

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

(a) A sealed source that does not exceed 1.11 GBq (30 mCi) that is manufactured and distributed by a person licensed under s. HFS 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 manufacturers approved instructions.

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

(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 μ Ci) or 1000 times the quantities in Appendix F.

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

(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.

(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 μ Ci) of radioactive material on the sample.

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

(e) If the leakage test reveals the presence of 185 Bq (0.005 μ Ci) 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. HFS 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 μ Ci) or less of beta or gamma-emitting material or 0.37 MBq (10 μ Ci) 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. HFS 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. HFS 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: NUREG 1556, Vol. 9, A Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses, 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://www.nrc.gov/NRC/NUREGS/indexnum.html#_1_3.

(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. HFS 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).

(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. HFS 157.71 (12) ~~(a)~~4(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. HFS 157.71(13) (a).

HFS 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. HFS 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 a manufacturer or preparer licensed under s. HFS 157.13 (4) (i) or equivalent NRC or other agreement state requirements.

(b) Is prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in sub. (5), or s. HFS 157.64 (4), or a person under the supervision of either as specified in s. HFS 157.61 (3).

(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/cber/ind/indpubs.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. HFS 157.61 (4), prepared for medical use that meets any of the following requirements:

(a) Is obtained from a manufacturer or preparer licensed under s. HFS 157.44 13 (4) (i) or equivalent NRC or agreement state requirements.

(b) 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. (5).
3. An individual under the supervision of an individual specified in subd. 1. or 2. as described in s. HFS 157.61 (3).

(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 MOLYBDENUM-99 CONCENTRATION. (a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 kilobecquerel (0.15 microcurie) of molybdenum-99 per megabecquerel of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with par. (a).

(c) A licensee that measures the molybdenum-99 concentration under par. (b) shall retain a record of each measurement under s. HFS 157.71 (14).

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

(a) 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 NRC or an agreement state.

(b) An authorized user under sub. (5) or s. HFS 157.64 (4) or equivalent NRC or other agreement state requirements.

(c) Completed 60 hours of certified training and experience 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 and radiation biology.

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

d. Chemistry of radioactive material for medical use.

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

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

b. Calibrating 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.

3. Written certification that the person has satisfactorily completed the requirements of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user that must be signed by a preceptor authorized user who meets the requirements in this subsection, sub. (5), s. HFS 157.64 (4) or equivalent NRC or other agreement state requirements.

(5) TRAINING FOR IMAGING AND LOCALIZATION STUDIES. Except as provided in s. HFS 157.61 (10), a licensee shall require an authorized user of unsealed radioactive material for imaging and localization studies for which a written directive is not required to be a physician who meets any of the following requirements:

(a) 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 NRC.

(b) An authorized user under s. HFS 157.64 (4) or equivalent NRC or agreement state requirements.

(c) Completed 700 hours of certified training and experience 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 and radiation biology.

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

d. Chemistry of radioactive material for medical use.

2. Work experience, under the supervision of an authorized user who meets the requirements in this subsection, s. HFS 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. Calibrating 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.

g. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs containing radioactive material.

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-99 and Ga-67.

3. Written certification that the individual has satisfactorily completed the requirements in this paragraph and has achieved a level of competency sufficient to function independently as an authorized user that must be signed by a preceptor authorized user who meets the requirements in this subsection, or s. HFS 157.64 (4) or equivalent NRC or other agreement state requirements.

HFS 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 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. HFS 157.13 (4) (i) or equivalent NRC or other agreement state requirements.

(b) 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. HFS 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. HFS 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. HFS 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. HFS 157.23 (1) (a) 1.

b. Visitation authorized under s. HFS 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. HFS 157.71 (15).

(3) SAFETY PRECAUTIONS. (a) For each patient or human research subject who cannot be released under s. HFS 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. HFS 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. HFS 157.61 (10), a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) to be a physician who meets any of the following criteria:

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

(b) Completed 700 hours of certified training and experience 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 and radiation biology.

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

d. Chemistry of radioactive material for medical use.

2. Supervised work experience, under the supervision of an authorized user who meets the requirements in this subsection or equivalent NRC or other agreement state requirements. A supervising authorized user, who meets the requirements of (c), must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience shall involve all the following:

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

b. Calibrating 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. Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.

g. Administering dosages 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; 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; and parenteral administration of any other radionuclide.

Note: 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. Written certification that the person has satisfactorily completed the requirements in this subds. 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user that must be signed by a preceptor authorized user who meets the requirements in this subsection.

(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. HFS 157.61 (10), a licensee shall require an authorized user of sodium iodide I-131, for oral administration, to be a physician who meets any of the following requirements:

(a) 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 NRC or an agreement state.

(b) An authorized user under subs. (4) (b) and (6) or equivalent NRC or other agreement state requirements.

(c) Successfully completed 80 hours of certified training and experience, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive, that includes all of the following:

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

a. Radiation physics and instrumentation.

b. Radiation protection and radiation biology.

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

d. Chemistry of radioactive material for medical use.

2. Work experience, under the supervision of an authorized user who meets the requirements in subs. (4) (a) and (b), (5) and (6) or equivalent NRC or other agreement state requirements, involving all of the following:

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

b. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for 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. Written certification that the person has satisfactorily completed the requirements in subs. 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user which must be signed by a preceptor authorized user who meets the requirements in this subsection, subs. (4) (a) or (b) 2. g. or (6). A supervising authorized user, who meets the requirements of sub. (4) (b), shall have experience in administering dosages as specified in sub. (4) (b) 2. g.

(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. HFS 157.61 (10), a licensee

shall require an authorized user of sodium iodide I-131, for oral administration, 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 NRC or agreement state.

(b) Is an authorized user under sub. (4) (a) or (b) or equivalent NRC or other agreement state requirements.

(c) Has successfully completed 80 hours of certified training and experience, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive, that includes all of the following:

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

a. Radiation physics and instrumentation.

b. Radiation protection and radiation biology.

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

d. Chemistry of radioactive material for medical use.

2. Work experience, under the supervision of an authorized user who meets the requirements in sub. (4) (a) or (b) or equivalent NRC or other agreement state requirements, involving all the following:

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

b. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for 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. Written certification that the person has satisfactorily completed the requirements in subds. 1. and 2. and has achieved a level of competency sufficient to function independently as an authorized user that must be signed by a preceptor authorized user who meets the requirements in this subsection or sub. (4) (a) or (b) 2. g. A supervising authorized user, who meets the requirements of sub. (4) (b), shall have experience in administering dosages in the same dosage as specified in sub. (4) (b) 2. g.

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

(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. HFS 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. HFS 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. HFS 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 calendar 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. HFS 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. HFS 157.23 (1) (a) 1.
 - b. Visitation authorized under s. HFS 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. HFS 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. HFS 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 SEALED SOURCES. (a) Prior to the first medical use of brachytherapy sealed sources on or after the effective date of this subchapter [reviser to insert effective date], a licensee shall do all the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of s. HFS 157.67 (6).

2. Determine source positioning accuracy within applicators.

3. Use published protocols accepted by nationally recognized bodies to meet the requirements of subsds. 1. and 2.

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).

(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.

1. For strontium-90 sources for ophthalmic treatments, only an authorized medical physicist may calculate the activity of each source used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under par. (a).

2. A licensee shall retain a record of the activity of each strontium-90 source under s. HFS 157.71 (28).

(c) A licensee shall retain a record of each calibration under s. HFS 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. HFS 157.61 (10), a licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under sub. (1) to be a physician who meets any of the following criteria:

(a) Certified by a medical specialty board whose certification process includes all of the requirements in par. (b) and whose certification has been recognized by the NRC or an agreement state.

(b) Completed a certified structured training 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 and radiation biology.

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

2. Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this subsection or equivalent NRC or other agreement state requirements at a medical institution, 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 sealed 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 or equivalent NRC or other 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 committee on postdoctoral training of the American osteopathic association. The experience may be obtained concurrently with the supervised work experience required by par. 2.

4. Written certification, signed by a preceptor authorized user who meets the requirements in this subsection, that the individual has satisfactorily completed the requirements in subs. 1., 2. and 3. and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for medical use.

(9) TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90. Except as provided in s. HFS 157.61 (10), a licensee shall require an authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who has had classroom and laboratory training in basic radioisotope handling techniques 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) Twenty-four hours of classroom and laboratory training that includes all of the following:

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

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of at least 5 persons. The clinical training shall include all of the following:

- 1. Examination of each person to be treated.
- 2. Calculation of the dose to be administered.
- 3. Administration of the dose.
- 4. Follow up and review of each individual's case history.

(c) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in this subsection or sub. (8), that the individual has satisfactorily completed the requirements in pars. (a) and (b) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

HFS 157.66 Sealed sources for diagnosis. (1) USE OF SEALED SOURCES FOR DIAGNOSIS. A licensee shall use only sealed sources for diagnostic medical uses as approved in the sealed source and device registry.

Note: The sealed source and device registrations may be obtained from the manufacturer or by writing the department at: Department of Health and Family 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. HFS 157.61 (10), a licensee shall require the authorized user of a diagnostic sealed source for the use in a device authorized under sub. (1) to be a physician, dentist or podiatrist who meets one 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 NRC or an agreement state.

(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 and radiation biology.
3. Mathematics pertaining to the use and measurement of radioactivity.
4. Training in the use of the device for the uses requested.

HFS 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 licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units or gamma stereotactic units for therapeutic medical uses that meet one of the following criteria:

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

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

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

Note: The FDA requirements for investigational devices may be found at: <http://www.fda.gov/cber/ind/indpubs.htm>

(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. HFS 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. HFS 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 instruction, initially and at least annually, to all persons who operate the unit, as appropriate to the person's assigned duties, in all 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 thereafter.

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

(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 percent. 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. HFS 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 percent 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 percent for the range of field sizes and for the distance or range of distances used for medical use.

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

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

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

5. On-off error.

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. HFS 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 percent of the source strength.

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. HFS 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 percent 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 percent.
2. Relative alignment 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 alignment 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 alignment 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 alignment helmet.
9. Emergency timing circuits.
10. Stereotactic frames and localizing devices.

(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. HFS.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. HFS 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. HFS 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 in writing of the results of each spot-check within 10 working days.

(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 physicist shall notify the licensee in writing of the results of the spot check review within 10 working days.

(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. 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. HFS 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. HFS 157.71 (25).

(14) **RADIATION SURVEYS.** (a) In addition to the survey requirement in s. HFS 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. HFS 157.71 (26).

(15) **FIVE-YEAR 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 or at intervals not to exceed 5 years, 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. HFS 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.** Except as provided in s. HFS 157.61 (10), a licensee

shall require an authorized user of a sealed source for a use authorized under sub. (1) to be a physician who meets any of the following requirements:

(a) Certified by a medical specialty board whose certification process includes all of the requirements in par. (b) and whose certification has been recognized by the NRC or an agreement state.

(b) Completed a certified structured training 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 and radiation biology.

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

2. Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this subsection or equivalent NRC or other agreement state requirements at a medical institution, 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 oncology under an authorized user who meets the requirements in this subsection or equivalent NRC or other 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 committee on postdoctoral training of the American osteopathic association. The clinical experience may be obtained concurrently with the supervised work experience required by par. 2.

4. Written certification that the individual has satisfactorily completed the requirements in subs. 1. to 3. and has achieved a level of competency sufficient to function independently as an authorized user of each type of medical therapy unit for which the individual is requesting authorized user status. The certification shall be signed by a preceptor authorized user who meets the requirements in this subsection.

HFS 157.68 [Reserved].

HFS 157.69 [Reserved].

HFS 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. HFS 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. HFS 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.

HFS 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. HFS 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. HFS 157.61 (1) (d). The record shall include the signature of the radiation safety officer and licensee management.

(2) RECORDS OF RADIATION PROTECTION PROGRAM SAFETY CHANGES. A licensee shall retain a record of each radiation protection program change made under s. HFS 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. HFS 157.61 (4) for 3 years.

(4) RECORDS OF MEDICAL EVENTS. (a) A licensee shall retain a record of medical events reported under s. HFS 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, 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. HFS 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) The social security number or other identification number, if one has been assigned 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. HFS 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. HFS 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. HFS 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 μ Ci), 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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 MOLYBDENUM-99 CONCENTRATIONS. A licensee shall maintain a record of the molybdenum-99 concentration tests required by s. HFS 157.63 (3) (b) for 3 years: The record shall include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel (microcurie) of molybdenum-99 per megabecquerel (millicurie) of technetium-99m (~~microcuries of molybdenum per millicurie of technetium~~), the time and date of the measurement and 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 s. HFS 157.64 (2), s. HFS 157.65 (4) and s. HFS 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 s. HFS 157.65 (2) and s. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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. HFS 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 INSPECTION FOR TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY UNITS. (a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by s. HFS 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. HFS 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. HFS 157.65 (6).

HFS 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 results in any of the following:

1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue or 0.5 Sv (50 rem) shallow dose equivalent to the skin and to which any of the following apply:

a. The total dose delivered differs from the prescribed dose by 20 percent or more.

b. The total dosage delivered differs from the prescribed dosage by 20 percent 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 percent or more.

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

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 an organ outside the intended treatment volume that exceeds the expected dose to that organ by 0.5 Sv (50 rem) where the excess dose is greater than 50 percent of the expected dose to that organ, excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site.

(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.

(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.

(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. HFS 157.71 (4). A copy of the record required under s. HFS 157.71 (4) shall be provided to the referring physician if other than the licensee.

(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, as determined by a physician.

(c) A licensee shall notify the department by telephone within 5 days after discovery of a dose to the embryo or fetus or nursing child that requires a report in par. (a) or (b).

(d) 1. A licensee shall submit a written report to the department no later than 30 days after discovery of a dose to the embryo or fetus or nursing child that requires a report in par. (a) or (b). The written report shall include all the following information:

- 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. The effect on the embryo or fetus or the nursing child.
- f. Any actions that have been taken or are planned to prevent recurrence.

2. The report required under par. (a) may not contain the individual's name or any other information that could lead to identification of the individual:

(e) A licensee shall notify the referring physician and also notify the pregnant person or mother, both hereafter referred to as the mother, within 5 working days of discovery of an event that would require reporting under par. (a) or (b) unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgement, telling the mother would be harmful.

(f) To meet the requirements of this subsection, the notification by the licensee may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate if the mother cannot be located or is unavailable.

(g) 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 5 days, a licensee shall make the appropriate notifications as soon as possible thereafter. A licensee may not delay any appropriate medical care for the embryo or fetus or for the nursing child, including any necessary remedial care resulting from the event, because of any delay in notification.

(h) If notification was made under pars. (e) or (f), a licensee shall also furnish, within 30 days after discovery of the event, a written report to the mother or responsible relative or guardian 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 embryo or fetus or nursing child.

(i) A licensee shall retain a record of a dose to an embryo or fetus or a nursing child under s. HFS 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. HFS 157.62 (5) reveals the presence of 185 Bq (0.005 μ Ci) 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.

Subchapter VII – Radiation Safety Requirements for Irradiators

HFS 157.73 Radiation safety requirements. (1) PERFORMANCE CRITERIA FOR SEALED SOURCES. (a) A sealed source installed ~~after the effective date of this subchapter~~ in an irradiator shall meet all of the following requirements:

1. Be evaluated and receive a certificate of registration under 10 CFR 32.210 or the equivalent agreement state regulation.
2. Be doubly encapsulated.
3. Use radioactive material that is as nondispersible and insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator.
4. Be encapsulated in a material resistant to general corrosion and to localized corrosion such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools.
5. In prototype testing of the sealed source, be leak tested and found leak-free after each of the tests in par. (b).

(b) A sealed source used in an irradiator shall be subjected to all of the following tests prior to use:

1. 'Temperature.' The test source shall be held at -40°C for 20 minutes, 600°C for one hour, and then be immediately subjected to thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

2. 'Pressure.' The test source shall be twice subjected for at least 5 minutes to an absolute external pressure of 2 million newtons per square meter.

3. 'Impact.' A 2 kilogram steel weight, 2.5 centimeters in diameter, shall be dropped from a height of one meter on to the test source.

4. 'Vibration.' The test source shall be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source shall be vibrated for 30 minutes at each resonant frequency found.

5. 'Puncture.' A 50 gram weight and pin, 0.3 centimeter pin diameter, shall be dropped from a height of one meter on to the test source.

6. 'Bend.' If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source shall be subjected to a force of 2000 newtons at its center equidistant from 2 support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

(2) ACCESS CONTROL. (a) Each entrance to a radiation room at a panoramic irradiator shall have a door or other physical barrier to prevent inadvertent entry of personnel when the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. ~~It must not be possible~~ **shall be impossible** to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed shall cause the sources to return promptly to the shielded position. The personnel entrance door or barrier shall have a lock that is operated by the same key used to move the sources. The control panel lock shall be designed so that the key cannot be removed unless the sources have been returned to the shielded position. The doors and barriers shall **may** not prevent any person in the radiation room from leaving.

(b) Each entrance to a radiation room at a panoramic irradiator shall have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall activate a visible and audible alarm to make the person entering the room aware of the hazard. The alarm shall also alert at least one other person who is on-site of the entry. The person alerted shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(c) A radiation monitor shall be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor shall be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels shall activate the alarm described in par. (b). The monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.

(d) Before the sources move from their shielded position in a panoramic irradiator, the source control shall automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms shall give persons enough time to leave the room before the sources leave the shielded position.

(e) Each radiation room of a panoramic irradiator shall have a clearly visible and readily accessible control that allows a person in the room to make the sources return to their fully shielded position.

(f) Each radiation room of a panoramic irradiator shall contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator shall have a sign bearing the radiation symbol and the words, "Caution (or danger), radioactive material." A panoramic irradiator shall have a sign stating "Grave (or Extreme) danger, very high radiation area," but the sign may be removed, covered or otherwise made inoperative when the sources are fully shielded.

(h) If the radiation room of a panoramic irradiator has roof plugs or movable shielding, no person may operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(i) An underwater irradiator shall have a personnel access barrier around the pool that shall be locked to prevent access when the irradiator is not attended. Only operators or facility management may have access to keys that operate the personnel access barrier. There shall be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm shall alert a person who is not necessarily on-site but who is prepared to respond or summon assistance.

(3) SHIELDING. (a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 mrem) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate shall be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Any area where the radiation dose rate exceeds 0.02 millisievert (2 mrem) per hour shall be locked, roped off or posted.

(b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 mrem) per hour when the sources are in the fully shielded position.

(c) The radiation dose rate at one meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 mrem) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 mrem) per hour.

(4) FIRE PROTECTION. (a) The radiation room of a panoramic irradiator shall have heat and smoke detectors. The detectors shall activate an audible alarm. The alarm shall be capable of alerting a person who is prepared to summon assistance promptly. The sources shall automatically become fully shielded if a fire is detected.

(b) The radiation room of a panoramic irradiator shall be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.

(5) RADIATION MONITORS. (a) An irradiator with an automatic product conveyor system shall have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm shall sound and

product conveyors shall stop automatically. The alarm shall be capable of alerting a person in the facility who is prepared to summon assistance. An underwater irradiator in which the product moves within an enclosed stationary tube is exempt from the requirements of this paragraph.

(b) An underwater irradiator that is not in a shielded radiation room shall have a radiation monitor over the pool to detect abnormal radiation levels. The monitor shall have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm shall be capable of alerting a person who is prepared to respond promptly.

(6) CONTROL OF SOURCE MOVEMENT. (a) The mechanism that moves the sources of a panoramic irradiator shall require a key to actuate. Actuation of the mechanism shall cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key shall be attached to a portable radiation survey meter by a chain or cable. The lock for source control shall be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room shall require the same key.

(b) The console of a panoramic irradiator shall have a source position indicator that indicates when the sources are in the fully shielded position, in transit and exposed.

(c) The control console of a panoramic irradiator shall have a control that promptly returns the sources to the shielded position.

(d) The function of each control for a panoramic irradiator shall be clearly marked.

(7) IRRADIATOR POOLS. (a) ~~For a license initially issued after the effective date of this subchapter [revisor to insert effective date],~~ An irradiator pool shall be one of the following:

1. Constructed with a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool.

2. Constructed so that there is a low likelihood of substantial leakage and with a surface designed to facilitate decontamination.

(b) A licensee shall have a method to safely store the sources during repairs of the pool.

(c) ~~For a license initially issued after the effective date of this subchapter [revisor to insert effective date],~~ An irradiator pool shall have no outlets more than 0.5 meter below the normal low water level that may allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that may act as siphons shall have siphon breakers to prevent the siphoning of pool water.

(d) A method shall be available to replenish water losses from the pool.

(e) A visible indicator shall be provided in a clearly observable location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(f) An irradiator pool shall be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly **are clearly visible**.

(g) A physical barrier, such as a railing or cover, shall be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection and service operations.

(h) If long-handled tools or poles are used in an irradiator pool, the radiation dose rate to the operator at the handling areas of the tools may not exceed 0.02 millisievert (2 mrem) per hour.

(8) **SOURCE RACK PROTECTION.** If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack shall be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

(9) **POWER FAILURES.** (a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources shall automatically return to the shielded position.

(b) The lock on the door of the radiation room of a panoramic irradiator shall remain locked in the event of a power failure.

(c) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

(10) **DESIGN REQUIREMENTS.** An irradiator whose construction begins after the effective date of this subchapter [revisor to insert effective date] shall meet all of the following design requirements:

(a) *Shielding.* For a panoramic irradiator, a licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of sub. (3). If the irradiator will use more than 2×10^{17} becquerels (5 million Ci) of activity, a licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(b) *Foundations.* For a panoramic irradiator, a licensee shall design the foundation, with consideration given to soil characteristics, to ensure that the foundation is adequate to support the weight of the facility shield walls.

(c) *Pool integrity.* For a pool irradiator, a licensee shall design the pool to ensure all of the following:

1. That the pool is leak resistant.
2. That the pool is strong enough to bear the weight of the pool water and shipping casks.
3. That a dropped shipping cask would not fall on sealed sources.
4. That all outlets or pipes meet the requirements of sub. (7).
5. That metal components are metallurgically compatible with other components in the pool.

(d) *Water handling system.* For a pool irradiator, a licensee shall verify that the design of the water purification system is adequate to meet the requirements of sub. (7) (f). The system shall be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(e) *Radiation monitors.* For all irradiators, a licensee shall evaluate the location and sensitivity of the **radiation** monitor to detect sources carried by the product conveyor system as required by sub. (5) (a). A licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For a pool irradiator, if the licensee uses radiation monitors to detect contamination under sub. (16) (b), the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(f) *Source rack.* For a pool irradiator, a licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For a panoramic irradiator, a licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables, or alternate means of support, will not cause loss of integrity of sealed sources. For a panoramic irradiator, a licensee shall review the design of the mechanism that moves the sources to ensure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free the rack with minimal risk to personnel.

(g) *Access control.* For a panoramic irradiator, a licensee shall verify from the design and logic diagram that the access control system shall meet the requirements of sub. (2).

(h) *Fire protection.* For a panoramic irradiator, a licensee shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. A licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(i) *Source return.* For a panoramic irradiator, a licensee shall verify that the source rack will automatically return to the fully shielded position if power is lost for more than 10 seconds.

(j) *Seismic.* For a panoramic irradiator to be built in seismic areas **where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent**, a licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing the irradiator to the seismic requirements of local building codes.

(k) *Wiring.* For a panoramic irradiator, a licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

(11) **CONSTRUCTION MONITORING AND ACCEPTANCE TESTING.** An irradiator whose construction begins after the effective date of this subchapter [revisor to insert effective date] shall meet all of the following requirements prior to loading sources:

(a) *Shielding.* For a panoramic irradiator, a licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and local building code requirements for reinforced concrete.

(b) *Foundations.* For a panoramic irradiator, a licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(c) *Pool integrity.* For a pool irradiator, a licensee shall verify that the pool meets design specifications and shall test the structural integrity of the pool and its ability to hold water. A licensee shall verify that outlets and pipes meet the requirements of sub. (7) (b) (c).

(d) *Water handling system.* For a pool irradiator, a licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(e) *Radiation monitors.* For all irradiators, a licensee shall verify the proper operation of the radiation monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by sub: (5) (a). For a pool irradiator, a licensee shall verify the proper operation of the radiation monitors and the related alarm, if used; to meet sub. (16) (b). For an underwater irradiator, a licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by sub. (5) (b).

(f) *Source rack.* For a panoramic irradiator, a licensee shall test the movement of the source racks for proper operation prior to source loading. The testing shall include source rack lowering due to simulated loss of power. For all irradiators with a product conveyor system, a licensee shall observe and test the operation of the conveyor system to assure that the requirements in sub. (8) are met for protection of the source rack and the mechanism that moves the rack. The testing shall include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves that rack from moving product carriers.

(g) *Access control.* For a panoramic irradiator, a licensee shall test the completed access control system to assure that the control system functions as designed and that all alarms, controls, and interlocks work properly.

(h) *Fire protection.* For a panoramic irradiator, a licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. A licensee shall test the operability of the fire extinguishing system.

(i) *Source return.* For a panoramic irradiator, the licensee shall demonstrate that the source racks may be returned to their fully shielded positions without power.

(j) *Computer systems.* For a panoramic irradiator that uses a computer system to control the access control system, a licensee shall verify that the access control system will operate properly if power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when the system is required to be operable.

(k) *Wiring.* For a panoramic irradiator, a licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

(12) TRAINING. (a) Before a person is permitted to may act as an irradiator operator without a supervisor present, the person shall be instructed in all the following:

1. The fundamentals of radiation protection applied to irradiators. The fundamentals shall include the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of

survey meters and personnel dosimeters, other radiation safety features of an irradiator and the basic function of the irradiator.

2. The requirements of subch. X and this subchapter.
3. The operation of the irradiator.
4. Operating and emergency procedures listed in sub. (13) that the person is responsible for performing.
5. Case histories of accidents or problems involving irradiators.

(b) Before a person ~~is permitted to~~ may act as an irradiator operator without a supervisor present, the person shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the person is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) Before a person ~~is permitted to~~ may act as an irradiator operator without a supervisor present, the person shall have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The person shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) A licensee shall conduct safety reviews for irradiator operators at least annually. At the review, the licensee shall give each operator a written test on the information presented during annual safety training. Each safety review shall include, to the extent appropriate, all of the following:

1. Any changes in operating and emergency procedures since the last review.
2. Any changes in regulations and license conditions since the last review.
3. Any reports on recent accidents, mistakes or problems that have occurred at irradiators.
4. Results of inspections of operator safety performance.
5. Results of the facility's inspection and maintenance checks.
6. A drill to practice an emergency or abnormal event procedure.

(e) A licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions and operating, safety and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Persons who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in sub. (13) that they are expected to perform or comply with and their proper response to alarms required in this subchapter. Tests may be oral.

(g) Persons who must be prepared to respond to alarms required by subs. (2) (b) and (i), (4) (a), (5) (a) and (b), and (16) (b) shall be trained and tested on how to respond. Each person shall be retested at least annually. Tests may be oral.

(13) OPERATING AND EMERGENCY PROCEDURES. (a) A licensee shall have and follow written operating procedures for all the following:

1. Operation of the irradiator including entering and leaving the radiation room.
2. Use of personnel dosimeters.
3. Surveying the shielding of panoramic irradiators.
4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas.
5. Leak testing of sources.
6. Inspection and maintenance checks required by sub. (17).
7. Loading, unloading and repositioning sources if the operations will be performed by the licensee.
8. Inspection of movable shielding required by sub. (2), if applicable.

(b) A licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for all of the following situations:

1. Sources stuck in the unshielded position.
2. Personnel overexposures.
3. A radiation alarm from the product exit portal monitor or pool monitor.
4. Detection of leaking sources, pool contamination or alarm caused by contamination of pool water.
5. A low or high water level indicator, an abnormal water loss or leakage from the source storage pool.
6. A prolonged loss of electrical power.
7. A fire alarm or explosion in the radiation room.
8. An alarm indicating unauthorized entry into the radiation room, area around pool or another alarmed area.
9. Natural phenomena, including an earthquake, a tornado, flooding or other phenomena as appropriate for the geographical location of the facility.
10. The jamming of automatic conveyor systems.

(c) A licensee may revise operating and emergency procedures without department approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility.
2. The revisions are consistent with the outline or summary of procedures submitted with the license application.
3. The revisions have been reviewed and approved by the radiation safety officer.
4. The users or operators are instructed and tested on the revised procedures before the procedures are implemented.

(14) PERSONNEL MONITORING. (a) Any irradiator operator shall wear either a film badge, a thermoluminescent dosimeter (TLD) or similar approved device while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor shall be accredited by the national voluntary laboratory accreditation program for high energy photons in the normal and accident dose ranges. Each film badge or TLD shall be assigned to and worn by only one person. Film badges shall be processed at least monthly and TLDs shall be processed at least quarterly.

Note: See s. HFS 157.25 (1) (c) for instructions concerning dosimetry processing.

(b) ~~Other persons~~ **A person other than an irradiator operator** who enters the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only 2 people who enter the radiation room are required to wear dosimeters.

(c) If pocket dosimeters are used to meet the requirements of par. (b), a check of their response to radiation shall be performed at least annually. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation dose.

(15) RADIATION SURVEYS. (a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator shall be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators shall be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding shall be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) If the radiation levels specified in sub. (3) are exceeded, the facility shall be modified to comply with the requirements in sub. (3).

(c) Portable radiation survey meters shall be calibrated at least annually to an accuracy of plus or minus 20 percent for the gamma energy of the sources in use. The calibration shall be performed at 2 points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters shall be of a type that does not fail and read zero at high radiation dose rates.

(d) Water from the irradiator pool, other potentially contaminated liquids and sediments from pool vacuuming shall be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations may not exceed those specified in Table II, Column 2 or Table III of Appendix E.

(e) Before releasing resins for unrestricted use, the resins shall be monitored before release in an area with a background level less than 0.5 microsievert (0.05 mrem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used shall be capable of detecting radiation levels of 0.5 microsievert (0.05 mrem) per hour.

(16) DETECTION OF LEAKING SOURCES. (a) Each dry-source-storage sealed source shall be tested for leakage at intervals not to exceed 6 months using a leak test kit or a method approved by the department, the ~~U.S. nuclear regulatory commission~~ **NRC**, another agreement state or a licensing state. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test shall be capable of detecting the presence of 200 becquerels (0.005 μ Ci) of radioactive material and shall be performed by a person approved by the department, the ~~U.S. nuclear regulatory commission~~ **NRC**, another agreement state or a licensing state to perform the test.

(b) For a pool irradiator, sources may not be put into the pool unless a licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been performed within the 6 months before the transfer. Water from the pool shall be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is performed by analysis of a sample of pool water, the results of the analysis shall be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels shall activate an alarm. The alarm set-point shall be set as low as practical, but high enough to avoid false alarms. A licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, a licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired or disposed of by a department, ~~U.S. nuclear regulatory commission~~ **NRC**, another agreement state or a licensing state licensee authorized to perform decontamination, repair or disposal. A licensee shall promptly check its personnel, equipment, facilities and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination shall be performed immediately. If contaminated equipment, facilities or products are found, a licensee shall arrange to have the equipment, facilities or products decontaminated or disposed of by a the department, the U.S. nuclear regulatory commission, another agreement state or a licensing state licensee authorized to perform decontamination or disposal. If a pool is contaminated, a licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table II, Column 2 of Appendix E.

(17) INSPECTION AND MAINTENANCE. (a) A licensee shall perform inspection and maintenance checks that include each of the following at the frequency specified in the license or license application:

1. Operability of each aspect of the access control system required by sub. (2).
2. Functioning of the source position indicator required by sub. (6) (b).

3. Operability of the radiation monitor for radioactive contamination in pool water required by sub. (16) (b) using a radiation check source, if applicable.

4. Operability of the over-pool radiation monitor at underwater irradiators as required by sub. (5) (b).

5. Operability of the product exit monitor required by sub. (5) (a).

6. Operability of the emergency source return control required by sub. (6) (c).

7. Visual inspection of leak-tightness of systems through which pool water circulates.

8. Operability of the heat and smoke detectors and extinguisher system required by sub. (4), without turning extinguishers on.

9. Operability of the means of pool water replenishment required by sub. (7) ~~(e)~~ (d).

10. Operability of the indicators of high and low pool water levels required by sub. (7) ~~(d)~~(e).

11. Operability of the intrusion alarm required by sub. (2) (i), if applicable.

12. Functioning and wear of the system, mechanisms and cables used to raise and lower sources.

13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by sub. (8).

14. Amount of water added to the pool to determine if the pool is leaking.

15. Electrical wiring on required safety systems for radiation damage.

16. Pool water conductivity measurements and analysis as required by sub. (18) (b).

(b) Malfunctions and defects found during inspection and maintenance checks shall be repaired within time frames specified in the license or license application.

(18) POOL WATER PURITY. (a) A pool water purification system shall be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, a licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) A licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

(19) ATTENDANCE DURING OPERATION. (a) Both an irradiator operator and at least one other person who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds shall be present on site during any of the following times:

1. Whenever the irradiator is operated using an automatic product conveyor system.

2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(b) A person who has received the training on how to respond to alarms described in sub. (12) (g) shall be on site at a panoramic irradiator at which product is exposed to radiation with no movement of the product.

(c) At an underwater irradiator, an irradiator operator shall be present at the facility whenever the product is moved into or out of the pool. Persons who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators, but shall have received the training described in sub. (12) (f) and (g). Static irradiations may be performed without a person present at the facility.

(20) ENTERING AND LEAVING THE RADIATION ROOM. (a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall do all the following:

1. Visually inspect the entire radiation room to verify that no one else is in it.

2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by sub. (5) (b) is operating with backup power.

(21) IRRADIATION OF EXPLOSIVE OR FLAMMABLE MATERIALS. (a) Irradiation of explosive material is prohibited unless a licensee has received prior written authorization from the department. Authorization may not be granted unless a licensee demonstrates that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems or cause radiation overexposures of personnel.

(b) Irradiation of more than small quantities of flammable material with a flash point below 140°F is prohibited in panoramic irradiators unless a licensee has received prior written authorization from the department. Authorization shall **may** not be granted unless a licensee demonstrates that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

(22) RECORDS AND RETENTION PERIODS. A licensee shall maintain all the following records at the irradiator for the periods specified:

(a) A copy of the license, the license conditions, documents incorporated into the license by reference and amendments thereto until superseded by new documents or until the department terminates the license for documents not superseded.

(b) Records of each individual's training, tests and safety reviews provided to meet the requirements of sub. 12 (a) to (d), (f) and (g) until 3 years after the person terminates work.

(c) Records of the annual evaluations of the safety performance of irradiator operators required by sub. (12) (e) for 3 years after the evaluation.

(d) A copy of the current operating and emergency procedures required by sub. (13) until superseded or until the department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by sub. (13) (c) 3. shall be retained for 3 years from the date of the change.

(e) Dosimetry results required by sub. (14) (a) and (b) until the department terminates the license.

(f) Records of radiation surveys required by sub. (15) for 3 years from the survey date.

(g) Records of radiation survey meter calibrations required by sub. (15) and pool water conductivity meter calibrations required by sub. (18) (b) until 3 years from the calibration date.

(h) Records of the results of leak tests required by sub. (16) (a) and the results of contamination checks required by sub. (16) (b) for 3 years from the date of each test.

(i) Records of inspection and maintenance checks required by sub. (17) for 3 years.

(j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.

(k) Records of the receipt, transfer and disposal of all licensed sealed sources as required by s. HFS 157.13 (12); 10 CFR 30.51 or the equivalent agreement state or licensing state regulations.

(L) Records on the design checks required by sub. (10) and the construction control checks as required by sub. (11) until the license is terminated. The records shall be signed and dated. The title or qualification of the person signing shall be included.

(m) Records related to decommissioning of the irradiator as required by this chapter, 10 CFR 30.35(g) or the equivalent state regulation.

(23) REPORTS. (a) In addition to the reporting requirements in other parts of this chapter, a licensee shall report to the department all of the following events:

1. Source stuck in an unshielded position.

2. Any fire or explosion in a radiation room.

3. Damage to the source racks.

4. Failure of the cable or drive mechanism used to move the source racks.

5. Inoperability of the access control system.

6. Detection of radiation source by the product exit monitor.
7. Detection of radioactive contamination attributable to licensed radioactive material.
8. Structural damage to the pool liner or walls.
9. Water loss or leakage from the source storage pool, greater than the irradiator pool design parameters submitted by the licensee or applicant.
10. Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) For any event in par. (a), a licensee shall provide a telephone report within 24 hours that meets the requirements of s. HFS 157.32 (2) and a written report within 30 days that meets the requirements of s. HFS 157.32 (3).

Subchapter VIII - X-ray Device Requirements

HFS 157.74 Administrative requirements. (1) GENERAL. The registrant shall be responsible for directing the operation of the x-ray systems under their administrative control. The registrant or the registrant's agent shall ensure the requirements of this section are met. An x-ray system shall meet the provisions of this subchapter to be operated for diagnostic or screening purposes. All images, hard copy or electronic, shall be interpreted by a licensed practitioner for the patient record.

(2) RADIATION SAFETY REQUIREMENTS. ~~(a) Any person operating a radiation machine for medical diagnosis or screening, except bone density devices, shall have or be one of the following:~~

~~1. Certified or be eligible for certification in radiography by the American registry of radiologic technologists.~~

~~2. A licensed practitioner.~~

~~3. Completed training that meets the requirements of Appendix L if the person is performing radiography limited to the chest or extremities, except bone density devices.~~

~~4. Licensed or certified by another state with requirements comparable to those of the American registry of radiologic technologists.~~

~~Note: The ARRT may be contacted at: The American Registry of Radiologic Technologists, 1255 Northland Drive, St. Paul, MN 55120-1155 or <http://www.arrt.org>.~~

~~5. Operators of bone density devices shall be specifically trained in the use of the device, including safe operation and emergency procedures.~~

~~(b) The names and training of all personnel currently operating a radiation machine shall be kept on file at the facility. Training information on former operators shall be retained for a period of at least 3 years beyond the last date they were authorized to operate a radiation machine at that facility.~~

(a) Each individual who operates x-ray equipment shall be instructed in the safe operating procedures for each specific device and be competent in the safe use of the equipment as determined by the registrant.

(e) (b) A chart shall be provided next to the control panel of a diagnostic x-ray system that specifies, for all examinations performed with that system, all of the following information:

1. Patient's body part to be examined and anatomical size, body part thickness or, for pediatrics, age versus technique factors to be utilized.
2. Type and size of the film or film-screen combination to be used.
3. Type and focal distance of the grid to be used, if any.
4. Except for dental intra-oral radiography, source to image receptor distance to be used.
5. Type and location of placement of patient shielding to be used.

Note: This chart may be electronic in the form of pre-programmed controls.

(e) (c) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding procedures and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(e) (d) Only the staff, ancillary personnel or other persons required for the medical procedure or training may be in the room during the radiographic exposure. Other than the patient, the following applies to all persons in the room:

1. All persons shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material. If the hands must be in the beam and unprotected, a ring badge on the hand in the beam shall be worn unless contraindicated by the clinical procedure.

2. All persons, including any patients who cannot be removed from the room, shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that all parts of the person's body are at least 2 meters from all of the following:

a. The tube head.

b. The direct beam.

c. The nearest part of the examined patient's body being struck by the useful beam.

(f) (e) Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which the shielding would interfere with the diagnostic procedure or for computed radiographic examinations.

(g)(f) Persons shall may not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. Deliberate exposure for any of the following purposes is prohibited:

1. Exposure of a person for training, demonstration or other non-healing arts purpose.
2. Exposure of a person for healing arts screening, except as authorized by the department.

Note: The procedure for requesting permission to conduct screening x-ray examination is in Appendix M.

(h)(g) When a patient or film must be provided with additional support during a radiation exposure, all of the following applies:

1. The human holder shall be instructed in personal radiation safety and protected as required by subd. 2. Written safety procedures are required.

2. In those cases where the patient must hold the film, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

3. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

4. Leaded aprons and gloves shall be inspected at least every 3 years for defects and replaced if defective. If visual inspection reveals possible defects, radiographic inspections shall be performed.

(i)(h) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized, as follows:

1. The speed of the screen and film combinations used shall be of a speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens may not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

~~3. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.~~

43. An x-ray system may not be utilized in a procedure where the source to patient distance is less than 30 centimeters, except for a veterinary system, bone density unit or a unit granted an exemption by the US food and drug administration.

54. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall meet all of the following requirements:

a. Be positioned with tube side facing the in right direction, and grid centered to the central ray.

b. Be of the proper focal distance for the SIDs being used. Grids shall be of the proper ratio to adequately reduce scatter for the procedure being performed.

c. Antiscatter grids or an appropriate air gap technique to reduce scatter to the image receptor shall be used for all x-ray examinations of the human torso utilizing stationary x-ray equipment for patients 12 years of age or older.

(j) (i) All persons associated with the operation of an x-ray system are subject to the requirements of s. HFS 157.22 (1), (5), (7) and (8).

(k) (i) A person proposing to conduct a healing arts screening program may not initiate a program without the department's prior approval. When requesting approval, the person shall submit the information outlined in Appendix M. If any information submitted to the department becomes invalid or outdated, the department shall be immediately notified.

(L) (k) All facilities performing mammography shall meet the requirements of 21 CFR 900, US food and drug administration, Mammography Quality Standards Act.

(3) X-RAY FILM PROCESSING EQUIPMENT AND PROCESSING PROCEDURES. (a) Each installation using a radiographic x-ray system for human diagnosis or screening and using analog image receptors shall have available suitable equipment for handling and processing radiographic film according to the film and chemistry manufacturer's instructions.

(b) Quality control and maintenance procedures shall be performed on a regular schedule according to the device manufacturer's recommendations.

(c) X-ray film processing control tests shall be performed on days when human patient films are being processed and prior to the processing of the first films of the day, except dental facilities and podiatry facilities.

(d) X-ray film processors in chiropractic, dental and podiatry facilities shall be tested at least once a week.

(4) OTHER REQUIREMENTS. (a) Pass boxes, if provided, shall be constructed to exclude light from the darkroom when cassettes are placed in or removed from the boxes and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(b) The darkroom shall be light tight with proper safelights so that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to 2 when processed may not suffer an increase in density greater than 0.1, or 0.05 for mammography, when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film. Darkrooms typically used by more than one person shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(c) Film shall be stored according to the manufacturer's requirements and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(d) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary and consistent with the manufacturer's instructions to best assure radiographs of good diagnostic quality.

(e) Outdated x-ray film may not be used for diagnostic radiographs.

(f) Film developing solutions shall be prepared using instructions given by the manufacturer and maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

HFS 157.75 General requirements for all diagnostic x-ray systems. Diagnostic x-ray systems shall meet all the following requirements:

(1) **WARNING LABEL.** The control panel containing the main power switch shall bear the following warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) **BATTERY CHARGE INDICATOR.** On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) **LEAKAGE RADIATION FROM THE DIAGNOSTIC SOURCE ASSEMBLY.** The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source may not exceed one mGy (115 milliroentgens) in one hour when an x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. Leakage technique factors may be any of the following:

(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, which is 10 mAs, or the minimum obtainable from the unit, whichever is larger.

(b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(c) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(4) **RADIATION FROM COMPONENTS OTHER THAN THE DIAGNOSTIC SOURCE ASSEMBLY.** The radiation emitted by a component other than the diagnostic source assembly may not exceed 20 μ Gy (2.15 milliroentgens) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) **BEAM QUALITY.** (a) The half-value layer of the useful beam for a given x-ray tube potential may not be less than the values shown in Table HFS 157.75. If it is necessary to

determine the half-value layer at an x-ray tube potential that is not listed in Table HFS 157.75, linear interpolation or extrapolation may be made.

TABLE HFS 157.75			
HALF-VALUE LAYER REQUIREMENTS			
Design Operating Range	Measured Potential (kVp)	Half-Value Layer In mm Aluminum	
		Dental Intra-Oral	All Other Diagnostic X-Ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(b) For x-ray systems using capacitor discharge to provide power to an x-ray tube, half-value layer shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

(c) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials that are permanently between the source and the patient.

(d) For x-ray systems with variable filtration controls, the system shall prevent an exposure unless the appropriate filtration is in place for the kilovolts peak selected.

(6) MULTIPLE TUBES. When 2 or more radiographic tubes are controlled by one exposure switch, the tube that has been selected shall be clearly indicated prior to initiation of the exposure. The indication shall be both on an x-ray control panel and at or near the selected tube housing assembly.

(7) **MECHANICAL SUPPORT OF TUBE HEAD.** The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube-housing movement is a designed function of an x-ray system.

(8) **TECHNIQUE INDICATORS.** (a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors, which are set prior to the exposure, shall be indicated.

(b) The requirement in par. (a) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(9) **MAINTAINING COMPLIANCE.** Diagnostic x-ray systems and their associated components used on humans and certified under the federal x-ray equipment performance standard, 21 CFR 1020, shall be maintained in compliance with applicable requirements of that standard.

(10) **LOCKS.** All position locking, holding and centering devices on x-ray system components and systems shall function as intended.

HFS 157.76 Fluoroscopic x-ray systems. All fluoroscopic x-ray systems shall be image intensified and, with the exception of therapy simulators, meet all the following requirements:

(1) **LIMITATION OF USEFUL BEAM.** (a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.

(b) An x-ray tube used for fluoroscopy shall may not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(c) For fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(d) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened during fluoroscopy or spot filming shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

(e) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field.

(f) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less.

(g) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less.

(h) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(i) For non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(j) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot film selector. The adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

(k) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences may not exceed 4 percent of the SID.

(l) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to or less than 5 centimeters by 5 centimeters.

(m) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

(n) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(o) If a method exists to override any of the automatic x-ray field size adjustments, that method shall meet all of the following requirements:

1. Designed for use only in the event of system failure.

2. Incorporates a signal visible at the fluoroscopist's position, which will indicate whenever the automatic field size adjustment is overridden.

3. Clearly and durably labeled as follows:

**FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE**

(2) **ACTIVATION OF THE FLUOROSCOPIC TUBE.** A device that requires continuous pressure by the fluoroscopist for the entire time of any exposure shall control x-ray production in the fluoroscopic mode. When recording serial fluoroscopic images, the fluoroscopist shall be able

to terminate the x-ray exposure at any time. A method of permitting completion of any single exposure of the series in process may be utilized.

(3) AIR KERMA RATE LIMITS AND ENTRANCE AIR KERMA ALLOWABLE LIMITS.

Fluoroscopic equipment may not be operable at any tube potential and current that will result in an air kerma rate in excess of 10 cGy/minute (11.5 R/min) at the point where the center of the useful beam enters the patient except under either of the following conditions:

(a) During the recording of images from an x-ray image intensifier tube using photographic film or a video camera when an x-ray source is operated in pulse mode.

(b) When an optional high-level control is activated, the equipment may not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of 20 cGy/minute (23 R/min) at the point where the center of the useful beam enters the patient. Special means of activation of the high-level controls shall be required. The high-level control shall only be operable when the operator provides continuous manual activation. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(4) AIR KERMA MEASUREMENTS. (a) Annual measurements of both typical and maximum air kerma shall be made by a medical physicist or a person approved by a medical physicist.

Note: Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements. Air kerma measurements do not include backscatter radiation.

(a) (b) Measurements shall be made annually or after any maintenance of the system that may affect the air kerma.

(b) (c) Conditions of periodic measurement of typical entrance air kerma rate are as follows:
1. The kVp, mA or other selectable parameters shall be adjusted to those settings typical of clinical use on a patient with a 23-centimeter thick abdominal measurement.

2. An x-ray system that incorporates automatic exposure rate control shall have sufficient attenuating material placed in the useful beam to produce a milliamperage or kilovoltage to simulate a patient with a 23 centimeter abdominal measurement.

3. (d) Conditions of periodic measurement of maximum entrance air kerma rate are as follows:

a 1. The kVp, mA or other selectable parameters shall be adjusted to those settings that give the maximum entrance air kerma rate.

b 2. An x-ray system or systems that incorporate automatic exposure rate control shall have sufficient attenuating material placed in the useful beam to produce the maximum entrance air kerma rate of the system.

4. (e) Compliance shall be determined as follows:

a 1. If the source is below the x-ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle attachment that allows the proper positioning of the patient in relation to an x-ray tube.

b 2. If the source is above an x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

c 3. For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

d 4. For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

e 5. The entrance air kerma rate shall be measured in a manner that excludes scatter contributions from any attenuating material placed into the useful beam or from the image receptor.

f 6. Fluoroscopic units used for therapy simulation are exempt from subd. pars. d. and e.

(5) BARRIER TRANSMITTED RADIATION RATE LIMITS: (a) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided; may not exceed 20 μ Gy (2.15 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each 1.0 cGy (one roentgen) per minute of entrance air kerma rate.

(b) Measurement of barrier transmission rates shall meet all the following criteria:

1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it may be placed, provided that it may not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

(6) INDICATION OF POTENTIAL AND CURRENT. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

(7) SOURCE-TO-SKIN DISTANCE. The SSD source-to-skin distance may not be less than one of the following:

(a) Thirty-eight centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974.

(b) Thirty-five and one-half centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974.

(c) Thirty centimeters on all mobile fluoroscopes, except as provided in par. (d).

(d) Twenty centimeters for all mobile fluoroscopes when used for specific surgical applications.

(8) **FLUOROSCOPIC TIMER.** (a) A method shall be available to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device may not exceed 5 minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. The signal shall continue to sound while x-rays are produced until the timing device is reset. As an alternative to the requirements of this subsection, radiation therapy simulators may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

(9) **CONTROL OF SCATTERED RADIATION.** (a) Fluoroscopic table designs when combined with procedures utilized may not expose any unprotected part of any staff or ancillary individual's body to unattenuated scattered radiation originating from under the table. The attenuation required shall be not less than 0.25-millimeter lead equivalent.

(b) No portion of any staff or ancillary person's body, except the extremities, may be exposed to the unattenuated scattered radiation emanating from above the tabletop unless either of the following conditions are met:

1. The person is at least 2 meters from the nearest part to the patient's body being struck by the useful beam or from the image receptor.

2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including drapes, panels or self-supporting curtains, in addition to any lead equivalency provided by the protective apron.

(c) The department may grant exemptions to lead drapes where a sterile field will not permit the use of the normal protective barriers only if the use of pre-fitted sterilized covers for the barriers is impractical.

Note: See Appendix N for a list of fluoroscopic procedures where an exemption will be is automatically granted.

(10) **SPOT FILM EXPOSURE REPRODUCIBILITY.** Fluoroscopic systems equipped with analog spot film mode shall meet the exposure reproducibility requirements when operating in the spot film mode.

(11) **RADIATION THERAPY SIMULATION SYSTEMS.** Radiation therapy simulation systems are exempt from all the following:

(a) Subsection (3).

(b) Subsections (1) and (5) provided that no individual other than the patient is in an x-ray room during periods of time when the system is producing x-rays.

(c) Subsection (8) if the systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require that the timer be reset between examinations.

(12) EQUIPMENT OPERATIONS. (a) The registrant shall allow the operation of x-ray fluoroscopy systems only under the direct supervision of a medical licensed practitioner.

(b) All imaging formed by the fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed medical practitioner.

(c) Fluoroscopy systems shall not be used as a positioning tool for general purpose radiographic examinations which would not normally involve fluoroscopy.

HFS 157.77 Radiographic systems other than fluoroscopic, dental intraoral or computed tomography x-ray systems-General purpose radiographic systems. (1) BEAM LIMITATION, EXCEPT MAMMOGRAPHIC SYSTEMS. (a) Collimation. The useful beam shall be limited to the area of clinical interest. This requirement is met if a positive beam-limiting device meeting manufacturer's specifications has been properly used or if evidence of collimation is shown on at least 3 sides or 3 corners of the film. **Mammography systems are exempt from the collimation requirement.**

(b) General purpose stationary and mobile x-ray systems. General purpose stationary and mobile x-ray systems, including veterinary systems other than portable, shall meet both of the following requirements:

1. Only x-ray systems provided with means for independent stepless adjustment of at least 2 dimensions of the x-ray field may be used.

2. A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field may not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(c) Stationary general purpose x-ray systems. Stationary general purpose x-ray systems, both certified and non-certified, shall meet all the following requirements:

1. A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID and to indicate the SID to within 2 percent.

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

3. Field size dimensions and SIDs shall be specified in inches or centimeters and shall ensure that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(d) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(e) *Miscellaneous and veterinary x-ray systems.* X-ray systems other than those described in pars. (a) to (c), veterinary systems installed prior to the effective date of this subchapter [revisor. to insert effective date] and all portable veterinary x-ray systems shall meet all of the following requirements:

1. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

3. The requirements in subds. 1. and 2. may be met with a collimator system that meets the requirements for a general purpose x-ray system or, when alignment means are also provided, may be met with either of the following:

a. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed.

b. A beam-limiting device with multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID that each aperture is designed for and shall indicate which aperture is in position for use.

(2) **RADIATION EXPOSURE CONTROL.** (a) *Exposure initiation.* Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall may not be initiated without such an action. In addition, it shall not be possible to initiate an exposure exposure may not be initiated when the timer is set to a "zero" or "off" position if either position is provided.

(b) *Exposure indication.* Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) *Exposure termination.* Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Except for dental panoramic systems; termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(d) *Manual exposure control.* An x-ray control shall be incorporated into each x-ray system so that the operator may terminate an exposure at any time except for any one of the following:

1. Exposure of 0.5 second or less.
2. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(e) *Automatic exposure controls.* When an automatic exposure control is provided, it shall meet all the following requirements:

1. Indication shall be made on the control panel when this mode of operation is selected.
2. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses.
3. The minimum exposure time for all equipment other than field emission equipment shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater.
4. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure.
5. A visible signal shall indicate when an exposure has been terminated and manual resetting shall be required before further automatically timed exposures can may be made.

(f) *Exposure duration linearity.* For systems having independent selection of exposure time settings, the average ratios of exposure to the indicated timer setting, in units of .001 mGy/s (mR/s), obtained at any 2 clinically used timer settings may not differ by more than 0.10 times their sum as expressed as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average .001 mGy/s (mR/s).

(g) *Exposure control location.* The x-ray exposure control shall be placed so that the operator may view the patient while making any exposure and at least 3 feet from the end of the protective barrier.

(h) *Operator protection, except veterinary systems.* X-ray systems, excluding veterinary systems, shall meet all the following requirements to protect the operator during system use, as applicable:

1. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

2. Mobile and portable x-ray systems used continuously for greater than one week in the same location shall meet the requirements of stationary systems.

3. Mobile and portable x-ray systems used for less than one week at the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures or a means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly during the exposure.

(i) *Operator protection for veterinary systems.* All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protection during exposures or a means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly during exposures. Persons restraining the animal during radiography shall be protected with at least 0.5mm lead aprons and full coverage gloves or full coverage mittens containing not less than 0.5mm lead equivalent material. The exposure control may be foot operated.

(3) **SOURCE-TO-SKIN DISTANCE.** All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

(4) **AIR KERMA REPRODUCIBILITY.** When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of air kerma for both manual and automatic exposure control systems may not exceed 0.05. This requirement applies to clinically used techniques.

(5) **RADIATION FROM CAPACITOR ENERGY STORAGE EQUIPMENT IN STANDBY STATUS.** Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated may not exceed a rate of 0.2 cGy (2 milliroentgens) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(6) **ACCURACY.** Deviation of measured technique factors from indicated values of kVp and exposure time may not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation may not exceed 10 percent of the indicated value for kVp and 10 percent for time of the time limit.

(7) **mA/mAs LINEARITY.** X-ray equipment that is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated shall meet all the following requirements:

(a) *Equipment having independent selection of x-ray tube current (mA).* The average ratios (X_1) of exposure to the indicated milliamperere-seconds product (0.001 mGy/mAs (or mR/mAs)) obtained at any 2 consecutive tube current settings may not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any of 2 consecutive tube current settings or at 2 settings differing by no more than a factor of 2 where the tube current selection is continuous.

(b) *Equipment having a combined x-ray tube current-exposure time product selector, but not a separate tube current selector.* The average ratios (X_1) of exposure to the indicated

milliampere-seconds product, in units of .001 mGy/mAs (or mR/mAs), obtained at any 2 consecutive mAs selector settings may not differ by more than 0.10 times their sum:

$$|X_1 - X_2| \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any 2 consecutive mAs selector settings, or at 2 settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(c) *Measuring compliance.* Determination of compliance shall be based on 10 exposures taken within a time period of one hour at each of the 2 settings. These 2 settings may include any 2 focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by an x-ray tube manufacturer.

(8) **ADDITIONAL REQUIREMENTS APPLICABLE TO CERTIFIED SYSTEMS ONLY.** A diagnostic x-ray system incorporating one or more certified components shall meet all of the following additional requirements that relate to that certified component or components:

(a) *Beam limitation for stationary and mobile general purpose x-ray systems.* Stationary and mobile general purpose x-ray systems shall meet all the following beam limitation requirements:

1. There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

2. When a light localizer type of collimator is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of one millimeter in diameter.

(b) *Beam limitation and alignment on stationary general purpose x-ray systems equipped with PBL.* If PBL is being used, the x-ray system shall meet all of the following requirements:

1. PBL shall prevent the production of x-rays when either one of the following occurs:

a. The length or width of the x-ray field in the plane of the image receptor differs, except as permitted by manual override, from the corresponding image receptor dimensions by more than 3 percent of the SID.

b. The sum of the length and width differences, without regard to positive or negative mathematical sign, exceeds 4 percent of the SID.

2. Compliance for exposure lock-out shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no more than 5 seconds after insertion of the image receptor.

3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through adjustment of the field size. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

4. The PBL system shall be designed such that a change in image receptor ~~must~~ causes the automatic return to PBL.

(c) *Beam limitation for portable x-ray systems.* Beam limitation for portable x-ray systems shall meet the beam limitation requirements for manual collimators.

(9) **TUBE STANDS FOR PORTABLE X-RAY SYSTEMS.** A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures.

HFS 157.78 Intraoral dental radiographic systems. (1) GENERAL. In addition to the provisions of ss. HFS 157.74 and 157.75, the requirements in this section apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are contained in s. HFS 157.77.

(1)(2) **SOURCE-TO-SKIN DISTANCE (SSD).** X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD source-to-skin distance to not less than either one of the following:

(a) 20 centimeters (8 inches) if operable above 50 kVp. Beam-limiting devices shall be lead lined.

(b) 10 centimeters (4 inches) if operable at 50 kVp only. Beam-limiting devices shall be lead lined.

(2)(3) **BEAM LIMITATION.** Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the beam at the minimum SSD shall be contained in a circle having a diameter of no more than 7 centimeters.

(3)(4) **RADIATION EXPOSURE CONTROL.** Intraoral radiographic systems shall meet all of the following exposure control requirements:

(a) *Exposure initiation.* Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure may not be initiated without such an action. An exposure may not be made when the timer is set to a "zero" or "off" position if either position is provided.

(b) *Exposure indication.* Means shall be provided for visual exposure indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) *Exposure termination.* Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero", except for panoramic systems that may pause during the exposure cycle.

(d) *Exposure control location and operator protection.* An x-ray system shall meet all the following requirements, as applicable, to ensure operator protection during use of the system:

1. A stationary x-ray system shall have an x-ray exposure control that may be moved to a protected area so that the operator is required to remain in that protected area during the entire exposure. The exposure cord shall be of sufficient length to allow the operator to be at least 2 meters (6.5 feet) from the x-ray tube head and not in the direction the tube is pointed. The operator shall be able to determine when the exposure has completed either by audible tone or by visible signal.

2. A mobile or portable x-ray system that is used for greater than one week in the same location, i.e., which is a room or suite, shall meet the requirements of stationary dental equipment.

3. A mobile or portable x-ray system that is used for less than one week in the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection or means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly while making exposures.

(4)(5) **REPRODUCIBILITY.** When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of air kerma may be no greater than 0.05 for any specific combination of selected technique factors.

(5)(6) **mA/mAs LINEARITY.** X-ray equipment that is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated shall meet all of the following requirements:

(a) *Equipment having independent selection of x-ray tube current (mA).* The average ratios (X_1) of air kerma to the indicated milliamperere-seconds product, in units of .001 mGy/mAs (mR/mAs), obtained at any 2 consecutive tube current settings may not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$
where X_1 and X_2 are the average values obtained at each of 2 consecutive tube current settings, or at 2 settings differing by no more than a factor of 2 where the tube current selection is continuous.

(b) *Equipment having a combined x-ray tube current-exposure time product selector but not a separate tube current (mA) selector.* The average ratios (X_1) of air kerma to the indicated milliamperere-seconds product, in units of .001 mGy/mAs (mR/mAs), obtained at any 2 consecutive mAs selector settings may not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$
where X_1 and X_2 are the average values obtained at any 2 consecutive mAs selector settings, or at 2 settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(c) *Measuring compliance.* Determination of compliance shall be based on 10 exposures taken within a time period of one hour at each of the 2 settings. The 2 settings may include any 2 focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by an x-ray tube manufacturer.

~~(6)~~(7) **ACCURACY.** Deviation of technique factors from indicated values for kVp and exposure time, if time is independently selectable, may not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation may not exceed 10 percent of the indicated value for kVp and 10 percent for time.

~~(7)~~(8) **KVP LIMITATIONS.** Dental x-ray machines with a nominal fixed kVp of less than 50 kVp may not be used to make diagnostic dental radiographs of humans.

~~(8)~~(9) **ADMINISTRATIVE CONTROLS.** (a) Intraoral film holding devices shall be used.

(b) The tube housing and the cone may not be hand-held during an exposure.

(c) The tube shall be stationary during exposure, except for panoramic systems. Any oscillation of the tube head shall cease before exposure is made.

HFS 157.79 Veterinary medicine x-ray systems. (1) GENERAL. The requirements of this section apply to all animal use x-ray systems used in veterinary practice and are in addition to other provisions in subchs. I and III.

(2) **EQUIPMENT.** (a) The tube housing shall be electrically shock proof and of a diagnostic type. The x-ray tube may not be hand-held during exposures.

(b) A device shall be provided to terminate the exposure after a preset time or exposure.

(c) A deadman type of exposure switch shall be provided with an electrical cord of sufficient length so that the operator may stand out of the useful beam and at least 2 meters (6.5 feet) from the animal during all x-ray exposures. A foot operated exposure switch may be used.

(3) **OPERATING PROCEDURES.** (a) The operator shall stand at least 2 meters (6.5 feet) from the tube housing and the animal during radiographic exposures. The operator may not stand in the useful beam. Hand-held fluoroscopic screens may not be used. The tube housing may not be held by the operator. No person other than the operator may be in an x-ray room while exposures are being made unless another person's assistance is required.

(b) During any application in which the operator is not located behind a protective barrier, the operator and any other persons in the room during exposures shall wear protective clothing consisting of a protective apron having a lead equivalent of not less than 0.5 millimeter unless measurements indicate otherwise.

(c) Any person holding or supporting an animal or the film during radiation exposure shall wear protective gloves that surround the hand and a protective apron having a lead equivalent of not less than 0.5 millimeter. Devices that only partially shield the hands are prohibited.

(d) Veterinary fluoroscopy systems shall be operated only under the direct supervision of the licensed veterinarian.

(4) ANIMAL SUPPORT. Mechanical restraints shall be used to restrict movement of the animal unless the restraints interfere with the examination of the animal. No persons may be regularly utilized to hold or support animals during radiation exposures. Operating personnel may not perform this service except in cases where no other person is available.

HFS 157.80 Computed tomography x-ray systems. (1) EQUIPMENT REQUIREMENTS.

A computed tomography (CT) x-ray system shall meet all of the following requirements, as applicable:

(a) *Termination of exposure.* Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. The termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a back-up timer or devices which monitor equipment function. A visible signal shall indicate when the x-ray exposure has been terminated. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

(b) *Tomographic plane indication and alignment.* A computed tomography x-ray system shall meet all of the following plane indication and alignment requirements, as applicable:

1. A single tomogram system shall allow for visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. A multiple tomogram system shall allow for visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

Note: The reference plane may be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy the requirements in subd. 2., the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(c) *Beam-on and shutter status indicators and control switches.* The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed. Each emergency button or switch shall be clearly labeled as to its function.

(d) *Indication of CT conditions of operation.* A CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of the scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(e) *Maximum surface CTDI100 identification.* The angular position where the maximum surface CTDI100 occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(f) *CT x-ray systems containing a gantry manufactured after September 3, 1985.* A computed tomography x-ray system containing a gantry that was manufactured after September 3, 1985, shall meet all the following requirements:

1. The total error in the indicated location of the tomographic plane or reference plane may not exceed 5 millimeters.

2. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment may not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this patient support device movement distance.

4. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

(2) OPERATING PROCEDURES. (a) A CT x-ray system may only be operated **for diagnostic procedures by an American registry of radiologic technologists** by a certified person who has been specifically trained in its operation.

(b) Information shall be available at the control panel regarding the operation and calibration of the system. The information shall include all of the following components:

1. Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.

2. Instructions on the use of the CT dosimetry phantom including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent spot checks conducted on the system.

3. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized.

4. A current technique chart available at the control panel, which specifies for each routine examination the CT conditions of operation and the number of scans per examination including body part size and correct kV/mA for that body part. **The technique chart shall be used to adjust techniques based on the body part being examined.**

(c) **Calibration and spot check measurements shall be made at a frequency recommended by the manufacturer.** If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the medical physicist.

(d) A facility shall follow the manufacturer's daily start up routines and preventative maintenance schedules for a specific computed tomography x-ray system.

HFS 157.81 Shielding plan review. (1) **PLAN REVIEW AND APPROVAL.** Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be submitted to the department for review and approval.

Note: Plans may be mailed to the department at: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659 or package delivery to: Department of Health and Family Services, Radiation Protection Section, Room 150, 1 West Wilson St, Madison WI 53702-0007.

(2) **EXEMPTIONS.** Dental, mammography, and bone density devices are exempt from this section.

(3) **PLAN SUBMITTAL REQUIREMENTS.** (a) A shielding plan for a facility with two or more x-ray rooms shall include a medical physicist recommendation for shielding.

(b) A shielding plan submitted for department review shall include all of the following:

1. The maximum rated technique factors of each machine.

2. A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by a person in such areas. In addition, the drawing shall include all of the following:

a. The type and thickness of materials, or lead equivalency, of each protective barrier.

b. The use and occupancy of the areas surrounding an x-ray room, including occupied areas above or below the an x-ray room.

c. The construction materials used for the floor and ceiling; if appropriate.

(c). The operator booth described in the shielding plan shall be designed to meet all the following requirements:

1. The view area of the window shall be at least 0.09 m² (144 square inches).

2. The window shall be placed so that the edge of the view window is at least 0.45 meters (18 inches) from the end of the barrier. The window shall be placed so that the patient may be observed at all times and each entrance to the room is observed from the operator position. Patient and entrance observation may be accomplished by the use of electronic devices or mirrors.

3. The shielding value of the window shall be equal to the wall in which it is mounted.

4. Booth walls shall be 2.1 meters (7 feet) in height and permanently attached to the floor or walls. The booth shall be at least 1.3 meters (4 feet) from the nearest vertical cassette holder or 0.3 meters (one foot) from the nearest corner of the examining table.

5. When a door or moveable panel is used as an integral part of the booth structure, it shall have a permissive device that prevents an exposure when the door or panel is not closed.

6. Verbal communication with the patient shall be possible at all times during the x-ray procedure.

(4) OPERATIONAL ANALYSIS. The department may require additional modifications to a shielding plan after initial approval of the plan if a subsequent analysis of operating conditions indicates the possibility of a person receiving a dose in excess of the limits prescribed in ss. HFS 157.22 (1) and (5) to (8) and 157.23 (1) and (2). **An existing x-ray room constructed using 5 mSv (500 mR) as the public exposure limit may continue to operate without modification until the x-ray equipment is replaced or the room is modified.**

HFS 157.82 General administrative requirements for facilities using therapeutic radiation machines for human use. (1) ADMINISTRATIVE CONTROLS. A registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the department. All persons associated with the operation of operating a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the radiation safety requirements of ss. HFS 157.22 (1) and (5) to (8) and 157.25 (2). A therapeutic radiation machine that does not meet the provisions of this subchapter but is of a type accepted by the US food and drug administration shall may not be used for irradiation of human patients.

(2) TRAINING FOR EXTERNAL BEAM RADIATION THERAPY AUTHORIZED USERS. (a) A registrant for any therapeutic radiation machine, except dermatology units under 150 kV, shall require the authorized user to be a physician who meets any of the following requirements:

1. Certified or board eligible in one or more of the following:
 - a. Radiology or therapeutic radiology by the American board of radiology.
 - b. Radiation oncology by the American osteopathic board of radiology.
 - c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology".
 - d. Therapeutic radiology by the Canadian royal college of physicians and surgeons.
2. Actively practices therapeutic radiology and has completed all of the following:
 - a. The radiation therapy residency.
 - b. Two hundred hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit.
 - c. Five hundred hours of supervised work experience in therapeutic radiology.
 - d. A minimum of 3 years of supervised clinical experience or 5 years of post graduate clinical experience in therapeutic radiology.
3. Has equivalent training and submits the training of the prospective authorized user physician for department review on a case-by-case basis.

(b) A dermatologist using x-ray units under 150 kV shall be board certified in dermatology or have 40 hours of instruction and 100 hours of supervised therapeutic work using x-ray units for the treatment of skin diseases.

(3) **VISITING AUTHORIZED USERS.** A registrant may permit any physician qualified under sub. (2) to act as a visiting authorized user under the term of the registrant's registration for up to 60 days per calendar year under all the following conditions:

(a) The visiting authorized user has the prior written permission of the registrant's management and if the use occurs on behalf of an institution, the institution's radiation safety committee.

(b) The registrant maintains copies of all records documenting the qualifications of the visiting authorized user for 3 years from the date of the last visit.

(4) **MEDICAL PHYSICIST SUPPORT. (a) The services of a medical physicist is required in facilities having one or more therapeutic radiation machines.**

(a)(b) The registrant for any therapeutic radiation machine shall require the medical physicist to have any of the following:

1. Certification by the American board of radiology in one or more of the following:

a. Therapeutic radiological physics.

b. Roentgen-ray and gamma-ray physics.

c. X-ray and radium physics.

d. Radiological physics.

2. Certification by the American board of medical physics in radiation oncology physics.

3. Certification by the Canadian college of medical physics.

4. A master's or doctor's degree in physics, biophysics, radiological physics or health physics and have completed one year of full-time training in therapeutic radiological physics and one year of full-time work experience under the supervision of a medical physicist at a medical institution. **A person qualifying under this subdivision shall work under the supervision of a medical physicist qualified under subd. 1., 2. or 3. A registrant employing a physicist who qualifies under this subdivision shall provide the department with a statement of training and experience, signed by the preceptor medical physicist or provide a letter from another state accepting the person as a therapeutic medical physicist.**

(b)(c) The services of a medical physicist shall be required in facilities having therapeutic radiation machines. The medical physicist shall be responsible for all of the following:

1. Full calibrations and protection surveys.

2. Supervision and review of dosimetry.

3. Beam data acquisition and transfer for computerized dosimetry and supervision of its use.
4. Quality control, including quality control check review.
5. Consultation with the physician user in treatment planning, as needed.
6. Performance of calculations and assessments regarding medical events.

7. Acceptance testing of the machine after any repair or service that may have altered the machine's performance characteristics.

~~(e)~~(d) If the medical physicist is not a full-time employee of the registrant, the operating procedures shall also specifically address how the medical physicist is to be contacted for problems or emergencies, as well as the specific actions to be taken until the medical physicist can **may** be contacted.

(5) QUALIFICATION OF OPERATORS. (a) A person who will be operating a therapeutic radiation machine for medical use shall be an American registry of radiologic technologists (ARRT) registered radiation therapy technologist, ~~an authorized user or a medical physicist~~ **or a user authorized under sub. (2) or (3)**. A person who is not an ARRT registered radiation therapy technologist shall submit evidence that he or she has satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the joint review committee on education in radiologic technology.

Note: "Essentials and Guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988, establishes the requirements for a therapy technologist training program. The document is available at: <http://www.jrcert.org/>.

(b) The names and training of all personnel currently ~~operating~~ **authorized to operate** a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least 3 years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(6) SAFETY PROCEDURES. Written safety procedures and rules shall be developed by a medical physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

(7) PRESCRIPTION **WRITTEN DIRECTIVE** REQUIRED. Persons shall **may** not be exposed to the useful beam except for medical therapy purposes and unless exposure has been ordered in writing by a ~~licensed practitioner of the healing arts who is specifically identified on the registration~~ **physician user qualified under sub. (2) or (3)**. This provision specifically prohibits deliberate exposure of an person for training, demonstration or other non-healing arts purposes.

(8) INFORMATION AND RECORDS. The registrant shall maintain all of the following information in a separate file or package for each therapeutic radiation machine for inspection by the department:

- (a) Report of acceptance testing.

(b) Records of all surveys, calibrations and periodic quality control checks of the therapeutic radiation machine; as well as the names of persons who performed those activities.

(c) Records of maintenance or modifications performed on the therapeutic radiation machines, as well as the names of persons who performed these services.

(d) Signature of each person authorizing the return of a therapeutic radiation machine to clinical use after service, repair or upgrade.

(9) RECORD RETENTION. All records required by sub. (8) shall be retained for 3 years or until disposal is authorized by the department. Any required record generated prior to the last department inspection may be microfilmed or otherwise archived as long as a complete legible copy of the record may be retrieved.

HFS 157.83 Administrative policies and procedures for radiation therapy machines.

(1) WRITTEN POLICIES. A registrant shall have written policies and procedures to ensure that radiation will be administered as directed by an authorized user. The policies shall meet all of the following specific objectives:

(a) Prior to administration, a written prescription directive is prepared for any external beam radiation therapy dose. A written revision to an existing written prescription directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose. If, because of the patient's condition, a delay to provide a written revision to an existing written prescription directive would jeopardize the patient's health, an oral revision to an existing written prescription directive shall be acceptable provided that the oral revision is documented immediately in the patient's record and a revised written prescription directive is signed by an authorized user within 24 hours of the oral revision.

(b) Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the person named in the written prescription directive.

(c) External beam radiation therapy final plans of treatment and related calculations are according to the respective written directives.

(d) Each administration is according to the written prescription directive.

(e) Any unintended deviation from the written prescription directive is identified, documented, evaluated and appropriate action is taken.

(2) DEVELOPMENT OF THE OPERATIONAL PROCEDURES PROGRAM. A therapy device registrant shall do all the following:

(a) Develop an operational procedures program that specifies staff duties and responsibilities, and equipment and procedures. The registrant shall implement the program upon issuance of a certificate of registration by the department.

(b) Develop procedures for and conduct a review of the program including, since the last review, an evaluation of a representative sample of patient administrations and all recordable events to verify compliance with all aspects of the operational procedures program.

(c) Conduct program reviews at intervals not to exceed 12 months.

(d) Evaluate each of the reviews specified in par. (b) to determine the effectiveness of the program and, if required, make modifications to meet the requirements of par. (b).

(e) Maintain records of each review specified in par. (b), including the evaluations and findings of the review, in an auditable form for 3 years.

(3) MEDICAL EVENTS. (a) A registrant shall report any of the following medical events:

1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue or 0.5 Sv (50 rem) shallow dose equivalent to the skin and any of the following exist:

a. The total dose delivered differs from the prescribed dose by 20 percent or more.

b. The fractionated dose delivered exceeds the prescribed dose, for a single fraction, by 50 percent or more.

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

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

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

3. A dose to an organ outside the intended treatment volume that exceeds the expected dose to that organ by 0.5 Sv (50 rem) where the excess dose is greater than 50 percent of the expected dose to that organ.

(b) In response to a medical event, a registrant shall do all of the following:

1. Notify their department head no later than the next calendar day after discovery of the medical event.

2. a. Submit a written report to the department within 15 working days after discovery of the medical event. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian and if not, why not; and if the patient was notified, what information was provided to the patient.

Note: Mail the report to the Department at: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659.

b. The report in subd. par. a. may not include the patient's name or other information that could lead to identification of the patient.

3. Notify the referring physician and the patient of the medical event no later than 24 hours after the medical event's discovery, unless the referring physician personally informs the registrant either that he or she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the

referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient of the medical event as soon as possible. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the medical event, because of any delay in notification.

4. Retain a record of each medical event for 3 years. The record shall contain all of the following:

a. The names of all persons involved.

b. The patient's social security number or identification number if one has been assigned **unique identification number**.

c. A brief description of the event, why it occurred and the effect on the patient.

d. What improvements are needed to prevent recurrence and the actions taken to prevent recurrence.

e. Whether the registrant notified the patient or patient's guardian and if not, why not, and if the patient was notified, what information was provided to the patient.

f. If information was not given to the patient at the direction of the referring physician, the reason why the information was not given to the patient.

5. If the patient was notified, furnish, within 15 working days after discovery of the medical **misadministration event**, a written report to the patient by sending either a copy of the report that was submitted to the department, or a brief description of both the event and the consequences as they may affect the patient, if a statement is included that the report submitted to the department may be obtained from the registrant.

(4) RIGHTS. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants and physicians in relation to each other, patients or the patient's responsible relatives or guardians.

HFS 157.84 Technical requirements for facilities using therapeutic radiation machines: (1) RADIATION PROTECTION SURVEYS. (a) A registrant shall ensure that radiation protection surveys of all new facilities and existing facilities not previously surveyed are performed with an operable, calibrated survey instrument. The radiation protection survey shall be performed by or under the direction of a medical physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation, all of the following requirements are met:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in s. HFS 157.22 (1) (a).

2. Radiation levels in unrestricted areas do not exceed the limits specified in s. HFS 157.23 (1) (a) and (b).

(b) A radiation protection survey shall be performed prior to any subsequent medical use after making any of the following changes:

1. Any change in the treatment room shielding.

2. Any change in the location of the therapeutic radiation machine within the treatment room.

3. Relocating the therapeutic radiation machine.

4. Using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(c) The survey record shall indicate all of the following:

1. Instances where the facility, in the opinion of the medical physicist, is in violation of applicable regulations.

2. The date of the measurements.

3. The reason the survey is required.

4. The radiation therapy machine manufacturer's name.

5. The model and serial number of the therapeutic radiation machine.

6. The instruments used to measure radiation levels and their last date of calibration.

7. A floor plan of the areas surrounding the treatment room that were surveyed.

8. The radiation level at several points in each area expressed in microsieverts or millirems per hour.

9. The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area.

10. The signature of the person responsible for conducting the survey.

(d) If the results of radiation protection surveys indicate any radiation levels in excess of the respective limit, the registrant shall lock the control in the "OFF" position and may not use the unit except under one or more of the following conditions:

1. As may be necessary to repair, replace or test the therapeutic radiation machine, the therapeutic radiation machine shielding or the treatment room shielding.

2. Until the registrant has received a specific exemption from the department.

(2) MODIFICATION OF RADIATION THERAPY UNIT OR ROOM BEFORE BEGINNING A TREATMENT PROGRAM. If the survey indicates that a person in an unrestricted area may be exposed to levels of radiation greater than those permitted by s. HFS 157.23 (1) (a) and (b), before beginning the treatment program, the registrant shall do all of the following:

(a) Equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with s. HFS 157.23 (1) (a) and (b).

(b) Perform the survey again.

(c) Include in the report the results of the initial survey, a description of the modification made and the results of the second survey.

(d) Submit facility design information to the department prior to installation of a therapeutic radiation machine of higher energy into a room not previously approved for that energy and receive approval from the department prior to actual installation of the therapeutic radiation machine.

(3) **DOSIMETRY EQUIPMENT.** (a) **1.** A registrant shall have a calibrated dosimetry system available for use. The dosimetry system shall be calibrated by a certified calibration facility at least every 24 months and after any servicing that may affect system calibration.

2. For beams with energies greater than one MeV, the dosimetry system shall be calibrated for Cobalt-60.

3. For beams with energies equal to or less than one MeV, the dosimetry system shall be calibrated at an energy or energy range appropriate for the radiation being measured.

(b) A registrant shall have a dosimetry system for quality control check measurements. The system may be compared with another system whose calibration is traceable to the national institute of standards and technology. The comparison shall be performed at least every 24 months and after each servicing that may affect system calibration.

(c) A registrant shall maintain a record of each dosimetry system calibration, intercomparison and comparison for the duration of the registration. For each calibration, intercomparison or comparison, the record shall include all of the following:

1. The date.
2. The model and serial numbers of the instruments that were calibrated, inter-compared or compared.
3. The correction factors that were determined.
4. The names of the persons who performed the calibration, intercomparison or comparison.
5. Evidence that the intercomparison was performed by or under the direct supervision and in the physical presence of a medical physicist.

(4) **SURVEY INSTRUMENTS.** Except for dermatology offices with systems operating at less than 150 kV, each facility location authorized to use a therapeutic radiation machine shall possess appropriately calibrated portable monitoring equipment. Equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (one mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated.

(5) **SHIELDING AND SAFETY DESIGN REQUIREMENTS.** (a) Each therapeutic radiation machine shall be provided with primary or secondary barriers as are necessary to ensure compliance with ss. HFS 157.22 (1) and 157.23 (1) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of

higher energy into a room not previously approved for that energy shall be submitted to the department and approved by the department prior to actual installation of the therapeutic radiation machine.

(b) Observation and communication with the patient shall be possible at all times.

HFS 157.85 Therapeutic radiation machines. (1) LEAKAGE RADIATION. (a) When a therapeutic radiation machine is operated at its maximum dose rate, the leakage air kerma rate may not exceed the value specified at the distance specified for that classification of therapeutic radiation machine.

(b) Leakage radiation from contact therapy systems may not exceed one mGy (103 mR) per hour at 5 centimeters from the surface of the tube housing assembly. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which may be positioned over the entire useful beam exit port during periods when the beam is not in use.

(c) Leakage radiation from systems operating at 150 kV or less may not exceed one mGy (103 mR) per hour at one meter from the tube housing.

(d) Leakage radiation from systems operating above 150 kV may not exceed 0.1 percent of the useful beam one meter from the source housing for any of its operating conditions.

(2) **PERMANENT BEAM-LIMITING DEVICES.** Permanent, non-adjustable collimators used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) **ADJUSTABLE OR REMOVEABLE BEAM-LIMITING DEVICES.** (a) All removable beam-limiting devices or diaphragms may not transmit more than one percent of the useful beam for the most penetrating beam used. This paragraph does not apply to beam shaping blocks or shaping materials.

(b) When adjustable beam-limiting devices are used, the position and shape of the useful beam shall be indicated by a light beam. These devices may transmit not more than 5 percent of the useful beam.

(4) **FILTER SYSTEMS.** The filter system shall be designed to meet all of the following requirements:

(a) Accidental displacement of filters is not possible at any tube orientation.

(b) If the proper filter is not in place, an interlock system shall prevent irradiation.

(c) The air kerma rate escaping from the filter placement opening slot in the tube head may not exceed 100 mGy (one rad) per hour at one meter under any operating conditions.

(d) Each filter shall be marked as to its material of construction and its thickness.

(e) Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray. If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be reestablished.

(f) If the absorbed dose rate information relates exclusively to operation with a field flattening filter or beam scattering foil in place, that foil or filter shall be removable only by the use of tools.

(5) TUBE IMMOBILIZATION. (a) An x-ray tube shall be mounted so that it cannot accidentally turn or slide with respect to the opening in the tube housing through which radiation is emitted.

(b) The tube housing assembly shall be capable of being immobilized.

(6) EMERGENCY SWITCHES. At least one emergency power cutoff switch shall be present. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality control checks of the emergency power cutoff switches may be conducted at the end of the treatment day to minimize possible stability problems with the therapeutic radiation machine.

(7) SOURCE MARKING. An x-ray tube housing assembly shall be marked so that it is possible to determine the location of the focal spot to within 5 millimeters and the marking shall be readily accessible for use during calibration procedures.

(8) TIMER. (a) A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval or after a preset radiation dose has been delivered.

(a)(b) A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator.

(b)(c) The A timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation may be reinitiated, it shall be necessary to reset the elapsed time indicator.

(c)(d) The A timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

(d)(e) The A timer may not permit an exposure if set at zero.

(e)(f) The A timer shall may not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer end effect correction to compensate for mechanical lag.

(f)(g) The A timer shall be accurate to within one percent of the selected value or one second, whichever is greater.

(9) CONTROL PANEL INDICATORS. The An x-ray unit shall have all of the following:

(a) An indication at the control panel of whether electrical power is on and if activation of the x-ray tube is possible.

(b) An indication of whether x-rays are being produced.

(c) A means for indicating x-ray tube potential and current.

(d) A means for terminating an exposure at any time.

(e) A locking device that will prevent unauthorized use of the therapeutic radiation machine.

(10) TARGET TO SKIN DISTANCE. There shall be a means of determining the central axis target to skin distance to within 2 millimeters and of reproducing this measurement to within 2 millimeters thereafter.

(11) SHUTTERS. Unless it is possible to bring the x-ray tube output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a shielding equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(12) LOW FILTRATION MACHINES. Each therapeutic radiation machine equipped with a beryllium or other low filtration window shall be clearly labeled on the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

(13) FULL CALIBRATION MEASUREMENTS. (a) Full calibration of a therapeutic radiation machine shall be performed by or under the direct supervision of a medical physicist under all of the following conditions:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine.

2. At intervals not exceeding 12 months.

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

a. Whenever quality control check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled.

b. Following any component replacement, major repair or modification of components that could significantly affect the characteristics of the radiation beam.

4.(b) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those operational modes or radiation energies that are not within their acceptable range.

5.(c) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality control check procedures.

(b)(d) Full calibration shall include all measurements recommended for annual calibration by protocols approved by recognized national or international organizations. An acceptable protocol is the "Protocol for clinical reference dosimetry of high-energy photon and electron beams" as stated in AAPM Report No. 67, American Association of Physicists in Medicine, 1999.

Note: Report No. 67 "Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams," was published in *Medical Physics*, 26 (9), September 1999, pp. 1847-70. The report may also be obtained from: Medical Physics Publishing, 4531 Vernon Blvd., Madison WI 53705-4964 or ordered from their website: www.medicalphysics.org.

(e)(e) A registrant shall maintain a record of each calibration for the duration of the registration. The record shall include all of the following:

1. The date of the calibration.
2. The manufacturer's name, model and serial number for both the therapeutic radiation machine and the x-ray tube.
3. The model and serial numbers of the instruments used to calibrate the therapeutic radiation machine.
4. The signature of the medical physicist responsible for performing the calibration.

(14) QUALITY CONTROL CHECKS. (a) Quality control checks shall be performed on therapeutic radiation machines.

(b) Quality control checks shall meet all of the following requirements:

1. A registrant shall perform quality control checks using written procedures established by a medical physicist.

2. The quality control check procedures shall specify the frequency at which tests or measurements are to be performed. The quality control check procedures shall specify that the quality control check be performed during calibration. The acceptable tolerance for each parameter measured in the quality control check when compared to the value for that parameter shall be stated **all of the following:**

a. The frequency at which tests or measurements are to be performed.

b. Which quality control checks are to be performed during calibration.

c. The acceptable tolerance for each parameter measured in the quality control check when compared to the value for that parameter.

(c) The cause for a parameter exceeding a tolerance set by the medical physicist shall be investigated and corrected before the system is used for patient irradiation.

(d) Whenever a quality control check indicates a significant change in the operating characteristics of a system, as specified in the medical physicist's quality control check procedures, the system shall be recalibrated.

(e) A registrant shall have the medical physicist review and sign the results of each radiation output quality control check within 10 working days of the date that the check was performed.

(f) A registrant shall ensure that daily safety quality control checks of therapeutic radiation machines are performed.

(g) Safety quality control checks shall **be performed prior to the first treatment of the day to** ensure proper operation of all of the following:

1. Electrical interlocks at each external beam radiation therapy room entrance.
2. The "BEAM-ON" and termination switches.
3. Beam status indicator lights on the access doors, control console and in the radiation therapy room.
4. Viewing systems.
5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(h) A registrant shall maintain a record of each quality control check for 3 years. The record shall include all of the following:

- 1. The date of the quality control check.**
- 2. The manufacturer's name, model and serial number of the therapeutic radiation machine.**
- 3. The manufacturer's name, model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine.**
- 4. The signature of the person who performed the periodic quality control check.**

(15) QUALITY CONTROL CHECKS FOR ACCELERATORS. (a) Periodic quality control checks shall be performed on all therapeutic radiation machines at intervals ~~not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," AAPM Report No. 46, American Association of Physicists in Medicine, April, 1994~~ **recommended by the manufacturer or by recognized national or international organizations.**

Note: An acceptable reference is "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," AAPM Report No. 46, American Association of Physicists in Medicine, April, 1994.

(b) Quality control checks shall include determination of central axis radiation output and a representative sampling of periodic quality control checks ~~contained in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," AAPM Report No. 46, American Association of Physicists in Medicine, April, 1994~~ **according to recommendations of national or international organizations.** Representative sampling shall include all referenced periodic quality control checks in an interval not to exceed 14 consecutive calendar months.

Note: An acceptable reference is "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," AAPM Report No. 46, American Association of Physicists in Medicine, April, 1994. The publication may be consulted at the Department of Health and Family Services, Radiation Protection Section, 1 West Wilson St, Room 150, Madison

WI 53701: AAPM reports may be obtained from Medical Physics Publishing, 4531 Vernon Blvd., Madison WI 53705-4964 or ordered from their website: www.medicalphysics.org.

~~(c) A registrant shall use a dosimetry system specified in s. HFS 157.84 (3) that has been inter-compared with a calibrated dosimetry system within the previous 12 months.~~

(16) OPERATING PROCEDURES. (a) A therapeutic radiation machine shall may not be left unattended unless secured.

(b) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices or other means recommended by a physician shall be used.

(c) The An x-ray tube housing assembly shall may not be held by a person during operation unless the assembly is designed to require holding and the peak tube potential of the system does not exceed 50 kV. In these cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV.

(d) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

(e) No person other than the patient may be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any person, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of s. HFS 157.22 (1).

(f) A registrant shall promptly repair any system that is not operating properly.

~~(g) A registrant shall maintain a record of each quality control check for 3 years. The record shall include all of the following:~~

- ~~1. The date of the quality control check.~~
- ~~2. The manufacturer's name, model and serial number of the therapeutic radiation machine.~~
- ~~3. The manufacturer's name, model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine.~~
- ~~4. The signature of the person who performed the periodic quality control check.~~

HFS 157.86 Registration of radiation machine facilities. (1) REGISTRATION FEES. (a) An annual registration fee shall be levied for each site registration under this section, according to the following schedule:

1. For a site having an ionizing radiation installation serving physicians and clinics, osteopaths and clinics, chiropractors or hospitals, the fee shall be \$36 for each site and \$44 for each x-ray tube.

2. For a podiatric or veterinary site having an ionizing radiation installation, the fee shall be \$36 for each site and \$44 for each x-ray tube.

3. For a dental site having an ionizing radiation installation, the fee shall be \$36 for each site and \$30 for each x-ray tube.

4. For an industrial, school, research project or other site having an ionizing radiation installation, the fee shall be \$36 for each site and \$44 for each x-ray tube.

5. An additional fee of \$25, regardless of the number of devices, shall be required for each registration whenever the annual fee for renewal is not paid prior to the expiration of the registration.

6. A change of ownership requires re-registration and fees paid by the new registrant.

7. Any change in registration information shall be submitted to the department within 30 days after the change takes place. No fee is required for recording changes in registration information.

8. Manufacturing, testing or servicing facilities shall be considered as one x-ray tube for registration purposes.

9. Electron microscopes and extremity bone densitometers are exempt from registration fees after the initial registration.

(2) EXEMPTIONS. The following items are exempted from the requirements of this section:

(a) Electronic equipment that produces radiation incidental to its operation for other purposes, **such as x-rays from radio or television transmitter high voltage tubes.** ~~The production, testing or factory servicing of the equipment shall not be exempt. Manufacturing, testing or servicing facilities shall be considered as one x-ray tube for registration purposes. Electron microscopes and extremity bone densitometers are exempt from registration fees after the initial registration.~~

(b) Radiation machines in transit or storage.

(c) Domestic television receivers and computer monitors.

(3) RECIPROCAL RECOGNITION OF OUT-OF-STATE RADIATION MACHINES. (a) Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring the machine into the state shall give written notice to the department by mail or facsimile at least 48 hours before the machine is to be used in the state. The notice shall include all the following information:

1. The type of radiation machine.

2. The nature, duration and scope of intended use.

3. The exact location or locations where the radiation machine is intended to be used.

4. States in which the machine is registered.

(b) If, for a specific case, the 48-hour notice period would impose an undue hardship on the person, that person may apply to the department for verbal permission to proceed sooner.

Note: The department may be contacted by phone at 608-267-4784 or facsimile at 608-267-4799.

(c) The person in control shall do all the following:

1. Comply with all applicable rules of the department.
2. Supply the department with other information as the department requests.
3. Not operate within the state on a temporary basis in excess of 30 calendar days per year without obtaining a Wisconsin registration.

Subchapter IX – Cabinet and Analytical X-ray Systems

HFS 157.87 Radiation safety requirements. (1) GENERAL REQUIREMENTS. For certified cabinet x-ray systems including those designed to allow admittance of individuals, all of the following requirements apply:

(a) No registrant may permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the system. Records that demonstrate training compliance with this paragraph shall be maintained for department inspection until disposal is authorized by the department.

(b) Tests for proper operation of all interlocks shall be conducted and recorded at intervals not to exceed 12 months. Records of these tests shall be maintained for department inspection until disposal is authorized by the department.

(c) Compliance with dose limit requirements and radiation monitoring requirements of s. HFS 157.23 (1) (a) to (c) and 21 CFR 1020.40 shall be evaluated at intervals not to exceed one year. Records of these evaluations shall be maintained for department inspection for 3 years after the evaluation.

(d) A certified cabinet x-ray system shall be maintained in compliance with 21 CFR 1020.40. No modification may be made to the system without prior department approval.

Note: The title of 21 CFR 1020.40 is Cabinet X-ray Systems (39 Federal Register 12986, April 10, 1974).

(2) RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY SYSTEMS. The following safety equipment shall be used with all analytical x-ray systems except as otherwise noted:

(a) *Safety device.* An analytical x-ray system utilizing an open beam configuration shall incorporate a safety device that prevents any portion of an individual's body from entering the primary x-ray beam path or that causes the beam to be shut off upon entry into its path. The person in control at the facility may apply to the department for an exemption from the requirement for a safety device. The application shall include all the following information:

1. A description of the various safety devices that have been evaluated by the person in control.

2. The reason each device evaluated in subd. 1. cannot be used.

3. A description of the alternative safety methods available to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices. The department shall approve the alternate safety devices prior to their installation on the system.

(b) *Warning devices.* Open-beam configurations shall be provided with a readily discernible indication of either of the following:

1. ~~X-ray tube status (ON-OFF) located near the radiation source housing~~ **An indication of whether the x-ray tube is on or off**, if the primary beam is controlled in this manner.

Note: The x-ray tube status is located near the radiation source housing.

2. ~~Shutter status (OPEN-CLOSED) located near each port on the radiation source housing~~ **An indication of whether the shutter is open or closed**, if the primary beam is controlled in this manner. Warning devices shall be labeled so that their purpose is easily identified.

Note: The shutter status is located near each port on the radiation source housing.

(c) *Ports.* Unused ports on radiation source housings shall be secured in the closed position in a manner that will prevent casual opening.

(d) *Labeling.* All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on an x-ray source housing.

2. "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube.

(e) *Shutters.* On open-beam configurations installed after January 1, 1979, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) *Warning lights.* An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located as follows:

1. Near any switch that energizes an x-ray tube and illuminates only when the tube is energized.

2. In the case of a radioactive source, near any switch that opens a housing shutter and illuminates only when the shutter is open.

(g) *Radiation source housing.* An x-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 centimeters from its surface is not be capable of producing an air kerma in excess of 25 uSv (2.5 mrem) in one hour at any specified tube rating.

(h) *Generator cabinet.* An x-ray generator shall be contained within a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface to no more than 2.5 uSv (2.5 mrem) in one hour.

(3) **AREA REQUIREMENTS.** (a) *Radiation levels.* The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control so no radiation levels exist in any area surrounding the local component group that could result in a dose to any individual in excess of the dose limits in s. HFS 157.23 (1). For systems utilizing x-ray tubes, the permissible radiation levels shall be met at any specified tube rating.

(b) *Surveys.* To demonstrate compliance with par. (a), radiation surveys of an analytical x-ray system shall be performed according to all the following criteria:

1. Upon installation of the equipment.
2. Following any change in the initial arrangement, number or type of local components in the system.
3. Following any maintenance requiring the disassembly or removal of a local component in the system.
4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed.
5. Any time a visual inspection of the local components in the system reveals an abnormal condition.
6. Whenever personnel monitoring devices show an increase of 50 percent over the previous monitoring period or the readings are approaching the limits of sub. (2) (g) or (h). Radiation survey measurements are not be required if a person in control demonstrates compliance with par. (a) in some other manner.

(c) *Posting.* Each area or room containing analytical x-ray equipment shall have at least one sign conspicuously posted bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT" or words having a similar intent.

(4) **OPERATING REQUIREMENTS.** (a) *Procedures.* Operating procedures shall be written and available to all analytical x-ray equipment workers. No individual may operate analytical x-ray equipment in any manner other than that specified in the procedures unless the individual has obtained written approval of the person in control.

(b) *Bypassing.* No individual may intentionally bypass a safety device unless the individual has obtained the approval of the person in control. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING" or words having a similar intent shall be placed on the radiation source housing.

(5) **PERSONNEL REQUIREMENTS.** (a) *Instruction.* No individual may operate or maintain analytical x-ray equipment unless the individual has received instruction in and demonstrated competence in all the following:

1. Identification of radiation hazards associated with use of the equipment.

2. Significance of the various radiation warning and safety devices incorporated into the equipment or the reasons the devices have not been installed on certain pieces of equipment and the extra precautions required in such cases.

3. Proper operating procedures for the equipment.

4. Symptoms of an acute localized exposure that may cause a radiation burn.

5. Proper procedures for reporting an actual or suspected exposure.

(b) *Personnel monitoring.* Finger or wrist dosimetry devices shall be provided to and used by any of the following individuals:

1. An analytical x-ray equipment worker using a system having an open-beam configuration and not equipped with a safety device.

2. Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed. Reported dose values may not be used for the purpose of determining compliance with s. HFS 157.22 unless the dose values are evaluated by a medical physicist.

(6) **IMAGING DEVICES.** Industrial uses of hand-held imaging intensification devices are exempt from the requirements of this subchapter if the air kerma 18 inches from the source of radiation to any individual does not exceed 25 uSv (2.5 mrem) per hour. A device that exceeds this limit shall meet the requirements of this subchapter and the licensing or registration requirements of subchs. II or VIII.

Subchapter-X-Notices, Instructions and Reports to Workers

HFS 157.88 Posting, notification and reporting requirements. (1) **POSTING OF NOTICES TO WORKERS.** (a) Except as provided in par. (b), a licensee or registrant shall post current copies of all the following documents in a conspicuous location that is accessible to workers on the way to or from the worker's work station or job location:

1. This subchapter and subch. III.

2. The license, conditions or documents incorporated into the license by reference and license amendments.

3. The operating procedures applicable to activities under the license or registration.

4. Any notice of violation, forfeiture assessment or order issued under s. 254.37 or 254.45, Stats., or this chapter and any response from the licensee or registrant until removal is authorized by the department.

5. The certificate of registration.

6. Emergency procedures that apply to activities conducted under the license or registration.

7. A "Notice to Employees" form that details the types of information that employers must give to their employees and department contact information.

Note: The "Notice to Employees" form may be obtained from the Department by writing: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659 or from the Department's website www.dhfs.state.wi.us/licensing.

(b) If posting of the documents specified in par. (a):1. to 3. is not physically practical, a licensee or registrant may post a summary of the documents that states where the full documents may be examined. The documents specified in par. (a) 4. to 7: shall be posted in their entirety.

(c) A document posted under par. (a) 4. shall be posted within 2 working days after receipt of the document from the department. A licensee's or registrant's response, if any, shall be posted within 2 working days after submitting the document to the department. The documents shall remain posted for a minimum of 5 working days or until the violation has been corrected, whichever is later.

(d) Documents, notices and forms posted under par. (a) shall be replaced within 10 days if defaced or altered.

(2) **INSTRUCTIONS TO WORKERS.** (a) All individuals who in the course of employment are likely to receive an occupational dose in excess of one mSv (100 millirem) in a year shall be given all of the following information annually:

1. The proper storage, transfer and use of sources of radiation in the licensee's or registrant's workplace.

2. Health risks to the individual and potential offspring associated with exposure to radiation and radioactive material, precautions and procedures the individual should use in the workplace to protect themselves and minimize exposure to radiation and radioactive material, and the purposes and functions of protective devices.

3. A worker's responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to or cause a violation of ss. 254.31 to 254.45, Stats., this chapter or a condition of the license:

4. How to respond in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.

5. Radiation exposure reports provided to workers under sub.(3).

(b) The extent of the instructions provided under par. (a) shall be commensurate with potential radiological health protection problems present in the workplace and shall take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material that can be reasonably be expected to occur during the life of the licensee's or registrant's activities.

(c) Records of instructions to workers required by this subsection shall be maintained by the licensee or registrant until reviewed by the department or for 5 years.

(3) **NOTIFICATIONS AND REPORTS TO INDIVIDUALS.** (a) *Radiation exposure reports.* Every 12 months, a licensee or registrant shall provide a written report of radiation exposure to

each employee who is required to be monitored for radiation exposure under s. HFS 157.25 (2). The report shall include all of the following:

1. Name of the licensee or registrant, the name of the individual and the individual's identification number.

2. Results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of the individual being monitored.

3. Any order issued under this chapter.

4. Any condition of the license or registration as shown in records maintained by the licensee or registrant under s. HFS 157.31 (7) **that relates to radiation exposure of employees.**

5. Each calendar quarter in which the worker's activities involved exposure to sources of radiation and the dates and locations of work. If a report under this paragraph is being provided to employees under par. (b) or (c), the report shall include the calendar quarter within which the employee terminates employment or requests a report under this subsection.

6. The radiation exposure report for each year the worker was required to be monitored under s. HFS 157.25 (2).

7. The statement: "This report is furnished to you under the provisions of Wisconsin Administrative Code, Chapter HFS 157, Radiation Protection. You should retain this report for future reference."

(b) *Reports to employees upon termination.* A licensee or registrant shall provide the report required under par. (a) to each employee within 30 days of the employee's termination.

(c) *Reports to employees upon request.* A licensee or registrant shall provide an employee with the report required under par. (a) within 30 days of receiving a written request from the employee, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later:

(d) *Reports to the department.* A licensee or registrant required to provide a report under s. HFS 157.32 (2) to (4) shall, on the same day, provide a copy of the report to the subject of the report.

(e) *Exposure request at time of termination.* At the request of a licensee's or registrant's employee or of a worker employed by another person but working in a licensee's or registrant's facility, a licensee or registrant shall, upon a worker's termination, provide to the worker, or to the worker's designee, a written report of the radiation dose received by that worker from operations of the licensee or registrant during the current calendar quarter or fraction thereof. If the most recent individual monitoring results are not available at that time, a licensee or registrant shall provide a written estimate of the dose, clearly indicating that it is an estimate.

(f) *Documentation required to be maintained.* Documentation that a report was provided as required under this subsection shall be maintained by the licensee or registrant for 3 years after generation of the documentation.

Subchapter XI - Inspection by the Department

HFS 157.89 Inspection requirements. (1) ACCESS BY DEPARTMENT INSPECTORS.

The department may inspect a licensee's or registrant materials, machines, devices, activities, facilities, premises and records under this chapter at any reasonable time.

(2) PRESENCE OF REPRESENTATIVES OF LICENSEE OR REGISTRANT DURING INSPECTION. (a) A licensee, registrant or designee may accompany department inspectors during an inspection.

(b) If, at the time of inspection, an individual has been authorized by the workers to represent them during department inspections, a licensee or registrant shall notify the inspectors of that authorization and shall permit the workers' representative to accompany the inspectors during the inspection of physical working conditions.

(c) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in s. HFS 157.88 (2).

(d) Different representatives of a licensee or registrant or workers may accompany the department's inspectors during different phases of an inspection if there is no interference with the conduct of the inspection, but only one workers' representative at a time may accompany the inspectors.

(e) With the approval of a licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, such as a consultant to the licensee or registrant or to the workers' representative, may accompany department inspectors during the inspection of physical working conditions.

(f) ~~Notwithstanding the other provisions of this subsection,~~ Department inspectors may refuse to permit any individual who deliberately interferes with a fair and orderly inspection to accompany them on the inspection. An individual may accompany an inspector in areas containing information classified by an agency of the U.S. government in the interest of national security only if the individual is authorized to do so by the licensee or registrant. The workers' representative may enter an area containing proprietary information only if the representative has been previously authorized by the licensee or registrant to enter that area.

(3) CONSULTATION WITH WORKERS DURING INSPECTIONS. (a) Department inspectors may consult privately with workers to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) Consultation with a worker under par. (a) may be written or oral and concern any past or present condition that the worker believes contributed to, caused or may cause a violation of the Act ss. 254.31 to 254.45, Stats., this chapter or a condition of the license, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Written information received by inspectors under this paragraph shall comply with the requirements of sub. (4).

(4) REQUEST BY WORKERS FOR AN INSPECTION. (a) A worker or workers' representative who believes that a violation of the Act ss. 254.31 to 254.45, Stats., this chapter or a condition of a license exists or has occurred may request an inspection by the department. The request shall be in writing, set forth the reasons for the request and be signed by the worker or workers' representative. The department shall provide a copy of the request to the licensee or registrant at the time of inspection granted under sub. (5). Upon request of the worker giving

notice, the department shall remove from the licensee's or registrant's copy of the request the worker or workers' representative's name and the names of other individuals.

(b) No licensee, registrant, contractor or subcontractor of a licensee or registrant may discharge or in any manner discriminate against any worker or workers' representative because the worker or workers' representative has filed a complaint under this subsection or instituted or caused to be instituted a proceeding under this chapter or has testified or is about to testify in any proceeding under this chapter, or because of the exercise by the worker on behalf of himself or herself or others of any right established under this subchapter.

Note: Requests may be made in writing to: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659.

(5) **INSPECTION WARRANTED.** If after reviewing a request submitted under sub. (4), the department determines it is probable an alleged violation has occurred, the department shall conduct an inspection as soon as is practicable. An inspection under this subsection need not be limited to an allegation set forth in a request under sub. (4).

(6) **INSPECTION NOT WARRANTED.** (a) If after reviewing a request submitted under sub. (4), the department decides not to conduct an inspection, the department shall notify the worker or workers' representative in writing of that determination.

(b) A worker or workers' representative may request a review of a decision under par. (a) by submitting a written request for review and statement of position to the department. The department shall send by certified mail to the licensee or registrant a copy of the statement of position received by the department under this paragraph.

(c) The licensee or registrant may submit to the department a written response to a statement of position submitted under par. (b). The department shall send by certified mail to the worker or workers' representative a copy of the response received by the department under this paragraph.

(d) Upon the request of the worker or workers' representative or the licensee or registrant, the department may next hold an informal conference in which the worker or the workers' representative and the licensee or registrant may orally present their views on the reason for the initial request for inspection. Disclosure of the identity of the worker or the workers' representative may be made only following receipt of written authorization from the worker or the workers' representative. After considering all written and oral views presented, the department shall affirm, modify or reverse the original determination and furnish the worker or the workers' representative and the licensee or registrant a written notice of the decision and the reason for the decision.

Note: Requests may be made in writing to: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659.

Subchapter XII – Enforcement

HFS 157.90 Violation and penalty criteria. (1) SEVERITY LEVELS. (a) Each violation of a condition of a license or registration or a requirement of ss. 254.31 to 254.45, Stats., or this chapter shall be classified as specified in pars. (b) to (f) after considering all of the following:

1. The actual or potential injury to the environment or to occupational or public health.

2. The actual or potential costs of the damage or injury to the environment or to occupational or public health caused by the violation.

3. The potential danger to the environment or to occupational or public health.

4. The willfulness of the violation.

5. The compliance history of the licensee or registrant.

(b) A violation may be classified at severity level one if any of the following exist:

1. Actual damage or injury to occupational or public health or to the environment are caused by the violation.

2. The violation is characterized by any of the following:

a. Willful action.

b. Multiple occurrence between inspections.

c. Contribution to one or more additional violations.

(c) A violation may be classified at severity level 2 if both of the following exist:

1. The violation results in a circumstance that creates a significant potential for injury or costs to occupational or public health or to the environment.

2. Any of the factors listed in par. (b) 2. are present.

(d) A violation may be classified at severity level 3 if any of the following exist:

1. The potential for danger to the environment or occupational or public health is significant.

2. Any of the factors listed in par. (b) 2. b. and c. are present.

(e) A violation may be classified at severity level 4 if both of the following exist:

1. The violation threatens the environment or occupational or public health.

2. The potential for danger to the environment or occupational or public health is probable.

(f) A violation may be classified at severity level 5 if it is unlikely to cause actual costs or injury to the environment or to occupational or public health.

Note: See Appendix R for examples of severity levels one through 5 violations.

(2) **ASSESSMENT OF FORFEITURES.** (a) The department may assess a direct forfeiture for each violation. If the department assesses a forfeiture, the amount of the forfeiture shall be derived from Tables HFS 157.90A and 157.90B.

(b) A forfeiture assessment shall may not be less than \$100 nor more than \$100,000 for each violation.

**Table HFS 157.90A
BASE FORFEITURES**

Type of User	Amount
All licensees or registrants	\$5,000
Persons not licensed or registered	\$10,000

**Table HFS 157.90B
PERCENTAGE OF BASE AMOUNTS BASED ON SEVERITY LEVEL OF VIOLATION**

Severity Level	Percent of Amount Listed in Table 157.90A
1	100
2	75
3	50
4	15
5	5

(c) Each day of continued violation constitutes a separate offense.

(d) The department shall send written notice of a forfeiture assessment to the person against whom the forfeiture is assessed. The notice shall specify all of the following:

1. The forfeiture amount.
2. The violation and severity level of the violation on which the forfeiture is based.
3. The statute or rule alleged to have been violated.
4. Notice that the person may contest the department's assessment of a forfeiture by requesting a hearing before the division of hearings and appeals. The notice shall describe the appeal process under s. HFS 157.91 (4).

(e) The department may, at any time, negotiate a settlement related to a violation.

(3) **FORFEITURE PAYMENT.** (a) A person against whom the department has assessed a forfeiture shall pay the forfeiture to the department within 10 days of the receipt of the notice under sub. (2) (d).

(b) **Except as provided in par. (c),** if a person contests a forfeiture under s. HFS 157.91 (4), and the division of hearings and appeals upholds the forfeiture assessment, the person shall pay the forfeiture within 10 days after receipt of the final decision after exhaustion of administrative review.

(c) If a person petitions for judicial review under ch. 227, Stats., and the court upholds the forfeiture assessment, the person shall pay the forfeiture within 10 days after receipt of the final judicial decision.

Note: Send forfeiture payments to: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659. Certified mail may be sent to: Department of Health and Family Services, Radiation Protection Section, 1 West Wilson St., Room 150, Madison, WI 53702-0007.

(d) The department shall remit all forfeitures paid to the state treasurer for deposit in the school fund.

HFS 157.91 Notices, orders, reviews and appeals. (1) **NOTICE OF VIOLATION AND ORDER OF ABATEMENT.** (a) If the department finds that a source of radiation as constructed, operated or maintained results in a violation of ss. 254.31 to 254.45, Stats., or of this chapter, the department shall notify in writing, the person in control that is causing, allowing or permitting the violation as to the nature of the violation. The notification shall do all of the following:

1. Specify each statute, rule or condition of a license or registration alleged to have been violated and the severity level of each violation.
2. Order, that prior to a specified time, the person in control shall cease and abate causing, allowing or permitting the violation and take such action as may be necessary to have the source of radiation constructed, operated, or maintained in compliance with ch. 254, Stats., or this chapter.
3. Give notice of any forfeiture assessment.
4. Give notice that an order issued under this paragraph is subject to review by the department.

(b) If the department finds that a condition exists that constitutes an immediate threat, the department shall include in a notice of violation and order issued under par. (a), the recitation of the existence of the threat and the findings pertaining to the threat. The department may summarily cause the abatement of the violation.

(c) Upon receipt of a notice of violation and order under this subsection the person in control shall do all of the following:

1. Cease and abate the violation and take action as necessary to comply with ss. 254.31 to 254.45, Stats., or this chapter, before the time specified in the order.

2. Send to the department a written plan of correction for each violation, within 10 days after receipt of the notice of violation and order, that describes the action taken to comply with the order and the date within which the violation was corrected.

(d) The department shall, within a reasonable period after receipt of the plan of correction, inspect the source of radiation to ensure that the violation that is the subject of an order under this subsection is in compliance with ss. 254.31 to 254.45, Stats., and this chapter.

(e) The department may extend the period specified in par. (c) 2., for submission by the person in control of a plan of correction.

Note: A plan of correction should be sent to: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659. Certified mail may be sent to: Department of Health and Family Services, Radiation Protection Section, 1 West Wilson St., Room 150, Madison, WI 53702-0007.

(2) PETITION FOR REVIEW. (a) A person to whom an order is issued under sub. (1) may petition the department for review of the order by submitting within 10 days after receipt of the department's order, to the administrator of the division of public health, a written petition for review. A petition for review shall include all of the following:

1. Name and address of the person filing the petition.
2. License number.
3. Reason for requesting the review.
4. Alternative solution.
5. Relief sought.
6. A copy of the notice of violation and order subject to review.
7. Written documentation in support of the petition for review.

Note: A petition for review should be sent to: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659. Certified mail may be sent to: Department of Health and Family Services, Radiation Protection Section, 1 West Wilson St, Room 150, Madison, WI 53702-0007.

(b) Failure to petition the department for review as required under par. (a) may result in a denial of the review.

(3) EMERGENCY ORDERS. (a) If the department finds that an emergency exists concerning a matter subject to regulation under ss. 254.31 to 254.45, Stats., or this chapter, that requires immediate action to protect the public health or safety, the department may issue an emergency order without hearing or notice. The order shall recite the existence of the emergency and state such action the department deems necessary to mitigate the emergency.

(b) An emergency order shall be issued within 24 hours of finding the emergency and shall be effective upon issuance. An emergency order shall remain in effect for up to 90 days after issuance, unless revoked or modified by the results of a hearing held under sub. (4). Any person to whom an emergency order is issued shall immediately comply with the order.

(c) A person to whom an emergency order is issued may contest the action by filing with the division of hearings and appeals, within 10 days after receipt of the emergency order, a written request for hearing under sub. (4).

(4) HEARING. (a) Any person against whom the department takes an action under sub. (3) or s. HFS 157.90 (2), may contest the action by sending to the division of hearings and appeals, within 10 days after receipt of the action, a written request for hearing under s. 227.44, Stats. The hearing request shall contain all of the following:

1. Name and address of the person filing the request.
2. The license number.
3. Reason for the hearing request.
4. Relief sought.
5. A copy of any notice issued by the department that is the subject of the action.

(b) Materials mailed to the division of hearings and appeals shall be considered filed with the division on the date of the postmark. Materials submitted by personal service or by inter-departmental mail shall be considered filed on the date the materials are received by the division. Materials transmitted by facsimile shall be considered filed on the date the materials are received by the division as recorded on the division facsimile machine.

Note: The mailing address of the Division of Hearings and Appeals is: 5005 University Avenue, Suite 201, Madison, WI 53705-5400. The facsimile transmission number is 608-267-2744.

(c) On the date a hearing request is sent to the division of hearings and appeals under par. (a), the petitioner shall send a copy of the hearing request to the department.

Note: A copy of the hearing request should be sent to: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659. Certified mail may be sent to: Department of Health and Family Services, Radiation Protection Section, 1 West Wilson St, Room 150, Madison, WI 53702-0007.

(d) The division of hearings and appeals shall commence a hearing within 30 days of receipt of a request for hearing and issue a final decision within 15 days after the close of the hearing. Proceedings before the division shall be governed by ch. 227, Stats.

Subchapter XIII – Transportation

HFS 157.92 General regulatory provisions. (1) REQUIREMENT FOR LICENSE. No person may transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the department under s. 254.365, Stats., or unless exempt under sub. (2).

(2) EXEMPTIONS. (a) Common and contract carriers, freight forwarders and warehouse workers who are subject to the requirements of 49 CFR 170 to 189 or the U.S. postal service.

regulations in the U.S. postal service domestic mail manual (DMM), Section C-023.9.0, and the U.S. postal service are exempt from the requirements of this section to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. department of transportation or U.S. postal service are subject to sub. (1).

(b) A licensee who delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 70 becquerel per gram (0.002 $\mu\text{Ci/g}$) shall be is exempt from the requirements of this subchapter.

Note: The U.S. postal service domestic mail manual (DMM), Section C-023.9.0, is available at <http://pe.usps.gov/>.

(c) Any physician licensed by the state of Wisconsin to dispense drugs in the practice of medicine is exempt from sub. (1) with respect to transport by the physician of radioactive material for use in the practice of medicine provided the physician is an authorized user under subch. II of this chapter.

(d) A licensee is exempt from all requirements of this subchapter except sub. (3) (a) and s. HFS 157.94 (2), with respect to shipment or transport any of the following:

1. Packages containing no more than Type A quantities of radioactive material if the package contains no fissile material.

2. A package containing low specific activity (LSA) material in group LSA-1 or surface contaminated objects (SCO) in group SCO-1.

(3) TRANSPORT OF LICENSED MATERIAL. (a) A licensee who transports licensed material outside the site of usage, as specified in the department license, or on public highways, or to a carrier for transport, shall do all the following:

1. Comply with the requirements, appropriate to the mode of transport, of the regulations of the U.S. department of transportation in all the following areas:

a. Packaging – 49 CFR 173: Subparts A and B and I.

b. Marking and labeling - 49 CFR 172: Subpart D, 172.400 to 172.407, 172.436 to 172.440 and Subpart E.

c. Placarding – 49 CFR 172: Subpart F, especially 172.500 to 172.519, 172.556 and Appendices B and C.

d. Accident reporting - 49 CFR 171: 171.15 and 171.16.

e. Shipping papers and emergency information - 49 CFR 172: Subpart C and Subpart G.

f. Hazardous material employee training - 49 CFR 172: Subpart H.

g. Hazardous material shipper/carrier registration - 49 CFR 107: Subpart G.

2. Comply with U.S. department of transportation regulations pertaining to all the following modes of transportation:

- a. Rail – 49 CFR 174: Subparts A to D and K.
- b. Air - 49 CFR 175.
- c. Vessel - 49 CFR 176: Subparts A to F and M.
- d. Public Highway - 49 CFR 177 and 49 CFR 390 to 397.

3. Send or otherwise make available any special instructions needed to safely open the package to the consignee under s. HFS 157.29 (6) (e).

(b) If the regulations of the U.S. department of transportation are not applicable to a shipment of licensed material, a licensee shall comply with the requirements of 49 CFR 170 to 189, appropriate to the mode of transport as if the shipment was subject to the regulations. **A request for modification, waiver or exemption from these requirements and any notification referred to in these requirements shall be submitted in writing to the department.**

Note: A request for modification, waiver or exemption shall be submitted to the department at the following address: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659. Certified mail may be sent to: Department of Health and Family Services, Radiation Protection Section, 1 West Wilson St, Room 150, Madison, WI 53702-0007. Requests may be sent by facsimile to 608-267-3695.

HFS 157.93 General licenses. (1) COMMON OR CONTRACT CARRIER. A general license is issued to any common or contract carrier not exempt under s. HFS 157.92 (2) to receive, possess, transport and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is under the applicable requirements, appropriate to the mode of transport, of the U.S. department of transportation 49 CFR 170 to 189 relating to loading and storage of packages, placarding of the transporting vehicle and incident reporting. Notification of an incident shall be filed with the department as prescribed in 49 CFR 170 to 189, in addition to notification made to the U.S. department of transportation or other agencies.

(2) PRIVATE CARRIER. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is under the applicable requirements, appropriate to the mode of transport, of the U.S. department of transportation insofar as the requirements relate to the loading and storage of packages, placarding of the transporting vehicle and incident reporting. Notification of an incident shall be filed with, or made to, the department as prescribed in 49 CFR 170 to 189, regardless of and in addition to notification made to the U.S. department of transportation or other agencies.

(3) EXEMPTION. A person who transports radioactive material under the general licenses in subs. (1) or (2) is exempt from the requirements of subchs. III and X only for the purposes of transporting radioactive material.

(4) NUCLEAR REGULATORY COMMISSION-APPROVED PACKAGES. (a) A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the nuclear regulatory commission.

(b) The general license issued in par. (a) applies only to a licensee who meets all the following criteria:

1. Has a copy of the specific license, certificate of compliance, or other approval by the nuclear regulatory commission of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment.

2. Complies with the terms and conditions of the license, certificate, or other approval by the nuclear regulatory commission, as applicable, and the applicable requirements of this subsection.

3. Prior to the licensee's first use of the package, has registered with the nuclear regulatory commission.

4. Has a quality assurance program that complies with s. HFS 157.94 (6).

(c) The general license in par. (a) applies only when the package approval authorizes use of the package under this general license.

(d) For a Type B or fissile material package, the design of which was approved by the nuclear regulatory commission before April 1, 1996, the general license issued in par. (a) is subject to the additional restrictions of sub. (5):

(5) PREVIOUSLY APPROVED PACKAGE. (a) A Type B package previously approved by the nuclear regulatory commission, but not designated as B(U) or B(M) in the identification number of the nuclear regulatory commission certificate of compliance, may be used under the general license of sub. (4) if the packaging meets all the following conditions:

1. Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with nuclear regulatory commission regulations at 10 CFR 71.85(c).

2. A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in US department of transportation regulations at 49 CFR 173.403.

3. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

(b) A Type B(U) package, a Type B(M) package, a low specific activity material package or a fissile material package, previously approved by the nuclear regulatory commission but without the designation "-85" in the identification number of the nuclear regulatory commission certificate of compliance, may be used under the general license of sub. (4) if the packaging meets all the following additional conditions:

1. Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with nuclear regulatory commission regulations at 10 CFR 71.85(c).

2. A package used for a shipment to a location outside the United States is subject to multilateral approval except approved under special arrangement in accordance with US department of transportation regulations at 49 CFR 173.403.

3. A serial number that uniquely identifies each packaging and which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(6) US DEPARTMENT OF TRANSPORTATION SPECIFICATION CONTAINER. (a) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

(b) The general license issued in par. (a) applies only to a licensee who meets all the following criteria:

1. Has a copy of the specification for the container.
2. Complies with the terms and conditions of the specification and the applicable requirements of this subchapter.
3. Has a quality assurance program that complies with s. HFS 157.94 (6).

(c) The general license issued in par. (a) is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

(7) USE OF FOREIGN APPROVED PACKAGE. (a) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package whose design has been approved in a foreign national competent authority certificate and which has been revalidated by the US department of transportation as meeting the applicable requirements of 49 CFR 171.12.

(b) The general license in par. (a) applies only to international shipments.

(c) The general license in par. (a) applies only to a licensee who meet all the following criteria:

1. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment.
2. Complies with the terms and conditions of the certificate and revalidation, and with the requirements of this subchapter.
3. The licensee Has a quality assurance program approved by the nuclear regulatory commission.

HFS 157.94 Operating controls and procedures. (1) ROUTINE DETERMINATIONS. Prior to each shipment of licensed material, a licensee shall determine all the following:

- (a) The package is proper for the contents to be shipped.
- (b) The package is in unimpaired physical condition except for superficial defects such as marks or dents.

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects.

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid.

(e) Any pressure relief device is operable and set under written procedures established by the carrier or licensee.

(f) The package has been loaded and closed under written procedures established by the carrier or licensee.

(g) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition.

~~(g)~~ (h) Any structural part of the package that can may be used to lift or tie down a package during shipment is rendered inoperable unless it satisfies design requirements specified by the U.S. nuclear regulatory commission NRC.

~~(h)~~ (i) The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable and does not exceed the levels specified in 49 CFR 173.443.

~~(i)~~ (j) External radiation levels around the package and around the vehicle do not exceed the limits specified in 49 CFR 173.441.

(k) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

(2) AIR TRANSPORT OF PLUTONIUM. Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this section or included indirectly by citation of the U.S. department of transportation regulations, a licensee may not transport or deliver plutonium in any form by air, or deliver to a carrier for air transport, except under any of the following conditions:

(a) The plutonium is contained in a medical device designed for individual human application.

(b) The plutonium is contained in a material in which the specific activity is not greater than 70 becquerel per gram (0.002 $\mu\text{Ci/g}$) of material and in which the radioactivity is essentially uniformly distributed.

(c) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped as provided in s. HFS 157.92 (3).

(d) The plutonium is shipped in a package specifically authorized in a certificate of compliance issued by the nuclear regulatory commission for the shipment of plutonium by air, and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704.

(3) SHIPMENT RECORDS. A licensee shall maintain for a period of 3 years after shipment a record of each shipment of licensed material not exempt under s. HFS 157.92 (2), showing all of the following:

- (a) Identification of the packaging by model number and serial number.
- (b) Verification that the packaging, as shipped, had no significant defect.
- (c) Volume and identification of coolant.
- (d) Type and quantity of licensed material in each package and the total quantity of each shipment.
- (e) Date of the shipment.
- (f) Name and address of the transferee.
- (g) Address to which the shipment was made.
- (h) Results of the determinations required by sub. (1) and by the conditions of the package approval.

Note: The approval of packaging and the conditions or limitations of that approval are reserved solely to the NRC.

(4) REPORTS. A licensee shall provide a written report to the department within 30 days of any of the following:

- (a) Any instance in which there is significant reduction in the effectiveness of any packaging during use.
- (b) Details of any defects with safety significance in the packaging after first use, and the means employed to repair the defects and prevent their recurrence.
- (c) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

(5) ADVANCE NOTIFICATION OF TRANSPORT OF NUCLEAR WASTE. (a) Prior to the transport of any nuclear waste meeting the criteria in par. (b) outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of the transport to the governor, or governor's designee, and to the department.

Note: Notification of transport of nuclear waste may be sent to: Division of Emergency Management, 2400 Wright Street, Madison, Wisconsin, 53704. Notification may also be made by: telephone at 608-242-3232; or fax at 608-242-3247. The telephone number of the 24-hour duty officer is 1-800-943-0003.

(b) Advance notification is required under any of the following conditions:

1. The nuclear waste is required to be in Type B packaging for transportation.

2. The nuclear waste is being transported through Wisconsin en route to a disposal facility or to a collection point for transport to a disposal facility.

3. The quantity of licensed material in a single package exceeds any of the following criteria:

a. Three thousand times the A_1 value of the radionuclides as specified in Appendix O, Table VI for special form radioactive material.

b. Three thousand times the A_2 value of the radionuclides as specified in Appendix O, Table VI for normal form radioactive material.

c. One thousand terabecquerel (27,000 Ci).

(c) Each advance notification required by par.(a) shall contain all the following information:

1. The name, address and telephone number of the shipper, carrier and receiver of the shipment.

2. A description of the nuclear waste contained in the shipment as required under 49 CFR 172.202 and 172.203.

3. The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur.

4. The 7-day period during which arrival of the shipment at state boundaries is estimated to occur.

5. The destination of the shipment and the 7-day period during which arrival of the shipment is estimated to occur.

6. A point of contact with a telephone number for current shipment information.

(d) The notification required by par. (a) shall be made in writing to the office of the governor, or governor's designee, and to the department. A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger or facsimile shall reach the office of the governor, or governor's designee, and the department at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 3 years.

(e) A licensee shall notify the governor, or governor's designee, and the department of any changes to schedule information provided under par. (a). Notification shall be by telephone or facsimile to a designated responsible individual in the office of the governor, or governor's designee, and to the department. A licensee shall retain for 3 years a record of the name of the individual contacted.

(f) A licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send to the governor, or governor's designee, and to the department a cancellation notice identifying the advance notification that is being canceled. A copy of the notice shall be retained by the licensee for 3 years.

(6) **QUALITY ASSURANCE REQUIREMENTS.** (a) Unless exempted by the department, a licensee shall establish, maintain and execute a quality assurance program to verify that deficiencies, deviations and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

(b) A licensee shall identify the material and components to be covered by the quality assurance program.

(c) A licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program under those procedures throughout the period during which packaging is used.

(d) Prior to the use of any package for the shipment of radioactive material, a licensee shall obtain approval of its quality assurance program from the department.

(e) A licensee shall maintain written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be retained for a period of 3 years after shipment.

(7) **ASSUMPTIONS AS TO UNKNOWN PROPERTIES OF FISSILE MATERIAL.** When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

(8) **PRELIMINARY DETERMINATIONS.** Prior to the first use of any packaging for the shipment of radioactive material a licensee shall do all the following:

(a) Ascertain that there are no defects that could significantly reduce the effectiveness of the packaging.

(b) Where the maximum normal operating pressure will exceed 35 kilopascal (5 lb/in²) gauge, test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure.

(c) Determine that the packaging has been fabricated in accordance with the design approved by the nuclear regulatory commission.

(d) Conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number as assigned by the nuclear regulatory commission.

Subchapter XIV – Radioactivity in Community Water Systems

HFS 157.95 Exemptions. A community water system is exempt from the provisions of this subchapter if all of the following apply:

(1) The community water system consists solely of distribution and storage facilities.

(2) The community water system does not include collection and treatment facilities.

(3) The community water system obtains all water from, but is not owned or operated by, a public water system to which the rules of this subchapter apply.

(4) The community water system does not sell water to any person.

(5) The community water system is not a carrier that conveys passengers in interstate commerce.

HFS 157.96 Requirements: (1) **MAXIMUM CONTAMINANT LEVELS.** (a) *Alpha activity.*

1. The maximum contaminant level for radium-226 and radium-228 in community water systems is 5 pCi/L.

2. The maximum contaminant level for gross alpha particle activity in community water systems is 15 pCi/L, including radium-226, but excluding radon and uranium.

(b) *Beta particle and photon radioactivity from man-made radionuclides in community water systems.* 1. The average annual concentration of beta particle and photon radioactivity from man-made radionuclides in drinking water may not produce an annual dose equivalent to the total body or any internal organ greater than 0.04 millisievert (4 millirem).

2. Except for the radionuclides listed in Table HFS 157.96A, the concentration of man-made radionuclides causing 0.04 millisievert (4 millirem) total body or organ dose equivalents shall be calculated on the basis of a 2-liter per day drinking water intake using the 168 hour data listed in "Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air or Water for Occupational Exposure", National Council on Radiation Protection and Measurements Report No. 22. If 2 or more radionuclides are present, the sum of their annual dose equivalent to the total body or to any organ may not exceed 0.04 millisievert (4 millirem).

Note: The publication "Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air or Water for Occupational Exposure" in the National Council on Radiation Protection and Measurements Report No. 22, is the same document as Handbook 69 published by the National Bureau of Standards and which the Department received permission from the Attorney General and the Revisor of Statutes on March 22, 1982 to incorporate into ch. HSS 157 by reference. The reference is no longer available through the federal government and the National Bureau of Standards no longer exists. However, the document may be consulted at the Department's Radiation Protection Section at 1 W. Wilson St. in Madison, WI or the Revisor of Statutes Bureau or the Secretary of State's Office and may be ordered from: NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda MD, 20814.

TABLE HFS 157.96A

AVERAGE ANNUAL CONCENTRATIONS ASSUMED TO PRODUCE A TOTAL BODY OR ORGAN DOSE OF 4 MILLISIEVERT (4 MILLIREM)/YEAR

Radionuclide	Critical Organ	pCi per liter
Tritium	Total body	20,000
Strontium-90	Bone marrow	8

(2) ANALYTICAL METHODS FOR RADIOACTIVITY IN WATER. (a) *Standard radionuclide*. The following methods used to measure radionuclides and specified in "Prescribed Procedures for Measurement of Radioactivity in Drinking Water" EPA-600/4-80-032 shall be used to determine compliance with sub. (1), except in cases where alternative methods have been approved under sub. (4):

1. Gross Alpha and Beta - Method 900.
2. Gross Radium Alpha - Method 900.1.
3. Radium-226 - Method 903.1.
4. Radioactive Strontium Method 905.
5. Tritium - Method 906.
6. Radioactive Cesium Method 901.
7. Uranium - Method 908 or 908.1.

Note: The publication "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," EPA-600 4-80-32, is on file in the Revisor of Statutes Bureau and the Secretary of State's Office and is available on-line at <http://www.epa.gov/safewater/methods/rads.html>.

(b) *Other radionuclides*. When the identification and measurement of radionuclides other than those listed in par. (a) is required, the following references shall be used, except in cases where alternative methods have been approved under sub. (4):

1. Procedures for Radiochemical Analysis of Nuclear Reactor Aqueous Solutions, H. L. Krieger and S. Gold, EPA-R4-73-014, May 1973.
2. Section 4.5.4 of the Health and Safety Laboratory Procedure Manual pertaining to testing water, ERDA-HASL 300, 28th Edition.

Note: 1. The Procedures for Radiochemical Analysis of Nuclear Reactor Aqueous Solutions, H. L. Krieger and S. Gold, EPA-R4-73-014, May 1973, is available upon written request to: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659.

2. The Health and Safety Laboratory Procedure Manual ERDA-HASL 300, 28th Edition, 1997, is available on-line at www.eml.doe.gov/publications/procman/ or by ordering from: The Environmental Measurements Laboratory (EML), 201 Varick St, NY, NY 10014-4811.

(c) *Sensitivity*. **1.** For the purpose of monitoring radioactivity concentrations in drinking water, the required sensitivity of the radioanalysis is defined in terms of a detection limit. The detection limit shall be that concentration that may be counted with a precision of plus or minus 100 percent at the 95 percent confidence level, where 1.96 is the standard deviation of the net counting rate of the sample.

2. To determine compliance with sub. (1) (a) 1., the detection limit may not exceed one pCi/L. To determine compliance with sub. (1) (a) 2., the detection limit may not exceed 3 pCi/L.

23. To determine compliance with sub. (1) (b), the detection limits may not exceed the concentrations listed in Table HFS 157.96B.

TABLE HFS 157.96B

DETECTION LIMITS FOR MAN-MADE BETA PARTICLE AND PHOTON EMITTERS

<u>Radionuclide</u>	<u>Detection Limit</u>
Tritium	1,000 pCi/L
Strontium-89	10 pCi/L
Strontium-90	2 pCi/L
Iodine-131	1 pCi/L
Cesium-134	10 pCi/L
Gross beta	4 pCi/L
Other radionuclides	1/10 of the applicable limit

(d) *Compliance.* To judge compliance with the maximum contaminant levels listed in sub. (1), averages of data shall be used and shall be rounded to the same number of significant figures as the maximum contaminant level for the substance in question.

(3) **MONITORING FREQUENCY IN COMMUNITY WATER SYSTEMS.** (a) *Monitoring requirements for gross alpha particle activity, radium-226 and radium-228.* 1. Compliance with sub. (1) (a) shall be based on the analysis of an annual composite of 4 consecutive quarterly samples or the average of the analyses of 4 samples obtained at quarterly intervals.

a. A gross alpha particle activity measurement may be substituted for the required radium-226 and radium-228 analyses provided that the measured gross alpha particle activity does not exceed 5 pCi/L at a confidence level of 95 percent, where 1.96 is the standard deviation of the net counting rate of the sample. In localities where radium-228 may be present in drinking water, the department may require radium-226 or radium-228 analyses or analyses of both when the gross alpha particle activity exceeds 2 pCi/L.

b. When the gross alpha particle activity exceeds 5 pCi/L, the same or an equivalent sample shall be analyzed for radium-228.

2. A supplier of water shall monitor water supplies at least once every 4 years following the procedure required by subd. 1. At the discretion of the department, when the record taken in conformance with subd. 1. establishes that the average annual concentration is less than half the maximum contaminant levels established by sub. (1) (a), analysis of a single sample may be substituted for the quarterly sampling procedure required by subd. 1.

a. When ordered by the department, more frequent monitoring shall be conducted in the vicinity of mining or other operations that may contribute alpha particle radioactivity to either surface or groundwater sources of drinking water.

b. A supplier of water shall monitor in conformance with subd. 1. within one year of the introduction of a new water source for a community water system. More frequent monitoring shall be conducted when ordered by the department if possible contamination or changes in the distribution system or treatment processing occur that may increase the concentration of radioactivity in finished water.

c. A community water system using 2 or more sources having different concentrations of radioactivity shall monitor source water and water from a free-flowing tap when required by the department.

d. Monitoring for compliance with sub. (2) (a) need not include radium-228 except when required by the department, provided that the average annual concentration of radium-228 has been assayed at least once using the quarterly sampling procedure required by subd. 1.

e. A supplier of water shall conduct annual monitoring of any community water system in which the radium-226 concentration exceeds 3 pCi/L, when required by the department.

3. If the average annual maximum contaminant level for gross alpha particle activity or total radium as set forth in sub. (1) (a) is exceeded, the supplier of a community water system shall give notice to the department under sub. (7) and notify the public as required by sub. (8). Monitoring at quarterly intervals shall be continued until the annual average concentration no longer exceeds the maximum contaminant level or until a monitoring schedule as a condition to a variance, exemption or enforcement action is no longer effective in effect.

(b) *Monitoring requirements for man-made radioactivity in community water systems.* 1. Community water systems using surface water sources and serving more than 100,000 persons and any other community water systems as are designated by the department shall be monitored for compliance with sub. (1) (b) by analysis of a composite of 4 consecutive quarterly samples or analysis of 4 quarterly samples. Compliance with sub. (1) (b) may be assumed without further analysis if the average annual concentration of gross beta particle activity is less than 50 pCi/L and if the average annual concentrations of tritium and strontium-90 are less than those listed in Table 157.96A, provided that if both radionuclides are present, the sum of their annual dose equivalents to bone marrow does not exceed 4 millirem.

a. If the gross beta particle activity exceeds 50 pCi/L, an analysis of the sample shall be performed to identify the major radioactive constituents present. The appropriate organ and total body doses shall be calculated to determine compliance with sub. (1) (b).

b. A supplier of water shall conduct additional monitoring, as required by the department, to determine the concentration of man-made radioactivity in principal watersheds designated by the department.

c. At the discretion of the department, a supplier of water utilizing only groundwaters may be required to monitor for man-made radioactivity.

2. After the initial analysis required by subd. 1., a supplier of water shall monitor at least every 4 years following the procedure given in subd. 1.

3. The supplier of any community water system designated by the department as utilizing water subject to contamination by effluents from nuclear facilities shall initiate quarterly monitoring for gross beta particle and iodine-131 radioactivity and annual monitoring for strontium-90 and tritium.

a. Quarterly monitoring for gross beta particle activity shall be based on the analysis of monthly samples or the analysis of a composite of 3 monthly samples. If the gross beta particle activity exceeds 50 pCi/L, an analysis of the sample shall be performed to identify the major radioactive constituents present and the appropriate organ and total body doses shall be calculated to determine compliance with sub. (1) (b).

b. For iodine-131, a composite of 5 consecutive daily samples shall be analyzed once each calendar quarter. As required by the department, more frequent monitoring shall be conducted when iodine-131 is identified in the finished water.

c. Annual monitoring for strontium-90 and tritium shall be conducted by means of the analysis of a composite of 4 consecutive quarterly samples or analysis of 4 quarterly samples.

d. Data obtained by the direct monitoring of water supplies in the areas surrounding nuclear facilities may be utilized by the supplier where the department determines such data is applicable to a particular community water system.

4. If the average annual maximum contaminant level for man-made radioactivity specified in sub. (1) (b) is exceeded, the operator of a community water system shall give notice to the department under sub. (7) and to the public as required by sub. (8). Monitoring at monthly intervals shall be continued until the concentration no longer exceeds the maximum contaminant level or until a monitoring schedule as a condition to a variance, exemption or enforcement action becomes effective.

(4) ALTERNATIVE ANALYTICAL TECHNIQUES. With the written permission of the department concurred in by the administrator of the U.S. environmental protection agency, an alternative analytical technique may be employed. An alternative technique shall be acceptable only if it is substantially equivalent to the prescribed test in sub. (1) in both precision and accuracy as it relates to the determination of compliance with any maximum contaminant level. The use of the alternative analytical technique shall may not decrease the frequency of monitoring required by sub. (3).

(5) APPROVED LABORATORIES. For the purpose of determining compliance with this section, samples shall be considered only if the samples have been analyzed by a laboratory approved by the department.

(6) MONITORING OF CONSECUTIVE PUBLIC WATER SYSTEMS. When a public water system supplies water to one or more other public water systems, the department of natural resources may modify the monitoring requirements imposed by this section if the interconnection of the systems justifies treating them as a single system for monitoring purposes. Any modified monitoring shall be conducted under a schedule specified by the department of natural resources and concurred in by the administrator of the U.S. environmental protection agency.

(7) REPORTING REQUIREMENTS. (a) *Routine reports.* Except where a shorter reporting period is specified in this section, a supplier of water shall report the results of a test, measurement or analysis required to be made under this section to the department within 40 days following the test, measurement or analysis.

(b) *Noncompliance reporting.* A supplier of water shall report to the department within 48 hours noncompliance with any ~~drinking water rule set forth in~~ provision of this section, including failure to comply with monitoring requirements.

(c) *Exceptions.* A supplier of water is not required to report analytical results to the department when the department performs the analysis.

(8) PUBLIC NOTIFICATION. Public notification shall be provided as prescribed in s. NR 809.81.

(9) RECORD MAINTENANCE. A supplier of water shall maintain records as prescribed in s. NR 809.82.

(10) VARIANCE AND EXEMPTIONS. Variances and exemptions may be granted from any requirement regarding a maximum contaminant level for radioactivity as prescribed in ss. NR 809.90 and 809.91.

Subchapter XV – Registration of Radioactive Materials

HFS 157.97 Exemptions. (1) If a person utilizes ~~naturally occurring or accelerator-produced radioactive materials~~ **NARM** in quantities less than those listed in Appendix B, the person shall be is exempt from the registration requirement and associated fee listed in this subchapter.

(2) If a person is licensed by the department to possess, receive, use, transfer, own, or acquire naturally-occurring or accelerator-produced radioactive materials, the person is exempt from the registration requirement and associated fee listed in this subchapter.

(3) If a person is licensed by an agreement state or licensing state on or after July 1, 2003, to possess, receive, use, transfer, own or acquire naturally-occurring or accelerator-produced radioactive materials, the person is exempt from the registration requirement and associated fee listed in this subchapter.

(4) If a person is exempt by the department for reasons other than those specified in subs. (1) to (3), the person shall be is exempt from the registration requirement and associated fee listed in this subchapter.

HFS 157.98 Registration. (1) DEFINITION. In this section, “the year of registration” means the period from January 1 to December 31 following the year in which the registration fee under sub. (2) is received by the department.

(2) REGISTRATION APPLICATION. **Except as provided in sub. (4)**, no person may operate an ionizing radiation installation if the person has not been issued a notice of registration by the department by January 1 of each year. Application for registration shall be made on a form furnished by the department. An application for registration shall be accompanied by the fee required under subs. (3) and (4), as applicable, and submitted to the department by December 31, prior to the year of registration.

Note: An application for registration may be obtained by writing the Department at: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659, or may be downloaded from the Department website: <http://www.dhfs.state.wi.us/licensing.htm>.

(3) REGISTRATION FEE. (a) A medical, veterinary, industrial, academic, research project or other site having radioactive materials in any quantity shall pay to the department, an annual registration fee of \$36 for each site.

(b) Following receipt of the registration fee, the department shall issue to the person in control a notice of registration.

(4) PENALTY FEE. If the annual registration fee is not paid by December 31 prior to the year of registration, the installation shall pay the department a penalty fee of \$25, in addition to the registration fee, before being issued a new notice of registration.

(5) AMENDMENT REQUIREMENTS. A person in control shall notify the department of any change in registration information within 30 days of the change. A fee is not required to record a change in registration information.

SECTION 2. Chapter HSS 157 is repealed.