sub. (1). The written attestation shall be signed by a preceptor authorized user who meets the requirements in this subsection, s. DHS 157.61 (10), or equivalent agreement state requirements. The preceptor authorized user, who meets the requirements in sub. (4) (b) or s. DHS 157.61 (10) shall have experience under sub. (4) (b) 2. g. in administering dosages in the same dosage category or categories as the individual requesting authorized user status.~~

1. A preceptor authorized user who meets the requirements in sub. (4), s. DHS 157.61(10)~~, DHS 157.64(4),~~ or equivalent NRC or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status~~; or~~

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in sub. (4), s. DHS 157.61 (10),~~DHS 157.61(10), DHS 157.64(4), or~~ or equivalent NRC or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in ~~ss. DHS 157.64(4)(a),~~sub. (4) (b).

(b) *Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).* As required by sub. (5) (c) 3., the~~A~~ licensee shall require an authorized user of sodium iodide I-131 for oral administration to have obtained written attestation that the individual has successfully ~~satisfactorily~~ completed the requirements in sub. (5) (c), and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under sub. (1). The attestation must be obtained from either of the following:~~A licensee shall require an authorized user of sodium iodide I-131 for oral administration to have obtained written attestation that the individual has satisfactorily completed the requirements in sub. (5) (c) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under sub. (1). The written attestation shall be signed by a preceptor authorized user who meets the requirements in sub. (4), (5) or (6), s. DHS 157.61 (10), or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements of sub. (4) (b) or s. DHS 157.61 (10), shall have experience in administering I–131 dosage less than 1.22 Gigabecquerels (33 millicuries) under sub. (4) (b) 2. g.~~

1. A preceptor authorized user who meets the requirements in sub. (4), (5) or (6), s. DHS 157.61 (10), ~~DHS 157.61(10), 64(4), 64(5) or 64(6)~~ or equivalent NRC or Agreement State requirements and has experience in administering sodium iodide I-131 dosages ~~dosages~~ as specified in sub. ~~DHS 157.64~~(4) (b) 2. g.~~or:~~

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in sub. (4), (5) or (6), s. DHS 157.61 (10). ~~DHS 157.61(10), 64(4), 64(5) or 64(6)~~ or equivalent NRC or Agreement State requirements, has experience in administering sodium iodide I-131 dosages as specified in sub. (4) (b) 2. g.~~§~~ DHS 157.64(4)(b)2.g, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. ~~DHS 157.64~~(5)(c).

(c) *Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).* As required by sub. (6) (c) 3., the~~A~~ licensee shall require an authorized user of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) to have obtained written attestation that the individual has successfully ~~satisfactorily~~ completed the requirements in sub. (6) (c), and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of~~ering~~ ~~dosages of I-131~~ greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131 under sub. (1).~~as specified in sub (4) (b) 2. g.~~ ~~–~~The attestation must be obtained from either of the following:~~A licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than Gigabecquerels (33 millicuries) to have obtained written attestation that the individual has satisfactorily completed the requirements in sub. (6) (c) and has achieved a level of competency sufficient to function independently as an authorized user under sub. (1). The written attestation shall be signed by a preceptor authorized user who meets the requirements in sub. (4) or (6), s. DHS 157.61 (10), or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements of sub. (4) (b) or s. DHS 157.61 (10), shall have experience in administering dosages of I-131 greater than 1.22 Gigabecquerels (33 millicuries) as specified in sub. (4) (b) 2. g.~~

1. A preceptor authorized user who meets the requirements in sub. (4) or (6), s. DHS 157.61 (10), ~~DHS 157.61(10), 64(4) or 64(6)~~ or equivalent NRC or Agreement State requirements and has experience in administering dosages of I-131

greater than 1.22 Gigabecquerels (33 millicuries) as specified in sub. (4) (b) 2. g.~~dosages as specified in DHS 157.64(4)(b)2.g. or:~~

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in sub. (4) or (6), s. DHS 157.61 (10),~~DHS 157.61(10), 64(4) or 64(6)~~ or equivalent NRC or Agreement State requirements, has experience in administering dosages of I-131 greater than 1.22 Gigabecquerels (33 millicuries) as specified in sub. (4) (b) 2. g.~~dosages as specified in § DHS 157.64(4)(b)2.g.~~ and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. ~~DHS 157.64~~(6) (c).

(d) *Parenteral administration of unsealed radioactive material requiring a written directive.* As required by sub. (7~~6~~) (c) 3., the~~A~~ licensee shall require a user for the parenteral administration of unsealed radioactive material requiring a written directive to have obtained written attestation that the individual has successfully ~~satisfactorily~~ completed the requirements in sub. (7) (c), and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive as specified in sub (4) (b) 2. g. The attestation must be obtained from either of the following:~~A licensee shall require an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive to have obtained written attestation that the individual has satisfactorily completed the requirements in sub. (7) (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 shall be signed by a preceptor authorized user who meets the requirements in sub. (4), s. DHS 157.61 (10), or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements in sub. (4) or s. DHS 157.61 (10) shall have experience in administering parenteral dosages as specified in sub. (4) (b) 2. g.~~

1. A preceptor authorized user who meets the requirements in sub. (4) or (6), s. DHS 157.61 (10),~~DHS 157.61(10), 64(4) or 64(7)~~ or equivalent NRC or Agreement State requirements and has experience in administering parenteral dosages as specified in sub. ~~DHS 157.64~~(4) (b) 2. g.~~ or:~~

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in sub. (4) or (6), s. DHS 157.61 (10),~~DHS 157.61(10), 64(4) or 64(7)~~ or equivalent NRC or Agreement State requirements, has experience in administering parenteral ~~-~~dosages as specified in sub.~~§ DHS 157.64~~(4) (b) 2. g, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. ~~DHS 157.64~~(7) (c).

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: r. and recr. (4) to (6), cr. (7) and (8) Register October 2006 No. 610, eff. 11-1-06; CR 09-062: am. (1) (a), (b) (intro.), (4) (b) 2. (intro.), (5) (b), (c) 2. (intro.), (6) (c) 2. (intro.), (7) (c) 2. (intro.), (8) (a) to (d) Register April 2010 No. 652, eff. 5-1-10.

DHS 157.65 **Manual brachytherapy. (1)** USE OF SOURCES FOR MANUAL BRACHYTHERAPY. A licensee shall use only brachytherapy sources for therapeutic medical uses under either of the following criteria:

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

(b) In research to deliver therapeutic doses for medical use in accordance with an active investigational device exemption application accepted by the FDA~~Investigational Device Exemption application accepted by the U.S. Food and Drug Administration~~ provided the requirements of s. DHS 157.61 (6) (a) are met.

~~(a) As approved in the sealed source and device registry.~~

~~(b) In research under an effective investigational device exemption application accepted by the FDA, provided the requirements of s. DHS 157.61 (6) (a) are met.~~

(2) SOURCE IMPLANT AND REMOVAL REQUIREMENTS. (a) Immediately after implanting sources in a patient or a human research subject, a licensee shall make 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, a licensee shall conduct a survey of the patient or the human research subject with a radiation detection survey instrument, with the sources shielded and outside the room, to confirm that all sources have been removed from the patient.

(c) A licensee shall retain a record of the surveys under s. DHS 157.71 (16).

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

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

(c) A licensee shall maintain a record of the brachytherapy source accountability under s. DHS 157.71 (17).

(4) SAFETY INSTRUCTION. In addition to the requirements of subch. X, a licensee shall do both of the following:

(a) Provide radiation safety instruction, initially and at least once in each year, at intervals no greater than 13 months, to personnel caring for patients or human research subjects undergoing implant therapy and cannot be released under s. DHS 157.62 (8). To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include all of 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 of the following:

a. Routine visitation of hospitalized individuals under s. DHS 157.23 (1) (a) 1.

b. Visitation authorized under s. DHS 157.23 (1) (b).

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 that causes the patient's condition to suddenly deteriorate.

(b) Retain a record under s. DHS 157.71 (15) of individuals receiving instruction.

(5) SAFETY PRECAUTIONS. (a) For each patient or human research subject receiving brachytherapy who may not be released under s. DHS 157.62 (8), a licensee shall do both the following:

1. Not quarter the patient or the human research subject in the same room as a person who is not receiving brachytherapy.
2. Visibly post a "Radioactive Materials" sign on the door of the patient's or human research subject's room 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 available, near each treatment room, emergency response equipment to respond to a source that is any of the following:

1. Inadvertently dislodged from the patient.
2. Inadvertently lodged within the patient following removal of the source applicators.

(c) A licensee shall 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.

(6) CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES. (a) Prior to the first medical use of brachytherapy sources, a licensee shall either comply with par. (b) or do all the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of s. DHS 157.67 (6).
2. Determine source positioning accuracy within applicators.
3. Use published protocols accepted by nationally recognized bodies to meet the requirements of subds. 1. and 2.

(b) Instead of a licensee making its own measurements as required in par. (a), the 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 par. (a).

~~**Note:** 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 par. (a).~~

(c~~b~~) A licensee shall mathematically correct the outputs or activities determined in par. (a) for physical decay at intervals consistent with one percent physical decay.

(d) A license shall retain a record of each calibration under s. DHS 157.71(18).

(6m) STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS.

(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in par. (b) of this section are performed by either of the following:

1. An authorized medical physicist.

2. An individual who meets all of the following:

a. Is identified as an ophthalmic physicist on a specific medical use license issued by the department, the NRC or an agreement state, or permit issued by the NRC or an agreement state broad scope medical use licensee, medical use permit issued by an NRC master material licensee, or permit issued by an NRC master material licensee broad scope medical use permittee.

b. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university.

c. Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist.

d. Has documented training in the creation, modification, and completion of written directives.

e. Has documented training in procedures for administrations requiring a written directive.

f. Has documented training in performing the calibration measurements of brachytherapy sources as detailed in sub. (6).

(b) The individuals who are identified in par. (a) 1. or 2. shall do all of the following:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under sub. (6).

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

(c) Licensees shall retain a record of the activity of each strontium-90 source in accordance with s. DHS 157.71(18).

(7) THERAPY-RELATED COMPUTER SYSTEMS. A licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems under published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of all of the following:

(a) Source-specific input parameters required by the dose calculation algorithm.

(b) Accuracy of dose, dwell time and treatment time calculations at representative points.

(c) Accuracy of isodose plots and graphic displays.

(d) Accuracy of the software used to determine radioactive source positions from radiographic images.

Note: An example of a nationally recognized body is the American Association of Physicists in Medicine.

(8) TRAINING FOR USE OF MANUAL BRACHYTHERAPY SOURCES. Except as provided in s. DHS 157.61 (10), a licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under sub. (1) ~~to have obtained written attestation under sub. (10) (a) and~~ to be a physician who meets either of the following requirements:

(a) Is certified by a medical specialty board whose certification process has been recognized by the department, the NRC or an agreement state. To ~~be~~ have its certification process recognized, a specialty board shall require all candidates for certification to do all of the following:

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 royal college of physicians and surgeons of Canada or the Council on Postdoctoral Training~~committee on post-graduate training~~ of the American osteopathic association.

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.

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

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

1. Two hundred hours of classroom and laboratory training in all of the following areas:

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Radiation biology.

2. Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this subsection, s. DHS 157.61 (10), - or equivalent NRC or agreement state requirements at a medical ~~institution~~ facility authorized to use ~~byproduct~~radioactive materials under sub. (1), involving all of the following:

a. Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys.

b. Checking survey meters for proper operation.

c. Preparing, implanting and removing brachytherapy sources.

d. Maintaining running inventories of material on hand.

e. Using administrative controls to prevent a medical event involving the use of radioactive material.

f. Using emergency procedures to control radioactive material.

3. Three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this subsection, s. DHS 157.61 (10), or ~~-~~ equivalent NRC 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 Council on Postdoctoral Training~~committee on postdoctoral~~ training of the American osteopathic association. The experience may be obtained concurrently with the supervised work experience required by subd. 2.

4. A written attestation under sub. (10) (a).

(9) TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90. Except as provided in s. DHS 157.61 (10), a licensee shall require an authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who meets any of the following requirements: ~~have obtained written attestation under sub. (10) (b) and be a physician who has had classroom and laboratory training applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy that meets all of the following criteria:~~

(a) Is an authorized user under sub. (8) or equivalent NRC or agreement state requirement.

(b) Has had classroom and laboratory training applicable to the use of strontium-90 for ophthalmic radiotherapy, a period of supervised clinical training in ophthalmic radiotherapy that includes all of the following:

~~(a)~~

1.Twenty-four hours of classroom and laboratory training that includes all of the following:

a~~1~~. Radiation physics and instrumentation.

b~~2~~. Radiation protection.

c~~3~~. Mathematics pertaining to the use and measurement of radioactivity.

d~~4~~. Radiation biology.

2.~~(b)~~ 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 5 individuals. The supervised clinical training shall include all of the following:

a~~1~~. Examination of each person to be treated.

b~~2~~. Calculation of the dose to be administered.

c~~3~~. Administration of the dose.

d~~4~~. Follow up and review of each individual's case history.

3. Has obtain written attestation under sub. (10) (b).

(10) WRITTEN ATTESTATION. (a) *Manual brachytherapy sources.* As required by sub. (8) (b) 4., a~~A~~ licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under sub. (1) to have obtained written attestation, signed by a preceptor authorized user who meets the requirements in sub. (8), s. DHS 157.61 (10), or equivalent NRC or agreement state requirements, that the individual has successfully ~~satisfactorily~~ completed the requirements in sub. (8) ~~(a) 1. or~~ (b) and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under sub. (1~~8~~). The attestation must be obtained from any of the following:

1. A preceptor authorized user who meets the requirements in sub. (~~1~~8), s. DHS 157.61(10), or equivalent NRC or agreement state requirements.

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in sub. (8~~1~~), s. DHS 157.61(10), or equivalent NRC or agreement state requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. (8) (b).

(b) *Ophthalmic use of strontium-90.* As required by sub. (9) (b) 3., a~~A~~ licensee shall require an authorized user for ophthalmic use of strontium-90 to have obtained written attestation, signed by a preceptor authorized user who meets the requirements in sub. (8) or (9), s. DHS 157.61 (10), or equivalent NRC or agreement state requirements, that the individual has successfully ~~satisfactorily~~ completed the requirements in subs. (9) ~~(a) and~~ (b) 1. and 2. and ~~has achieved a level of competency sufficient to function independently~~ able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: am. (1) (intro.) and (6) (a) (intro.), r. and recr. (8) and (9), cr. (10) Register October 2006 No. 610, eff. 11-1-06; CR 09-062: am. (8) (b) 2. (intro.), 3., and (10) Register April 2010 No. 652, eff. 5-1-10.

DHS 157.66 **Sealed sources for diagnosis. (1)** USE OF SEALED SOURCES FOR DIAGNOSIS. (a) A licensee may use sealed sources that are not in medical devices for diagnostic medical uses if all of the following are met:

1. The sealed sources are approved in the sealed source and device registry for diagnostic medicine.

2. If the diagnostic medical uses are not explicitly listed in the sealed source and device registry, the sealed sources are used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.
~~A licensee shall use only sealed sources for diagnostic medical uses as approved in the sealed source and device registry.~~

(b)) A licensee may use medical devices containing sealed sources for diagnostic medical uses if all the following are met:

1. Both the sealed sources and medical devices are approved in the sealed source and device registry for diagnostic medical uses.

2. If the diagnostic medical uses are not explicitly listed in the sealed source and device registry, the diagnostic medical devices are used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

(c) Sealed sources and devices for diagnostic medical uses may be used for research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration, and provided the requirements of s. DHS 157.61(6) are met.

Note: The sealed source and device registrations may be obtained from the manufacturer or by writing the department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659.

(2) TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS. Except as provided in s. DHS 157.61 (10), a licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under sub. (1) to have received training in the use of the device for the uses requested. ~~–~~The licensee shall also require the authorized user to be a physician, dentist or podiatrist who meets ~~either~~ any of the following requirements:

(a) Is certified by a specialty board whose certification process includes all of the requirements in par. (b) and whose certification is recognized by the department, the NRC or an agreement state.

Note: Specialty boards whose certification processes have been recognized by the department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

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

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

(c) Is an authorized user under s. DHS 157.63 (2), or equivalent NRC or agreement state requirements.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: r. and recr. (2) Register October 2006 No. 610, eff. 11-1-06.

DHS 157.67 **Photon emitting remote afterloader, teletherapy and gamma stereotactic radiosurgery units. (1)** USE OF A SEALED SOURCE IN A REMOTE AFTERLOADER, TELETHERAPY OR GAMMA STEREOTACTIC RADIOSURGERY UNIT. (a) A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units or gamma stereotactic units for therapeutic medical uses that meet ~~one~~ any of the following criteria:

~~(a)~~1. Is approved in the sealed source and device registry.

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Note: The sealed source and device registrations may be obtained from the manufacturer or by writing the department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659.

2.~~(b)~~ In research ~~under an~~ involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active effective investigational device exemption application accepted by the FDA provided the requirements of s. DHS 157.61 (6) (a) are met.

Note: The FDA requirements for investigational devices may be found at: https://www.fda.gov/radiation-emitting-products~~http://www.fda.gov/RadiationEmittingProducts/default.htm~~.

(b) A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units that meet any of the following criteria:

1. Is approved in the sealed source and device registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the sealed source and device registry, but must be used in accordance with radiation safety conditions and limitations described in the sealed source and device registry.
2. In research in accordance with an active Investigational Device Exemption application accepted by the FDA and provided the requirements of s. DHS 157.61(6) are met.

(2) 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 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 under s. DHS 157.71 (16).

(3) INSTALLATION, MAINTENANCE, ADJUSTMENT AND REPAIR. (a) A person shall be specifically licensed by the department, NRC or another agreement state to install, maintain, adjust or repair a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source driving unit used to move the source or other electronic or mechanical component that could expose the source, reduce the shielding around the source or compromise the radiation safety of the unit or the source.

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the department, NRC or another agreement state may install, replace, relocate or remove a sealed source or source contained in other remote afterloader units, teletherapy units or gamma stereotactic units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the department, NRC or another agreement state, or an authorized medical physicist, shall install, replace, relocate or remove a sealed source 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 under s. DHS 157.71 (19).

(4) SAFETY PROCEDURES AND INSTRUCTIONS FOR REMOTE AFTERLOADER, TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS. (a) A licensee shall do all of the following:

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

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.

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

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

a. Instructions for responding to equipment failures and the names of the persons responsible for implementing corrective actions.

b. The process for restricting access to and posting signs in the proximity of the treatment area to minimize the risk of inadvertent exposure.

c. The names and telephone numbers of the authorized users, the authorized medical physicist and the radiation safety officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by par. (a) 4. shall be physically located at the unit console.

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

1. The location of the procedures required by par. (a) 4.

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 operational and safety instruction, initially and at least annually, at intervals not to exceed 13 months, to all persons who operate the unit, as appropriate to the person's assigned duties, in all of the following:

1. The procedures identified in par. (a) 4.

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, at intervals not to exceed 13 months, thereafter.

(f) A licensee shall retain a record of individuals receiving instruction required under s. DHS 157.71 (15).

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

(h) A licensee shall retain a copy of the procedures required by pars. (a) 4. and (d) 2. until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

(5) SAFETY PRECAUTIONS FOR REMOTE AFTERLOADER, TELETHERAPY 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 accomplishes all the following:

1. Prevents the operator from initiating the treatment cycle unless each treatment room entrance door is closed.

2. Causes the source to be shielded promptly when an entrance door is opened.

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

(c) A licensee shall require any person entering the treatment room to assure, via 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 that allow for expeditious removal of a decoupled or jammed source.

(f) A licensee shall do all the following:

1. For medium dose-rate and pulsed dose-rate remote afterloader units, require all the following:

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

b. An authorized medical physicist and either an authorized user or a person under the supervision of an authorized user who has been trained to remove the source applicator in the event of an emergency involving the unit to be immediately available during continuation of all patient treatments involving the unit.

2. For high dose-rate remote afterloader units, require all the following:

a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit.

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

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

4. Notify the radiation safety officer or his or her designee and an authorized user immediately if the patient or human research subject has a medical emergency or if the patient dies.

(g) A licensee shall have available near each treatment room, emergency response equipment, as applicable, to respond to all of the following:

1. A source inadvertently remaining in the unshielded position.

2. A source inadvertently lodged within the patient following completion of the treatment.

(6) 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 conditions shall be met:

1. The system shall have been calibrated using a system or source traceable to the national institute of standards and technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American association of physicists in medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration.

Note: An example of a nationally recognized body is the American Association of Physicists in Medicine.

2. The system shall have been calibrated within the previous 4 years. Eighteen to 30 months after that calibration, the system shall have been compared to another dosimetry system that was calibrated within the past 24 months by the national institute of standards and technology or by a calibration laboratory accredited by the American association of physicists in medicine. The results of the comparison shall have indicated that the calibration factor of the licensee's system had not changed by more than 2%. A licensee may not use the intercomparison result to change the calibration factor. When comparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, a 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) A licensee shall have available for use a dosimetry system for spot-check output measurements to periodically measure the radiation output of the device for consistency, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated under par. (a). The comparison shall have been performed within the previous 12 months 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 par. (a).

(c) A licensee shall retain a record of each calibration and comparison under s. DHS 157.71 (20).

(7) 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 under any of the following circumstances:

1. Before the first medical use of the unit.

2. Before medical use under all of the following conditions:

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

b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location.

c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly.

3. At intervals not exceeding one year.

(b) To satisfy the requirements of par. (a), full calibration measurements shall include determination of all of the following:

1. The output within plus or minus 3% for the range of field sizes and for the distance or range of distances used for medical use.

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

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.

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

(c) A licensee shall use the dosimetry system described in sub. (6) (a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in par. (b) may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall perform a full calibration required by par. (a) under published protocols accepted by nationally recognized bodies.

Note: An example of such a nationally recognized body is the American Association of Physicists in Medicine.

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

(f) Full calibration measurements required by par. (a) and physical decay corrections required by par. (e) shall be performed by an authorized medical physicist.

(g) A licensee shall retain a record of each calibration under s. DHS 157.71 (21).

(8) FULL CALIBRATION MEASUREMENTS ON REMOTE AFTERLOADER UNITS. (a) A licensee authorized to use a remote afterloader unit for medical use shall perform a full calibration measurement on each unit under any of the following circumstances:

1. Before the first medical use of the unit.

2. Before medical use under all the following conditions:

a. Following replacement of any source or following reinstallation of the unit in a new location outside the facility.

b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly.

3. Each calendar quarter, at intervals not exceeding 100 days for high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days.

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

(b) To satisfy the requirement of par. (a), a full calibration measurement shall include, as applicable, determination of all the following:

1. The output within 5%.

2. Source positioning accuracy to within plus or minus one millimeter.

3. Source retraction with backup battery upon power failure.

4. Length of the source transfer tubes.

5. Timer accuracy and linearity over the typical range of use.

6. Length of the applicators.

7. Function of the source transfer tubes, applicators and transfer tube-applicator interfaces.

(c) In addition to the requirement for full calibration for low dose-rate remote afterloader units in par. (b), a licensee shall perform an autoradiograph of the source to verify inventory and source arrangement at intervals not exceeding one calendar quarter.

(d) A licensee shall use the dosimetry system described in sub. (6) (a) to measure the output.

(e) A licensee shall make a full calibration measurement required by par. (a) under published protocols accepted by nationally recognized bodies.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made under pars. (a) to (e).

(g) A licensee shall mathematically correct the outputs determined in par. (b) 1. for physical decay at intervals consistent with one percent physical decay.

(h) A full calibration measurement required by par. (a) and physical decay correction required by par. (g) shall be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration under s. DHS 157.71 (21).

(j) In addition to the requirements for full calibration for low dose rate remote afterloaders, as specified in par. (b), a licensee shall perform an autoradiograph of the source or sources to verify inventory and source arrangement at intervals not to exceed 3 months.

(9) 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 under any of the following circumstances:

1. Before the first medical use of the unit.

2. Before medical use under all of the following conditions:

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

b. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location.

c. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly.

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

(b) To satisfy the requirement of par. (a), a full calibration measurement shall include determination of all the following:

1. The output within plus or minus 3%.

2. Relative helmet factors to verify that the helmet material provides the required shielding to the patient.

3. Isocenter coincidence to confirm the centering accuracy of the radiation beam relative to the helmet openings.

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

5. On-off error.

6. Trunnion centricity to determine the rotational center of the source relative to the helmet openings.

7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the main power to the unit off.

8. Helmet microswitches to determine if the switches terminate the radiation beam when tripped by unintended movement of the helmet.

9. Emergency timing circuits.

10. Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in sub. (6) (a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in par. (b) 1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make a full calibration measurement required by par. (a) under published protocols accepted by nationally recognized bodies.

Note: An example of such a nationally recognized body is the American Association of Physicists in Medicine.

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

(f) A full calibration measurement required by par. (a) and physical decay correction required by par. (e) shall be performed by an authorized medical physicist.

(g) A licensee shall retain a record of each calibration under s. DHS 157.71 (21).

(10) 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 all of the following:

1. Timer constancy 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 sub. (6) (b).

6. The difference between the measurement made in this subd. 5. and the anticipated output expressed as a percentage of the anticipated output, which is the value obtained at last full calibration corrected mathematically for physical decay.

(b) A licensee shall perform measurements required by par. (a) under procedures established by the authorized medical physicist. 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 working days. The authorized medical physicist shall notify the licensee in writing of the results of each spot-check within 10 working days.

(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 all of the following:

1. Electrical interlocks at each teletherapy room entrance.

2. Electrical or mechanical stops installed to limit use of the primary beam of radiation.

Note: Examples of the limitations in subd. 2. include 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.

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

(e) If the results of the checks required in par. (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 pars. (a) and (d), under s. DHS 157.71 (22).

(11) PERIODIC SPOT-CHECKS FOR REMOTE AFTERLOADER UNITS. (a) A licensee authorized to use remote afterloader units for medical use shall perform a spot-check of each remote afterloader facility and on each unit according to the following criteria:

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.

3. After each source installation.

(b) A licensee shall have an authorized medical physicist establish written procedures for performing the spot-checks required in par. (a) of this section. The authorized medical physicist need not actually perform the spot check measurements.

(c) To satisfy the requirements of par. (a), a spot-check shall assure proper operation of all of the following:

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. The date and time of the clock in the unit's computer.

8. Decayed source activity in the unit's computer.

(d) If the results of the checks required in par. (c) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as necessary to repair, replace or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by par. (c) under s. DHS 157.71 (23).

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

(12) 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 at all of the following times:

1. Monthly.

2. At the beginning of each day of use.

3. After each source installation.

(b) A licensee shall have an authorized medical physicist do all the following:

1. Establish written procedures for performing the spot-checks required in par. (a).

2. Review the results of each spot-check required by par. (a) 1. within 15 working days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

3. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of the spot check.

(c) To satisfy the requirements of par. (a) 1., a spot-check shall do all of the following:

1. Assure proper operation of treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; helmet microswitches; emergency timing circuits and stereotactic frames and localizing devices.

2. Determine all of the following:

a. The output for one typical set of operating conditions measured with the dosimetry system described in sub. (6) (b).

b. The difference between the measurement made in subd. 2. a. and the anticipated output expressed as a percentage of the anticipated output.

c. Source output against computer calculation.

d. Timer accuracy and linearity over the range of use.

e. On-off error.

f. Trunnion centricity.

(d) To satisfy the requirements of par. (a) 2. and 3., a spot-check shall assure proper operation of all of the following:

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 of the radiation beam.

5. Radiation monitors used to indicate room exposures.

6. Emergency off buttons.

(e) A licensee shall arrange for prompt repair of any system identified in par. (c) or (d) that is not operating properly.

(f) If the results of the checks required in par. (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 pars. (c) and (d) under s. DHS 157.71 (24).

(13) ADDITIONAL TECHNICAL REQUIREMENTS FOR MOBILE REMOTE AFTERLOADER UNITS. (a) A licensee providing mobile remote afterloader service shall do all of the following:

1. Check survey instruments before medical use at each client's address of use or on each day of use, whichever is more frequent.

2. Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by sub. (11), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address. A check shall be made to verify the operation of all the following:

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

(c) 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 par. (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 par. (b) under s. DHS 157.71 (25).

(14) RADIATION SURVEYS. (a) In addition to the survey requirement in s. DHS 157.25 (1), a person licensed to possess or use photon emitting remote afterloader, teletherapy or gamma stereotactic radiosurgery units shall perform surveys of the device and ensure the results of the surveys from the surface of the main source safe, with the sources in the shielded position, do not exceed the maximum and average radiation levels listed in the sealed source and device registry.

(b) A licensee shall make the survey required by par. (a) at installation of a new source and following repairs to source shielding, a source driving unit or other electronic or mechanical component that could expose a source, reduce the shielding around a source or compromise the radiation safety of the unit or a source.

(c) A licensee shall retain a record of the radiation surveys required by par. (a) under s. DHS 157.71 (26).

(15) ~~FIVE-YEAR~~ FULL-INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOTHERAPY UNITS. (a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit inspected for proper operation and serviced during source replacement to assure proper functioning of the source exposure mechanism. The ~~or at~~ intervals between full inspection and servicing shall not to exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit~~, whichever comes first, to assure proper functioning of the source exposure mechanism.~~

(b) Inspection and servicing of a teletherapy or gamma stereotactic radiosurgery unit may only be performed by a person specifically licensed to do so by the department, the NRC or another agreement state.

(c) A licensee shall keep a record of the inspection and servicing under s. DHS 157.71 (27).

(16) THERAPY-RELATED COMPUTER SYSTEMS. A licensee shall perform acceptance testing on the treatment planning system under published protocols accepted by nationally recognized bodies. The acceptance testing shall include, as applicable, verification of all of the following:

(a) Source-specific input parameters required by the dose calculation algorithm used to calculate the dose to the patient.

(b) Accuracy of dose, dwell time of the radioactive source at a particular location and treatment time calculations at representative points.

(c) Accuracy of isodose graphic plots on paper and graphic displays.

(d) Accuracy of the software used to determine radioactive source positions from radiographic images.

(e) Accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system that was used to calculate the patient dose and radioactive source dwell times.

Note: An example of such a nationally recognized body is the American Association of Physicists in Medicine.

(17) TRAINING FOR USE OF REMOTE AFTERLOADER, TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS. A licensee shall require an authorized user of a sealed source for a use authorized under sub. (1) to have received training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought. This training requirement may be satisfied by ~~satisfactory~~ successful 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 of use for which the individual is seeking authorization. Except as provided in s. DHS 157.61 (10), a licensee shall require an authorized user of sealed source for a use authorized under sub. (1) ~~to have obtained written attestation under sub. (18) and~~ to be a physician who meets either of the following requirements:

(a) Is certified by a medical specialty board whose certification process has been recognized by the department, the NRC or an agreement state. To ~~be~~ have its certification process recognized recognized, a specialty board shall require all candidates for certification to do all of the following:

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 Council of Postdoctoral Training~~committee on post-graduate training~~ of the American osteopathic association.

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.

Note: Specialty boards whose certification processes have been recognized by the Department, the NRC or an agreement state will be posted on the NRC's web site at www.nrc.gov.

(b) 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 all of the following:

1. Two hundred hours of classroom and laboratory training in all the following areas:

a. Radiation physics and instrumentation.

b. Radiation protection.

c. Mathematics pertaining to the use and measurement of radioactivity.

d. Radiation biology.

2. Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this subsection, s. DHS 157.61 (10), or equivalent NRC or agreement state requirements at a medical ~~institution~~ facility authorized to use byproduct materials under sub. (1), involving all of the following:

a. Reviewing full calibration measurements and periodic spot checks.

b. Preparing treatment plans and calculating treatment doses and times.

c. Using administrative controls to prevent a medical event involving the use of radioactive material.

d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console.

e. Checking and using survey meters.

f. Selecting the proper dose and how it is to be administered.

3. Three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in this subsection, s. DHS 157.61 (10), or equivalent NRC 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 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 subd. 2.

4. Has obtained written attestation under sub. (18).

(18) WRITTEN ATTESTATION. A licensee shall require an authorized user of a sealed source for a use authorized under sub. (17) to have obtained written attestation that the individual has successfully ~~satisfactorily~~ completed the requirements in sub. (17) ~~(a) 1. or~~ (b), 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 shall be signed by a preceptor authorized user who meets the requirements in sub. (17), s. DHS 157.61 (10), or equivalent agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.~~ The attestation must be obtained from either of the following:

(a) A preceptor authorized user who meets the requirements in sub. (17), s. DHS 157.61 (10), or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

(b). A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in sub. (17), s. DHS 157.61(10), or equivalent NRC or agreement state requirements user for each type of therapeutic medical unit for which the individual is requesting authorized user status~~-~~. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sub. (17) (b).

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; correction in (4) (f) made under s. 13.93 (2m) (b) 7., Stats., Register July 2002 No. 559; CR 06-021: am. (9) (b) 2., 3., 6., 8. and 10., r. and recr. (17), cr. (18) Register September 2006, No. 609, eff. 10-1-06; CR 09-062: am. (8) (b) 1., (17) (b) 2. (intro.), 3. and (18) Register April 2010 No. 652, eff. 5-1-10; **CR 16-078: am. (11) (f), (12) (b) 3. Register January 2018 No. 745, eff. 2-1-18.**

DHS 157.68 **Radioactive drugs for medical use. (1)** PREPARATION. A licensee authorized to manufacture, prepare or transfer for commercial distribution or noncommercial transfer to medical use licensees in a consortium radioactive drugs shall ensure that any individual preparing the drugs is one of the following:

(a) An authorized nuclear pharmacist.

(b) An individual under the supervision of an authorized nuclear pharmacist.

(c) A pharmacist that meets any of the following criteria:

1. The requirements for an authorized nuclear pharmacist as specified in s. DHS 157.61 (9) and (11).

2. Is identified as an authorized nuclear pharmacist on a license issued by the department, an agreement state or the NRC.

3. Is identified as an authorized nuclear pharmacist by a licensee who is authorized by the department, an agreement state or the NRC to designate authorized nuclear pharmacists operating under their license.

4. Functioned as a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009.

(2) DOCUMENTATION. A licensee shall provide to the department a copy of all the following, as appropriate:

(a) A copy of each individual's certification by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state as specified in s. DHS 157.61 (9).~~Each individual's certification by the board of pharmaceutical specialties.~~

(b) The department, NRC or agreement state license.

(c) The permit issued by a licensee of broad scope.

(d) A list of authorized nuclear pharmacists designated by a licensee under sub. (1) (c) 3.

(e) The state pharmacist licensure, no later than 30 days after the date that the licensee allows, under sub. (1) (c) 1. and 2., the individual to work as an authorized nuclear pharmacist.

(f) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009.

History: CR 06-021: cr. Register October 2006 No. 610, eff. 11-1-06; CR 09-062: am. (1) (intro.) and (2) (e), cr. (1) (c) 4. and (2) (f) Register April 2010 No. 652, eff. 5-1-10.

DHS 157.70 **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 ss. DHS 157.63 to 157.67 if all of the following criteria are met:

(1) APPLICATION. The applicant or licensee has submitted the information required by s. DHS 157.59 (2) (b) and (c).

(2) APPROVAL. The applicant or licensee has received written approval from the department in a license and uses the material under this chapter and specific conditions the department considers necessary for the medical use of the material.

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter.

DHS 157.71 **Records. (1)** RECORDS OF AUTHORITY AND RESPONSIBILITIES FOR RADIATION PROTECTION PROGRAMS. (a) A licensee shall retain a record of actions taken by the licensee's management under s. DHS 157.61 (1) (a) for 5 years. The record shall include a summary of the actions taken and a signature of licensee management.

(b) A licensee shall retain a current copy of the authorities, duties and responsibilities of the radiation safety officer as required by s. DHS 157.61 (1) (d). The record shall include the signature of the radiation safety officer and licensee management.

(c) For each Associate Radiation Safety Officer appointed under s. DHS 157.61 (1) (b) , the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

(2) RECORDS OF RADIATION PROTECTION PROGRAM SAFETY CHANGES. A licensee shall retain a record of each radiation protection program change made under s. DHS 157.61 (2) (a) for 5 years. The record shall 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.

(3) RECORDS OF WRITTEN DIRECTIVES. A licensee shall retain a copy of each written directive as required by s. DHS 157.61 (4) for 3 years.

(4) RECORDS OF MEDICAL EVENTS. (a) A licensee shall retain a record of medical events reported under s. DHS 157.72 (1) for 3 years.

(b) The record shall contain all of the following:

1. The licensee's name.
2. Names of the persons involved.
3. ~~The social security number or other identification number, if one has been assigned,~~ An identification number assigned by the licensee or, if no other identification number is available, the social security number of any person who is the subject of a medical event.
4. A brief description of the event and why it occurred.
5. The effect, if any, on any individual.
6. The actions, if any, taken or planned to prevent recurrence.
7. Whether the licensee notified the affected individual or the affected individual's responsible relative or guardian and, if not, whether the failure to notify was based on guidance from the referring physician.

(5) RECORD OF A DOSE TO AN EMBRYO OR FETUS OR A NURSING CHILD. A licensee shall retain a record of a dose to an embryo or fetus or a nursing child reported under s. DHS 157.72 (2) for 3 years. The record shall contain all of the following:

(a) The licensee's name.

(b) The names of all the individuals involved.

(c) ~~social security number or other identification number, if one has been assigned~~ An identification number assigned by the licensee or, if no other identification number is available, the social security number of the pregnant individual or nursing child who is the subject of the event.

(d) A brief description of the event, why it occurred, any effect on the embryo or fetus or nursing child and any actions taken or planned to prevent recurrence.

(e) Whether the licensee notified the pregnant individual or mother, or the mother's or child's responsible relative or guardian, and if the licensee did not, whether such failure to notify was based on guidance from the referring physician.

(6) RECORDS OF INSTRUMENT CALIBRATIONS. A licensee shall maintain a record of instrument calibrations required by s. DHS 157.62 (1) for 3 years. The record shall 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.

(7) RECORDS OF RADIATION SURVEY INSTRUMENT CALIBRATIONS. A licensee shall maintain a record of radiation survey instrument calibrations required by s. DHS 157.62 (2) for 3 years. The record shall include the date of the calibration, the results of the calibration, the name of the person who performed the calibration, and the model and serial number of the instrument.

(8) RECORDS OF DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE. A licensee shall maintain a record of dosage determinations required by s. DHS 157.62 (3) for 3 years. The record shall contain the radiopharmaceutical, patient's or human research subject's name or identification number if one has been assigned, the prescribed dosage, the determined dosage or a notation that the total activity is less than 1.1 MBq (30 microcuries), the date and time of the dosage determination and the name of the individual who determined the dosage.

(9) RECORDS OF POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES. (a) A licensee shall retain a record of leak tests required by s. DHS 157.62 (5) (b) for 3 years. The record shall contain the model number and serial number if one has been assigned of each source tested, the identity of each source radionuclide and its estimated activity, the results of the test, the date of the test and the name of the person who performed the test.

(b) A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by s. DHS 157.62 (5) (g) for 3 years. The inventory record shall 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 person who performed the inventory.

(10) RECORDS OF SURVEYS FOR AMBIENT RADIATION EXPOSURE RATE. A licensee shall retain a record of each survey required by s. DHS 157.62 (7) for 3 years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey and the name of the person who performed the survey.

(11) RECORDS OF THE RELEASE OF PERSONS CONTAINING RADIOACTIVE DRUGS OR IMPLANTS CONTAINING RADIOACTIVE MATERIAL. (a) A licensee shall retain a record of the basis for authorizing the release of a person for 3 years after the date of release if the total effective dose equivalent is calculated by any of the following methods:

1. Using the retained radioactivity in the body rather than the radioactivity administered.
2. Using an occupancy factor less than 0.25 at one meter to determine radiation exposure to persons physically near the patient.
3. Using the biological or effective half-life of the radioactive material retained in the body.
4. Considering the shielding by tissue to calculate the exposure to persons physically near the patient.

(b) A licensee shall retain a record for 3 years after the date of release that the instructions required by s. DHS 157.62 (8) (b) were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(12) RECORDS OF ADMINISTRATIVE AND TECHNICAL REQUIREMENTS THAT APPLY TO THE PROVISION OF MOBILE SERVICES. (a) A licensee shall retain a copy of the letter that permits the use of radioactive material at a client's address of use, as required by s. DHS 157.62 (9) (a) 1., for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by s. DHS 157.62 (9) (a) 4. for 3 years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey and the name of the person who performed the survey.

(13) RECORDS OF DECAY-IN-STORAGE. A licensee shall maintain a record of the disposal of licensed materials as required by s. DHS 157.62 (10) for 3 years. The record shall include the date of the disposal, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container and the name of the person who performed the disposal.

(14) RECORDS OF CONTAMINANT CONCENTRATION. A licensee shall maintain a record of the contaminant concentration tests required by s. DHS 157.63 (3) (b) for 3 years. The record shall include, for each measured elution or extract, all of the following:

(a) The ratio of the measures expressed as kilobecquerel (microcurie) of molybdenum-99, strontium -82 or strontium-85 per megabecquerel of technetium-99m or rubidium-82 chloride injection.

(b) The time and date of the measurement.

(c) The name of the person who made the measurement.

(15) RECORDS OF INSTRUCTION AND TRAINING. A licensee shall maintain a record of instructions and training required by ss. DHS 157.64 (2), 157.65 (4) and 157.67 (4) for 3 years. The record shall include a list of the topics covered, the date of the instruction or training, the names of the attendees and the names of the persons who provided the instruction.

(16) RECORDS OF RADIATION SURVEYS OF PATIENTS AND HUMAN RESEARCH SUBJECTS. A licensee shall maintain a record of the surveys required by ss. DHS 157.65 (2) and 157.67 (2) for 3 years. Each record shall include the date and results of the survey, the survey instrument used and the name of the person who made the survey.

(17) RECORDS OF BRACHYTHERAPY SOURCE INVENTORY. (a) A licensee shall maintain a record of brachytherapy source accountability required by s. DHS 157.65 (3) for 3 years.

(b) For temporary implants, the record shall include all of the following:

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the person who removed them from storage and the location of use.
2. The number and activity of sources returned to storage, the time and date they were returned to storage and the name of the person who returned them from storage.

(c) For permanent implants, the record shall include all of the following:

1. The number and activity of sources removed from storage, the date they were removed from storage and the name of the person 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 person who returned them to storage.

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

(18) RECORDS OF CALIBRATIONS ON BRACHYTHERAPY SOURCES. A licensee shall maintain a record of the calibrations on brachytherapy sources required by s. DHS 157.65 (6) for 3 years after the last use of the source. The record shall include the date of the calibration, the manufacturer's name, model number and serial number for the source and instruments used to calibrate the source, the source output or activity, source positioning accuracy within applicators and the signature of the authorized medical physicist.

(19) RECORDS OF INSTALLATION, MAINTENANCE, ADJUSTMENT AND REPAIR. A licensee shall retain a record of the installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units and gamma stereotactic units as required by s. DHS 157.67 (3) for 3 years. For each installation, maintenance, adjustment and repair, the record shall include the date, description of the service and names of the persons who performed the work.

(20) RECORDS OF DOSIMETRY EQUIPMENT. (a) A licensee shall retain a record of the calibration, intercomparison and comparisons of its dosimetry equipment done under s. DHS 157.67 (6) for the duration of the license.

(b) For each calibration, intercomparison or comparison, the record shall include all of the following:

1. The date.

2. The model numbers and serial numbers of the instruments that were calibrated, intercompared or compared.

3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison.

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

(21) 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 s. DHS 157.67 (7) to (9) for 3 years.

(b) The record required under par. (a) shall include all of the following:

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, source and instruments used to calibrate the unit.

3. The results and an assessment of the full calibrations.

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

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

(22) 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 s. DHS 157.67 (10) for 3 years.

(b) The record required under par. (a) shall include all of the following:

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.

9. The name of the person who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(23) 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 s. DHS 157.67 (11) for 3 years.

(b) The record required under par. (a) shall include all of the following, 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.

5. The name of the person who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(24) 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 s. DHS 157.67 (12) for 3 years.

(b) The record required under par. (a) shall include all of the following:

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.
9. The name of the person who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(25) 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 s. DHS 157.67 (13) for 3 years.

(b) The record required under par. (a) shall include all the following:

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.
5. The signature of the person who performed the check.

(26) RECORDS OF SURVEYS OF THERAPEUTIC TREATMENT UNITS. (a) A licensee shall maintain a record of radiation surveys of treatment units made under s. DHS 157.67 (14) for the duration of use of the unit.

(b) The record required under par. (a) shall include all the following:

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.
4. The signature of the person who performed the test.

(27) RECORDS OF ~~5-YEAR~~ FULL-INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS. (a) A licensee shall maintain a record of the ~~5-year~~ full-inspections for teletherapy and gamma stereotactic radiosurgery units required by s. DHS 157.67 (15) for the duration of use of the unit.

(b) The record required under par. (a) shall contain all the following:

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.
5. The signature of the inspector.

(28) RECORDS OF DECAY OF STRONTIUM-90 SOURCES FOR OPHTHALMIC TREATMENTS. (a) A licensee shall maintain a record of the activity of a strontium-90 source required by s. DHS 157.65 (6) for the life of the source.

(b) The record required under par. (a) shall include both of the following:

1. The initial activity of the source and date.
2. For each decay calculation, the date and the source activity as determined under s. DHS 157.65 (6).

History: CR 01-108: cr. Register July 2002 No. 559, eff. — see Note at the start of the chapter; CR 06-021: r. and recr. (14) Register October 2006 No. 610, eff. 11-1-06; **CR 16-078: am. (8) Register January 2018 No. 745, eff. 2-1-18.**

DHS 157.72 **Reports. (1)** REPORTS OF MEDICAL EVENTS. (a) A licensee shall report to the department any event, except for events that result from intervention by a patient or human research subject, in which the administration of radioactive material or resulting radiation, except for permanent implant brachytherapy, results in any of the following:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue or 0.5 Sv (50 rem) shallow dose equivalent to the skin and to which any of the following apply:
   a. The total dose delivered differs from the prescribed dose by 20% or more.
   b. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range.
   c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

a. An administration of a wrong pharmaceutical.

b. An administration of a radioactive drug containing radioactive material by the wrong route of administration.

c. An administration of a dose or dosage to the wrong patient or human research subject.

d. An administration of a dose delivered by the wrong mode of treatment.

e. A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more 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)~~.

(am) For permanent implant brachytherapy, a licensee shall report to the department any event, except for events that result from intervention by a patient or human research subject, in which the administration of byproduct material or radiation from byproduct material, excluding sources that were implanted in the correct site but migrated outside the treatment site, results in any of the following:

1. The total source strength administered that differs by 20% or more from the total source strength documented in the post-implantation portion of the written directive.

2. The total source strength administered outside of the treatment site exceeding 20% of the total source strength documented in the post-implantation portion of the written directive.

3. Administration of the wrong radionuclide.

4. Administration to the wrong individual or human research subject.

5. Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive.

6. A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

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

(c) A licensee shall notify the department by telephone no later than the next calendar day after discovery of the medical event.

Note: Submit report to the Department via telephone at (608) 267-4797 or via facsimile at (608) 267-3695.

(d) 1. A licensee shall submit a written report to the department within 15 working days after discovery of the medical event.

2. The written report required in subd. 1. shall include all the following:

a. The licensee's name.

b. The name of the prescribing physician.

c. A brief description of the event.

d. Why the event occurred.

e. Any effect on the person who received the administration.

f. Any actions that have been taken or are planned to prevent recurrence.

g. Whether the licensee notified the person or the person's responsible relative or guardian and if not, why not.

h. If there was notification, what information was provided.

3. The report required in subd. 1. may not contain the affected individual's name or any other information that could lead to identification of the person.

Note: Submit written reports to the Department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659.

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

(f) If the person who is the subject of the medical event was notified under par. (d), a licensee shall also furnish within 30 days after discovery of the medical event a written report to the person by sending either of the following:

1. A copy of the report that was submitted to the department.

2. A brief description of both the event and the consequences as they may affect the person.

(g) Aside from the notification requirement, nothing in this subsection affects any rights or duties of a licensee or physician in relation to each other, to any person affected by the medical event or to any individual's responsible relatives or guardians.

(h) A licensee shall retain a record of a medical event under s. DHS 157.71 (4). A copy of the record required under s. DHS 157.71 (4) shall be provided to the referring physician, if other than the licensee, no later then 15 days after the discovery of the event.

(2) REPORT OF A DOSE TO AN EMBRYO OR FETUS OR A NURSING CHILD. (a) A licensee shall report to the department any dose to an embryo or fetus that is greater than 50 mSv (5 rem) 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 or fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report to the department any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that meets either of the following criteria:

1. Greater than 50 mSv (5 rem) total effective dose equivalent.

2. Resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) A licensee shall notify the department by telephone no later than the next calendar day after discovery of a dose to the embryo, fetus or nursing child that requires a report in par. (a) or (b).

(d) A licensee shall submit a written report to the department within 15 days after discovery of a dose to the embryo, fetus or nursing child that requires a report in par. (a) or (b). The written report shall include all of the following information:

1. The licensee's name.

2. The name of the prescribing physician.

3. A brief description of the event.

4. Why the event occurred.

5. The effect, if any, on the embryo, fetus or the nursing child.

6. What actions, if any, have been taken or are planned to prevent recurrence.

7. Certification that the licensee notified the pregnant individual or mother or the mother's or child's responsible relative or guardian, and if not, why not.

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

(e) A licensee shall provide notification of the event to 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 par. (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. A 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, a licensee shall make the appropriate notifications as soon as possible thereafter. A licensee may not delay any appropriate medical care for the embryo, fetus or 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. 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. A licensee shall provide such a written description if requested.

(f) A licensee shall do all the following:

1. Annotate a copy of the report provided to the department with all of the following information:

a. Name of the pregnant individual or the nursing child who is the subject of the event.

b. ~~Social security number or other identification number, if one has been assigned,~~ Identification number or if no other identification number is available, the social security number of the pregnant individual or the nursing child who is the subject of the event.

2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(g) A licensee shall retain a record of a dose to an embryo, fetus or a nursing child under s. DHS 157.71 (5).

(3) REPORTS OF LEAKING SOURCES. A licensee shall submit a written report to the department within 5 working days if a leakage test required by s. DHS 157.62 (5) reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The written report shall 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.

(4) REPORTS FOR AN ELUATE EXCEEDING PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATION

(a) The licensee shall notify by telephone the department and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in s. DHS 157.63 (3) (a) at the time of generator elution. The telephone report to the department must include all of the following information:

1. The manufacturer, model number, and serial or lot number of the generator.

2. The results of the measurement and the date of the measurement.

3. Whether dosages were administered to patients or human research subjects.

4. When the distributor was notified.

5. The action taken in response.

Note: A report may be submitted to the department via telephone at (608) 267-4797.

(b) A licensee who makes a report required by par. (a) shall submit a written report within 30 days of the initial telephone or facsimile report containing all of the following information:

1. The action taken by the licensee.
2. The patient dose assessment.
3. The methodology used to make the dose assessment if the eluate was administered to patients or human research subjects.
4. The probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination.
5. The information in the telephone report as required by par. (a).

Note: A written report may be submitted to: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659

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