STATE OF WISCONSIN

AGREEMENT STATE

FINAL APPLICATION

SEPTEMBER, 2002

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STATE OF WISCONSIN

AGREEMENT STATE APPLICATION
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ENCLOSURE 1

AGREEMENT
BETWEEN
THE UNITED STATES NUCLEAR REGULATORY COMMISSION
AND
THE STATE OF WISCONSIN
FOR THE
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY AND RESPONSIBILITY WITHIN THE STATE PURSUANT TO SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

WHEREAS, The United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of the State of Wisconsin providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e. (1) and (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

WHEREAS, The Governor of the State of Wisconsin is authorized under s. 254.335 (1), Wisconsin Statutes, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the State of Wisconsin certified on **[date?]** that the State of Wisconsin (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory authority for such materials; and,

WHEREAS, The Commission found on **[date?]** that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and,

WHEREAS, The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

WHEREAS, The Commission and the State recognize the desirability of the reciprocal recognition of licenses, and of the granting of limited exemptions from licensing of those materials subject to this Agreement; and,

WHEREAS, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the State, acting on behalf of the State, as follows:

ARTICLE I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

A. By-product materials as defined in Section 11e. (1) of the Act;

B. Source materials;

C. Special nuclear materials in quantities not sufficient to form a critical mass.

ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to:

A. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;

B. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;

C. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear material wastes as defined in the regulations or orders of the Commission;

D. The regulation of the disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed without a license from the Commission;

E. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission;

F. The regulation of the land disposal of byproduct, source, or special nuclear material waste received from other persons;

G. The extraction or concentration of source material from source material ore and the management and disposal of the resulting byproduct material.

ARTICLE III

With the exception of those activities identified in Article II, paragraphs A through D, this Agreement may be amended, upon application by the State and approval by the Commission, to include the additional areas specified in Article II, paragraphs E, F and G, whereby the State can exert regulatory authority and responsibility with respect to those activities and materials.

ARTICLE IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE V

This Agreement shall not affect the authority of the Commission under subsection 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data, or to guard against the loss or diversion of special nuclear material.

ARTICLE VI

The Commission will cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that Commission and State programs for protection against hazards of radiation will be coordinated and compatible. The State agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and will assure that the State's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The State and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations, and to provide each other the opportunity for early and substantive contribution to the proposed changes.

The State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implication or otherwise be of regulatory interest.

ARTICLE VII

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any other agreement state. Accordingly, the Commission and the State agree to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

ARTICLE VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all or part of this agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect public health and safety, or (2) the State has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to section 274j of the Act, temporarily suspend all or part of this agreement if, in the judgement of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review this Agreement and actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act which requires a State program to be adequate to protect public health and safety with respect to the materials covered by the Agreement and to be compatible with the Commission's program.

ARTICLE IX

This Agreement shall become effective on **[date?]** and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at Madison, Wisconsin this **[date?]** day of **[month?], [year?].**

FOR THE UNITED STATES NUCLEAR REGULATORY COMMISSION

Richard A. Meserve, Chairman

FOR THE STATE OF WISCONSIN

Scott McCallum, Governor

Draft, July, 2002

Enclosure 2
Statutes and Rule Overview

Statutes

Statutory authority for Wisconsin's radiation control and proposed agreement state activities is primarily found in Wisconsin Statutes, Sections 254.31 - .45 (i.e., ss. 254.31 - .45, WI Stats). A copy of these statutes is included in the request for agreement.

There are additional, ancillary statutes that either generally apply to state agency activities or are mentioned in Ch. HFS 157, Radiation Protection. These statutes are referenced below but not included in the request for agreement.

Statutory reference	Subject	Reason for mention
s. 19.35 (1), WI Stats	Open records	Statute provides for public inspection of state agency records. It also provides the authority for an agency to withhold public access to records in certain situations. This provision allows the department to maintain the confidentiality of an alleger.
s. 153.50, WI Stats	Protection of patient confidentiality	Provisions of this statute apply to the protection of personnel radiation exposure records from public disclosure, as mentioned in s. HFS 157.31 (7).
Ch. 227, WI Stats	Administrative procedure and review	Statute details administrative and judicial requirements, such as requesting and holding hearings, that apply to persons and the department. Statute referenced in ss. HFS 157.90 - .91.

Rules

Wisconsin's radiation control rules "relating to protecting public health by regulating the sources and use of ionizing radiation" are found in Wisconsin Administrative Code, Ch. HFS 157, Radiation Protection. A copy of the final Ch. HFS 157 is included in the request for agreement. In addition, we have included a version of Ch. HFS 157 that shows the changes made in the final rule in response to public and NRC comments on the draft rule. Deletions are ~~crossed-out~~ while additions are shown in **bold and underlined type**. The draft rule was initially submitted to NRC for review attached to a transmittal letter dated September 20, 2001.

SUBCHAPTER III
RADIATION PROTECTION

254.31 Definitions. In this subchapter:

(1) "By–product material" means any of the following:

(a) Radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

(b) The tailings or waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

(2) "Decommissioning" means conducting final operational activities at a nuclear facility to dismantle site structures, to decontaminate site surfaces and remaining structures, to stabilize and contain residual radioactive material and to carry out any other activities necessary to prepare the site for postoperational care.

(2m) "General license" means a license, under requirements prescribed by the department by rule, to possess, use, transfer or acquire by–product material or devices or equipment utilizing byproduct material without the filing of a license application by a person or issuance of licensing confirmation by the department.

(3g) "Ionizing radiation" means all radiations capable of producing ions directly or indirectly in their passage through matter, including all of the following:

(a) Electromagnetic radiations, including X–rays and gamma rays.

(b) Particulate radiations, including electrons, beta particles, protons, neutrons, alpha particles and other nuclear particles.

(3p) "Nonionizing radiation" means electromagnetic radiation, other than ionizing radiation, and any sonic, ultrasonic or infrasonic wave.

(4) "Nuclear facility" means any reactor plant, any equipment or device used for the separation of the isotopes of uranium or plutonium, the processing or utilizing of radioactive material or handling, processing or packaging waste; any premises, structure, excavation or place of storage or disposition of waste or byproduct material; or any equipment used for or in connection with the transportation of such material.

(4p) "Radiation" means both ionizing and nonionizing radiation.

(5) "Radiation generating equipment" means a system, manufactured product or device or component part of such a product or device that, during operation, is capable of generating or emitting ionizing radiation without the use of radioactive material. "Radiation generating equipment" does not include a device that emits nonionizing radiation.

(6) "Radiation installation" is any location or facility where radiation generating

equipment is used or where radioactive material is produced, transported, stored, disposed of or used for any purpose.

(9) "Radiation source" means radiation generating equipment or radioactive material.

(9m) "Radioactive material" includes any solid, liquid or gaseous substance which emits ionizing radiation spontaneously, including accelerator–produced material, by–product material, naturally occurring material, source material and special nuclear material.

(10) "Source material" means uranium, thorium, any combination thereof in any physical or chemical form, or ores that contain by weight 0.05% or more of uranium, thorium, or any combination thereof. "Source material" does not include special nuclear material.

(11) "Special nuclear material" means plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the nuclear regulatory commission determines to be special nuclear material; or any material artificially enriched by any of the foregoing. Special nuclear material does not include source material.

(11g) "Specific license" means a license, under requirements prescribed by the department by rule, to possess, use, manufacture, produce, transfer or acquire radioactive material or devices or equipment utilizing radioactive material.

(11m) "Transuranic" means a radioactive material having an atomic number that is greater than 92.

(12) "X–ray tube" means any electron tube that is contained in a device and that is specifically designed for the conversion of electrical energy into X–ray energy.

254.33 Public policy. Since radiations and their sources can be instrumental in the improvement of the health and welfare of the public if properly utilized, and may be destructive or detrimental to life or health if carelessly or excessively employed or may detrimentally affect the environment of the state if improperly utilized, it is hereby declared to be the public policy of this state to encourage the constructive uses of radiation and to prohibit and prevent exposure to radiation in amounts which are or may be detrimental to health. It is further the policy for the department to advise, consult and cooperate with other agencies of the state, the federal government, other states and interstate agencies and with affected groups, political subdivisions and industries; and, in general, to conform as nearly as possible to nationally accepted standards in the promulgation and enforcement of rules.

254.335 Agreements with the U.S. nuclear regulatory commission transition. (1) The governor may, on behalf of the state, enter into agreements with the U.S. nuclear regulatory commission, as provided in 42 USC 2021 (b), to discontinue certain federal licensing and related regulatory authority with respect to by–product material, source material and special nuclear material and to assume state regulatory authority.

(2) Any person who, on the effective date of an agreement specified under sub. (1), possesses a license issued by the U.S. nuclear regulatory commission that is subject to the agreement is considered to possess a specific license issued under s. 254.365 (1) (a) or to fulfill requirements specified for a general license under s. 254.365 (1) (b). The

specific license expires 90 days after the date of receipt by the person from the department of a notice of expiration of the license or on the date of expiration that was specified in the license or on the date of expiration that was specified in the license issued by the U.S. nuclear regulatory commission, whichever is earlier.

254.34 Powers and duties. (1) The department is the state radiation control agency and shall do all of the following:

(a) Promulgate and enforce rules, including registration and licensing of sources of ionizing radiation, as may be necessary to prohibit and prevent unnecessary radiation exposure. The rules may incorporate by reference the recommended standards of nationally recognized bodies in the field of radiation protection and other fields of atomic energy, under the procedure established by s. 227.21 (2). The rules for by–product material, source material and special nuclear material shall be in accordance with the requirements of 42 USC 2021 (o) and shall otherwise be compatible with the requirements under 42 USC 2011 to 2114 and regulations adopted under 42 USC 2011 to 2114.

(am) A rule identical to a rule specified under par. (a) may be promulgated by a state agency other than the department and an ordinance identical to a rule specified under par. (a) may be enacted by a local governmental unit, but no rule may be promulgated or ordinance may be enacted that differs from a rule under par. (a) and relates to the same subject area except as provided under ss. 166.03 (2) (b) 6., 293.15 (8) and 293.25.

(b) Administer this subchapter and the rules promulgated under this subchapter.

(c) Develop comprehensive policies and programs for the evaluation, determination and reduction of hazards associated with the use of radiation that are compatible with requirements of the U.S. nuclear regulatory commission for the regulation of by–product material, source material and special nuclear material. The department shall maintain all of the following records:

1. Files of all license applications, issuances, denials, transfers, renewals, modifications, suspensions and revocations under s. 254.365.

2. Files of all registrants under s. 254.35 and any related administrative or judicial action.

(d) Advise, consult and cooperate with other agencies of the state, the federal government, other states and interstate agencies, and with affected groups, political subdivisions and industries.

(e) Encourage, participate in or conduct studies, investigations, training, research and demonstrations relating to the control of radiation hazards, the measurement of radiation, the effects on health of exposure to radiation and related problems as it deems necessary or advisable for the discharge of its duties under this subchapter.

(f) Collect and disseminate health education information relating to radiation protection as it deems proper.

(g) Review and approve plans and specifications for radiation sources submitted pursuant to rules promulgated under this sub-chapter; and inspect radiation sources, their shielding and immediate surroundings and records concerning their operation for the determination of any possible radiation hazard.

(h) With respect to radon and with the department serving as the lead agency, do all of the following:

1. Develop and disseminate current radon information to the news media, builders, realtors and the general public.

2. Coordinate a program of measuring radon gas accumulation, including use of the radon canister counting system, in educational institutions, nursing homes, low–income housing, public buildings, homes, private industries and public service organizations.

3. Work with staff of local health departments to perform home surveys and diagnostic measurements and develop mitigation strategies for homes with elevated radon gas levels.

4. Develop training materials and conduct training of staff of local health departments, building contractors and others in radon diagnosis and mitigation methods.

5. Develop standards of performance for the regional radon centers and, from the appropriation under s. 20.435 (5) (ed), allocate funds based on compliance with the standards to provide radon protection information dissemination from the regional radon centers.

(2) The department may:

(a) Enter, at all reasonable times, any private or public property for the purpose of investigating conditions relating to radiation control.

(b) Accept and utilize grants or other funds or gifts from the federal government and from other sources, public or private, for carrying out its functions under this subchapter. The studies, investigations, training and demonstration may be conducted independently, by contract, or in cooperation with any person or any public or private agency, including any political subdivision of the state.

(c) Develop requirements for qualification, certification, training, and experience of an individual who does any of the following:

1. Operates radiation generating equipment.

2. Utilizes, stores, transfers, transports, or possesses radioactive materials.

3. Acts as a radiation safety consultant to any person who possesses a license or registration issued by the department under this subchapter.

(d) Recognize certification by another state or by a nationally recognized certifying organization of an individual to perform acts under par. (c) 1. to 3. if the standards for the other state's certification or the organization's certification are substantially equivalent

to the standards of the department for certification of individuals under par. (c).

254.345 Assessment of Fee. (1) The department may annually assess a fee of 36% of the U.S. nuclear regulatory com-mission license application fee and materials license annual fee, for any licensee of the U.S. nuclear regulatory commission in this state. The fee amounts shall be used by the department for the department's activities under this subchapter. The department may revise the fee amounts by rule.

(2) This section does not apply after December 31, 2002.

254.35 Registration of ionizing radiation installations.

(1) APPLICATION. For every site in this state that has an ionizing radiation installation that is not exempted by this section or the rules of the department, the person in control of the installation, including installations in sites that are administered by a state agency or in an institution under the jurisdiction of a state agency, shall, prior to operation, register the ionizing radiation installation with the department. No ionizing radiation installation may be operated thereafter unless the site has been duly registered by January 1 of each year and a notice of the registration is possessed by the person in control. The application for registration shall be made on forms provided by the department which shall be devised to obtain any information that is considered necessary for evaluation of hazards. Multiple radiation sources at a single radiation installation and under the control of one person shall be listed on a single registration form. Registration fees shall be levied in accordance with sub. (3). Registration alone does not imply approval of manufacture, storage, use, handling, operation or disposal of the radiation installation or radioactive materials, but serves merely to inform the department of the location and character of radiation sources. Persons engaged in manufacturing, demonstration, sale, testing or repair of radiation sources are not required to list such sources on the registration form.

(2) AMENDED REGISTRATION. If the person in control increases the number of sources, source strength, rated output or energy of radiation produced in any installation, he or she shall notify the department of the increase prior to operation on the revised basis. The department shall record the change in the registration. No registration is transferable from one premises to another or from one person to another. If the person in control intends to transfer control of ownership of the radiation installation to another per-son, at least 15 days before the final transfer the registrant shall notify the department of the transfer and the intended transferee shall file under sub. (1) an application for registration. If any installation is discontinued, the person in control shall notify the department within 30 days of the discontinuance.

(3) REGISTRATION FEES. (a) An annual registration fee under pars. (b) to (fm) shall be levied for each site registration under this section. An additional penalty fee of $25, regardless of the number of X–ray tubes or generally licensed devices, shall be required for each registration whenever the annual fee for renewal is not paid prior to expiration of the registration. No additional fee may be required for recording changes in the registration information.

(b) For a site having an ionizing radiation installation serving physicians and clinics, osteopaths and clinics, chiropractors or hospitals that possesses radioactive materials in any quantity, the fee shall be at least $36 for each site and at least $44 for each X–ray

tube.

(c) For a podiatric or veterinary site having an ionizing radiation installation, the fee shall be at least $36 for each site and at least $44 for each X–ray tube.

(d) For a dental site having an ionizing radiation installation, the fee shall be at least $36 for each site and at least $30 for each X–ray tube.

(f) For an industrial, school, research project or other site having an ionizing radiation installation, the fee shall be at least $36 for each site and at least $44 for each X–ray tube.

(fm) For any site that has generally licensed devices that are not exempted by the department, the fee shall be at least $100 for each site and at least $50 for each device that contains at least 370 MBq or 10 mCi of cesium–137; 37 MBq or 1.0 mCi of cobalt–60; 3.7 MBq or 0.1 mCi of strontium–90; or 37 MBq or 1.0 mCi of a transuranic.

(g) The fees under this subsection shall be as stated unless the department promulgates rules to increase the annual registration fee for a site having an ionizing radiation installation, for an X–ray tube or for generally licensed devices that are not exempted by the department.

(4) EXEMPTIONS. After initial registration under sub. (1), the department may exempt from annual registration any source of radiation that the department finds to be without undue radiation hazard.

254.365 Licensing of radioactive material. (1) LICENSE REQUIRED. No person may possess, use, manufacture, transport, store, transfer or dispose of radioactive material or a device or item of equipment that uses radioactive material or may operate a site that uses radioactive material that is not under the authority of the U.S. nuclear regulatory commission unless one of the following applies:

(a) The person has a specific license issued by the department.

(b) The person meets general license requirements.

(c) The person possesses a license issued by another state or by the U.S. nuclear regulatory commission that is reciprocally recognized by the department.

(d) The person is exempted from licensure under sub. (7).

(2) APPLICATION. Application for a license under sub. (1) (a) or for reciprocal recognition under sub. (1) (c) shall be made on forms provided by the department.

(3) MODIFICATION OR TERMINATION OF LICENSE. Within 30 days after any change to the information on a license issued under this section, the licensee shall inform the department of the change and the department shall record the changed information. Within 30 days after termination of an activity licensed under this section, the person in control of the activity shall notify the department. The department may require that the person in control submit to the department for approval a plan for decommissioning the activity.

(4) RULES. The department shall promulgate rules for all of the following:

(a) The issuance, modification, suspension, termination and revocation of specific licenses under sub. (1) (a) under the standards specified in s. 254.34 (1) (a).

(b) The requirements for a general license under sub. (1) (b).

(5) FEES AND CHARGES. (a) The department may assess fees, the amounts of which are prescribed by the department by rule, for any of the following:

1. Issuance of an initial or renewal specific license under sub. (1) (a).

2. Annual license maintenance.

3. Issuance of a license amendment.

4. Termination of a license.

5. Issuance of reciprocal recognition of a license for radioactive materials of another state or the U.S. nuclear regulatory commission.

(b) The department may assess a late payment charge of 25% of the specific license renewal fee, in addition to the fee under par. (a) for renewal of a specific license, if payment for renewal of a specific license is not made within 30 days after the license expiration date.

(6) DENIAL, SUSPENSION OR REVOCATION OF LICENSURE. The department may, after a hearing under ch. 227, refuse to issue a license or suspend or revoke a license for failure by the licensee to comply with this subchapter, rules promulgated by the department under this subchapter or any condition of the license.

(7) EXEMPTION. The department may exempt from licensing requirements of this section radioactive material that the department finds is without undue radiation hazard. **NOTE: This section is created eff. 01–01–03 by 1999 Wis. Act 9.**

254.37 Enforcement. (1) NOTIFICATION OF VIOLATION AND ORDER OF ABATEMENT. Whenever the department finds, upon inspection and examination, that a source of radiation as constructed, operated or maintained results in a violation of this subchapter or of any rules promulgated under this subchapter, the department shall do all of the following:

(a) Notify the person in control that is causing, allowing or permitting the violation as to the nature of the violation.

(b) 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 this subchapter and rules promulgated under this subchapter.

(2) ORDERS. The department shall issue and enforce such orders or modifications of previously issued orders as may be required in connection with proceedings under this

subchapter. The orders shall be subject to review by the department upon petition of the persons affected. Whenever the department finds that a condition exists that constitutes an immediate threat to health due to violation of this subchapter or any rule or order promulgated under this subchapter, it may issue an order reciting the existence of the threat and the findings pertaining to the threat. The department may summarily cause the abatement of the violation.

(3) RULES. The department shall promulgate and enforce the rules pertaining to ionizing radiation.

(4) JURISDICTION. The circuit court of Dane County shall have jurisdiction to enforce the orders by injunctional and other appropriate relief.

254.38 Emergency authority. (1) IMPOUNDING MATERIALS. The department may impound or order the sequestration of sources of radiation in the possession of any person who is not equipped to observe or who fails to observe safety standards to protect health that are established in rules promulgated by the department.

(2) EMERGENCY ORDERS. If the department finds that an emergency exists concerning a matter subject to regulation under this subchapter that requires immediate action to protect the public health or safety, the department may issue an emergency order without notice or hearing that recites the existence of the emergency and requires such action as is necessary to mitigate the emergency. Any person to whom the order is issued shall immediately comply with the order. A person to whom an emergency order is issued shall be afforded a hearing within 30 days after receipt by the department of a written request for the hearing. An emergency order is effective upon issuance and remains in effect for up to 90 days after issuance, except that the order may be revoked or modified based on the results of the hearing.

254.39 Exceptions. (1) Nothing in this subchapter may be interpreted as limiting intentional exposure of persons to radiation for the purpose of analysis, diagnosis, therapy, and medical, chiropractic or dental research as authorized by law.

(2) This subchapter does not apply to on–site activities of any nuclear reactor plant licensed by the U.S. nuclear regulatory commission.

254.41 Radiation monitoring of nuclear power plants. The department shall take environmental samples to test for radiation emission in any area of the state within 20 miles of a nuclear power plant. The department shall charge the owners of each nuclear power plant in the state an annual fee of $30,000 per plant, commencing in fiscal year 1983–84, to finance radiation monitoring under this section. The department may change this annual fee by rule.

254.45 Penalties. (1) GENERAL. (a) Any person who violates this subchapter or a rule promulgated under this subchapter or a condition of a license or registration issued by the department under this subchapter may be required to forfeit not less than $100 nor more than $100,000. Each day of continued violation constitutes a separate offense.

(b) The amount of the forfeiture assessed under par. (a) shall be determined by considering all of the following:

1. The willfulness of the violation.

2. The person's previous violations, if any, of this subchapter, rules promulgated under this subchapter or conditions of a license or registration issued by the department under this subchapter.

3. The potential danger or actual or potential injury to the environment or to public health caused by the violation.

4. The actual or potential costs of the damage or injury caused by the violation.

(2) ASSESSMENT OF FORFEITURES; NOTICE. The department may directly assess forfeitures provided for in sub. (1). If the department determines that a forfeiture should be assessed for a particular violation, the department shall send a notice of assessment to the person. The notice shall specify the amount of the forfeiture assessed and the violation and the statute or rule alleged to have been violated and shall inform the person of the right to hearing under sub. (3).

(3) HEARING. A person upon whom a forfeiture is imposed may contest the action by sending, within 10 days after receipt of notice of a contested action, a written request for hearing under s. 227.44 to the division of hearings and appeals created under s. 15.103 (1). The administrator of the division may designate a hearing examiner to preside over the case and recommend a decision to the administrator under s. 227.46. The decision of the administrator of the division shall be the final administrative decision. The division shall commence the hearing within 30 days of receipt of the request for hearing and shall issue a final decision within 15 days after the close of the hearing. Proceedings before the division are governed by ch. 227.

(4) FORFEITURE PAYMENT AND DISPOSITION. (a) A person against whom the department has assessed a forfeiture shall pay the forfeiture to the department within 10 days after receipt of the notice under sub. (2) or, if the person contests the assessment, within 10 days after receipt of the final decision after exhaustion of administrative review. If the person petitions for judicial review under ch. 227, the person shall pay the forfeiture within 10 days after receipt of the final judicial decision.

(b) The department shall remit all forfeitures paid to the state treasurer for deposit in the school fund.

(5) ENFORCEMENT. The attorney general may bring an action in the name of the state to collect any forfeiture imposed under this section if the forfeiture has not been paid as required under sub. (4). The only issue to be contested in an action under this subsection is whether the forfeiture has been paid.

FINAL HFS 157

August 1, 2002

Chapter HFS 157

RADIATION PROTECTION

Note: Chapter HSS 157 as it existed on July 31, 2002 was repealed and a new chapter HFS 157 was created effective August 1, 2002, except subchapters II, VI and VII will go into effect 30 days after signature by the Governor of an agreement transferring regulatory authority to the state.

Subchapter I — General Provisions

HFS 157.01 Authority and purpose. (1) This chapter is promulgated under the authority of ss. 254.31 to 254.45, Stats. to regulate the receipt, use, transfer, possession, ownership or acquisition of any source of radiation. The standards in this chapter generally conform to nationally accepted standards for protection against the harmful effects of ionizing radiation. The publications referenced in this chapter are available for inspection at the department, the secretary of state's office, the office of the revisor of statutes and at the respective federal agency or organization website.

(2) Subchapter I establishes the definitions used in this chapter, prohibitions and general regulatory requirements.

(3) Subchapter II establishes requirements for the licensing of radioactive material, license fee schedules, registration requirements for certain types of devices purchased under a general license and reciprocity requirements.

(4) Subchapter III establishes standards for protection against ionizing radiation resulting from activities conducted under a license or registration issued by the department. The require-

ments of subch. III are designed to control the receipt, possession, use, transfer and disposal of sources of radiation by any licensee or registrant so that the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in subch. III. However, nothing in subch. III limits actions the department may take to protect health and safety in an emergency.

(5) Subchapter IV establishes radiation safety requirements for persons using sources of radiation in industrial radiography.

(6) Subchapter V establishes radiation safety requirements for using sources of radiation for wireline service operations including mineral–logging, radioactive markers and subsurface tracer studies. The requirements of subch. V are in addition to the requirements of subchs. I, II, III, VIII and X.

(7) Subchapter VI establishes requirements for the medical use of radioactive material. The requirements provide for the radiation safety of workers, the general public and human research subjects.

(8) Subchapter VII establishes radiation safety requirements for operating irradiators that use sealed sources containing radioactive material to irradiate objects or materials using gamma radiation.

(9) Subchapter VIII establishes requirements for the use of diagnostic or therapeutic x–ray equipment, including accelerators, by or under the supervision of an individual authorized and licensed by state statutes to engage in the healing arts or veterinary medicine, and to establish registration requirements for radiation machines.

(10) Subchapter IX establishes radiation safety requirements for the use of cabinet and analytical x–ray systems.

(11) Subchapter X establishes requirements for persons licensed or registered under this chapter to provide workers with notices, instructions and reports relating to activities under a license or registration.

(12) Subchapter XI establishes options available to facilities and individuals in connection with department inspections to determine compliance with the provisions of this chapter and radiological working conditions or other requirements specified in a license.

(13) Subchapter XII establishes classification and fiscal penalty criteria for violations of license conditions, emergency orders or the requirements of this chapter; and criteria for requesting and scheduling hearings to contest department assessments of forfeiture, licensing actions or emergency orders.

(14) Subchapter XIII establishes requirements for the packaging, preparation for shipment and transportation of radioactive material.

(15) Subchapter XIV establishes radioactivity requirements for community water systems.

(16) Subchapter XV establishes fees for the annual registration of ionizing radiation installations utilizing radioactive materials. The fees in subch. XV replace the fees established in s. 254 35 (3) (f), Stats., as allowed under s. 254.35 (3) (g), Stats.

History: CR 01–108: cr. Register July 2002 No. 559, eff. 8–1–02; corrections in (16) made under s. 13.93 (2m) (b) 7., Stats., Register July 2002 No. 559.

HFS 157.02 Applicability. (1) Except as specified, this chapter applies to all persons who receive, possess, use, transfer, own or acquire any source of radiation, except that nothing in this chapter shall apply to any person subject to regulation by the U.S nuclear regulatory commission.

(2) A licensee subject to the requirements of subch. II is also subject to the requirements of subchs. I, III, X and XIII.

(3) Subchapter III applies to all persons licensed or registered by the department to receive, possess, use, transfer or dispose of sources of radiation. The limits in subch. III do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs

(4) The requirements of subch. IV are for industrial radiography operations and are in addition to the requirements of subchs. I, II, III, VIII, X, XI, XII, XIII and XV.

(5) Subchapter V applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral–logging, radioactive markers and subsurface tracer studies. The requirements of subch V are in addition to the requirements of subchs. I, II, III, VIII, X, XI, XII, XIII and XV.

(6) Subchapter VI applies to all persons using radioactive material in the healing arts. The requirements of subch. VI are in addition to the requirements of subchs. I, II, III, X, XI, XII, XIII and XV.

(7) Subchapter VII applies to panoramic irradiators having either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are submerged. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by subch. VII. Nothing in subch VII relieves a licensee from complying with other federal, state and local regulations governing the siting, zoning, land use and building code requirements for industrial facilities. Subchapter VII does not apply to self–contained dry–source–storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel, medical radiology or teletherapy, radiography for the irradiation of materials for nondestructive testing purposes, gauging or open–field, agricultural irradiations. The requirements of subch. VII are in addition to the requirements of subchs. I, II, III, X, XI, XII, XIII and XV

(8) Subchapter VIII applies to all persons registered to use x–ray devices. The requirements of subch. VIII are in addition to the requirements of subchs. I, III, X, XI and XII.

(9) Subchapter IX applies to all persons registered to use cabinet and analytical x–ray devices. The requirements of subch. IX are in addition to the requirements of subchs. I, III, VIII, X, XI and XII.

(10) The requirements of subch. X apply to all persons who receive, possess, use, own or transfer sources of radiation registered with or licensed by the department under subchs. II, VIII and XV of this chapter.

(11) Subchapter XI applies to all persons who receive, possess, use, own or transfer radioactive materials or radiation producing machines licensed by or registered with the department.

(12) Subchapter XII applies to all persons who possess, use, store, transfer or receive radioactive materials, or who possess radiation machines.

(13) Subchapter XIII applies to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

(14) The radioactivity requirements in subch. XIV apply to all community water systems, except those meeting all of the conditions of s. HFS 157 95.

(15) The fees established in subch. XV apply to all ionizing radiation installations utilizing naturally occurring or accelerator produced radioactive materials in any quantity.

History: CR 01–108: cr. Register July 2002 No. 559, eff. 8–1–02.

HFS 157.03 Definitions. In this chapter:

(1) "A_1" means the maximum activity of special form radioactive material permitted in a type A package.

(2) "A_2" means the maximum activity of radioactive material, other than special form, LSA and SCO material, permitted in a type A package.

Note: The maximum activity values are either listed in Appendix O, table VI or may be derived under the procedure prescribed in Appendix O

(3) "Absorbed dose or "D" means the energy imparted by ionizing radiation per unit of mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

(4) "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for accelerators.

(5) "Accelerator" means any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particle or other radiation into a medium at energies usually in excess of one MeV.

(6) "Accelerator–produced material" means any material made radioactive by an accelerator.

(7) "Accessible surface" means surface of equipment or of an equipment part, housing or enclosure of the radiation producing machine that may be easily or accidentally touched by persons without the use of a tool.

(8) "Act" means ss. 254 31 to 254.45, Stats.

(9) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel and the curie.

(10) "Added filtration" means any filtration which is in addition to the inherent filtration.

(11) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, used or stored.

(12) "Adult" means an individual 18 or more years of age.

(13) "Agreement state" means any state with which the U.S. nuclear regulatory commission or the U.S. atomic energy commission has entered into an effective agreement under 42 USC 2201.

(14) "Air–purifying respirator" means a respirator with an air–purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air–purifying element.

(15) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors or gases.

(16) "Airborne radioactivity area" means a room, enclosure or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations that meet either of the following criteria:

(a) In excess of the derived air concentrations specified in Appendix E, table I.

(b) An individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake or 12 DAC–hours.

(17) "Air kerma" or "K" means the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles per unit mass of air. Kerma is determined as the quotient of dE divided by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray.

(18) "Alarming ratemeter" means a radiation measurement device that may be set to alarm at a pre–set dose rate.

(19) "Alert" means an event may occur, is in progress, or has occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect people offsite.

(20) "Alignment helmet" means a guide placed on the head that directs radiation to a specific site during stereotactic surgery.

(21) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

Note: The nominal chemical composition of type 1100 aluminum is 99 00 percent minimum aluminum and 0.12% copper.

(22) "Analytical x–ray system" means x–ray equipment designed to analyze the composition of materials.

(23) "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography.

(24) "Annual limit on intake" or "ALI" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. Annual limit on intake is the smaller value of intake of a given radionuclide in a year by the reference person that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue.

Note: Annual limit on intake values for intake by ingestion and by inhalation of selected radionuclides are given in table I, columns 1 and 2, of Appendix E.

(25) "ANSI" means the American National Standards Institute.

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

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

(28) "Assembler" means any person engaged in the business of assembling, replacing or installing one or more components into an x–ray system or subsystem. The term includes the owner of an x–ray system or his or her employee or agent who assembles components into an x–ray system that is subsequently used to provide professional or commercial services.

(29) "Assigned Protection Factor" or "APF" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly trained and fitted users. Operationally, the inhaled concentration may be estimated by dividing the ambient airborne concentration by the APF.

(30) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides or comes in contact with the source.

Note: Examples of associated equipment include a guide tube, control tube, control cable, removable source stop, "J" tube and collimator when used as an exposure head.

(31) "Atmosphere–supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied–air respirators and self–contained breathing apparatus units.

(32) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

(33) "Authorized nuclear pharmacist" means a pharmacist licensed by the state under ch. 450, Stats., and who fulfills at least one of the following:

(a) Meets the requirements in s. HFS 157.61 (9) and (11).

(b) Is identified as an authorized nuclear pharmacist on a nuclear regulatory commission or agreement state license or other equivalent permit or license recognized by the NRC that authorizes the medical use of radioactive material or the practice of nuclear pharmacy.

(c) Is identified as an authorized nuclear pharmacist on a permit issued by an NRC or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material or the practice of nuclear pharmacy.

(d) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy authorized by the NRC or an agreement state to approve authorized nuclear pharmacists.

(34) "Authorized user" means a state licensed person engaged in the healing arts who fulfills at least one of the following

(a) Meets the recentness of training requirements in s. HFS 157 61 (11) and the certification requirement, depending upon the desired use of the radioactive material, found in any of the following:

1. Section HFS 157.63 (4) (a).
2. Section HFS 157.63 (5) (a).
3. Section HFS 157.64 (4) (a).
4. Section HFS 157.64 (5) (a).
5. Section HFS 157.64 (6) (a).
6. Section HFS 157.65 (8) (a).
7. Section HFS 157.66 (2) (a).
8. Section HFS 157.67 (17) (a).

(b) Is identified as an authorized user on a nuclear regulatory commission or agreement state license or other equivalent permit or license recognized by the NRC that authorizes the medical use of radioactive material.

(c) Is identified as an authorized user on a permit issued by a nuclear regulatory commission or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

(35) "Automatic exposure control" or "AEC" means a device that automatically controls one or more technique factors to obtain at a preselected location a required quantity of radiation.

Note: Examples of an automatic exposure control includes devices such as phototimers and ion chambers.

(36) "Autoradiograph" means a radiographic image created by placing a sealed source on radiographic film to directly expose the film.

(37) "Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of a licensee or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by the department.

(38) "Barrier" means a device or material used to restrict access to an area.

(39) "Beam axis" means a line from the source through the centers of the radiation fields.

(40) "Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam

(41) "Beam scattering foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons to provide a more uniform electron distribution in the useful beam.

(42) "Beam-limiting device" means a field defining collimator that provides a means to restrict the dimensions of the useful beam to the desired dimensions.

(43) "Becquerel" or "Bq" means the SI unit of activity. One becquerel equals one disintegration or transformation per second. The special unit of decay is the curie and is being replaced by the becquerel

(44) "Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

(45) "Bioassay" means the determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting or by analysis and evaluation of materials excreted or removed from the human body.

(46) "Brachytherapy" means a method of radiation therapy in which sealed sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary or interstitial application.

(47) "Brachytherapy source" means a radioactive material or a manufacturer-assembled material train or a combination of these materials.

(48) "Broad scope license" means a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of up to multi-curie quantities of radioactive material, including the establishment of administrative procedures that assure control of procurement and safe use of radioactive materials.

Note: Section HFS 157 13 (3) (b) describes the different types of broad scope licenses

(49) "Buffer zone" means a portion of a disposal site that is controlled by the licensee that lies under the disposal units and is between the disposal units and the site boundary.

(50) "Byproduct material" means either of the following:

(a) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

(51) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in s. HFS 157 23 (1)

(52) "Cabinet x-ray system" means an x-ray system, manufactured under the requirements of 21 CFR 1020.40, with an x-ray tube installed in an enclosure that is independent of existing architectural structures except the floor. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and exclude personnel from its interior during generation of radiation. "Cabinet x-ray system" includes x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and in similar facilities. An x-ray tube used within a shielded part of a building or x-ray equipment that may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(53) "Calendar quarter" means a period of time equal to one-fourth of the year observed by the licensee or registrant, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Note: A calendar quarter is approximately 13 consecutive weeks

(54) "C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system to maintain a desired spatial relationship. The system allows the operator to change the projection of the beam through the patient without changing the position of the patient.

(55) "Calibration" means determining either of the following:

(a) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument.

(b) The strength of a source of radiation relative to a standard.

(56) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract or private carrier or by civil aircraft.

(57) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(58) "Certified components" means components of x-ray systems subject to 21 CFR 1010.2.

(59) "Certified system" means any x-ray system that has one or more components certified under 21 CFR 1010.2.

(60) "Certifying entity" means an independent certifying organization meeting the requirements in 10 CFR 34, Appendix A or an agreement state meeting the requirements in 10 CFR 34, Appendix A, Parts II and III.

(61) "Changeable filters" means any filter, exclusive of inherent filtration, that may be removed from the useful beam through any electronic, mechanical or physical process.

(62) "Chelating agent" means a chemical compound used to remove radioactive material from other substances.

Note: Examples of chelating agents are amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid and polycarboxylic acids

(63) "Chiropractor" means an individual licensed under ch. 446, Stats., to practice chiropractic.

(64) "Class" means a classification scheme for inhaled material according to the material's rate of clearance from the pulmonary region of the lung. Materials are classified as D, W or Y, depending on the amount of time half of the material clears from human lungs. Half of class D material clears from lungs in less than 10 days; half of class W material clears from lungs in from 10 to 100 days; and half of class Y material clears from lungs in greater than 100 days.

(65) "Cinefluorography" means the continuous recording of a fluoroscopy image using movie film.

(66) "Client's address" means the area of use or a temporary jobsite for the purpose of providing mobile medical service.

(67) "Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing a radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides and ends. In the case of packaged materials, the vehicle may be of the "see-through" type that allows observation of the packages while prohibiting access.

(68) "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a set of observations. Coefficient of variation is estimated using the following equation:

where:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}(x_i-\bar{x})^2}{n-1}\right]^{1/2}$$

s = standard deviation of the observed values;

$\bar{x}$ = mean value of observations in sample;

x_i = ith observation in sample; and

n = number of observations in sample.

(69) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(70) "Collimator" means one of the following:

(a) A radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is moved into position to make a radiographic exposure.

(b) A device attached to an x-ray tube that limits the radiation area.

(71) "Commission" means the United States nuclear regulatory commission.

(72) "Committed dose equivalent" or "CDE" means the dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(73) "Committed effective dose equivalent" or "CEDE" is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues.

Note: Committed effective dose equivalent ($H_{E,50}$) equals the sum of the weighting factor (w_T) times the committed dose equivalent ($H_{T,50}$)

(74) "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(75) (a) "Computed tomography dose index" or "CTDI" means the integral from –10T to +10T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT}\int_{-10T}^{+10T} D(z)dz$$

where:

z = position along a line perpendicular to the tomographic plane;

D(z) = dose at position z;

T = nominal tomographic section thickness in millimeters;

n = number of tomograms produced in a single scan.

(b) The definition of "computed tomography dose index" assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

(76) "Constraint" means a value above which specified licensee or registrant actions are required.

(77) "Contact therapy system" means a therapeutic radiation machine with a short target to skin distance, usually less than 5 centimeters.

(78) "Control cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

(79) "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

(80) "Control panel" means that part of an x-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

(81) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

(82) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which may be limited by the licensee or registrant for any reason.

(83) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(84) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(85) "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system includ-

ing nominal tomographic section thickness, filtration and the technique factors as defined in s. HFS 157.84.

(86) "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors and the supporting structures and frames that hold these components.

(87) "CT number" or "CTN" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image as expressed in the following equation:

$$CTN = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

K = a constant, a normal value of 1,000 when the Hounsfield scale of CTN is used,

μ_x = linear attenuation coefficient of the material of interest;

μ_w = linear attenuation coefficient of water.

(88) "Curie" or "Ci" means 3.7×10^{10} disintegrations per second = 3.7×10^{10} becquerels = 2.22×10^{12} disintegrations per minute

(89) "Dead-man switch" means a switch so constructed that a circuit closing contact may be maintained only by continuous pressure on the switch by the operator.

(90) "Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(91) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license; or release of the property under restricted conditions and termination of the license.

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

(93) "Deep dose equivalent" or "H_d" means the dose equivalent at a tissue depth of one centimeter (1000 mg/cm^2) and applies to external whole body exposure.

(94) "Deliberate misconduct" means an intentional act or omission that the person knows would cause any of the following:

(a) A licensee, registrant or applicant to be in violation of any requirement under this chapter, any order of the department, or any term, condition or limitation of any license or registration issued by the department under this chapter.

(b) A violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, registrant, applicant, or contractor or subcontractor of a licensee, registrant or applicant.

(95) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the face piece only when a negative pressure is created inside the facepiece by inhalation.

(96) "Dentist" means an individual licensed under ch. 447, Stats., to practice dentistry.

(97) "Department" means the department of health and family services.

(98) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(99) "Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI.

Note: For purposes of this chapter, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, column 3, of Appendix E.

(100) "Derived air concentration-hour" or "DAC-hour" means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(101) "Detector" means a device which in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(102) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(103) "Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

(104) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus.

Note: Sorbent exhaustion refers to the inability of an absorbent material to absorb any more of the material for which it was designed.

(105) "Disposal" means the isolation of radioactive wastes from the environment inhabited by man and containing his food-chains by emplacement in a land disposal facility.

(106) "Disposal site" means that portion of a land disposal facility which is used for the disposal of waste. It consists of disposal units and a buffer zone.

(107) "Disposal unit" means a discrete portion of a disposal site into which waste is placed for disposal.

(108) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of that site or, in the case of structures, in similar materials using adequate measurement technology, survey and statistical techniques.

(109) "Dose equivalent" or "H_T" means the product of the absorbed dose in tissue, quality factor and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert and rem.

(110) "Dose limits" means the permissible upper bounds of radiation doses established under this chapter.

(111) "Dose monitor unit" means a unit response from the beam monitoring system from which the absorbed dose may be calculated

(112) "Dose profile" means the dose as a function of position along a line.

(113) "Dosimeter" means a recording device used to measure exposure to ionizing radiation.

(114) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices to determine the radiation dose delivered to the monitoring devices

(115) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

(116) "Effective dose equivalent" or "EDE" means the sum of the products of the dose equivalent to each organ or tissue and the weighting factor applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma\, w_T H_T$).

Note: Effective dose equivalent (H_E) equals the sum of the weighting factor (w_T) times the dose equivalent to each organ or tissue (H_T).

(117) "Electron microscope" means a microscope utilizing electrons to provide high magnification examination of materials.

(118) "Elemental area" means the smallest area within a tomogram for which the x–ray attenuation properties of a body are depicted.

(119) "Embryo or fetus" means the developing human organism from conception until the time of birth.

(120) "Emergency" means an event requiring prompt action to mitigate a threat to the health and safety of workers and the public or a threat of damage to the environment.

(121) "Energy compensation source" or "ECS" means a small sealed source, with an activity not exceeding 3.7 MBq (100 microcuries), used within a well logging tool, or other tool components, to provide a reference standard to maintain the well logging tool's calibration when in use.

(122) "Enriched uranium" means uranium containing more uranium–235 than the naturally occurring distribution of uranium isotopes.

(123) "Entrance air kerma rate" means the air kerma free in air per unit time at the point where the center of the useful beam enters the patient.

(124) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(125) "Explosive material" means any chemical compound, mixture or device that produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(126) "Exposure" means the quotient of dQ divided by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram. The standard unit of exposure is the roentgen.

(127) "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position.

(128) "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

(129) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(130) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

(131) "External sinking fund" means an account, segregated from licensee assets and outside the licensee's administrative control, into which monies are periodically deposited that are sufficient to pay decommissioning costs expected at the time licensee operations are terminated.

(132) "Extremity" means hand, elbow, arm below the elbow, foot, knee and leg below the knee.

(133) "Extremity bone densitometer" means a device that tests the mineral content of the bone of the fore arm, hand or foot.

(134) "FDA" means the U.S. food and drug administration.

(135) "Field emission equipment" means equipment that uses an x–ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(136) "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

(137) "Film badge" means a dosimeter containing radiation sensitive photographic film for measuring radiation dose plus various filters that characterize the type of radiation encountered. When developed, the darkness of the film is directly proportional to the amount of radiation received.

(138) "Filter" means material placed in the useful beam to preferentially absorb selected radiation energies.

(139) "Filtering facepiece" means a negative pressure respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

Note: Elastomeric refers to material that is elastic and form fitting to provide a tight seal against the face.

(140) "Fissile material" means plutonium–238, plutonium–239, plutonium–241, uranium–233, uranium–235 or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition.

(141) "Fissile material package" means a fissile material packaging together with its fissile material contents.

(142) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(143) "Fit test" means the use of a protocol to qualitatively ir quantitatively evaluate the fit of a respirator on an individual.

(144) "Fluoroscopic imaging assembly" means a subsystem in which x–ray photons produce a visible image. It includes the image receptor such as the image intensifier and spot–film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(145) "Fresh water aquifer" means, for the purposes of this chapter, a geologic formation that is capable of yielding fresh water to a well or spring.

(146) "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

(147) "General purpose radiographic x–ray system" means any radiographic x–ray system, which, by design, is not limited to radiographic examination of specific anatomical regions.

(148) "Gamma stereotactic radiosurgery" means the use of a device containing a radioactive material providing multiple point radiation therapy treatment to a specific tumor site.

(149) "Generally applicable environmental radiation standards" means standards issued by the U.S. environmental protection agency under the authority of 42 USC 23, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(150) "Gonad shield" means a protective barrier for the testes or ovaries.

(151) "Gray" or "Gy" means the SI unit of absorbed dose, air kerma and specific energy imparted equal to one joule per kilogram.

Note: The special unit of absorbed dose is being replaced by the gray. 1 Gy equals 100 rad.

(152) "Guide tube" means a flexible or rigid tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

(153) "Half–value layer" or "HVL" means the thickness of specified material which attenuates an x–ray or gamma radiation beam such that the air kerma rate at a point within the radiation beam is reduced to one–half of the air kerma rate at the same point without the material present. In this definition, the contribution of all scattered radiation, other than any that might be present initially in the radiation beam concerned, is excluded.

(154) "Hands–on experience" means experience in all of those areas considered to be directly involved in the radiography process.

Note: "Hands–on experience" includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of warning signs in radiation areas, transportation of radiography equipment, posting on a bulletin board of records and radiation area surveillance, as applicable

(155) "Healing arts" means a profession concerned with diagnosis and treatment of human maladies, including the practice of medicine, dentistry, osteopathy chiropractic and podiatry.

(156) "Healing arts screening" means the exposure of a human being to x–rays without prior examination disclosing a need for an x–ray procedure and prescription for such a study by a practitioner of the healing arts

(157) "Heat unit" means a unit of energy equal to 0.75 joule. It is approximately equal to the energy given by the product of the peak kilovoltage, milliampere and seconds, which is kVp x mA x time in seconds.

(158) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(159) "High dose–rate remote afterloader" or "HDR" means a device that delivers a dose rate in excess of 12 gray (1200 rads) per hour.

(160) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

(161) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(162) "Human use" means the internal or external administration of radiation or radioactive material to human beings.

(163) "Image intensifier" means a device, installed in its housing, which instantaneously converts an x–ray pattern into a corresponding light image of higher intensity.

(164) "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

(165) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x–ray photons either into a visible image or into another form that may be made into a visible image by further transformations.

(166) "Independent certifying organization" means an independent organization that meets all of the criteria specified in 10 CFR 34, Appendix A.

(167) "Individual" means any human being.

(168) "Individual monitoring" means the assessment of any of the following:

(a) Dose equivalent by the use of individual monitoring devices or by the use of survey data.

(b) Committed effective dose equivalent by bioassay or by determination of the time–weighted air concentrations to which an individual has been exposed

(169) "Individual monitoring devices," mean devices designed to be worn by a single individual for the assessment of dose equivalent. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters, optically stimulated luminescent dosimeters, pocket dosimeters, direct reading dosimeters and personal air sampling devices.

(170) "Industrial radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

(171) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

(172) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

(173) "Inspection" means an official examination or observation by the department including tests, surveys and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the department.

(174) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(175) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body

(176) "Ionizing radiation" means alpha particles, beta particles, gamma rays, x rays, neutrons, high–speed electrons, high–speed protons and other particles capable of producing ions "Ionizing radiation" does not include radiowaves or microwaves, visible, infrared or ultraviolet light.

(177) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

(178) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(179) "Irradiator operator" means an individual who has successfully completed the training and testing described in s. HFS 157.73 (12) and is authorized by the terms of the license to operate the irradiator without a supervisor present.

(180) "Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in s. HFS 157.73 (12).

(181) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

(182) "Kilovolt" or "kV" means the energy equal to that acquired by a photon with one electron charge in passing through a potential difference of 1,000 volts in a vacuum.

Note: Current convention uses kV to designate photons and keV to designate electrons.

(183) "Kilovolts peak" or "kVp" means the maximum value of the potential difference across an x–ray tube during an exposure

(184) "kWs" means kilowatt second

(185) "Land disposal facility" means the land, buildings and structures, and equipment used for the disposal of radioactive wastes.

(186) "Lay–barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

(187) "Lead equivalent" means the thickness of the material in question affording the same attenuation as lead.

(188) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for any of the following:

(a) The useful beam.

(b) Radiation produced when the exposure switch or timer is not activated

(189) "Lens dose equivalent" or "LDE" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).

(190) "Licensed or registered material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license or registration issued by the department.

(191) "Licensed practitioner" means a chiropractor, dentist, physician or podiatrist licensed in the state of Wisconsin.

(192) "Licensing state" means any state approved by the Conference of Radiation Control Program Directors, Inc., as having regulations equivalent to the Suggested State Regulations for Control of Radiation relating to NARM and an effective program for the regulatory control of NARM.

(193) "Light field" means the area of the intersection of the light beam from the beam–limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one–fourth of the maximum in the intersection.

(194) "Logging tool" means a device used subsurface to perform well logging.

(195) "Loose–fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(196) "Lost or missing licensed or registered source of radiation" means a licensed or registered source of radiation whose location is unknown. This definition includes licensed or registered material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(197) "Low dose–rate remote afterloader" or "LDR" means a device that delivers a dose rate of less than or equal to 2 gray (200 rads) per hour.

(198) "Low specific activity – I" or "LSA–I material" means any of the following:

(a) Ores containing only naturally occurring uranium or thorium decay series radionuclides and uranium or thorium concentrates of such ores.

(b) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures.

(c) Radioactive material, other than fissile material, for which the A_2 value is unlimited.

(d) Mill tailings, contaminated earth, concrete, rubble, other bulk debris and activated material in which the radioactive material is essentially uniformly distributed and the average specific activity does not exceed 10^{-6} A_2/g.

(199) "Low specific activity – II" or "LSA–II material" means either of the following:

(a) Water with tritium concentration up to 0.8 terabecquerel per liter (20.0 Ci/L).

(b) Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed 10^{-4} A_2/g for solids and gases and 10^{-5} A_2/g for liquids.

(200) "Low specific activity – III" or "LSA–III material" means solids, such as consolidated wastes or activated materials, for which all of the following apply:

(a) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent, for example, concrete, bitumen or ceramic.

(b) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed 0.1 A_2.

(c) The average specific activity of the solid does not exceed 2×10^{-3} A_2/g.

(201) "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium–235, uranium–238, thorium–232, thorium–228 or thorium–230 when contained in ores or physical or chemical concentrates; or alpha emitters with a half–life of less than 10 days.

(202) "mA" means milliampere.

(203) "Mammography" means radiography of the breast, but does not include radiography of the breast performed during invasive interventions for localization or biopsy procedures.

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

(205) "Manual brachytherapy" means a type of brachytherapy in which the radioactive sources are manually inserted either into the body cavities that are in close proximity to a tumor or directly into the tumor volume.

Note: Examples of radioactive sources are seeds and ribbons

(206) "mAs" means milliampere second.

(207) "Maximum line current" means the root–mean–square current in the supply line of an x–ray machine operating at its maximum rating.

(208) "Medical event" means an improper administration of radiation or radioactive material to a patient or human research subject that requires reporting to the department.

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

(210) "Medical physicist" means an individual with any of the following qualifications:

(a) Certified by the American board of radiology in one or more of the following:

1. Therapeutic radiological physics.
2. Roentgen–ray and gamma–ray physics.
3. X–ray and radium physics.
4. Radiological physics.

(b) Certified by the American board of medical physics in radiation oncology physics.

(c) Certified by the Canadian college of medical physics.

(d) Meets the requirements specified in s. HFS 157.61 (8) and (11).

(e) Identified as a medical physicist on a specific medical use license or approved by a broad scope licensee, as specified in s. HFS 157.13 (3) (b).

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

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

(213) "Megavolt" or "MV" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum.

Note: The current convention is to use MV to designate photons and MeV to designate electrons

(214) "Member of the public" means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

(215) "Minor" means an individual less than 18 years of age.

(216) "Mobile medical service supplier" means a mobile service that carries or receives radioactive materials for medical use at a client's address.

(217) "Mobile x–ray equipment" means x–ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(218) "Moderator" means a material that decreases the energy of neutrons.

(219) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

(220) "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other or with any planned change of absorbed dose distribution It includes arc, skip, conformal, intensity modulation and rotational therapy.

(221) "Multiple tomogram system" means a computed tomography x–ray system that obtains x–ray transmission data simultaneously during a single scan to produce more than one tomogram image.

(222) "NARM" means any naturally occurring or accelerator–produced radioactive material. It does not include byproduct, source or special nuclear material.

(223) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

(224) "Natural thorium" means thorium isotopes with a naturally occurring distribution, which is essentially 100 weight percent thorium–232.

(225) "Natural uranium" means uranium isotopes with the naturally occurring distribution of uranium, which is approximately 0.711 weight percent uranium–235, and the remainder by weight essentially uranium–238.

(226) "Negative pressure respirator – tight fitting" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator

(227) "Neutron absorber" means a material that absorbs neutrons emitted from radioactive material.

(228) "Noble gas" means a chemically inert gas that does not combine with other elements.

(229) "Nominal tomographic section thickness" means the full width at half–maximum of the sensitivity profile taken at the center of the cross–sectional volume over which x–ray transmission data are collected.

(230) "Nominal treatment distance" means:

(a) For electron irradiation, the distance from the scattering foil, virtual source or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For x–ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non–isocentric equipment, this distance shall be that specified by the manufacturer.

(231) "Nonstochastic effect" or "deterministic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation–induced cataract formation is an example of a nonstochastic effect.

(232) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as special form radioactive material.

(233) "Notice of violation" means a written notice provided in response to an alleged infraction of ss. 254.31 to 254.45, Stats., this chapter, the conditions of a license or an order issued by the department.

(234) "NRC" means the U.S. nuclear regulatory commission.

(235) "Nuclear waste" means a quantity of source, byproduct or special nuclear material required to be in NRC–approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

Note: The definition of nuclear waste in this chapter is the same as that in 49 CFR 173.403

(236) "Optically stimulated luminescent dosimeter" or "OSL" means a dosimeter containing a crystalline solid for measuring radiation dose plus filters to help characterize the type of radiation encountered.

Note: When exposed to the appropriate energy of light, exposed optically stimulated luminescent crystals give off light proportional to the energy received from the radiation

(237) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation, or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee, registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under s. HFS 157.62 (8), from voluntary participation in medical research programs or as a member of the public.

(238) "Offshore platform radiography" means industrial radiography conducted from a platform over a body of water

(239) "Offsite response organization" means the non–licensee offsite organizations that may be needed to respond to an emergency, including local fire, police, ambulance and hospital services

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

(241) "Package" means the packaging together with its radioactive contents as presented for transport.

(242) "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of 49 CFR Part 173, Subpart I. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding and devices for cooling or absorbing mechanical shocks. The vehicle, tie–down system and auxiliary equipment may be designated as part of the packaging.

(243) "Panoramic dry–source–storage irradiator" means a device in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam–type dry–source–storage devices in which only a narrow beam of radiation is produced.

(244) "Panoramic irradiator" means a device in which the irradiations are performed in air in areas potentially accessible to personnel The term includes beam–type devices.

(245) "Panoramic wet–source–storage irradiator" means a device in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(246) "Pass box" means a box with openings on each side that is placed in a wall between an x–ray room and a darkroom allowing transfer of film holders between the 2 rooms.

(247) "Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

(248) "Periodic quality control check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

(249) "Permanent radiographic installation" means an enclosed shielded room, cell or vault, not located at a temporary jobsite, in which radiography is performed.

(250) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state

or political subdivision or agency thereof and any legal successor, representative, agent or agency of the foregoing, but does not include federal government agencies or Indian tribes or bands.

(251) "Person in control" means the individual directly responsible for safe operation of the radiation installation.

(252) "Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact may be maintained and immediate assistance given as required.

(253) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Note: This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

(254) "Pharmacist" means an individual licensed under ch. 450, Stats., to practice pharmacy.

(255) "Physician" means a medical doctor or doctor of osteopathy licensed under ch. 448, Stats., to prescribe drugs in the practice of medicine.

(256) "Picture element" means an elemental area of a tomogram.

(257) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits, that requires a licensee or registrant to calculate the dose to be received by individuals prior to initiation of the planned task, as required under s. HFS 157.22 (6).

(258) "Pocket dosimeter" means a type of individual monitoring device that allows the user to view the accumulated radiation exposure received as recorded by the device.

(259) "Podiatrist" means an individual licensed under ch. 448, Stats., to practice podiatry.

(260) "Pool irradiator" means any irradiator where the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

(261) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

(262) "Position indicating device" or "PID" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface distance from the skin.

Note: A position indicating device may or may not incorporate or serve as a beam-limiting device.

(263) "Positive beam limitation" or "PBL" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

(264) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(265) "Powered air-purifying respirator" or "PAPR" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(266) "Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

(267) "Preceptor" means an individual who provides or directs the training and experience requirements.

(268) "Prescribed dosage" means the specified activity or a range of activities of a drug containing radioactive material as documented by any of the following means:

(a) In a written directive or prescription.

(b) Under directions of the authorized user for procedures not requiring a written directive.

(269) "Prescribed dose" means any of the following:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive.

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive.

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

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

(270) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(271) "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

(272) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

(273) "Principal activities" means activities authorized by the license that are essential to achieving the purpose for which the license was issued or amended. "Principal activities" do not include storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning.

(274) "Product conveyor system" means a system for moving the product to be irradiated to, from and within the area where irradiation takes place.

(275) "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure to the wearer.

(276) "Protective barrier" means a primary or secondary protective barrier of radiation absorbing material or materials used to reduce radiation exposure.

(277) "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure and that surrounds the hand and fingers.

(278) "Public dose" means the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant or to any other source of radiation under the control of a licensee or registrant. It does not include occupational dose, dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under s. HFS 157.62 (8) or from voluntary participation in medical research programs.

(279) "Pulsed dose-rate remote afterloader" or "PDR" means a device that uses a single source capable of delivering dose rates in the high dose-rate range, but has both of the following characteristics:

(a) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources.

(b) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(280) "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 54.4° C (130° F). This includes spontaneously combustible and water-reactive materials.

(281) "Pyrophoric solid" means any solid material, other than an explosive material, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which may be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling or disposal hazard.

(282) "Qualitative fit test" or "QLFT" means a pass or fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(283) "Quality control" means an ongoing program to ensure continued reliable performance of the equipment designed to

detect changes which may result in a clinically significant degradation in image quality or a significant increase in radiation exposure.

(284) "Quality factor" or "Q" means the modifying factor listed in tables 157.06A and 157.06B of s HFS 157.06 (4) that is used to derive dose equivalent from absorbed dose.

(285) "Quantitative fit test" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(286) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

(287) "Radiation" means alpha particles, beta particles, gamma rays, x rays, neutrons, high–speed electrons, high–speed protons and other particles capable of producing ions. "Radiation" does not include non–ionizing radiation, such as radiowaves or microwaves, visible, infrared or ultraviolet light.

(288) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(289) "Radiation head" means the structure from which the useful beam emerges.

(290) "Radiation incident" means the loss of control of a radioactive source or materials or the unintended exposure of an individual to radiation that exceeds the limits in this chapter.

(291) "Radiation installation" means any location or facility where radiation machines are used or where radioactive material is produced, transported, stored, disposed of or used for any purpose.

(292) "Radiation machine" means any device capable of producing radiation, except those devices with radioactive material as the only source of radiation.

(293) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(294) "Radiation safety officer" or "RSO" means an individual who has the knowledge and training to apply appropriate radiation regulations and has been assigned the responsibility for the overall radiation safety program by the registrant or licensee and is identified on a registration or a specific license.

(295) "Radiation safety officer for industrial radiography" means an individual with the responsibility for the overall radiation safety program for a licensee or registrant and who meets the requirements of s. HFS 157.44 (2).

(296) "Radiation therapy simulation system" means a radiographic or fluoroscopic x–ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

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

(298) "Radioactive marker" means radioactive material placed in the well–bore or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

(299) "Radioactive material" means any solid, liquid or gas that emits radiation spontaneously

(300) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

(301) "Radiograph" means an image which is created directly or indirectly by radiation and results in a permanent record, either film or electronically stored image.

(302) "Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of this chapter and the conditions of the license or registration.

(303) "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the equivalent radiation safety, testing and experience criteria in s. HFS 157.44 (3) (a).

(304) "Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools or radiation survey instruments in industrial radiography.

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

(306) "Radiographic imaging system" means any system whereby a permanent or semi–permanent image is recorded on an image receptor by the action of ionizing radiation.

(307) "Radiographic operations" means all activities performed with a radiographic exposure device or with a radiation machine. Activities include using, transporting, except by common or contract carriers or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

(308) "Radionuclide" means a radioactive form of an element.

(309) "Rating" means the operating limits as specified by the component manufacturer.

(310) "Redundant beam monitoring system" means a combination of 2 dose monitoring systems in which each system is designed to terminate irradiation under a pre–selected number of dose monitor units.

(311) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(312) "Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

(313) "Regulations of the U.S Department of Transportation" means the regulations in 49 CFR 100 to 189 and 390 to 397.

(314) "Rem" means the special unit of any of the quantities expressed as dose equivalent.

Note: The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor One rem equals 0 01 sievert.

(315) "Research and development" means either of the following:

(a) Theoretical analysis, exploration or experimentation.

(b) The practical application of investigative findings and theories of a scientific or technical nature for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

(316) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater and other media at a site resulting from activities under the licensee's or registrant's control. "Residual radioactivity" includes radioactivity from all sources used by the licensee or registrant, but excludes background radiation. "Residual radioactivity" also includes radioac-

tive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of this chapter.

(317) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(318) "Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. "Restricted area" does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(319) "Roentgen" or "R" means the special unit of exposure. One roentgen equals 2.58E–4 coulombs per kilogram of air.

Note: See the definition of the term "exposure" and also s HFS 157 06 (4) for a further explanation of units of exposure.

(320) "Sanitary sewerage" means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks and leach fields owned or operated by the licensee or registrant.

(321) "Scan" means the complete process of collecting x–ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

(322) "Scan increment" means the amount of relative displacement of the patient with respect to the CT x–ray system between successive scans measured along the direction of such displacement.

(323) "Scan sequence" means a pre–selected set of 2 or more scans performed consecutively under pre–selected CT conditions of operation.

(324) "Scan time" means the period of time between the beginning and end of x–ray transmission data accumulation for a single scan.

(325) "Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

(326) "SCO–I" means an SCO for which all of the following apply:

(a) The non–fixed contamination on the accessible surface averaged over 300 cm^2 or the area of the surface if less than 300 cm^2 does not exceed 4 becquerels (10^{-4} μCi) per cm^2 for beta and gamma and low toxicity alpha emitters, or 0.4 becquerels (10^{-5} μCi) per cm^2 for all other alpha emitters.

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 or the area of the surface if less than 300 cm^2, does not exceed $4x10^4$ becquerels (1.0 μCi) per cm^2 for beta and gamma and low toxicity alpha emitters, or $4x10^3$ becquerels (0.1 μCi) per cm^2 for all other alpha emitters.

(c) The non–fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed $4x10^4$ becquerels (1.0 μCi) per cm^2 for beta and gamma and low toxicity alpha emitters, or $4x10^3$ becquerels (0.1 μCi) per cm^2 for all other alpha emitters.

(327) "SCO–II" means an SCO for which all of the following apply:

(a) The non–fixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed 400 becquerels (10^{-2} μCi) per cm^2 for beta and gamma and low toxicity alpha emitters or 40 becquerels (10^{-3} μCi) per cm^2 for all other alpha emitters.

(b) The fixed contamination on the accessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed $8x10^5$ becquerels (20 μCi) per cm^2 for beta and gamma and low toxicity alpha emitters, or $8x10^4$ becquerels (2 μCi) per cm^2 for all other alpha emitters.

(c) The non–fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2, or the area of the surface if less than 300 cm^2, does not exceed $8x10^5$ becquerels (20 μCi) per cm^2 for beta and gamma and low toxicity alpha emitters, or $8x10^4$ becquerels (2 μCi) per cm^2 for all other alpha emitters.

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

(329) "Sealed Source and Device Registry" or "SSDR" means the national registry that contains all the registration certificates, maintained by the NRC that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(330) "Secondary dose monitoring system" means a system that will terminate irradiation in the event of failure of the primary dose monitoring system.

(331) "Secondary protective barrier" means the material that attenuates stray radiation.

(332) "Self–contained breathing apparatus" or "SCBA" means an atmosphere–supplying respirator for which the breathing air source is designed to be carried by the user.

(333) "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

(334) "Shallow dose equivalent," "H_s" or "SDE" means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of one square centimeter. "Shallow dose equivalent" applies to the external exposure of the skin or an extremity.

(335) "SI" means the abbreviation for the International System of Units.

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

(337) "Shutter" means a device attached to the tube housing assembly which may totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(338) "Sievert" or "Sv" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The special unit of dose equivalent (rem) is being replaced by the sievert. 1 Sv=100 rem.

(339) "Single tomogram system" means a CT x–ray system which obtains x–ray transmission data during a scan to produce a single tomogram.

(340) "Site area emergency" means an event may occur, is in progress, or has occurred that could lead to a significant release of radioactive material and require a response by offsite response organizations to protect people offsite.

(341) "Site boundary" means that line beyond which the land or property is not owned, leased or otherwise controlled by the licensee or registrant.

(342) "Source" means the region and material from which the radiation emanates.

(343) "Source applicator" means a device used to place a radioactive source in a precise anatomical location within the body.

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

(345) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices

and which may also be used for transporting and storing sealed sources.

(346) "Source holder" means a housing or assembly into which a radioactive source is placed to facilitate the handling and use of the source in well logging operations.

(347) "Source–image receptor distance" or "SID" means the distance from the source of radiation to the center of the input surface of the image receptor.

(348) "Source material" means either of the following.

(a) Uranium or thorium, or any combination thereof, in any physical or chemical form.

(b) Ores that contain by weight one–twentieth of one percent or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

(349) "Special form radioactive material" means radioactive material that satisfies all the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that may be opened only by destroying the capsule.

(b) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 in.).

(c) It satisfies the test requirements specified by the NRC in 10 CFR 71.75 at the time of its design or construction.

(350) "Special nuclear material" means plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the nuclear regulatory commission determines to be special nuclear material; or any material artificially enriched by any of the foregoing. Special nuclear material does not include source material.

(351) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U–235 in quantities not exceeding 350 grams of contained U–235, uranium–233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them under the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination may not exceed one

Note: For example, the following quantities in combination would not exceed the limitation and are within the formula.

$$\frac{175 \text{ (grams contained U–235)}}{350} + \frac{50 \text{ (grams U–233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(352) "Special unit" means the alternative system of units for quantifying absorbed dose in rad, dose equivalent in rem and radioactivity in curie.

(353) "Specific activity" of a radionuclide means the radioactivity per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(354) "Specific license" means a license, under requirements prescribed by the department by rule, to possess, use, manufacture, produce, transfer or acquire radioactive material or devices or equipment utilizing radioactive material.

(355) "Spot film" means a radiograph, which is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

(356) "Spot–film device" means a device intended to transport and position a radiographic image receptor between an x–ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

(357) "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(358) "Stationary x–ray equipment" means x–ray equipment that is installed in a fixed location.

(359) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to deliver a dose to a tissue volume from multiple sources of radiation simultaneously.

(360) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

(361) "Storage area" means any secure location, facility or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, a storage container or a sealed source, when it is not in use.

(362) "Storage container" means a device in which sealed sources or radiation machines are secured and stored.

(363) "Stray radiation" means the sum of leakage and scattered radiation.

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

(365) "S–tube" means a tube through which the radioactive source travels when inside a radiographic exposure device

(366) "Subsurface" means below the surface of the earth

(367) "Subsurface tracer study" means the release of a substance tagged with radioactive material to trace the movement or position of the tagged substance in the well–bore or adjacent formation.

(368) "Supplied–air respirator" or "SAR" means an atmosphere–supplying respirator for which the source of breathing air is not designed to be carried by the user

(369) "Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

(370) "Surface contaminated object" or "SCO" means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces.

(371) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal or presence of sources of radiation. When appropriate, an evaluation includes tests, physical examinations and measurements of levels of radiation or concentrations of radioactive material present.

(372) "Target" means that part of an x–ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

(373) "Target–skin distance" or "TSD" means the distance measured along the beam axis from the center of the front surface of the x–ray target or electron virtual source to the surface of the irradiated object or patient.

(374) "Technique factors" means the following conditions of operation:

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x–ray pulses.

(c) For CT x–ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x–ray pulse width in milliseconds, and the number of x–ray pulses per scan; or the product of tube current, x–ray pulse width, and the number of x–ray pulses per scan expressed as mAs.

(d) For CT x–ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan

time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent.

(e) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

(375) "Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered from a source at a distance from the patient or human research subject.

(376) "Temporary job site" means a location where any of the following occur:

(a) Radiographic operations are performed and sources of radiation may be stored other than at the location or locations of use authorized on the license or registration.

(b) Radioactive materials are present for the purpose of performing wireline service operations or subsurface tracer studies.

(377) "Tenth–value layer" or "TVL" means the thickness of a specified material that attenuates x–radiation or gamma radiation to an extent that the air kerma rate; exposure rate or absorbed dose rate is reduced to one–tenth of the value measured without the material at the same point.

(378) "Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(379) "Test" means the process of verifying compliance with an applicable regulation.

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

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

(382) "Therapeutic radiation machine" means x–ray, gamma ray or electron–producing equipment designed and used for external beam radiation therapy.

(383) "Thermoluminescent dosimeter" or "TLD" means a dosimeter containing a crystalline solid for measuring radiation dose, plus filters to help characterize the types of radiation encountered. When heated, TLD crystals that have been exposed to ionizing radiation give off light proportional to the energy they received from the radiation.

(384) "Tight–fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(385) "Tomogram" means the depiction of the x–ray attenuation properties of a section through the body.

(386) "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

(387) "Tomographic section" means the volume of an object whose x–ray attenuation properties are imaged in a tomogram.

(388) "Total effective dose equivalent" or "TEDE" means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(389) "Total organ dose equivalent" or "TODE" means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose.

(390) "Transport index" means the dimensionless number, rounded up to the next tenth, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level at one meter (3.3 feet) from the external surface of the package in millisieverts per hour multiplied by 100, which is equivalent to the maximum radiation level in millirem per hour at one meter.

(391) "Transuranic waste" means waste containing elements having an atomic number greater than 92, a half–life greater than 5 years and in quantities greater than 3.7 kBq/gm (100 nCi/gm).

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

(393) "Tritium neutron generator target source" means a tritium target source used within a neutron generator tube to produce neutrons for use in well logging applications.

(394) "Tube housing assembly" means the tube housing with tube installed. It includes high–voltage, filament transformers and other appropriate elements which are contained within the tube housing.

(395) "Tube" means an x–ray tube, unless otherwise specified.

(396) "Type A package" means a packaging that, together with its radioactive contents limited to A_1 or A_2 as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding required under normal conditions of transport as demonstrated by the tests set forth in 49 CFR 173.465 or 173.466, as appropriate.

(397) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Appendix O or may be determined by procedures described in Appendix O.

(398) "Type B package" means packaging and the radioactive contents of the packaging that meet the requirements of 49 CFR Part 173.

Note: A Type B package design is designated as B(U) or B(M) B(U) refers to the need for unilateral approval of international shipments, B(M) refers to the need for multilateral approval. No distinction is made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173 .A Type B package approved prior to September 6, 1983 was designated only as Type B.

(399) "Type B quantity" means a quantity of radioactive material greater than a type A quantity.

(400) "Type of use" means use of radioactive material as specified in s. HFS 157.63 (1) or (2), 157.64 (1), 157.65 (1), 157.66 (1) or 157.67 (1).

(401) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

(402) "Underwater radiography" means industrial radiography performed when the radiographic exposure device and related equipment are beneath the surface of the water.

(403) "Unit dosage" means a quantity of radioactive material that meets all the following criteria:

(a) Is obtained or prepared under the requirements in s. HFS 157.63 (1) or (2) or 157.64 (1).

(b) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared, except to adjust the dosage to patient needs.

(404) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, refining or altering the ore from its natural state.

(405) "Unrestricted area" or "uncontrolled area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

(406) "Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

(407) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam–limiting device when the exposure controls are in a mode to cause the system to produce radiation.

(408) "User seal check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(409) "Variable–aperture beam–limiting device" means a beam–limiting device that has capacity for stepless adjustment of the x–ray field size at a given SID.

(410) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates.

(411) "Virtual source" means a point from which radiation appears to originate.

(412) "Visible area" means that portion of the input surface of the image receptor over which incident x–ray photons are producing a visible image.

(413) "Waste" means those materials having a low level of radioactivity that are acceptable for disposal in a land disposal facility and are not classified as high–level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in 42 USC 2011.

(414) "Waste handling licensee" mean a person licensed to receive and store radioactive residue prior to disposal and a person licensed to dispose of radioactive residue.

(415) "Wedge filter" means a filter which effects continuous change in transmission over all or a part of the useful beam.

(416) "Week" means 7 consecutive days starting on Sunday.

(417) "Weighting factor" or "w_T" for an organ or tissue means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

Organ Dose Weighting Factors

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a/]
Whole Body	1.00[b/]

a/ 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses

b/ For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The department shall approve the use of other weighting factors for external exposure on a case–by–case basis until such time as specific guidance is issued.

(418) "Well–bore" means a drilled hole in which wireline service operations or subsurface tracer studies are performed.

(419) "Well logging" means all operations involving the lowering and raising of measuring devices or tools which may contain sources of radiation into well–bores or cavities for the purpose of obtaining information about the well or adjacent formations.

(420) "Well logging supervisor" means any individual who uses sources of radiation or provides personal supervision of the use of sources of radiation at the well site and who is responsible for assuring compliance with the requirements of this chapter.

(421) "Well logging tool" means a device used subsurface to perform well logging.

(422) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow or legs above the knee.

(423) "Wipe sample" means a piece of material used to wipe over the area of a surface or device to collect radioactive contamination.

(424) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well–bore.

(425) "Wireline service operation" means any evaluation or mechanical services which is performed in the well–bore using devices on a wireline.

(426) "Worker" means an individual engaged in work under a license or registration issued by the department and controlled by a licensee or registrant, but does not include the licensee or registrant.

(427) "Working level" or "WL" means any combination of short–lived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short–lived radon daughters are for radon–222: polonium–218, lead–214, bismuth–214 and polonium–214; and for radon–220. polonium–216, lead–212, bismuth–212, and polonium–212.

(428) "Working level month" or "WLM" means an exposure to one working level for 170 hours 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

(429) "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material or a radiation machine to a specific patient or human research subject.

(430) "X–ray equipment" means an x–ray system, subsystem or component thereof that is one of the following:

(a) Mobile x–ray equipment.

(b) Portable x–ray equipment.

(c) Stationary x–ray equipment.

(431) "X–ray exposure control" means a device, switch, button or other similar means by which an operator initiates or terminates the radiation exposure. An x–ray exposure control may include such associated equipment as timers and back–up timers

(432) "X–ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor whose perimeter is the locus of points at which the exposure rate is one–fourth of the maximum in the intersection.

(433) "X–ray high–voltage generator" means a device that transforms electrical energy from the potential supplied by an x–ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for an x–ray tube or tubes, high–voltage switches, electrical protective devices and other appropriate elements.

(434) "X–ray system" means an assemblage of components for the controlled production of x–rays. It includes minimally an x–ray high–voltage generator, an x–ray control, a tube housing assembly, a beam–limiting device and the necessary supporting structures. Additional components, which function with the system, are considered integral parts of the system.

(435) "X–ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy An x–ray table includes any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray, cassette tunnel, image intensifier or spot–film device beneath the tabletop.

(436) "X-ray tube" means any electron tube designed to be used primarily for the production of x-rays.

(437) "Year" means the period beginning on January 1st used to determine compliance with the provisions of this chapter. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.04 Exemptions from the regulatory requirements. **(1)** GENERAL. The department may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of this chapter as it determines are authorized by law and will not result in undue hazard to public health and safety or property or endanger the common defense and security.

(2) US DOE AND NRC CONTRACTORS U.S. department of energy contractors or subcontractors and any NRC contractor or subcontractor in any of the following categories operating within this state are exempt from this chapter to the extent that the contractor or subcontractor under their contract receives, possesses, uses, transfers or acquires sources of radiation:

(a) Prime contractors performing work for the U.S. department of energy at U.S. government owned or controlled sites, including the transportation of byproduct material to or from such sites and the performance of contract services during temporary interruptions of such transportation.

(b) Prime contractors of the U.S. department of energy performing research in, or development, manufacture, storage, testing or transportation of atomic weapons or components of atomic weapons.

(c) Prime contractors of the U.S. department of energy using or operating nuclear reactors or other nuclear devices in a United States government owned vehicle or vessel.

(d) Any other prime contractor or subcontractor of the U.S. department of energy or of the NRC when the state and the NRC jointly determine all the following:

1. The exemption of the prime contractor or subcontractor is authorized by law.

2. Under the terms of the contract or subcontract, there is adequate assurance that the work may be accomplished without undue risk to the public health and safety.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.05 Prohibitions. **(1)** DEVICES. The following devices may not be used in Wisconsin:

(a) A hand-held fluoroscopic screen with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the FDA, center for devices and radiological health.

(b) A shoe-fitting fluoroscopic device.

(2) DELIBERATE MISCONDUCT. No person may do any of the following:

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant or applicant under this chapter to be in violation of any rule or order of the department; or any term, condition or limitation of any license or registration issued by the department under this chapter.

(b) Deliberately submit to the department; a licensee, registrant or applicant under this chapter; or a contractor or subcontractor of a licensee, registrant or applicant under this chapter; any information that the person knows to be incomplete or inaccurate.

(3) RADIATION SURVEY INSTRUMENTATION. No person may operate a portable device containing radioactive material designed to measure moisture content or density of materials unless calibrated and operable radiation survey instrumentation that meets the requirements of s. HFS 157.52 (4) is available for use at each site where the portable devices are used.

(4) TRAINING (a) No person may use a portable device containing radioactive material used to measure moisture content or density of materials or determine lead content of paint unless the person has completed 8 hours of manufacturer's training or equivalent training that meets the requirements of Appendix S.

(b) A person providing equivalent training under par. (a) for certified lead inspectors or risk assessors shall meet the qualification requirements of s. HFS 163.24 (3) (a) 1. and 3. and shall complete an additional 8 hours of radiation safety training.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.06 General regulatory requirements. **(1)** RECORDS A licensee or registrant shall maintain records showing the receipt, transfer and disposal of all sources of radiation until the department terminates the license or registration authorizing possession of the device or material, and for 3 years following transfer or disposal of the device or material.

Note: Additional record requirements are specified elsewhere in this chapter.

(2) INSPECTIONS (a) A licensee or registrant shall afford the department at all reasonable times opportunity to inspect sources of radiation, packaging and the premises and facilities on which the sources of radiation are used or stored and consult with workers.

(b) Each licensee and registrant shall make available to the department for inspection, upon reasonable notice, records maintained under this chapter.

(c) The department shall provide official notification in writing of the inspection findings, including any notice of violation, to the licensee or registrant.

(3) TESTS A licensee or registrant shall perform upon instructions from the department, or shall permit the department to perform, such reasonable tests as the department deems appropriate or necessary including tests of any of the following:

(a) Sources of radiation.

(b) Facilities wherein sources of radiation are used or stored.

(c) Radiation detection and monitoring instruments.

(d) Other equipment and devices used with utilization or storage of licensed or registered sources of radiation.

(4) UNITS OF EXPOSURE AND DOSE. (a) The unit of exposure is the coulomb per kilogram of air. One roentgen is equal to 2.58E-4 coulomb per kilogram of air.

(b) The units of dose are any of the following:

1. Gray is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad).

2. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0 01 joule per kilogram.

3. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor.

Note: 0 01 sievert equals one rem.

4. Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor.

Note: One sievert equals 100 rem

(c) The quality factors for converting absorbed dose to dose equivalent are shown in Table HFS 157.06A.

TABLE HFS 157.06A

Quality Factors and Absorbed Dose Equivalencies

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent
X, gamma, or beta radiation and high–speed electrons	1	1
Alpha particles, multiple–charged particles, fission fragments and heavy particles of unknown charge	20	0 05
Neutrons of unknown energy	10	0.1
High–energy protons	10	0.1

Note: Absorbed dose in gray equal to one Sv or the absorbed dose in rad equal to one rem

(d) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in par. (c), 0.01 Sv (1 rem) of neutron radiation of unknown energies may be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body If sufficient information exists to estimate the approximate energy distribution of the neutrons, a licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table HFS 157 06B to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem

TABLE HFS 157.06B

Mean Quality Factors, Q, and Fluence Per Unit Dose Equivalent For Monoenergetic Neutrons

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per unit dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Fluence per unit dose Equivalent (neutrons cm^{-2} Sv^{-1})
(thermal)	2 5E–8	2	980E+6	980E+8
	1E–7	2	980E+6	980E+8
	1E–6	2	810E+6	810E+8
	1E–5	2	810E+6	810E+8
	1E–4	2	840E+6	840E+8
	1E–3	2	980E+6	980E+8
	1E–2	2.5	1010E+6	1010E+8
	1E–1	7.5	170E+6	170E+8
	5E–1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6 5	24E+6	24E+8
	14	7 5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3 5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

a Value of quality factor at the point where the dose equivalent is maximum in a 30–centimeter diameter cylinder tissue–equivalent phantom.

b Monoenergetic neutrons incident normally on a 30–centimeter diameter cylinder tissue–equivalent phantom.

(5) UNITS OF ACTIVITY For purposes of this chapter, activity is expressed in the SI unit of becquerel or in the special unit of curie, or their multiples, or disintegrations or transformations per unit of time. One becquerel = one disintegration or transformation per second One curie = 3.7E+10 disintegrations or transformations per second = 3.7E+10 becquerel = 2.22E+12 disintegrations or transformations per minute.

History: CR 01–108: cr. Register July 2002 No. 559, eff. 8–1–02.

Subchapter II — Licensing of Radioactive Material

HFS 157.09 Exemptions. (1) EXEMPTIONS OF SOURCE MATERIAL. (a) A person is exempt from this subchapter if the person receives, possesses, uses, owns or transfers any of the following types and forms of source material:

1. Any chemical mixture, compound, solution or alloy in which the source material by weight is less than 1/20 of one percent of the mixture, compound, solution or alloy.

2. Unrefined and unprocessed ore containing source material provided that, except as authorized in a specific license, the person does not refine or process the ore

3. Rare earth metals and compounds, mixtures and products containing not more than 0.25% by weight thorium, uranium or any combination of these.

4 Any quantities of thorium contained in any of the following:

a Incandescent gas mantles

b Vacuum tubes.

c. Welding rods.

d. Electric lamps for illuminating purposes provided that a lamp does not contain more than 50 milligrams of thorium.

e. Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that a lamp does not contain more than 2 grams of thorium.

f. Personnel neutron dosimeters, provided that a dosimeter does not contain more than 50 milligrams of thorium.

5. Source material contained in any of the following products:

a. Glazed ceramic tableware, provided that the glaze contains not more than 20% by weight source material.

b. Glassware containing not more than 10% by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction.

c. Glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States or initially distributed by manufacturers in the United States, before July 25, 1983.

d. Piezoelectric ceramic containing not more than 2% by weight source material.

6. Photographic film, negatives and prints containing uranium or thorium.

7. Any finished product or part fabricated of tungsten–thorium or magnesium–thorium alloys, or containing tungsten–thorium or magnesium–thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that this exemption is not deemed to authorize the chemical, physical or metallurgical treatment or processing of any product or part.

8. Uranium contained in counterweights installed in aircraft, rockets, projectiles or missiles or stored or handled in connection with installation or removal of the counterweights, under all of the following conditions:

a. The counterweights are manufactured under a specific license issued by the NRC, authorizing distribution by the licensee under 10 CFR 40.

b. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM". This requirement need not be met by counterweights manufactured prior to December 31, 1969 provided that the counterweights are impressed with the legend "CAUTION – RADIOACTIVE MATERIAL – URANIUM".

c. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement, "UNAUTHORIZED ALTERATIONS PROHIBITED". This requirement need not be met by counterweights manufactured prior to December 31, 1969 provided that the counterweights are impressed with the legend "CAUTION – RADIOACTIVE MATERIAL – URANIUM".

d. This exemption may not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any of these counterweights other than repair or restoration of any plating or other covering.

9. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that the shipping container is conspicuously and legibly impressed with the legend "CAUTION – RADIOACTIVE SHIELDING – URANIUM"; and the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 3.2 millimeter (one–eighth inch).

10. Thorium contained in finished optical lenses, provided that a lens does not contain more than 30% by weight of thorium and that this exemption is not deemed to authorize either of the following:

a. The shaping, grinding or polishing of the lens or manufacturing processes other than the assembly of the lens into optical systems and devices without any alteration of the lens.

b. The receipt, possession, use or transfer of thorium contained in contact lenses, spectacles, eyepieces in binoculars or other optical instruments.

11. Uranium contained in detector heads for use in fire detection units, provided that a detector head contains not more than 185 becquerel (0.005 microcurie) of uranium.

12. Thorium contained in any finished aircraft engine part containing nickel–thoria alloy, provided that the thorium is dispersed in the alloy in the form of finely divided thoria, and the thorium content in the nickel–thoria alloy does not exceed 4% by weight.

(b) The exemptions in par. (a) do not authorize the manufacture of any of the products described.

(2) EXEMPTIONS OF RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL. (a) *Exempt concentrations.* Except as provided in this paragraph, a person is exempt from this subchapter to the extent that the person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations no greater than those listed in Appendix A of this chapter. A person may not introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this paragraph or equivalent regulations of the NRC, any agreement state or licensing state, except under a specific license issued under s. HFS 157.13 (4) (a) or the general licenses under s. HFS 157.14.

1. This paragraph does not authorize the import of radioactive material or products containing radioactive material.

2. A manufacturer, processor or producer of a product or material is exempt from the requirements of subch. II if the product or material is in concentrations not in excess of those in Appendix A and is transferred to a licensee holding a specific license issued by the department, an agreement state or the NRC expressly authorizing introduction of the material into a product. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by or application to a human being.

(b) *Exempt quantities.* Except as provided in this paragraph, a person is exempt from this subchapter to the extent that the person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B of this chapter.

1. This paragraph does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

2. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this chapter to any person exempt from this chapter or equivalent regulations of the NRC, an agreement state or a licensing state, except under a specific license issued by the NRC under 10 CFR 32.18, or by the department under s. HFS 157.13 (4) (b) which license states that the radioactive material may be transferred by the licensee to persons exempt under this paragraph or the equivalent regulations of the NRC, an agreement state or a licensing state.

Note: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C., 20555.

(c) *Exempt items.* Except for persons who apply radioactive material to the following products, or incorporate radioactive material into the following products, a person is exempt from this subchapter if the person receives, possesses, uses, initially transfers for sale or distribution, owns or acquires any of the following products:

1. Timepieces, hands or dials containing not more than the following specified quantities of radioactive material:

a. 925 MBq (25 Millicuries) of tritium per timepiece.

b. 185 MBq (5 millicuries) of tritium per hand.

c. 555 MBq (15 millicuries) of tritium per dial.

Note: Bezels, when used, should be considered as part of the dial.

d. 3.7 MBq (100 microcuries) of promethium–147 per watch or 7.4 MBq (200 millicuries) of promethium–147 per any timepiece.

e. 0.74 MBq (20 microcuries) of promethium–147 per watch hand or 1 48 MBq (40 microcuries) of promethium–147 per other timepiece hand.

f. 2.22 MBq (60 microcuries) of promethium–147 per watch dial or 4.44 MBq (120 microcuries) of promethium–147 per other timepiece dial (bezels when used shall be considered as part of the dial).

Note: Bezels, when used, should be considered as part of the dial

2. Timepieces, hands or dials containing promethium–147 or radium–226, when measured through 50 milligrams per square centimeter of absorber, not exceeding the following radiation dose rate:

a. For wrist watches, one μGy (0.1 millirad) per hour at 10 centimeters from any surface

b. For pocket watches, one μGy (0.1 millirad) per hour at one centimeter from any surface.

c. For any other timepiece, 2 μGy (0 2 millirad) per hour at 10 centimeters from any surface

3. Timepieces containing up to 37 kBq (1.0 microcurie) of radium–226 per timepiece acquired prior to the effective date of August 1, 2002.

4. Lock illuminators containing not more than 555 MBq (15 millicuries) of tritium or not more than 74 MBq (2 millicuries) of promethium–147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium–147 may not exceed 10 μGy (1 millirad) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

5. Precision balances containing not more than 37 MBq (1 millicurie) of tritium per balance or not more than 18.5 MBq (0 5 millicurie) of tritium per balance part.

6. Automobile shift quadrants containing not more than 925 MBq (25 millicuries) of tritium.

7 Marine compasses containing not more than 27.8 GBq (750 millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 millicuries) of tritium gas.

8. Thermostat dials and pointers containing not more than 925 MBq (25 millicuries) of tritium per thermostat.

9. Electron tubes, including spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick–up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents, provided that the radiation dose rate from each electron tube containing radioactive material does not exceed 10 uGy (1 millirad) per hour at one centimeter from any surface when measured through 7 milligrams per square centimeter of absorber and that each tube does not contain more than one of the following specified quantities of radioactive material:

a. 5.55 GBq of tritium per microwave receiver protector tube or 370 MBq (10 millicuries) of tritium per any other electron tube.

b. 37 kBq (1 microcurie) of cobalt–60.

c. 185 kBq (5 microcuries) of nickel–63.

d. 1.11 MBq (30 microcuries) of krypton–85.

e. 185 kBq (5 microcuries) of cesium–137.

f 1.11 MBq (30 microcuries) of promethium–147

10. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided all the following conditions are met:

a. Each source contains no more than one exempt quantity set forth in Appendix B of this chapter.

b Each instrument contains no more than 10 exempt quantities. For the purposes of this subd. par., an instrument's source or sources may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this chapter, provided that the sum of the fractions does not exceed unity.

c. For purposes of this subdivision, 1.85 kBq (0 05μCi) of Americium–241 is considered to be an exempt quantity.

11 Spark gap irradiators containing not more than 37 kBq (1 microcurie) of cobalt–60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 11.4 liters (3 gallons) per hour.

12. Self–luminous products containing any of the following radioactive material:

a Tritium, Krypton–85, or Promethium–147 in self–luminous products manufactured, processed, produced or initially transferred for sale or distribution under a specific license issued by the NRC under 10 CFR 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this subdivision paragraph does not apply to a person who manufactures, processes or produces self–luminous products containing tritium, krypton–85 or promethium–147, or to products containing these isotopes primarily used for frivolous purposes, toys or adornments.

b. Radium–226 in products containing less than 37 kBq (1.0 microcurie) of radium–226 which were acquired prior to the effective date of August 1, 2002.

13. Gas and aerosol detectors containing radioactive material, provided that the following conditions are met:

a. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, a person is exempt from this chapter if the person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that the detectors containing radioactive material have been manufactured or initially transferred for sale or distribution under a specific license issued by the NRC under 10 CFR 32.26, a licensing state, other agreement state or the department under s. HFS 157.13 (4) (c), which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

b. Gas and aerosol detectors previously manufactured and distributed to general licensees under the specific license issued by an agreement state shall be considered exempt under this subdivision provided that the device is labeled under the specific license authorizing distribution of the generally licensed device and provided further that they meet the requirements of s. HFS 157.13 (4) (c).

c. Gas and aerosol detectors containing NARM previously manufactured and distributed under a specific license issued by a licensing state shall be considered exempt under this subdivision provided the devices are labeled under the specific license authorizing distribution, and provided further that they meet the requirements of s. HFS 157.13 (4) (c)

14 Resins containing scandium–46 and designed for sand consolidation in oil wells, to the extent that a person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium–46 which are designed for sand consolidation in oil wells. These resins shall have been manufactured or initially transferred for sale or distribution under a specific license issued by the NRC, or shall have been manufactured under the

specifications contained in a specific license issued by the department or any agreement state to the manufacturer of the resins under licensing requirements equivalent to those in 10 CFR 32.16 and 32.17. This exemption does not authorize the manufacture of any resins containing scandium–46.

15. Radioactive drug capsules containing no more than 37 kBq (1 μCi) carbon–14 urea each for in vivo diagnostic use for humans. This exemption does not authorize any of the following:

a. The use of carbon–14 urea capsules for research involving human subjects.

b. The manufacture, preparation, packaging, repackaging, processing, production or transfer for commercial distribution of carbon–14 urea capsules.

Note: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D C. 20555

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

HFS 157.10 License types and fees. (1) TYPES OF LICENSES A license for radioactive materials may be one of the following:

(a) *General.* A general license is effective without the filing of an application with the department or the issuance by the department of licensing documents to the particular person, although the filing of a certificate with the department may be required by the particular general license. The general licensee is subject to all other applicable parts of this chapter and any limitations of the general license.

(b) *Specific.* A specific license requires the submission of an application to the department and the issuance of a licensing document by the department. A licensee is subject to all applicable parts of this chapter as well as any limitations specified in the licensing document. A licensee shall pay the license fees as specified in sub. (3).

(2) PAYMENT OF FEES (a) *Application fee.* An application for a specific license shall be accompanied by payment in the full amount of the fee specified in sub. (3). The department may not process the application prior to receipt of the required fee. The application fee is not refundable except in those cases where the department determines that a license is not required. The department will consider any application abandoned if the department does not receive a reply within 90 days of its most recent request for additional information. In such cases, the applicant shall submit a new application with the application fee specified in sub. (3).

(b) *Annual fee.* A person holding a specific license in effect prior to the effective date of August 1, 2002, or a specific license issued after the effective date of August 1, 2002, shall pay the annual fee specified in sub. (3) at least 60 days prior to the anniversary date of the issuance of the license. The annual fee is not refundable except in those cases where the department determines that the fee is not required.

(c) *Amendment fee.* An application for amendment to a specific license shall be accompanied by payment in full of the fee specified in sub. (3). The department may not process the application prior to the department's receipt of the required fee. The department may not charge an amendment fee to modify a license on its own initiative.

(d) *Reciprocity fee.* A person submitting an application for reciprocal recognition of a materials license issued by an agreement state or the nuclear regulatory commission shall include remittance for the full amount of the fee specified in sub. (3). The department may not process the application prior to the department's receipt of the appropriate fee. Requests for reciprocal recognition approved by the department prior to November 1 shall remain in effect until December 31 of that year. Requests for reciprocal recognition approved on or after November 1 shall remain in effect until December 31 of the subsequent year.

(3) FEE SCHEDULE. The following is the schedule of application, annual, amendment and reciprocity fees for specific radioactive material licenses.

Category	License Type	Application & Annual Fee
1.	**Special Nuclear Material**	
A.	License for possession and use of SNM in sealed sources contained in devices used in measuring systems	$1,000
B.	License for use of SNM to be used as calibration and reference sources	$300
C.	SNM – all other, except license authorizing special nuclear material in unsealed form that would constitute a critical mass	$1,500
2.	**Source Material**	
A.	Source material processing and distribution	$4,000
B.	Source material in shielding [Fee waived if facility holds additional license category]	$400
C.	Source material – all other, excluding depleted uranium used as shielding or counterweights	$3,000
3.	**Byproduct, NARM**	
A.	License of broad scope for processing or manufacturing of items for commercial distribution	$20,000
B.	License for processing or manufacturing and commercial distribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$12,000
C.	License for commercial distribution or redistribution of radiopharmaceuticals, generators, reagent kits and sources or devices	$3,000
D.	Other licenses for processing or manufacturing of items for commercial distribution	$4,000
E.	License for industrial radiography operations performed only in a shielded radiography installation	$3,000
F.	License for industrial radiography performed only at the address indicated on the license, and at temporary job sites	$5,000

G.	License for possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is not removed from the shield [Fee waived if facility holds additional irradiator license category]	$2,000
H.	License for possession and use of less than 370 TBq (10,000 curies) of radioactive material in sealed sources for irradiation of materials where the source is exposed where the source is not exposed)	$3,000
I.	License for possession and use of at least 370 TBq (10,000 curies) and less than 3.7 PBq (100,000 curies)of radioactive material in sealed sources for irradiation of materials	$5,000
J.	License for possession and use of 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources for irradiation of materials	$12,000
K	License to distribute items containing radioactive materials to persons under a general license	$2,000
L.	License to possess radioactive materials intended for distribution to persons exempt from licensing	$2,500
M	License of broad scope for research and development that does not authorize commercial distribution	$6,000
N.	Other licenses for research and development that do not authorize commercial distribution	$1,800
O	License for installation, repair, maintenance leak testing or other service of devices or items containing radioactive material, excluding waste transportation or broker services	$1,800
P.	License for portable gauges, including industrial *Lixiscope®*	$1,400
Q	License for portable x–ray fluorescence analyzer calibration flood source or gas chromatograph	$200
R.	All other byproduct, naturally–occurring or accelerator–produced material licenses, except as otherwise noted	$2,000
4.	**Waste Processing**	
A.	Commercial waste treatment facilities, including incineration	$200,000
B.	All other commercial facilities involving waste compaction, repackaging, storage or transfer	$25,000
C.	Waste processing – all other, including decontamination service	$5,000
5.	**Well Logging**	
A.	License for well logging using sealed sources or sub–surface tracer studies	$4,000
B.	License for well logging using sealed sources and sub–surface tracer studies	$5,000
6.	**Nuclear Laundry**	
A.	License for commercial collection and laundry of items contaminated with radioactive material	$16,000
7.	**Medical/Veterinary**	
A.	License for human use of byproduct, source, special nuclear or NARM material in sealed sources contained in teletherapy, high dose rate afterloading orstereotactic radiosurgery devices, including mobile therapy	$12,000
B	License of broad scope for human use of byproduct, source, special nuclear or NARM materials used in medical diagnosis, treatment, research and development, excluding teletherapy, high dose rate afterloading or stereotactic radiosurgery devices	$20,000
C.	License for mobile nuclear medicine	$2,500
D.	Medical – all others, including SNM pacemakers	$5,000
E.	License for veterinary use of radioactive materials	$2,000
8.	**Academic**	
A.	License for possession and use of byproduct,naturally–occurring or accelerator produced radioactive material for educational use or academic research and development that does not authorize commercial distribution, excluding broad scope or human use licenses, with a combined possession limit of 6 isotopes and 37 GBq (1 curie) total activity	$1,000

9.	Accelerator	
A.	License for accelerator production of radioisotopes with commercial distribution	$4,000
B.	Accelerator isotope production – all other [Fee waived if facility holds medical broad scope license with no commercial distribution]	$2,000
10.	Reciprocity	
A.	Reciprocal recognition of an out–of–state specific license	50% of annual fee of applicable category
11.	Amendments	
A.	Request to amend specific license – no license review	$0

Note: Examples include spelling corrections and adding or removing previously authorized users.

B.	Request to amend specific license – license review required	$200

Note: Examples include new isotopes and procedural changes

C.	Request to amend specific license – license review and site visit required	$400

Note: Examples include a facility move and new processes.

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

HFS 157.11 General licenses. (1) GENERAL LICENSES – SOURCE MATERIAL (a) *General license for certain organizations to use and transfer limited amounts of source material.* A general license is issued authorizing commercial and industrial firms, research, educational and medical institutions and state and local government agencies to use and transfer not more than 6.82 kg (15 pounds) of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material under this general license may not receive more than a total of 68.2 kg (150 pounds) of source material in any one year.

1. A person who receives, possesses, uses or transfers source material under the general license issued under this paragraph is exempt from the provisions of subchs. III and X to the extent that the receipt, possession, use or transfer is within the terms of the general license, except that this exemption does not apply to any person who is also in possession of source material under a specific license issued under this section.

2. A person who receives, possesses, uses or transfers source material under the general license issued under this paragraph may not administer source material, or radiation from the source material, either externally or internally, to human beings except as authorized by the department in a specific license.

(b) *General license authorizing receipt of title to source material without regard to quantity.* A general license is issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

Note: A person may take title to source material under a general license. In order to receive, possess, use or transfer source material, he or she must obtain a specific license under s. HFS 157.13

(c) *General license relating to depleted uranium in industrial products and devices.* 1. A general license is issued to receive, acquire, possess, use or transfer, under the provisions of subds. 2., 3., 4., 5. and 6., depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license issued under this paragraph applies only to industrial products or devices that have been manufactured or initially transferred either under a specific license issued to the manufacturer of the products or devices under s. HFS 157.13 (4) (k) or under a specific license issued to the manufacturer by the NRC or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the NRC or the agreement state.

3. A person who receives, acquires, possesses or uses depleted uranium under the general license under this paragraph shall file a "Certificate – Use of Depleted Uranium Under General License" form with the department. The form shall be filed within 30 days after the first receipt or acquisition of depleted uranium and is considered filed when it is received by the department. The general licensee shall furnish on the "Certificate – Use of Depleted Uranium Under General License" all of the following information and any other information required by that form:

a. Name and address of the general licensee.

b. A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in this paragraph and designed to prevent transfer of the depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.

c. Name and title, address and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in subd. 3. b.

4. The general licensee possessing or using depleted uranium under the general license established under this paragraph shall report in writing to the department any changes in information furnished by that person in the "Certificate – Use of Depleted Uranium Under General License". The report shall be filed within 30 days after the effective date of the change.

5. A person who receives, acquires, possesses or uses depleted uranium under the general license established under this paragraph shall comply with all of the following:

a. Not introduce the depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

b. Not abandon the depleted uranium.

c. Transfer or dispose of the depleted uranium only under the provisions of s. HFS 157.13 (15). In the case where the transferee receives the depleted uranium under the general license established under this paragraph, the party making the transfer shall furnish the transferee a copy of this subsection and a copy of the "Certificate – Use of Depleted Uranium Under General License". In the case where the transferee receives the depleted uranium under a general license contained in the NRC or agreement state regulations equivalent to this paragraph, the party making the transfer shall furnish the transferee a copy of this subsection and a copy of "Certificate – Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is regulated by the NRC or an agreement state under requirements substantially the same as those in this subsection.

d. Within 30 days following a transfer, report in writing to the department the name and address of the person receiving the depleted uranium under the transfer.

e. Not export the depleted uranium except under a license issued by the NRC under 10 CFR 110.

6. A person receiving, acquiring, possessing, using or transferring depleted uranium under the general license established under this paragraph is exempt from the requirements of subchs. III and X with respect to the depleted uranium covered by that general license.

Note: The "Certificate – Use of Depleted Uranium Under General License" form 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 by downloading from the Department website at www.dhfs state.wi us/licensing/. Completed forms may be mailed to the Department at the same address.

(2) GENERAL LICENSES – RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL. (a) *General license relating to certain devices and equipment.* A general license is issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in all the following devices or equipment which have been manufactured, tested and labeled by the manufacturer under a specific license issued to the manufacturer by the NRC for use under 10 CFR 31.3. This general license is exempt from the requirements of subch III, with the exception of ss. HFS 157 30 (1), 157.32 (1) and (2), and subch X.

1. 'Static elimination device ' Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium–210 per device.

2. 'Ion generating tube.' Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of not more than 18.5 MBq (500 microcuries) of polonium–210 per device or a total of not more than 1 85 GBq (50 mCi) of hydrogen–3 per device.

(b) *General license relating to certain measuring, gauging or controlling devices.* 1. A general license is issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business and state or local government agencies to own, receive, acquire, possess, use or transfer under the provisions of subds. 1. to 4., radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere.

2. The general license issued under this paragraph applies only to radioactive material contained in devices that have been manufactured and labeled under the specifications contained in a specific license issued by the department under s. HFS 157.13 (4) (d) or under the specifications contained in a specific license issued by the NRC, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the NRC, an agreement state or a licensing state.

Note: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production required certain additional labeling thereon which is found in 21 CFR 179 21

3 A person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device under the general license under this paragraph shall do all the following:

a. Ensure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited, are maintained on the device and shall comply with all instructions and precautions provided by such labels.

b. Ensure that the device is tested for leakage of radioactive material and proper operation of the "on–off" mechanism and indicator, if any, at no longer than 6–month intervals or at such other intervals as are specified in the label, except for devices containing only krypton, tritium, not more than 3.7 MBq (100 microcuries) of other beta and gamma–emitting material, or 0.37 MBq (10 microcuries) of alpha–emitting material, and devices held in storage in the original shipping container prior to the initial installation.

c Ensure that other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed under the instructions provided by the labels, or by a person holding an applicable specific license from the department, the NRC, an agreement state or a licensing state to perform such activities.

d. Maintain records showing compliance with the requirements of subd. 3. b. and c. The records shall show the results of tests. The records shall also show the dates of performance of tests, and the names of persons performing, testing, installation, servicing and removal from installation of the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by subd. 3. b. shall be maintained for 3 years or until the sealed source is transferred or disposed of. Records of tests of the "on–off" mechanism and indicator required by subd. 3. b shall be maintained for 3 years or until the sealed source is transferred or disposed of. Records that are required by subd 3 c. shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed of

e. Upon the occurrence of a failure of or damage to or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on–off" mechanism or indicator, or upon the detection of 185 Bq (0.005 microcurie) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the NRC, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device The licensee shall file a written report containing a brief description with the department within 30 days of the event.

f. Not abandon the device containing radioactive material.

g. Except as provided in subd. 3. h., transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the NRC, an agreement state or a licensing state whose specific license authorizes that person to receive the device and within 30 calendar days after transfer of a device to a specific licensee shall furnish to the department a written report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee to obtain a replacement device.

h. Transfer the device to another general licensee only where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee, or where the device remains in use at a particular location. In the latter case, the transferor shall give the transferee a copy of sub. (2) (b) and any safety documents identified in the label on the device and within 30 calendar days of the transfer. the licensee shall report to the department the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and position of an individual who may constitute a point of contact between the department and the transferee.

i. Comply with the provisions of s. HFS 157.32 (1) and (2) for reporting radiation incidents, theft or loss of licensed material, but is exempt from the other requirements of subchs. III and X

4 The general license under this paragraph does not authorize the manufacture of devices containing radioactive material.

5 The general license under this paragraph is exempt from the requirements of subch. III, with the exception of ss. HFS 157.30 (1), 157.32 (1) and (2), and subch. X.

(c) *General license relating to luminous safety devices for aircraft.* A general license is issued to own, receive, acquire, possess and use tritium or promethium–147 contained in luminous safety devices for use in aircraft, provided that each device contains not more than 370 GBq (10 curies) of tritium or 11.1 GBq (300 millicuries) of promethium–147, and that each device has been manufactured, assembled or imported under a specific license issued by the NRC, or manufactured or assembled under the specifications contained in a specific license issued by the department

or any agreement state to the manufacturer or assembler of such device under licensing requirements equivalent to those in 10 CFR 32.53.

1. A person who owns, receives, acquires, possesses or uses luminous safety devices under the general license under this paragraph is exempt from the requirements of subchs. III and X except that they shall comply with the provisions of s. HFS 157.32 (1) and (2).

2. The general license under this paragraph does not authorize the manufacture, assembly or repair of luminous safety devices containing tritium or promethium–147.

3. The general license under this paragraph does not authorize the ownership, receipt, acquisition, possession or use of promethium–147 contained in instrument dials.

4. The general license under this paragraph is exempt from the requirements of subch. III, with the exception of ss. HFS 157.30 (1), 157.32 (1) and (2), and subch. X.

(d) *General license relating to ownership of radioactive material.* A general license is issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this section, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

Note: A person may own radioactive material without the material being in their immediate possession. This general license does not allow the person to manufacture, produce devices containing material, transfer, receive, posses or use the material. A specific license is required for these activities.

(e) *General license relating to calibration and reference sources.* A general license is issued to own, receive, acquire, possess, use and transfer americium–241, plutonium or radium–226 in the form of calibration or reference sources, under the provisions of subds. 1. to 5., to any person who holds a specific license issued by the department or the NRC which authorizes the person to receive, possess, use and transfer radioactive material.

Note: For Americium–241 and plutonium, a specific license issued by the NRC is also required for any person to receive, possess or use and transfer special nuclear material.

1. The general license under this paragraph applies only to calibration or reference sources that have been manufactured under the specifications contained in a specific license issued to the manufacturer or importer of the sources by the NRC under 10 CFR 32.57 or 10 CFR 70.39 or that have been manufactured under the specifications contained in a specific license issued to the manufacturer by the department, an agreement state or licensing state under licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR 70.39.

2. The general license under this paragraph is exempt from the requirements of subch. III, with the exception of ss. HFS 157.30 (1), 157.32 (1) and (2), and subch. X.

3. A person who owns, receives, acquires, possesses, uses or transfers one or more calibration or reference sources under the general licenses provided under this paragraph may not receive, possess, use or transfer the source unless the source or the storage container bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

a. The receipt, possession, use and transfer of this source, Model ____, Serial No. ____, is subject to a general license and the regulations of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM–241). (PLUTONIUM) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

Note: The label is to show only the name of the appropriate material

b. The receipt, possession, use and transfer of this source, Model _____, Serial No. ____, is subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS RADIUM–226.
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

4. A person who owns, receives, acquires, possesses, uses or transfers one or more calibration sources under the general license under this paragraph shall do all the following:

a. Not transfer, abandon or dispose of the source except by transfer to a person authorized by a license from the department, the NRC, an agreement state or a licensing state to receive the source.

b. Store the source, except when the source is being used, in a closed container adequately designed and constructed to contain americium–241, plutonium or radium–226 that might otherwise escape during storage.

c. Not use the source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

d. Not possess at any one time, at any one location of storage or use, more than 185 kBq (5 microcuries) of americium–241, plutonium or radium–226.

5. The general license under this paragraph does not authorize the manufacture of calibration or reference sources containing americium–241, plutonium or radium–226.

(f) *General license for use of radioactive material for certain in vitro clinical or laboratory testing.* 1. A general license is issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, under the provisions of subds. 2. to 6., the following radioactive materials in prepackaged units for use as in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

a. Carbon–14, in units not exceeding 370 kBq (10 microcuries) each.

b. Cobalt–57, in units not exceeding 370 kBq (10 microcuries) each.

c. Hydrogen–3, in units not exceeding 1.85 MBq (50 microcuries) each.

d. Iodine–125, in units not exceeding 370 kBq (10 microcuries) each.

e. Mock Iodine–125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine–129 and 185 Bq (0.005 microcurie) of americium–241 each.

f. Iodine–131, in units not exceeding 370 kBq (10 microcuries) each.

g. Iron–59, in units not exceeding 740 kBq (20 microcuries) each.

h. Selenium–75, in units not exceeding 370 kBq (10 microcuries) each.

Note: 21 USC 301 also governs the availability and use of any specific diagnostic drugs in interstate commerce

2. No person may receive, acquire, possess, use or transfer radioactive material under the general license established under this paragraph until the person has filed a "Certificate – In Vitro Testing with Radioactive Material Under General License" form with the department and received from the department a validated copy of the form with certification number assigned. A physician, veterinarian, clinical laboratory or hospital shall furnish on the "Certificate – In Vitro Testing with Radioactive Material Under

General License" all the following information and such other information as may be required by that form:

a. Name and address of the physician, veterinarian, clinical laboratory or hospital.

b. The location of use.

c. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized by the general license under this paragraph and that the tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material

Note: The "Certificate – In Vitro Testing with Radioactive Material Under General License" form 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 by downloading from the Department website at www.dhfs.state.wi.us/licensing/

3. A person who receives, acquires, possesses or uses radioactive material under the general license under this paragraph shall comply with all the following:

a. The general licensee may not possess at any one time, under the general license under this paragraph, at any one location for storage or use, a total amount of iodine–125, iodine–131, selenium–75, iron–59, or cobalt–57 in excess of 7.4 MBq (200 microcuries).

b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

c. The general licensee shall use the radioactive material only for the uses authorized by subd. 1.

d. The general licensee may not transfer the radioactive material to a person who is not authorized to receive it under a license issued by the department, the NRC, any agreement state or a licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

e. The general licensee shall dispose of the Mock Iodine–125 reference or calibration sources described in subd. 1. e. as required by s. HFS 157.23 (1).

4. The general licensee may not receive, acquire, possess, or use radioactive material under subd. 1. except in prepackaged units which are labeled under the provisions of an applicable specific license issued under s. HFS 157.13 (4) (g) or under the provisions of a specific license issued by the NRC, any agreement state or a licensing state which authorizes the manufacture and distribution of iodine–125, iodine–131, carbon–14, hydrogen–3, iron–59, selenium–75, cobalt–57 or Mock Iodine–125 to persons generally licensed under subd. 1. or its equivalent and one of the following statements or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package.

a. This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the NRC or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

b. This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

_____
Name of manufacturer

5. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license under this paragraph shall report in writing to the department any changes in the information furnished by that person in the "Certificate – In Vitro Testing with Radioactive Material Under General License". The report shall be furnished to the department within 30 days after the effective date of such change.

6. Any person using radioactive material under the general license under this paragraph is exempt from the requirements of subchs. III and X with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine–125 described in subd. 1. e. shall comply with the provisions of ss. HFS 157.23 (1) and 157.32 (1) and (2).

(g) *General license relating to ice detection devices.* A general license is issued to own, receive, acquire, possess, use and transfer strontium–90 contained in ice detection devices, provided each device contains not more than 1.85 MBq (50 microcuries) of strontium–90 and each device has been manufactured or imported under a specific license issued by the NRC or each device has been manufactured under the specifications contained in a specific license issued by the department or an agreement state to the manufacturer of the device under licensing requirements equivalent to those in 10 CFR 32.61.

1. A person who owns, receives, acquires, possesses, uses or transfers strontium–90 contained in ice detection devices under the general license under this paragraph shall do all the following:

a. Upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the NRC or an agreement state to manufacture or service the devices, or shall dispose of the device under the provisions of s. HFS 157.30 (1).

b. Assure that all labels affixed to the device at the time of receipt and which bear a statement that prohibits removal of the labels, are maintained on the device.

2. A person who owns, receives, acquires, possesses, uses or transfers strontium–90 contained in ice detection devices under the general license under this paragraph are exempt from the requirements of subchs. III and X except that the person shall comply with the provisions of ss. HFS 157.23 (1) and 157.32 (1) and (2).

3. The general license in this paragraph does not authorize the manufacture, assembly, disassembly or repair of strontium–90 in ice detection devices.

4. The general license in this paragraph is exempt from the requirements of subch. III with the exception of ss. HFS 157.30 (1), 157.32 (1) and (2), and subch. X.

History: CR 01–108: cr. Register July 2002 No. 559, eff. – see Note at the start of the chapter; corrections in (1) (c) 3. c. and (2) (g) 1. a. made under s. 13.93 (2m) (b) 7., Stats., Register July 2002 No. 559.

HFS 157.12 Registration of generally licensed devices. (1) REGISTRATION REQUIREMENT No person may possess, receive, use, own or transfer a device purchased under a general license that contains at least 370 MBq (10 millicuries) of cesium–137, 3.7 MBq (0.1 millicurie) of strontium–90, 37 MBq (1 millicurie) of cobalt–60 or 37 MBq (1 millicurie) of americium–241 or any other transuranic unless that person registers annually with the department and pays a fee as prescribed in sub. (6).

(2) EXEMPTIONS A person who possesses, receives, uses, owns or transfers a device purchased under a general license that is included under a new or existing specific license or that contains

isotopes different from those listed in sub. (1) is exempt from the requirements of this section.

(3) INFORMATION REQUIREMENTS A general licensee shall provide all the following information and any other information requested on the application form provided by the department:

(a) Name and mailing address of the general licensee.

(b) Information about each device: the manufacturer, model number, serial number, radioisotope and activity as indicated on the label.

(c) Name and telephone number of the individual designated by management as a representative of the general licensee.

(d) Address at which the device is used or stored. For a portable device, the address of the primary place of storage.

(e) Certification by signature from the individual representing the general licensee that the information concerning the device or devices has been verified through a physical inventory and check of label information.

(f) Certification by signature from the individual designated by management to represent the general licensee that the individual is aware of the requirements of the general license.

Note: The application for registration of general license devices may be obtained by writing the Department at: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659, or by downloading from the Department's website at: www dhfs state.wi.us/licensing/

(4) CHANGE OF ADDRESS. A general licensee shall report, in writing, an address change to the department within 30 calendar days after moving the devices. In the case of portable devices, a general licensee shall report the device's primary storage location.

(5) INVENTORY CHANGES. A general licensee shall report, in writing, additions to or deletions from device inventory or changes in other registration information to the department within 30 calendar days after the change.

(6) FEES (a) A general licensee shall pay an annual registration fee of $100 per site and $50 per device specified in sub. (1). The department may not assess an additional fee for recording changes in registration information.

(b) The annual registration fee for the next year shall be paid by December 31 of the prior year of registration. The department shall issue a notice of registration following receipt of the registration fee. If the annual registration fee for the next year is not received by the department by December 31 of the prior year of registration, a licensee shall pay a penalty fee of $25, in addition to the registration fee and regardless of the number of devices, before the department will issue a new notice of registration.

(7) INSPECTION BY MAIL. (a) A general licensee shall complete an inspection by mail form, provided by the department with each annual registration renewal, and return it to the department by December 31 of that year. The form shall include information deemed necessary by the department.

(b) No additional fee may be required for this form.

(c) A general licensee who fails to complete this form may be subject to a site inspection.

Note: The inspection by mail form may be obtained by writing the Department at: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659, or by downloading from the Department website at www dhfs state wi.us/licensing/.

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

HFS 157.13 Specific licenses. (1) FILING APPLICATION FOR SPECIFIC LICENSES. (a) An application for a specific license shall be filed on a form prescribed by the department.

Note: A specific license application form may be obtained by writing the Department, including a description of the proposed activity to be licensed. The Department's address is: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659, or by downloading from the Department's website at: www.dhfs.state.wi.us/licensing/

(b) The department may at any time after the filing of the original application, and before the expiration of the license, require further statements to enable the department to determine whether the application should be granted or denied or whether a license should be modified, suspended or revoked.

(c) The applicant, licensee or a person authorized to act on behalf of the applicant or licensee shall sign the application.

(d) A license application may include a request for a license authorizing one or more activities.

(e) In the application, the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the department provided such references are clear and specific.

(f) The department shall make applications and documents submitted to the department available for public inspection under ss. 19.32 to 19.39, Stats.

(g) Each application to possess radioactive material in unsealed form, on a foil or plated source, or sealed in glass in excess of the quantities in Appendix P, "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release", shall contain one of the following:

1. An evaluation showing that the projected dose to a person offsite due to a release of radioactive material would not exceed 0.01 Sievert (1 rem) total effective dose equivalent or 0.05 Sievert (5 rem) to the thyroid.

2. An emergency plan, reviewed and commented on by offsite response organizations expected to respond in the event of an accident, that contains the information described in Appendix Q for responding to any event in which radioactive material could be released from the site.

(h) Each application to use radioactive material in the form of a sealed source or in a device that contains a sealed source shall contain either of the following:

1. Information that identifies the source or device by manufacturer and model number as registered with the NRC or an agreement state.

2. The information identified in 10 CFR 32.210(c)

(2) GENERAL REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES. The department shall approve a license application within 180 working days of filing of a complete application if the department determines that all the following apply:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested under the requirements of this chapter in a manner that minimizes danger to public health and safety or property.

(b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property.

(c) 1. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the department determines will significantly affect the quality of the environment, the department, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values.

2. Commencement of construction prior to the department's conclusion in subd. 1. shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other pre-construction monitoring or testing to establish background

information related to the suitability of the site or the protection of environmental values.

(d) The applicant satisfies any applicable requirements in subs. (3), (4) and (6), s. HFS 157 15 and subchs. IV, V and VI.

(e) The applicant pays all applicable fees as specified in s. HFS 157.10.

(f) In the case of an application for a license to possess and use an x–ray fluorescence analyzer (XRF) for the detection of lead in paint or portable gauges using sealed sources, the applicant shall verify that the operator training requirements of Appendix S are met prior to the operator using the device

(3) SPECIAL REQUIREMENTS FOR SPECIFIC LICENSES OF BROAD SCOPE (a) This subsection prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of the licenses.

(b) The different types of broad scope licenses are as follows

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose The quantities specified are usually in the multicurie range, but may be limited based on types of radioactive materials, proposed use and the training and experience of users.

2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix C, for any authorized purpose The possession limit for a Type B license of broad scope, if only one radionuclide is possessed under the license, is the quantity specified for that radionuclide in Appendix C, Column I. If 2 or more radionuclides are possessed under the license, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix C, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license may not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix C, for any authorized purpose The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix C, Column II. If 2 or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix C, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license may not exceed unity.

(c) The department shall approve an application for a Type A specific license of broad scope if all the following occurs.

1 The applicant satisfies the general requirements specified in sub. (2).

2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material.

3. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, accounting and management review that are necessary to assure safe operations, including all of the following·

a. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management and persons trained and experienced in the safe use of radioactive material.

b The appointment of a radiation safety officer who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiation safety matters.

c. The establishment of appropriate administrative procedures to assure control of procurement and use of radioactive material; completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prior to use of the radioactive material.

(d) The department shall approve an application for a Type B specific license of broad scope if all the following occurs:

1. The applicant satisfies the general requirements specified in sub. (2).

2. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, accounting and management review that are necessary to assure safe operations, including all the following:

a. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiation safety matters.

b The establishment of appropriate administrative procedures to assure control of procurement and use of radioactive material, completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prior to use of the radioactive material.

(e) The department shall approve an application for a Type C specific license of broad scope if all the following occurs:

1 The applicant satisfies the general requirements specified in sub (2).

2. The applicant submits a statement that radioactive material will be used only by or under the direct supervision of individuals who have received all the following:

a. A college degree at the bachelor level in the physical or biological sciences or in engineering or equivalent training and experience.

b. At least 40 hours of training and experience in the safe handling of radioactive material and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

3. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control, accounting and management review necessary to assure safe operations.

(f) A specific license of broad scope is subject to all of the following conditions.

1. Unless specifically authorized, a person licensed under sub. (3) may not do any of the following:

a Conduct tracer studies in the environment involving direct release of radioactive material.

b. Receive, acquire, own, possess, use or transfer devices containing 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources used for irradiation of materials.

c. Conduct activities for which a specific license issued by the department under sub. (4) or subch VI is required

d. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

2. A Type A specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license may only be used by or under the direct supervision of individuals approved by the licensee's radiation safety committee.

3. A Type B specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license may only be used by or under the direct supervision of individuals approved by the licensee's radiation safety officer.

4. A Type C specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license may only be used by or under the direct supervision of individuals who satisfy the requirements of par. (e).

(4) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL. (a) *Licensing the introduction of radioactive material into products in exempt concentrations.* 1. In addition to the requirements set forth in sub. (2), a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to a person exempt under s. HFS 157.09 (2) (a) shall be issued only under all the following conditions:

a. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material and estimated concentration of the radioactive material in the product or material at the time of transfer.

b. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A of this chapter, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A is not likely, that use of lower concentrations is not feasible and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by or application to a human being.

2. A person licensed under this paragraph shall file an annual report with the department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made under par. (a) during the reporting period, the report shall so indicate. The report shall cover the previous 12-month period ending June 30 and shall be filed within 30 days thereafter.

Note: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D C. 20555

(b) *Licensing the commercial distribution of radioactive material in exempt quantities.* 1. The department shall approve an application for a specific license to distribute NARMs to persons exempted from this chapter under s. HFS 157.09 (2) (b) only under all the following conditions:

a. The radioactive material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion, inhalation by or application to a human being.

b. The radioactive material is in the form of processed chemical elements, compounds or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

c. The applicant submits copies of prototype labels and brochures and the department approves such labels and brochures.

d. Out of state manufacturers of the product hold a license issued by a licensing or agreement state.

2. The license issued under this paragraph is subject to all the following conditions:

a. No more than 10 exempt quantities may be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions do not exceed unity.

b. Each exempt quantity shall be separately and individually packaged. No more than 10 packaged exempt quantities may be contained in any outer package for transfer to persons exempt under s. HFS 157.09 (2) (b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 5 μSv (0.5 millirem) per hour.

c. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label that identifies the radionuclide and the quantity of radioactivity and bears the words "Radioactive Material".

d. In addition to the labeling information required by this subd. 2. c., the label affixed to the immediate container or an accompanying brochure shall state that the contents are exempt from licensing or agreement state requirements; the words "Radioactive Material – Not for Human Use – Introduction into Foods, Beverages, Cosmetics, Drugs or Medicinals or into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not Be Combined"; and appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

3. A person licensed under this paragraph shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under s. HFS 157.09 (2) (b) or the equivalent regulations of a licensing or agreement state and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made under this paragraph during the reporting period, the report shall so indicate.

(c) *Licensing the incorporation of NARM into gas and aerosol detectors.* The department shall approve an application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under s. HFS 157.09 (2) (c) 13. if the application satisfies requirements equivalent to those contained in 10 CFR 32.26. The maximum quantity of radium-226 in each device may not exceed 3.7 kBq (0.1 microcurie).

(d) *Licensing the manufacture and distribution of devices to persons generally licensed under s. HFS 157.11 (2) (b).* 1. The department shall approve an application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under s. HFS 157.11 (2) (b) or equivalent regulations of the NRC,

an agreement state or a licensing state only under all the following conditions

a. The applicant satisfies the general requirements of sub. (2)

b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions and potential hazards of the device to provide reasonable assurance that the device may be safely operated by persons not having training in radiological protection.

c. The applicant submits sufficient information, as specified in subd. 1. b , to provide reasonable assurance that under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of 10% of the annual limits specified in s. HFS 157.22 (1) (a).

d The applicant submits sufficient information, as specified in subd 1. b., to provide reasonable assurance that under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye ... . 150 mSv (15 rems)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter .... .2 Sv (200 rems)

Other organs .... 500 mSv (50 rems).

e. Each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement, the following information: instructions and precautions necessary to assure safe installation, operation and servicing of the device; and the requirement or lack of requirement, for leak testing or for testing any "on–off" mechanism and indicator, including the maximum time interval for such testing and the identification of radioactive material by isotope, quantity of radioactivity and date of determination of the quantity.

Note: Documents such as operating and service manuals may be identified in the label and used to provide instructions and precautions necessary to assure safe installation, operation and servicing of the device

2. Unless the model, serial number and name of the manufacturer or distributor is specified elsewhere in labelling affixed to the device, the label or labels identified in subd 1. e. shall also contain one of the following statements, as appropriate, in the same or substantially similar form:

a. The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the NRC or a state with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited

CAUTION – RADIOACTIVE MATERIAL

_____

Name of manufacturer or initial distributor

b. The receipt, possession, use, and transfer of this device, Model _____, Serial No _____, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

_____

Name of manufacturer or initial distributor

3. If the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on–off" mechanism and indicator, if any or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on–off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the applicant shall submit all of the following information:

a. Primary containment of the source capsule.

b Protection of primary containment.

c. Method of sealing containment

d. Containment construction materials

e. Form of contained radioactive material.

f Maximum temperature withstood during prototype tests

g Maximum pressure withstood during prototype tests.

h. Maximum quantity of contained radioactive material.

i. Radiotoxicity of contained radioactive material

j. Operating experience with identical devices or similarly designed and constructed devices.

4 If the applicant desires that the general licensee under s. HFS 157.11 (2) (b) or equivalent regulations of the NRC, an agreement state or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on–off" mechanism and indicator or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities and bases for the estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in s HFS 157 22 (1) (a).

5 A person licensed under this paragraph to distribute devices to generally licensed persons shall do all the following:

a. Furnish a copy of the general license contained in ss. HFS 157.11 (2) (b), 157.02, 157.06 (1), 157.13 (18) and 157.32 (1) and (2), notification of the registration requirement contained in s. HFS 157.12 (1), a list of the services that can only be performed by a specific licensee, information on disposal options including estimated costs of disposal and the penalties for improper disposal under s. HFS 157.90 to each person to whom he or she directly or through an intermediate person transfers radioactive material in a device for use under the general license contained in s. HFS 157.11 (2) (b). Section HFS 157.11 (2) (b) 3 b. to 3. d may be omitted from a copy of the general license, or notification of the registration requirements of s. HFS 157.12 (1) may be omitted if the requirements do not apply to a particular device.

b. Furnish a copy of the general license contained in the NRC's, agreement state's or licensing state's regulation equivalent to ss. HFS 157.02, 157 06 (1), 157.11 (2) (b), 157 13 (18) and 157 32 (1) and (2), notification of the registration requirement equivalent to s. HFS 157.12 (1), a list of the services that can only be performed by a specific licensee, information on disposal options including estimated costs of disposal, and the name or title, address, and phone number of the contact at the agreement state or NRC from which additional information may be obtained to each person to whom he or she directly or through an intermediate person transfers radioactive material in a device for use under the general license of the NRC, the agreement state or the licensing state prior to the transfer. If a copy of the general license in s. HFS 157.11 (2) (b) is furnished to the person, it shall be accompanied by a note explaining that the use of the device is regulated by the NRC, agreement state or licensing state under requirements substantially the same as those in s. HFS 157.11 (2) (b). Regula-

tions from the NRC, agreement state or licensing state that are equivalent to s. HFS 157.11 (2) (b) 3. b. to 3. d., may be omitted from a copy of the general license if the requirements do not apply to a particular device. Notification of the registration requirement equivalent to s. HFS 157.12 (1) may also be omitted if it does not apply to a particular device.

c. Report to the department all transfers of such devices to persons for use under the general license in s. HFS 157.11 (2) (b). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons generally licensed under s. HFS 157.11 (2) (b) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter

d. Report to the NRC all transfers of such devices to persons for use under the NRC general license in 10 CFR 31.5. If no transfers have been made to NRC licensees during the reporting period, the report shall so indicate and be reported to the NRC.

e. For devices shipped to another state, report to the responsible state agency all transfers of devices manufactured and distributed under this paragraph for use under a general license in that state's regulations equivalent to s. HFS 157.11 (2) (b). If no transfers have been made to general licensees within a particular state during the reporting period, the report shall so indicate and be sent to the responsible state agency upon request of that agency.

f. The reports in subd. 5. d. and e. shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If any changes are made to a device, such that the label is changed to update required information, the report shall identify the general licensee, the device, and the changes in information on the device label. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person, cover each calendar quarter and clearly indicate the period covered by the report

g. For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number and serial number of the device received and the date of receipt. In the case of devices not initially transferred by the reporting licensee, the report shall also include the name of the manufacturer or initial transferor.

h. Retain records showing the name, address, and the point of contact for each general licensee to whom he or she directly or through an intermediate person transfers radioactive material in devices for use under the general license provided in s. HFS 157.11 (2) (b) or equivalent regulations of the NRC, an agreement state or a licensing state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, compliance with the report requirements of this subdivision and be retained for 5 years from the date of transfer.

i. If a notification of bankruptcy has been made under s. HFS 157.13 (10) or the license is to be terminated, a person licensed under this paragraph shall provide, upon request, to the department, NRC and to any appropriate agreement state, records of final disposition required under subd. 5. h.

(e) *Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft.* The department shall approve an application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium–147 for use in aircraft, for distribution to persons generally licensed under s. HFS 157.11 (2) (c) if the applicant satisfies the general requirements specified in sub. (2) and the requirements of 10 CFR 32.53 to 32.56, 32.101 and 32.110 or their equivalent.

(f) *Special requirements for license to manufacture calibration or reference sources containing americium–241, plutonium or radium–226 for distribution to persons generally licensed under s. HFS 157.11 (2) (e).* The department shall approve an application for a specific license to manufacture calibration or reference sources containing americium–241, plutonium or radium–226 to persons generally licensed under s. HFS 157.11 (2) (e) if the applicant satisfies the general requirement of sub. (2) and the requirements of 10 CFR 32.57 to 32.59, 10 CFR 32.102 and 10 CFR 70.39 or their equivalent.

(g) *Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.* The department shall approve an application for a specific license to manufacture or distribute radioactive material for use under the general license of s. HFS 157.11 (2) (f) if all of the following conditions are satisfied:

1. The applicant satisfies the general requirements specified in sub. (2).

2. The radioactive material is to be prepared for distribution in prepackaged units of one of the following:

a. Carbon–14 in units not exceeding 370 kBq (10 microcuries) each.

b. Cobalt–57 in units not exceeding 370 MBq (10 microcuries) each.

c. Hydrogen–3 in units not exceeding 1.85 MBq (50 microcuries) each.

d. Iodine–125 in units not exceeding 370 MBq (10 microcuries) each.

e. Mock Iodine–125 in units not exceeding 1.85 MBq (0.05 microcurie) of iodine–129 and 185 MBq (0.005 microcurie) of americium–241 each.

f. Iodine–131 in units not exceeding 370 kBq (10 microcuries) each.

g. Iron–59 in units not exceeding 740 kBq (20 microcuries) each.

h. Selenium–75 in units not exceeding 370 kBq (10 microcuries) each.

3. Each prepackaged unit bears a durable, clearly visible label that does all the following:

a. Identifies the radioactive contents as to chemical form and radionuclide, and indicates that the amount of radioactivity does not exceed 370 kBq (10 microcuries) of iodine–125, iodine–131, carbon–14, cobalt–57, or selenium–75; 1.85 MBq (50 microcuries) of hydrogen–3; 740 kBq (20 microcuries) of iron–59; or Mock Iodine–125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine–129 and 185 Bq (0.005 microcurie) of americium–241 each.

b. Displays the radiation caution symbol described in s. HFS 157.29 (1) (a) and the words "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

4. One of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

a. This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation from the material, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority

_____
Name of manufacturer

b. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

_____
Name of manufacturer

5 The label affixed to the unit or the leaflet or brochure that accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine–125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in s. HFS 157.30 (1).

(h) *Licensing the manufacture and distribution of ice detection devices.* The department shall approve an application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under s. HFS 157.11 (2) (g) if all the following applies:

1. The applicant satisfies the general requirements of sub. (2).

2. The criteria of 10 CFR 32 61, 32 62, 32.103 and 32.110 are met.

(i) *Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under subchapter VI* The department shall approve an application for a specific license to manufacture, prepare, or transfer for commercial distribution drugs containing radioactive material for use by a person authorized under subchapter VI if all the following conditions are satisfied:

1. The applicant satisfies the general requirements specified in sub. (2).

2. The applicant submits evidence that the applicant is at least one of the following:

a. Registered or licensed with the FDA as a drug manufacturer.

b Registered or licensed with a state agency as a drug manufacturer.

c. Licensed as a pharmacy by a state board of pharmacy.

d. Operating as a nuclear pharmacy within a Federal medical institution.

3. The applicant submits all of the following information on the radionuclide:

a. The chemical and physical form of the radiopharmaceutical.

b. The maximum activity per vial, syringe, generator, or other container of the radioactive drug and the shielding provided by the packaging to show medical use licensees that it is safe to handle and store.

4. The applicant satisfies all of the following labeling requirements:

a. A label is affixed to each transport radiation shield, whether the shield is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted

b. A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container may be correlated with the information on the transport radiation shield label.

5. The applicant shall submit information to demonstrate that the individuals who prepare radiopharmaceuticals for medical use are one of the following:

a. Qualified as an authorized nuclear pharmacist as specified in s. HFS 157.61 (9) and (11).

b Authorized as an experienced nuclear pharmacist under s. HFS 157.61 (10).

6. The applicant shall submit information that he or she will do all of the following:

a. Possess and use instrumentation to measure the radioactivity of the drugs The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon–emitting drugs prior to transfer for commercial distribution.

b. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary.

c. Check each instrument for constancy and proper operation at the beginning of each day of use.

7. Nothing in this paragraph relieves a licensee or registrant from complying with applicable FDA, other federal and state requirements governing radioactive drugs.

(j) *Manufacture and distribution of sources or devices containing radioactive material for medical use.* The department shall approve an application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under subch. VI for use as a calibration or reference source or for the uses listed in ss. HFS 157.65 (1), 157.66 (1) and 157.67 (1) if all of the following conditions are satisfied:

1. The applicant satisfies the general requirements in sub. (2)

2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including all of the following:

a. The radioactive material contained, its chemical and physical form and amount.

b. Details of design and construction of the source or device.

c. Procedures for and results of prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents.

d. For devices containing radioactive material, the radiation profile of a prototype device.

e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests.

f. Procedures and standards for calibrating sources and devices.

g. Legend and methods for labeling the radioactive content of sources and devices.

h. Instructions for handling and storing the source or device from the radiation safety standpoint The instructions shall be included on a durable label attached to the source or device or

attached to a permanent storage container for the source or device; provided, that instructions that are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

3. The label affixed to the source or device or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the department for distribution to persons licensed under subch. VI and s. HFS 157.62 (4) or under equivalent licenses of the NRC, an agreement state or a licensing state.

4 If the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source. In determining the acceptable interval for the test for leakage of radioactive material, the applicant shall submit all of the following information:

a. Primary containment of the source capsule

b. Protection of primary containment.

c. Method of sealing containment.

d. Containment construction materials.

e. Form of contained radioactive material.

f. Maximum temperature withstood during prototype tests.

g. Maximum pressure withstood during prototype tests.

h. Maximum quantity of contained radioactive material.

i. Radiotoxicity of contained radioactive material.

j Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(k) *Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass–volume applications.* 1. The department shall approve an application for a specific license to manufacture industrial products and devices containing depleted uranium for use under s. HFS 157.11 (1) (c) or equivalent regulations of the NRC or an agreement state under the following conditions:

a. The applicant satisfies the general requirements specified in sub. (2).

b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one year a radiation dose in excess of 10% of the annual limits specified in s. HFS 157.22 (1).

c. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass–volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

2. In the case of an industrial product or device whose unique benefits are questionable, the department shall approve an application for a specific license under this paragraph only if the department determines that the product or device combines a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

3. The department may deny any application for a specific license under this paragraph if the end use or uses of the industrial product or device cannot be reasonably foreseen.

4. A person licensed under subd. 1. shall do all of the following:

a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device and in the installation of the depleted uranium into the product or device.

b. Label or mark each unit to identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium and the quantity of depleted uranium in each product or device; and state that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or an agreement state.

c. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium".

d. Furnish a copy of the general license contained in s. HFS 157.11 (1) (c) and a copy of the "Certificate – Use of Depleted Uranium Under General License" to each person to whom he or she transfers depleted uranium in a product or device; or furnish a copy of the general license contained in the NRC's or agreement state's regulation equivalent to s. HFS 157.11 (1) (c) and a copy of the NRC's or agreement state's certificate with a note explaining that use of the product or device is regulated by the NRC or an agreement state under requirements substantially the same as those in s. HFS 157.11 (1) (c).

e. Report to the department all transfers of industrial products or devices to persons for use under the general license in s. HFS 157.11 (1) (c). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred and the quantity of depleted uranium contained in the product or device. The report shall be filed with the department within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under s. HFS 157.11 (1) (c) during the reporting period, the report shall so indicate.

f. Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in 10 CFR 40.25.

g. Report to the responsible state agency all transfers of devices manufactured and distributed under this paragraph for use under a general license in that state's regulations equivalent to s. HFS 157.11 (1) (c)

h. The report required in subd. 4. f. and g shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the department and the general licensee, the type and model number of the device transferred and the quantity of depleted uranium contained in the product or device. The report shall be filed with the department within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

i. If no transfers have been made to NRC licensees during the reporting period, the report shall so indicate.

j. If no transfers have been made to general licensees within this state or another particular agreement state during the reporting period, this information shall be reported to the department or the responsible agency in another agreement state, upon the request of that agency

k. Keep records showing the name, address and point of contact for each general licensee to whom he or she transfers depleted uranium in industrial products or devices for use under the general license provided in s. HFS 157.11 (1) (c) or equivalent regulations of the NRC or an agreement state. The records shall be maintained for a period of 3 years from the date of each transfer respectively

and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of this section.

(5) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE FOR MEDICAL USE OF RADIOACTIVE MATERIAL. (a) *License application.* The department shall approve an application for a specific license for medical use of radioactive material if all of the following conditions are satisfied:

1. The applicant satisfies the general requirements specified in sub. (2)

2. The applicant submits procedures required by s. HFS 157.67, as applicable.

3. In addition to the requirements in this paragraph and par (b), an application for a license or amendment for medical use of radioactive material as described in s. HFS 157.70 shall also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in ss. HFS 157.59 to 157 62, as well as any specific information on each of the following

a. Radiation safety precautions and instructions.

b. Training and experience of proposed users.

c Methodology for measurement of dosages or doses to be administered to patients or human research subjects.

d. Calibration, maintenance and repair of instruments and equipment necessary for radiation safety.

4. An applicant for a license for mobile services shall assure that release of individuals or human research subjects to whom radioactive drugs or implants containing radioactive material are administered will be released under s HFS 157 62 (8).

5. The applicant or licensee shall provide any other information requested by the department in its review of the application.

(b) *License amendment.* An application for a license amendment shall meet all of the following requirements:

1. A licensee shall apply for and must receive a license amendment before the licensee does any of the following:

a. Receives or uses radioactive material for a type of use that is permitted under this subchapter, but that is not authorized on the licensee's current license issued under this subchapter.

b Permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is certified by a specialty board appropriate to the intended use of radioactive material and recognized by the NRC; or is named as an authorized user, authorized nuclear pharmacist or authorized medical physicist on a department, NRC or other agreement state license, or on a permit issued by a licensee who is authorized by a Type A license of broad scope to permit the medical use of radioactive material.

c Changes radiation safety officers, except as provided in s HFS 157.61 (1) (c)

d. Receives radioactive material in excess of the amount or in a different form or receives a different radionuclide than is authorized on the license

e. Adds to or changes the areas identified in the application or on the license, except for areas where radioactive material is used only under s. HFS 157 63 (1) and (2)

f. Changes the address or addresses of use identified in the application or on the license

2. An application for a license amendment shall include procedures required by s. HFS 157.67, as applicable.

(c) *Notifications.* A licensee shall make all of the following notifications:

1 Provide to the department a copy of the board certification, the NRC or agreement state license or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under par. (b) 1 b

2. Notify the department in writing no later than 30 days after any of the following occurs:

a. An authorized user, an authorized nuclear pharmacist, a radiation safety officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change.

b The licensee's mailing address changes.

c The licensee's name changes but the name change does not constitute a transfer of control of the license

d. The licensee has added to or changed the areas where radioactive material is used under s. HFS 157 63 (1) and (2).

(d) *Exemptions for Type A broad scope licensees.* 1. A licensee possessing a Type A specific license of broad scope for medical use is exempt from all of the following requirements:

a. The provisions of par. (a) 3. regarding the need to file an amendment to the license for medical uses of radioactive material as described in s. HFS 157.70.

b. The provisions of par. (b) 1. b.

c. The provisions of par. (b) 1. e regarding additions to or changes in the areas of use only at the addresses specified in the license.

d. The provisions of par (c) 1.

e The provisions of par. (c) 2 a. for an authorized user, an authorized nuclear pharmacist or an authorized medical physicist.

f. The provisions of s. HFS 157.61 (6) (a).

(6) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO CONDUCT INDUSTRIAL RADIOGRAPHY OPERATIONS. The department shall approve an application for a specific license to conduct radiography using radioactive materials if all the following conditions are satisfied:

(a) The applicant satisfies the general requirements specified in sub. (2).

(b) The applicant has an adequate program for training radiographers and radiographer's assistants that meets the requirements of s HFS 157.44 (3).

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

(d) The applicant submits written operating and emergency procedures that meet the requirements of s. HFS 157.44 (4).

(e) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months that meets the requirements of s. HFS 157.44 (3) (e).

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

(g) The applicant submits the qualifications of the individual designated as the radiation safety officer.

(h) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium shielding, the applicant shall describe the procedures for performing the test. The description shall include all of the following:

1. Methods of collecting the samples.

2 Qualifications of the individual who analyzes the samples.

3 Instruments to be used.

4. Methods of analyzing the samples.

(i) The applicant verifies that calibration of survey meters and alarming rate meters is performed according to the requirements of ss. HFS 157.38 and 157.44 (6) (g) 4., respectively.

(j) The applicant identifies and describes the location or locations of all field stations and permanent radiographic installations.

(k) The applicant identifies the location or locations where all records required by this and other subchapters will be maintained.

(L) If a license application includes underwater radiography, a description of all of the following:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography.

2. Radiographic equipment and radiation safety equipment unique to underwater radiography.

3. Methods for gas–tight encapsulation of equipment.

(m) If an application includes offshore platform or lay–barge radiography, a description of all of the following:

1. Transport procedures for radioactive material to be used in industrial radiographic operations.

2. Storage facilities for radioactive material.

3. Methods for restricting access to radiation areas.

(n) The applicant describes the program for inspection and maintenance of radiographic exposure devices and storage containers to ensure proper functioning of components important to safety.

(7) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO CONDUCT IRRADIATOR OPERATIONS (a) The department shall approve an application for a specific license for the use of radioactive material in an irradiator if all the following conditions are satisfied.

1. The applicant satisfies the general requirements in sub. (2).

2. The applicant submits an adequate program for training irradiator operators that includes all of the following:

a. Classroom training.

b. On–the–job or simulator training.

c. Safety reviews.

d. The method employed by the applicant to test each operator's understanding of the department's regulations and licensing requirements and the irradiator operating, safety and emergency procedures.

e. Minimum training and experience of personnel who may provide training.

3. The applicant submits an outline of the written operating and emergency procedures that describes the radiation safety aspects of the procedures.

4. The applicant submits a description of the overall organizational structure for managing the irradiator, including the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have radiation safety responsibilities or authorities, and who within the management structure has the authority to stop unsafe operations. The applicant shall also describe the training and experience required for the position of radiation safety officer.

5. The applicant includes a description of the access control systems required by s. HFS 157.73 (2), radiation monitors required by s. HFS 157.73 (5), the method of detecting leaking sources required by s. HFS 157.73 (16) including the sensitivity of the method and a diagram of the facility showing the locations of all required interlocks and radiation monitors

6. If the applicant intends to perform leak testing, the applicant shall establish procedures for performing leak testing of dry–source–storage sealed sources and submit a description of these procedures to the department. The description shall include all the following:

a. Methods of collecting the leak test samples.

b. Qualifications of the individual who collects the samples.

c. Instruments to be used.

d. Methods of analyzing the samples.

7. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading shall only be done by a person specifically authorized by the department, the NRC or another agreement state to load or unload irradiator sources. The information in this subdivision shall also be indicated on the application.

8. The applicant describes the inspection and maintenance checks, including the frequency of the checks required by s. HFS 157.73 (17).

(b) A license issued under par. (a) is subject to all of the following conditions:

1. The applicant may not begin construction of a new irradiator prior to the submission to the department of both an application for a specific license for the irradiator and the fee required by s. HFS 157.10 (3). As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site, but does not include engineering and other design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license by the department.

2. Any application for a license or for amendment of a license authorizing use of a teletherapy–type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this subsection. The department shall approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates the likely provision of an adequate level of safety for workers and the public.

3. Each license will be issued with the condition that the licensee will, at any time before expiration of the license, upon the department's request, submit a written statement to enable the department to determine whether the license should be modified, suspended or revoked.

(8) SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO CONDUCT WIRE–LINE OPERATIONS AND SUBSURFACE TRACER STUDIES The department shall approve an application for a specific license for the use of radioactive material in wire–line service operations and subsurface tracer studies if all the following conditions are satisfied:

(a) The applicant satisfies the general requirements specified in sub. (2).

(b) The applicant submits an adequate program for training well logging supervisors and well logging assistants that includes all the following:

1. Initial training.

2. On–the–job training.

3. Annual safety reviews provided by the licensee.

4. Means by which the applicant will demonstrate the well logging supervisor's knowledge and understanding of and ability to comply with the department's rules and licensing requirements and the applicant's operating and emergency procedures.

5. Means by which the applicant will demonstrate the well logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(c) The applicant submits to the department written operating and emergency procedures as described in s. HFS 157.53 (2) or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(d) The applicant establishes and submits to the department the applicant's program for annual inspections of the job performance of each well logging supervisor to ensure that the department's rules, license requirements, and the applicant's operating and emergency procedures are followed. The applicant's inspection

records shall be retained for 3 years after each annual internal inspection.

(e) The applicant submits a description of its overall organizational structure as it applies to the radiation safety responsibilities in wire–line services or subsurface tracer studies, including specified delegations of authority and responsibility.

(f) If an applicant wants to perform leak testing of sealed sources, the applicant identifies the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant establishes procedures to be followed and submits a description of these procedures to the department The description shall include all the following:

1 Instruments to be used

2. Methods of performing the analysis.

3. Pertinent experience of the person who will analyze the wipe samples

(9) ISSUANCE OF SPECIFIC LICENSES. (a) If the department determines that an application meets the applicable requirements, the department shall issue a specific license within 180 days of filing of a complete application authorizing the proposed activity in such form and containing such conditions and limitations as the department deems appropriate or necessary

(b) The department may incorporate in any license at the time of issuance or thereafter, any additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this section as the department deems appropriate or necessary.

(10) SPECIFIC TERMS AND CONDITIONS OF LICENSES. (a) A license issued under this section shall be subject to all the provisions of ss. 254 31 to 254 45, Stats., this chapter and orders of the department.

(b) No license issued or granted under this section and no right to possess or utilize radioactive material granted by any license issued under this subsection may be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department, after securing full information, finds that the transfer complies with the applicable provisions of the statutes, rules and orders of the department, and gives its consent in writing.

(c) A person licensed by the department under this section shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) A licensee shall notify the department in writing within 30 days of the decision by the licensee to permanently discontinue all activities involving materials authorized under the license.

(e) A licensee shall notify the department in writing within 10 days following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 of the United States Code by or against any one of the following.

1. The licensee.

2. An entity defined in 11 USC 101(14) controlling the licensee or listing the license or licensee as property of the estate.

3. An affiliate defined in 11 USC 101(2) of the licensee.

Note: Title 11 of the U.S. Code deals with bankruptcy.

(f) The notification specified in par. (e) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(11) EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING OF SITES AND SEPARATE BUILDING OR OUTDOOR AREAS (a) Except as provided in sub. (12) (b), a specific license shall expire at the end of the specified day in the month and year stated in the license. If an application for license renewal has been filed at least 30 days prior to the expiration date stated in the existing license and the department denies the renewal application, the license shall expire on the date as stated in the determination of denial. If an application for license renewal is filed less than 30 days from the expiration date stated in the existing license, the department may deny the renewal application and the license shall expire on the expiration date stated in the license.

(b) A specific license revoked by the department expires at the end of the day on the date of the department's final determination, or on the expiration date stated in the determination, or as otherwise provided by department order.

(c) A specific license remains valid, with respect to possession of radioactive material, until the department notifies the licensee in writing that the license is terminated. While the license is valid, the licensee shall do all of the following

1. Limit actions involving radioactive material to those related to decommissioning and other activities related to preparation for release for unrestricted use.

2 Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the department notifies the licensee in writing that the license is terminated.

(d) A licensee shall do all of the following:

1 Notify the department within 60 days of any of the following:

a. Expiration of the license pursuant to par. (a) or (b).

b The licensee's deciding to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with department requirements.

c. The absence of conduct of any principal activities under the license for a period of 24 months

d. The absence of conduct of any principal activities for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with department requirements.

2. If any separate building or outdoor area contains residual radioactivity so that the building or outdoor area is unsuitable for release, do one of the following:

a. Begin decommissioning its site, separate building or outdoor area if a decommissioning plan has been previously approved by the department.

b Submit a decommissioning plan within 12 months if required by par. (f) and begin decommissioning upon approval of that plan

(e) Concurrent with the notification required by par. (d), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to s. HFS 157.15 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance shall be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to par. (f) 4. Following approval of the decommissioning plan and with the department's approval, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site

(f) A licensee shall submit a decommissioning plan to the department if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site, separate building or outdoor area have not been previously approved by the department and the procedures and activities may adversely effect the health and safety of workers or the public. The procedures may not be carried out prior to the department's approval of the decommissioning plan. Examples of applicable procedures and activities include any of the following cases:

1 Procedures that would involve techniques not applied routinely during cleanup or maintenance operations.

2. Procedures by which workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation.

3. Procedures that could result in significantly greater airborne concentrations of radioactive materials than are present during operation.

4. Procedures that could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(g) The department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to par. (d) if the department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(h) The proposed decommissioning plan for the site or separate building or outdoor area shall include all of the following elements:

1. A description of the conditions of the site, separate building or outdoor area sufficient to evaluate the acceptability of the plan

2. A description of planned decommissioning activities.

3. A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.

4. A description of the planned final radiation survey.

5. An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

6. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in par. (i).

(i) The department shall approve the proposed decommissioning plan if the information in the plan demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be ensured.

(j) Except as provided in paragraph (h), a licensee shall complete decommissioning of the site or separate building or outdoor area no later than 24 months following the initiation of decommissioning. When decommissioning involves the entire site, a licensee shall request license termination no later than 24 months following the initiation of decommissioning.

(k) The department may approve a request for an alternative schedule for completion of decommissioning of the site, separate building or outdoor area, and license termination if appropriate, if the department determines that the alternative is warranted after consideration of all the following:

1. Whether it is technically feasible to complete decommissioning within the allotted 24–month period.

2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24–month period.

3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short–lived radionuclides to decay.

4. Whether a significant reduction in radiation exposure to workers may be achieved by allowing short–lived radionuclides to decay.

5. Other site–specific factors which the department may consider appropriate on a case–by–case basis, such as the regulatory requirements of other government agencies, court decisions, ground–water treatment activities, monitored natural ground–water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(L) As the final step in decommissioning, a licensee shall do all the following:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed department form for disposition of radioactive materials or equivalent information.

Note: The form may be obtained by writing the Department at: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701–2659; or by downloading from the Department website at: www.dhfs.state.wi.us/licensing/.

2. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in s. HFS 157.33.

3. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels per 100 square centimeters, disintegrations per minute per 100 square centimeters or microcuries per 100 square centimeters – removable and fixed – for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete.

4. Specify the survey instruments used and certify that each instrument is properly calibrated and tested.

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

(m) The department shall terminate a specific license, including an expired license, by written notice to the licensee when the department determines all of the following have occurred:

1. Radioactive material has been properly disposed of.

2. Reasonable effort has been made to eliminate residual radioactive contamination, if present.

3. The licensee has filed with the department sufficient information, including a radiation survey, to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in s. HFS 157.33.

4. The licensee has submitted records required under s. HFS 157.13 (18) (b) and (d) to the department.

(12) RENEWAL OF LICENSES (a) An application for renewal of a specific license shall be filed under sub.(1).

(b) If a licensee, not less than 30 days prior to expiration of his or her existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the license may not expire until final action by the department.

Note: A license renewal form 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 by downloading from the Department website at: www.dhfs.state.wi.us/licensing/.

(13) AMENDMENT OF LICENSES AT REQUEST OF LICENSEE. An application for amendment of a license shall be filed under sub (1) and shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment. The licensee shall include the appropriate fee specified in s HFS 157.10 (3) with the amendment application.

(14) DEPARTMENT ACTION ON APPLICATIONS TO RENEW OR AMEND. In considering an application by a licensee to renew or amend the license, the department shall apply the criteria set forth in subs. (2), (3) and (4) and in subchs. IV, V and VI, as applicable.

(15) TRANSFER OF MATERIAL. (a) No licensee may transfer radioactive material except as authorized under this subsection.

(b) Except as otherwise provided in its license and subject to the provisions of pars. (c) and (d), a licensee may transfer radioactive material to any of the following:

1. The department only after receiving prior approval from the department.

2. The U.S. department of energy.

3. Any person exempt from these regulations to the extent permitted under the exemption.

4. Any person authorized to receive radioactive material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the NRC, any agreement state, any licensing state or to any person otherwise authorized to receive radioactive material by the federal government or any agency thereof, the department, an agreement state or a licensing state.

5. Any person as otherwise authorized by the department in writing.

6 The agency in another state that regulates radioactive material under 42 USC 5801

(c) Before transferring radioactive material to a specific licensee of the department, the NRC, an agreement state or a licensing state, or to a general licensee who is required to register with the department, the NRC, an agreement state or a licensing state prior to receipt of the radioactive material, a licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred

(d) A licensee transferring radioactive materials as described in par. (c) may use any of the following methods for verification:

1. The transferor may possess and read a copy of the transferee's specific license or registration certificate that is currently in force.

2. The transferor may possess a written statement, from the transferee, certifying that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date.

3. For emergency shipments, the transferor may accept an oral statement by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date, provided that the oral statement is confirmed in writing within 10 days.

4 The transferor may obtain other information compiled by a reporting service from official records of the department, the NRC, an agreement state or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration.

5. When none of the methods of verification described in subds. 1. to 4. are readily available or when a transferor desires to verify that information received by one of such methods is correct or up–to–date, the transferor may obtain and record confirmation from the department, the NRC, an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

(e) Shipment and transport of radioactive material shall be under the provisions of subch. XIII.

(16) MODIFICATION, SUSPENSION AND REVOCATION OF LICENSES (a) The terms and conditions of a license shall be subject to amendment, revision or modification by the department. The department may suspend, revoke or modify the license due to amendments to ss. 254.31 to 254.45, Stats., this chapter or orders issued by the department.

(b) The department may revoke, suspend or modify any license or reciprocal recognition of an out–of–state license, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of ss 254.31 to 254.45, Stats., or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the department to refuse to grant a license on an original application or for violation of or failure to observe any of the terms and conditions of ss. 254.31 to 254 45, Stats , this chapter or orders issued by the department or voluntary application for amendment, revision or modification submitted by the licensee.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the department may not modify, suspend or revoke a license unless, prior to such action, the department notifies the licensee, in writing, of the facts or conduct that warrant the action and the licensee has been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements

(d) A person who considers himself or herself affected by a department denial of license application or amendment, license revocation, or license suspension may submit to the department a written request for hearing about the license action. A written request for hearing on a license action shall be received by the department within 10 days after receipt of a notice of the department's decision to deny license application or renewal or revoke or suspend a license. The hearing request shall include the information required in s HFS 157.90 (3)

Note: Hearing requests shall be sent to: Department of Health and Family Services, Radiation Protection Section, PO 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

(17) EVENT REPORTING (a) *Events that must be reported immediately.* A licensee shall notify the department by telephone as soon as possible but not later than 4 hours after the discovery of an event, such as a fire, explosion or toxic gas release, which prevents immediate protective actions necessary to avoid exposures to radiation, radioactive materials or releases of licensed radioactive material that could exceed regulatory limits established in this chapter.

(b) *Events that must be reported within 24 hours* A licensee shall notify the department within 24 hours by telephone, facsimile, or in person after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that meets any of the following criteria:

a. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area.

b. Involves a quantity of material greater than 5 times the lowest annual limit on intake specified in Appendix E for the material.

c. Restricts access to the area for a reason other than to allow isotopes with a half–life of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed under any of the following circumstances:

a The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident.

b. The equipment is required to be available and operable when it is disabled or fails to function

c No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. A fire or explosion damaging any licensed material or any device, container or equipment containing licensed material under any of the following circumstances:

a. The quantity of material involved is greater than 5 times the lowest annual limit on intake specified in Appendix E for the material limits.

b. The damage affects the integrity of the licensed material or its container.

(c) *Content and submission of reports.* 1. Reports required to be submitted to the department under pars. (a) and (b) shall, to the extent that the information is available, include all the following information:

a. The caller's name and call back telephone number.

b. A description of the event, including the date and time of its occurrence.

c. The exact location of the event.

d. The isotopes, quantities, and chemical and physical form of the licensed material involved in the event.

e. Any personnel radiation exposure data available.

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

a. A description of the event, including the probable cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned.

b. The exact location of the event.

c. The isotopes, quantities, and chemical and physical form of the licensed material involved.

d. The date and time of the event.

e. Corrective actions taken or planned and the results of any evaluations or assessments.

f. The extent to which individuals were exposed to radiation or to radioactive materials without identification of individuals by name.

(18) RECEIPT, TRANSFER AND DISPOSAL RECORDS (a) *Record retention.* A licensee shall retain records required by s. HFS 157.06 (1) or by license condition. If a retention period is not otherwise specified by this chapter or license condition, the record shall be retained until the department terminates each license.

(b) *Transfer of records to the department.* Prior to license termination, a licensee authorized to possess radioactive material, in an unsealed form, with a half-life greater than 120 days, shall forward to the department all records of disposal of licensed material made under s. HFS 157.30 (2) to (5), including burials authorized before January 28, 1981, and the results of measurements and calculations required by s. HFS 157.31 (3).

(c) *Transfer of records to new licensee.* 1. If licensed activities are transferred or assigned in accordance with s. HFS 157.13 (10) (b), each licensee authorized to possess radioactive material in unsealed form, with a half-life greater than 120 days, shall transfer the following records to the new licensee:

a. Records of disposal of licensed material made under s. HFS 157.30 (2) to (5), including burials authorized before January 28, 1981.

b. Records of the results of measurements and calculations required by s. HFS 157.31 (3)

2. The new licensee shall be responsible for maintaining the records required in subd. 1. until the license is terminated.

(d) *Transfer of records of decommissioning activities.* A licensee shall forward the records required by s. HFS 157.15 (7) to the department prior to license termination.

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

HFS 157.14 Reciprocity. (1) RECOGNITION OF LICENSES ISSUED BY THE NRC OR OTHER STATES. The department shall reciprocally recognize radioactive material licenses issued by the NRC or a state agency in another state under the conditions set forth in this section.

(2) LICENSES OF BYPRODUCT, SOURCE AND SPECIAL NUCLEAR MATERIAL IN QUANTITIES NOT SUFFICIENT TO FORM A CRITICAL MASS (a) Subject to this chapter, any person who holds a specific license from the NRC or another agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any year provided that all of the following occur:

1. The licensing document does not limit the activity authorized by the document to specified installations or locations.

2. The out-of-state licensee notifies the department in writing at least 3 days prior to engaging in the activity. The notification shall indicate the exact location of use, start date, time period, names, documentation of training, in-state address of the individual performing the activity, radiation sources to be used within the state, operating and emergency procedures and shall be accompanied by a copy of the pertinent licensing document. The out-of-state licensee shall also notify the department of any changes in the work location, schedule, radioactive material or work activities. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon written application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of the year following the receipt of the initial notification from a person engaging in activities under the general license granted under this paragraph.

Note: The form 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 by downloading from the department website at: www.dhfs.state.wi.us/licensing/.

3. The out-of-state licensee complies with this chapter and with all the terms and conditions of the licensing document, except any terms and conditions that may be inconsistent with this chapter.

4. The out-of-state licensee supplies any other information as required by the department.

5. The out-of-state licensee does not transfer or dispose of radioactive material possessed or used under the general license granted under this paragraph except by transfer to a person who is either specifically licensed by the department or by the NRC to receive the material, or is exempt from the requirements for a license for the material under s. HFS 157.09 (2) (a).

6. The out-of-state licensee pays the fee prescribed in s. HFS 157.10 (3).

(b) Notwithstanding the provisions of par. (a), any person who holds a specific license issued by the NRC or another agreement state authorizing the holder to manufacture, transfer, install or service a device described in s. HFS 157.11 (2) (b) within areas subject to the jurisdiction of the licensing body is granted a general license to install, transfer, demonstrate or service the device in this state provided that all of the following occur:

1. The person files a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom the device is transferred by name and address, the type and model number of device transferred and the quantity and type of radioactive material contained in the device.

2. The device has been manufactured, labeled, installed and serviced under applicable provisions of the specific license issued to the person by the NRC or an agreement state.

3. The person provides assurance that any labels required to be affixed to the device under regulations of the authority that licensed manufacture of the device bear the following statement: "Removal of this label is prohibited."

4. The holder of the specific license furnishes to each general licensee to whom the device is transferred or on whose premises the device is installed a copy of the general license contained in

s. HFS 157 11 (2) (b) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(c) The department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the NRC or an agreement state or any product distributed under the licensing document upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

(3) LICENSES OF NARM (a) Subject to this chapter, any person who holds a specific license for NARM from a licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is granted a general license to conduct the activities authorized within this state for a period not in excess of 180 days in any year provided that all of the following occur:

1. The licensing document does not limit the authorized activity to specified installations or locations.

2 The out–of–state licensee notifies the department in writing at least 3 days prior to engaging in such activity. The notification shall indicate the location, period and type of proposed possession and use within the state and shall be accompanied by a copy of the pertinent licensing document. If, for a specific situation, the 3–day period would impose an undue hardship on the out–of–state licensee, the licensee may, upon written application to the department, obtain permission to proceed sooner.

Note: The department may waive the 3–day notification requirement when the activities of the out–of–state licensee are routinely scheduled at the same location in the state

3. The out–of–state licensee complies with this chapter and with all the terms and conditions of the licensing document except any terms and conditions that may be inconsistent with this chapter.

4. The out–of–state licensee supplies any other information as required by the department.

5 The out–of–state licensee does not transfer or dispose of radioactive material possessed or used under the general license granted in this paragraph except by transfer to a person who is either specifically licensed by the department or by another licensing state to receive radioactive material, or exempt from the requirements for a license for radioactive material under s. HFS 157 09 (1).

6. The out–of–state licensee pays the fee prescribed in s HFS 157.10 (3).

(b) Notwithstanding the provisions of par. (a), any person who holds a specific license issued by a licensing state authorizing the holder to manufacture, transfer, install or service a device described in s. HFS 157.11 (2) (b) within areas subject to the jurisdiction of the licensing body is granted a general license to install, transfer, demonstrate or service the device in this state provided that all of the following conditions are met.

1. The person files a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state Each report shall identify each general licensee to whom the device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device.

2. The device has been manufactured, labeled, installed and serviced under applicable provisions of the specific license issued to the person by a licensing state.

3. The person assures that any labels required to be affixed to the device under regulations of the authority that licensed manufacture of the device bears the following statement: "Removal of this label is prohibited."

4. The holder of the specific license furnishes to each general licensee to whom the holder transfers the device or on whose premises the holder installs the device a copy of the general license contained in s. HFS 157.11 (2) (b) or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(c) The department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by a licensing state or any product distributed under the licensing document upon determining that the action is necessary to prevent undue hazard to public health and safety or property

(4) JURISDICTIONAL STATUS (a) A licensee shall determine the jurisdictional status of a temporary job–site before radioactive materials may be used at a job site at any federal facility within the state. If the jurisdictional status is unknown, the licensee shall contact the federal agency that controls the site to determine if the job site is under exclusive federal jurisdiction.

(b) A licensee shall obtain authorization from another agreement state or the NRC before radioactive material may be used at a temporary job site in another state. Authorization may be obtained either by applying for reciprocity or a specific license from that state or the NRC.

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

HFS 157.15 Financial assurance and records for decommissioning. (1) FINANCIAL ASSURANCE REQUIREMENT FOR A SPECIFIC LICENSE. (a) *Unsealed radioactive material* A person applying for a specific license authorizing the possession and use of unsealed radioactive material shall submit a decommissioning funding plan as described in sub. (5) with the license application for any of the following types of materials:

1. Unsealed radioactive material with a half–life greater than 120 days and in quantities greater than 10^5 times the applicable quantities listed in Appendix I.

2. Unsealed radioactive material involving a combination of isotopes with R divided by 10^5 being greater than one, where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix I.

(b) Other radioactive material. A person applying for a specific license authorizing the possession and use of radioactive material not covered by par. (a) with a half–life greater than 120 days and in quantities specified in sub. (4) shall do either of the following:

1. Submit a decommissioning funding plan as described in sub. (5)

2. Submit a written certification, signed by the chief financial officer or other individual designated by management to represent the licensee, that financial assurance has been provided in the amount prescribed in sub. (4) using one of the methods described in sub. (5) and a signed original of the financial instrument obtained to satisfy the requirements of sub (6). The written certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued by the department but before receipt of radioactive material by the applicant. If the applicant defers execution of the financial instrument until after the license has been issued, the applicant shall submit to the department a signed original of the financial instrument obtained before receipt of licensed material.

(2) EXEMPTIONS The following are exempt from the requirements of this section:

(a) A state, local or other government agency, except for a government agency licensed to handle or process radioactive waste.

(b) A person authorized to possess only radioactive materials with a half–life of 65 days or less.

(c) Other persons exempted by the department based on a review of the license application.

(3) IMPLEMENTATION. (a) A person who possesses a specific license authorizing the possession and use of radioactive material issued on or after the effective date of August 1, 2002, which is of a type described in sub. (1), shall provide financial assurance for decommissioning under this section

(b) A person who possesses a specific license issued before the effective date of August 1, 2002, shall do one of the following:

1. For a license authorizing the use of radioactive material meeting the criteria of sub. (1) (a), submit a decommissioning funding plan as described in sub. (5) and a certification of financial assurance for at least $750,000, under the criteria in sub. (4), with any application for license renewal.

2. For a license authorizing the use of radioactive material meeting the criteria of sub. (1) (b), submit a decommissioning funding plan as described in sub. (5) or a certification of financial assurance for decommissioning according to the criteria of sub. (4) with any application for license renewal.

(c) The term of the financial assurance shall be from the issuance or renewal of the license until the department terminates the license.

(d) A licensee's financial assurance arrangements may be reviewed annually by the department to recognize any increases or decreases resulting from inflation or deflation, changes in engineering plans, activities performed or any other condition affecting costs for decommissioning to ensure that sufficient funding is available to cover liability that remains until license termination

(4) REQUIRED AMOUNTS FOR FINANCIAL ASSURANCE (a) A licensee shall provide the following minimum amounts of financial assurance for decommissioning, unless otherwise specified by the department:

1. Seven hundred fifty thousand dollars if the quantity of material is greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix I in unsealed form. For a combination of isotopes, R divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one.

2. One hundred fifty thousand dollars if the quantity of material is greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix I in unsealed form. For a combination of isotopes, R divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one.

3. Seventy–five thousand dollars if the quantity of material is greater than 10^{10} times the applicable quantities of Appendix I in sealed sources or plated foils. For a combination of isotopes, R divided by 10^{10} is greater than one.

(b) The department may eliminate, reduce or raise the required amount of financial assurance under par. (a) for an individual applicant or licensee based on the cost estimate for decommissioning included in the decommissioning funding plan required under sub. (5) (a).

(5) DECOMMISSIONING FUNDING PLAN (a) A decommissioning funding plan shall include all the following information:

1. A cost estimate for decommissioning that considers all of the following:

a. Probable extent of contamination through the use or possession of radioactive material at the facility or site and the projected cost of removal of the contamination to a level specified by the department. The evaluation shall encompass probable contaminating events associated with the licensee's or applicant's operation and shall be based on factors such as quantity, half–life, radiation hazard, toxicity and chemical and physical forms.

b. The extent of possible offsite property damage caused by operation of the facility or site.

c. The cost of removal and disposal of radiation sources that are or would be generated, stored, processed or otherwise present at the licensed facility or site.

d. The costs involved in reclaiming the property on which the facility or site is located and all other properties contaminated by radioactive material authorized under the license.

2. A description of the method of assuring funds for decommissioning according to sub. (6).

3. A description of the method for adjusting cost estimates and associated funding levels periodically over the life of the facility.

(b) The decommissioning funding plan shall also contain the licensee's certification that financial assurance has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of sub. (6).

(6) FINANCIAL ASSURANCE OPTIONS A licensee may use any of the following methods to provide financial assurance for decommissioning:

(a) *Prepayment.* Prepayment is the deposit prior to operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets in an amount sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities.

(b) *Surety method, insurance or other guarantee.* Payment of future decommissioning costs shall be guaranteed by a surety method, insurance or other guarantee. A surety method may be in the form of a surety bond, letter of credit or line of credit. Self insurance, or any method which essentially constitutes self–insurance, may not be used as a method of providing financial assurance. Any surety method or insurance used to provide financial assurance for decommissioning must meet all of the following criteria:

1. The surety method or insurance shall be open–ended or, if written for a specified term, renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the department, the beneficiary and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the department within 30 days after receipt of notification of cancellation.

2. The surety method or insurance shall be payable to a trust established for decommissioning costs. The department shall approve the trustee and the trust.

Note: An acceptable trustee includes the State of Wisconsin or an entity having the authority to act as a trustee and whose trust operations are regulated and examined by a state or federal government agency

3. The surety method or insurance shall remain in effect until the department terminates the license.

(c) *External sinking fund.* An external sinking fund may be used in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities. The surety or insurance provisions shall meet the requirements of par. (b).

(d) *Statement of intent.* A state or local government licensee exempt under sub (2) shall submit a written statement of intent containing a cost estimate for decommissioning or an amount based on sub. (4). The cost estimate shall indicate that funds for decommissioning will be obtained when necessary.

(7) RECORDS (a) A licensee shall keep the following records of information related to decommissioning of a facility in an identified location until the site is released for unrestricted use:

1. Records of spills or other unusual occurrences involving the spread of radioactive contamination in and around the facility, equipment or site. The records may be limited to instances where contamination remains after any cleanup procedures or when there is reasonable likelihood that radioactive contaminants may have spread to inaccessible areas or into porous materials such as concrete. The records shall include any known information on

identification of involved nuclides, quantities, forms and concentrations.

2. As–built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes that may contain radioactive contaminants. If required drawings are referenced, each relevant document does not need to be indexed individually. If drawings are not available, a licensee shall substitute appropriate records of available information concerning the areas and locations of inaccessible contamination.

Note: As–built architectural and engineering drawings need to reflect the final details of the structures and equipment as they were constructed.

3. Except for areas containing only sealed sources that have not leaked or where no contamination remains after a leak, or byproduct materials with half–lives of less than 65 days, a list containing all the following:

a. All areas currently and formerly designated as restricted areas

b. All areas outside of restricted areas that require documentation under subd 1

c. All areas outside of restricted areas where current and previous wastes have been buried as documented under s. HFS 157 31 (9)

d. All areas outside of restricted areas that contain radioactive material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in s. HFS 157 13 (11) (d) or apply for approval for disposal under s. HFS 157.30 (2).

4. Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning and records of the funding method used for assuring funds.

(b) A licensee shall keep the records in par. (a) until the site is decommissioned and approved by the department for unrestricted use.

(c) Prior to a licensed activity being transferred to another licensee under s. HFS 157.13 (10) (b), the original licensee shall transfer all records under par. (a) to the new licensee. The new licensee shall be responsible for maintaining the records until their license is terminated by the department.

(d) The list under par. (a) 3. shall be updated every 2 years

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

HFS 157.16 Licenses held on the effective date of this subchapter. A person who on the effective date *(see Note at the start of chapter)*, possesses a general or specific license issued by the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass shall be deemed to possess an identical license issued under the authority of s. 254 365, Stats , and this chapter, the license to expire either 90 days after receipt from the department of a notice of expiration of the license or on the date of expiration specified in the NRC license, whichever is earlier

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

HFS 157.17 NARM held on the effective date of this subchapter. A person who on the effective date of *(see Note at the start of chapter)*, possesses naturally–occurring and accelerator produced radioactive material for which a specific license is required by this subchapter shall be deemed to possess a license issued by the department under the authority of s. 254.365, Stats., and this chapter. The license shall expire 90 days after the effective date of this subchapter, except that if within the 90–day period the person possessing the material files an application in proper form for a license, the existing license may not expire until the department has made a final determination on the application

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

Subchapter III — Standards for Protection from Radiation

HFS 157.20 Implementation. (1) Any existing license or registration condition more restrictive than this subchapter remains in force until there is an amendment or renewal of the license or registration.

(2) If a condition attached to a license or registration exempts a licensee or registrant from a provision of this subchapter in effect on or before August 1, 2002, the condition also exempts the licensee or registrant from the corresponding provision of this subchapter

(3) If a condition attached to a license or registration cites provisions of this subchapter in effect prior to August 1, 2002, that do not correspond to any provisions of this subchapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes the condition.

History: CR 01–108: cr. Register July 2002 No. 559, eff. 8–1–02.

HFS 157.21 Radiation protection programs. (1) A licensee or registrant shall develop, document and implement a radiation protection program sufficient to ensure compliance with the provisions of this subchapter.

Note: See s. HFS 157 31 (2) for record keeping requirements relating to programs in this subchapter

(2) A licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable.

(3) A licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

(4) To implement the ALARA requirements of sub (2), and notwithstanding the requirements in s HFS 157 23 (1), a licensee shall establish a constraint on air emissions of radioactive material to the environment, excluding Radon–222 and its progeny, so that an individual member of the public likely to receive the highest dose does not receive a total effective dose equivalent in excess of 0.1 mSv (10 mrem) per year from the air emissions. A licensee to whom this requirement applies shall report as provided in s. HFS 157.32 (3) any time the licensee exceeds the dose limit of 0.1 mSv (10 mrem) per year and shall promptly take appropriate corrective action to safeguard against recurrence

History: CR 01–108: cr. Register July 2002 No. 559, eff. 8–1–02.

HFS 157.22 Occupational dose limits. (1) OCCUPATIONAL DOSE LIMITS FOR ADULTS (a) A licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures under sub. (6), to the following dose limits:

1. An annual limit, which is the more limiting of either of the following:

a. The total effective dose equivalent being equal to 0 05 Sv (5 rem)

b. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem)

2. The annual limits to the lens of the eye, to the skin and to the extremities which are.

a. A lens dose equivalent of 0 15 Sv (15 rem).

b. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime

(c) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure, as follows:

1. The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable

2. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in s. HFS 157.25 (2) (a) 5., the effective dose equivalent for external radiation shall be determined as follows:

a. When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the exposure is less than 25% of any limit specified in par. (a), the reported deep dose equivalent shall be the effective dose equivalent for external radiation.

b. When only one individual monitoring device is used and it is located at the neck outside the apron and the exposure is greater than 25% of the any limit specified in par. (a), the effective dose equivalent shall be the deep dose equivalent multiplied by 0.3.

c. If a protective apron is worn, the individual monitoring device shall be located at the neck, which is, collar. If a second monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The estimated effective dose equivalent (H_E) when wearing 2 monitoring devices, one located outside and one under a protective apron, shall be calculated using the following formula: H_E (estimate) = 1.5 H_W + 0.04 H_N where H_W = badge reading from the waist badge under the apron and H_N = badge reading from the neck badge worn outside the apron.

(d) Derived air concentration and annual limit on intake values are specified in Table I of Appendix E and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

Note: See s HFS 157.31 (7) for instructions about recording the exposure levels

(e) In addition to the annual dose limits, a licensee or registrant shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity.

Note: See footnote a/ of Appendix E for the calculation method for determining DAC for soluable mixtures of uranium.

(f) A licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year.

Note: See sub. (5) for instruction on determining occupational dose.

(2) COMPLIANCE WITH REQUIREMENTS FOR SUMMATION OF EXTERNAL AND INTERNAL DOSES (a) If a licensee or registrant is required to monitor under both s. HFS 157.25 (2) (a) and (b), a licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If a licensee or registrant is required to monitor only under s. HFS 157.25 (2) (a) or (b), then summation is not required to demonstrate compliance with the dose limits. A licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions in par. (b) and the conditions of pars. (c) and (d). The dose equivalents for the lens of the eye, the skin and the extremities are not included in the summation, but are subject to separate limits.

(b) If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and any one of the following, does not exceed unity:

1. The sum of the fractions of the inhalation ALI for each radionuclide.

2. The total number of derived air concentration–hours for all radionuclides divided by 2,000.

3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this subdivision, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10% of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(c) If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10% of the applicable oral ALI, a licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

(d) A licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen–3 and does not need to be evaluated or taken into account.

(3) DETERMINATION OF EXTERNAL DOSES FROM AIRBORNE RADIOACTIVE MATERIAL. (a) A licensee or registrant shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud.

Note: See Appendix E, footnotes a/ and b/ for methods used for calculating dose from exposure to a radioactive cloud for materials that have a half–life of less than 2 hours

(b) Airborne radioactivity measurements and DAC values may not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform in its distribution of radioactive material in the cloud. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(4) DETERMINATION OF INTERNAL EXPOSURE. (a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, a licensee or registrant shall, when required under s. HFS 157.25 (2), take suitable and timely measurements of all of the following:

1. Concentrations of airborne radioactive materials in work areas.

2. Quantities of radionuclides in the body.

3. Quantities of radionuclides excreted from the body.

4. Combinations of the measurements in subds. 1. to 3.

(b) Unless respiratory protective equipment is used, as provided in s. HFS 157.27 (3), or the assessment of intake is based on bioassays, a licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(c) When the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, a licensee or registrant may do any of the following:

1. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record.

2. Upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density.

3. Separately assess the contribution of fractional intakes of Class D, W or Y compounds of a given radionuclide to the committed effective dose equivalent.

Note: See Appendix E for a description of the pulmonary clearance times of the compounds involved in the exposure

(d) If a licensee or registrant chooses to assess intakes of Class Y material using the measurements given in par. (a) 2. or 3., a licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by s. HFS 157.32 (2) or (3).

Note: The delay permits the licensee or registrant to make additional measurements basic to the assessments

(e) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC–hours shall be either of the following:

1. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W or Y, from Appendix E for each radionuclide in the mixture

2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(g) When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if all of the following apply.

1 The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in s. HFS 157 22 (1) and in complying with the monitoring requirements in s. HFS 157.25 (2) (b)

2. The concentration of any radionuclide disregarded is less than 10% of its DAC.

3. The sum of the percentages under subds. 1 and 2 for all of the radionuclides disregarded in the mixture does not exceed 30 percent

(h) When determining the committed effective dose equivalent, the following information may be considered:

1. To calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC–hours, results in a committed effective dose equivalent of 0 05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

2. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0 05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix E. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in s. HFS 157 22 (1) (a) 1. b is met.

(5) DETERMINATION OF PRIOR OCCUPATIONAL DOSE. (a) For each individual who may enter a licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring under s. HFS 157 25 (2), a licensee or registrant shall determine the occupational radiation dose received during the current year.

(b) Before an individual may participate in a planned special exposure, a licensee or registrant shall determine all of the following:

1. The internal and external doses from all previous planned special exposures.

2. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

(c) In complying with the requirements of par. (a), a licensee or registrant may use either of the following means

1. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year.

2. Obtain, by telephone, facsimile, electronic media or letter, reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant. A licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(d) 1. A licensee or registrant shall record the exposure history, as required by par. (a), on a occupational radiation exposure form provided by the department, or other clear and legible record of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which a licensee or registrant obtains reports, a licensee or registrant shall use the dose shown in the report in preparing the occupational radiation exposure form or equivalent. For any period in which a licensee or registrant does not obtain a report, a licensee or registrant shall place a notation on the occupational radiation exposure form or equivalent indicating the periods of time for which data are not available

Note: An occupational radiation exposure history form may be obtained by writing to. Department of Health and Family Services, Radiation Protection Section, P O Box 2659, Madison WI 53701–2659, or by downloading the form from the Department website at www dhfs state wi.us/licensing/

2. A licensee or registrant is not required to partition historical dose between external dose equivalents and internal committed dose equivalents Further, occupational exposure histories obtained and recorded on the department's occupational radiation exposure form or equivalent before the effective date of August 1, 2002, may not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(e) If a licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, a licensee or registrant shall assume all the following:

1. In establishing administrative controls under sub. (1) (f) for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

2. That the individual is not available for planned special exposures.

(f) A licensee or registrant shall retain the records on the department's occupational radiation exposure form or equivalent until the department terminates each pertinent license or registration requiring this record. A licensee or registrant shall retain records used in preparing the occupational radiation exposure form or equivalent for 3 years after the record is made.

Note: The department's occupational radiation exposure history form may be obtained by writing to Department of Health and Family Services, Radiation Protection Section, P O Box 2659, Madison WI 53701–2659, or by downloading the form from the department website at: www dhfs state wi us/licensing/

(6) PLANNED SPECIAL EXPOSURES A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in sub. (1) provided that each of the following conditions is satisfied:

(a) A licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might

avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

(b) A licensee or registrant and employer, if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(c) Before a planned special exposure, a licensee or registrant ensures that each individual involved has been informed and instructed in all the following:

1. The purpose of the planned operation

2. The estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task.

3. The measures to be taken to keep the dose ALARA considering other risks that may be present.

(d) Prior to permitting an individual to participate in a planned special exposure, a licensee or registrant ascertains prior doses as required by sub. (5) (b) during the lifetime of the individual for each individual involved.

(e) Subject to sub. (1) (b), a licensee or registrant may not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of any of the following limits:

1. The numerical values of any of the dose limits in sub. (1) (a) in any year.

2. Five times the annual dose limits in sub. (1) (a) during the individual's lifetime.

(f) A licensee or registrant maintains records of the conduct of a planned special exposure under s. HFS 157.31 (6) and submits a written report under s. HFS 157.32 (4).

(g) A licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures may not be considered in controlling future occupational dose of the individual under sub. (1) (a) but shall be included in evaluations required by pars. (d) and (e).

(7) OCCUPATIONAL DOSE LIMIT FOR A MINOR. (a) The annual occupational dose limit for a minor is 10% of the annual occupational dose limits specified for adult workers in sub. (1).

(b) A minor may not work in an area where the minor could receive a deep dose equivalent in excess of .02 mSv (2 mrem) in any one hour unless authorized in writing by the department.

(8) DOSE EQUIVALENT TO AN EMBRYO OR FETUS. (a) A licensee or registrant shall ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (500 mrem).

Note: See HFS 157.31 (7) for record keeping requirements

(b) A licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in par. (a).

Note: The National Council on Radiation Protection and Measurements recommended in NCRP Report No 91, "Recommendations on Limits for Exposure to Ionizing Radiation," June, 1, 1987, that no more than 0.5 mSv (50 mrem) to the embryo or fetus be received in any one month.

(c) The dose to an embryo or fetus is the sum of all of the following:

1. The deep dose equivalent to the declared pregnant women.

2. The dose equivalent to the embryo or fetus resulting from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.

(d) If the dose equivalent to the embryo or fetus is found to have exceeded 5 mSv (500 mrem), or is within 0.5 mSv (50 mrem) of this dose, by the time the woman declares the pregnancy to a licensee or registrant, a licensee or registrant shall be deemed to be in compliance with par. (a) if the additional dose equivalent to the embryo or fetus does not exceed 0.5 mSv (50 mrem) during the remainder of the pregnancy.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.23 Radiation dose limits for individual members of the public. (1) DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC. (a) A licensee or registrant shall conduct operations to meet all of the following:

1. The total effective dose equivalent to individual members of the public from the licensed or registered operation may not exceed one mSv (100 mrem) in a year, exclusive of the dose contribution from background radiation, medical radiation exposure, exposure to individuals administered radioactive material and released in accordance with s. HFS 157.62 (8), voluntary participation in medical research programs and the licensee's or registrant's disposal of radioactive material into sanitary sewerage under s. HFS 157.30 (3). Facilities with radiation machines installed prior to the effective date of August 1, 2002, that meet the requirements of 5 mSv (500 mrem) in a year are exempt from this requirement.

2. The dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour, exclusive of the dose contributions from patients administered radioactive material and released in accordance with s. HFS 157.62 (8).

(b) If a licensee or registrant permits members of the public to have access to controlled areas, the limits under par. (a) 1. for members of the public continue to apply to those individuals.

(c) A licensee or a registrant or an applicant for a license or registration may apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (500 mrem). The application shall include all the following information:

1. Demonstration of the need for and the expected duration of operations exceeding the limit in par. (a).

2. A licensee's or registrant's program to assess and control dose within the 5 mSv (500 mrem) annual limit.

3. The procedures to be followed to maintain the dose ALARA.

(d) In addition to the requirements of this section, a licensee or registrant subject to the provisions of the U.S. environmental protection agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

(e) The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents to restrict the collective dose.

(f) A licensee or registrant may permit visitors to individuals who cannot be released under s. HFS 157.62 (8). A visitor may receive a radiation dose greater than one mSv (100 mrem) if both of the following conditions are met:

1. The radiation dose received by the visitor does not exceed 5 mSv (0.5 rem).

2. The authorized user has predetermined that the visit is appropriate.

(2) COMPLIANCE WITH DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC. (a) A licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in sub. (1).

(b) A licensee or registrant shall show compliance with the annual dose limit in sub. (1) by either of the following means:

1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the

highest dose from the licensed or registered operation does not exceed the annual dose limit.

2. Demonstrating both of the following

a The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix E.

b If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (50 mrem) in a year.

(c) Upon approval from the department, a licensee or registrant may adjust the effluent concentration values in Table II of Appendix E for members of the public to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density and chemical form.

History: CR 01–108: cr. Register July 2002 No. 559, eff. 8–1–02.

HFS 157.24 Testing for leakage or contamination of sealed sources. **(1)** GENERAL REQUIREMENTS A licensee or registrant in possession of any sealed source shall ensure that all of the following requirements are met:

(a) Each sealed source, other than hydrogen–3, with a half–life of 30 days or more and in any form other than gas or seeds of iridium–192 encased in nylon ribbon, shall be tested for leakage or contamination as follows:

1. Prior to initial use.

2. Unless otherwise authorized by the department, the NRC or another agreement state, at intervals not to exceed 6 months, except that each source designed to emit alpha particles shall be tested at intervals not to exceed 3 months.

3. At any time there is reason to suspect that a sealed source might have been damaged or might be leaking, it shall be tested for leakage before further use.

4 In the absence of a certificate from a transferor indicating that a test for leakage has been made within 6 months prior to the transfer, the sealed source may not be put into use until tested and the results received.

(b) Notwithstanding the provisions of par. (a), sources not in use and identified as being in storage shall meet all the following conditions:

1. Sources other than brachytherapy or teletherapy sources shall be tested for leakage at intervals not to exceed 5 years.

2. Sources shall be tested for leakage and test results received prior any use or transfer, unless a test for leakage has been made within 6 months prior to the date of use or transfer.

3 Sources in storage shall be inventoried at intervals not to exceed 6 months.

(c) Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0 005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate For a sealed source contained in a device, test samples shall be obtained when the source is in the "off" position.

(d) Tests for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of radon–222 in a 24 hour period when the collection efficiency for radon–222 and its progeny has been determined with respect to collection method, volume and time.

(e) Test samples shall be taken from the interior surfaces of the container in which sealed sources of radium are stored. The test shall be capable of detecting the presence of 185 Bq (0 005 μCi) of a radium daughter that has a half–life greater than 4 days

(2) EXEMPTIONS Notwithstanding the requirements in sub. (1), any sealed source is exempt from tests for leakage when the sealed source contains 3 7 MBq (100 μCi) or less of beta– or gamma–emitting material or 0.37 MBq (10 μCi) or less of alpha–emitting material.

(3) AUTHORIZATION TO CONDUCT TESTING Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the department, an agreement state, a licensing state or the NRC to perform the services.

(4) RECORDS. Records of test results for sealed sources shall be made under s. HFS 157.31 (4)

(5) LEAKAGE CRITERIA Any of the following shall be considered evidence that a sealed source is leaking:

(a) The presence of 185 Bq (0 005 μCi) or more of removable contamination on any test sample

(b) Leakage of 37 Bq (0 001 μCi) of radon–222 per 24 hours for sources manufactured to contain radium.

(c) The presence of removable contamination resulting from the decay of 185 Bq (0 005 μCi) or more of radium

(6) ACTION REQUIRED DUE TO A LEAKING SOURCE A licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of under the requirements of this chapter.

(7) REPORTS Reports of test results for leaking or contaminated sealed sources shall be prepared under s. HFS 157.32 (7) and retained for 3 years after disposal or repair of the source.

History: CR 01–108: cr. Register July 2002 No. 559, eff. 8–1–02.

HFS 157.25 Surveys and monitoring. **(1)** GENERAL REQUIREMENTS (a) A licensee or registrant shall make or cause to be made all the following surveys:

1. Surveys necessary for the licensee or registrant to comply with this subchapter.

2. Surveys necessary and reasonable under the circumstances to evaluate any of the following:

a. Radiation levels.

b. Concentrations or quantities of radioactive material.

c. The potential radiological hazards.

(b) A licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, including dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified elsewhere in this chapter or in a license condition.

(c) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with s. HFS 157.22 (1), with other applicable provisions of this chapter or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor that meets both of the following conditions:

1. Holds current personnel dosimetry accreditation from the national voluntary laboratory accreditation program of the national institute of standards and technology

2. Is approved in this accreditation process for the type of radiation or radiations included in the national voluntary laboratory accreditation program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored

(2) CONDITIONS REQUIRING INDIVIDUAL MONITORING OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE. A licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this subchapter. Monitoring devices may be changed quarterly, provided the assignee has not exceeded 10% of the occupational limits in s HFS 157.22 (1) (a). If the assignee exceeds 10% of the occupational limits, the monitoring device shall be changed

monthly. As a minimum, a licensee or registrant shall do all the following:

(a) Monitor occupational exposure to radiation sources under their control and supply and require the use of individual monitoring devices by all of the following:

1. Adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in s. HFS 157.22 (1) (a). Monitoring devices shall be individually assigned and not shared.

2. Minors who are at risk of receiving over 10% of the applicable limits in s. HFS 157.22 (7) (a).

3. A declared pregnant woman likely to receive, in one year from sources external to the body, a dose in excess of one mSv (0.1 rem).

4. An individual entering a high or very high radiation area.

5. An individual working within 6 feet of operating medical fluoroscopic equipment.

6. Individuals operating portable moisture or density measuring devices.

(b) Monitor, to determine compliance with s. HFS 157.22 (4), the occupational intake of radioactive material by and assess the committed effective dose equivalent to all of the following individuals:

1. Adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in Table I, Columns 1 and 2, of Appendix E.

2. Minors likely to receive, in one year, a committed effective dose equivalent in excess of 1.0 mSv (100 mrem).

3. Declared pregnant women likely to receive, during the entire pregnancy, a committed dose equivalent in excess of 1.0 mSv (100 mrem).

(3) LOCATION OF INDIVIDUAL MONITORING DEVICES. A licensee or registrant shall ensure that individuals who are required to monitor occupational doses under sub. (2) wear individual monitoring devices as follows:

(a) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure.

(b) If a protective apron is worn, the individual monitoring device shall be located at the neck, which is the collar. If a second monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The estimated effective dose equivalent (H_E) when wearing 2 monitoring devices, one located outside and one under a protective apron, shall be calculated using the following formula: H_E (estimate) = 1.5 H_W + 0.04 H_N where H_W = badge reading from the waist badge under the apron and H_N = badge reading from the neck badge worn outside the apron.

(c) An individual monitoring device used for monitoring the dose to an embryo or fetus of a declared pregnant woman, under s. HFS 157.22 (8) (a), shall be located at the waist under any protective apron being worn by the woman.

(d) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with s. HFS 157.22 (1) (a) 2. a., shall be located at the neck or collar, outside any protective apron being worn by the monitored individual or at an unshielded location closer to the eye.

(e) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with s. HFS 157.22 (1) (a) 2. b., shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; correction in (2) (a) 2. made under s. 13.93 (2m) (b) 7., Stats., Register July 2002 No. 559.

HFS 157.26 Control of exposure from external sources in restricted areas. (1) CONTROL OF ACCESS TO HIGH RADIATION AREAS (a) A licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

1. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of one mSv (100 mrem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

2. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the area are made aware of the entry.

3. Entryways that are locked, except during periods when access to the areas is required, with control over each individual entry.

(b) In place of the controls required under par. (a) for a high radiation area, a licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(c) A licensee or registrant may apply to the department for approval of alternative methods for controlling access to high radiation areas.

(d) A licensee or registrant shall establish the controls required under par. (a) 1. and 3. in a way that does not prevent individuals from leaving a high radiation area.

(e) A licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled under the regulations of the U.S. department of transportation provided that all of the following conditions are met:

1. The packages do not remain in the area longer than 3 days.

2. The dose rate at one meter from the external surface of any package does not exceed 0.1 mSv (10 mrem) per hour.

(f) A licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this subchapter and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(g) A registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area if the registrant has met all the specific requirements for access and control specified in other applicable parts of this chapter, such as subch. IV for industrial radiography and subch. VIII for x-rays in the healing arts and accelerators.

(2) CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS (a) In addition to the requirements in sub. (1), a licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation or to non-self-shielded irradiators.

(b) A licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in par. (a) if the licensee or registrant has met all the specific requirements for access and control specified in other applicable parts of

this chapter, such as subch. IV for industrial radiography and subch. VIII for x-rays in the healing arts and accelerators.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.27 Respiratory protection and controls to restrict internal exposure in restricted areas. (1) USE OF PROCESS OR OTHER ENGINEERING CONTROLS A licensee or registrant shall use, to the extent practical, process or other engineering controls, such as containment, decontamination or ventilation, to control the concentrations of radioactive material in air

(2) USE OF OTHER CONTROLS (a) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, a licensee or registrant shall increase monitoring and limit intakes by one or more of the following means

1. Control of access.
2 Limitation of exposure times.
3 Use of respiratory protection equipment.
4. Other controls.

(b) If a licensee or registrant performs an ALARA analysis to determine whether or not respirators should be used, a licensee or registrant may also consider the impact of respirator use on workers' industrial health and safety

(3) USE OF INDIVIDUAL RESPIRATORY PROTECTION EQUIPMENT. (a) If a licensee or registrant uses respiratory protection equipment to limit intakes under sub. (2), all of the following criteria shall apply.

1. Except as provided in subd. 2., a licensee or registrant shall use only respiratory protection equipment that is tested and certified by the U.S. national institute for occupational safety and health.

2 A licensee or registrant may use equipment that has not been tested or certified by the U.S. national institute for occupational safety or for which there is no schedule for testing or certification, provided the licensee or registrant has submitted to the department and the department has approved a request for authorized use of that equipment. The request shall include documentation of a demonstration by testing, or a demonstration on the basis of test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

3. A licensee or registrant shall implement and maintain a respiratory protection program that includes all of the following

a. Air sampling sufficient to identify the potential hazard, permit proper equipment selection and estimate doses.

b Surveys and bioassays, as necessary, to evaluate actual intakes.

c. Testing of respirators for operability immediately prior to each use.

4 A licensee or registrant shall have written procedures regarding all of the following:

a. Monitoring, including air sampling and bioassays.
b Supervision and training of respirator users.
c Fit testing
d. Respirator selection.
e Breathing air quality
f. Inventory and control.
g. Storage, issuance, maintenance, repair, testing and quality assurance of respiratory protection equipment.
h. Record keeping of all items in this subd. par.

i. Limitations on periods of respirator use and relief from respirator use

5. Prior to initial fitting of respirators, and at least every 12 months thereafter, a physician shall determine that the individual user is physically able to use the respiratory protection equipment.

6. Fit testing, with a fit factor >/= 10 times the assigned protection factor for negative pressure devices, and a fit factor >/= 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing shall be performed with the facepiece operating in the negative pressure mode.

(b) A licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(c) A licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(d) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons shall be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards The standby rescue persons shall observe or otherwise maintain continuous communication with the workers via visual, voice, signal line, telephone, radio, or other suitable means, and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons shall be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

Note: Examples of means of continuous communication are visual, voice, signal line, telephone, radio or other suitable means

(e) Atmosphere-supplying respirators shall be supplied with respirable air that meets the following requirements:

1 Oxygen content of 19.5-23 5 percent
2 Condensed hydrocarbon content of 5 milligrams per cubic meter of air or less.
3 Carbon monoxide content of 10 ppm or less.
4 Carbon dioxide content of 1,000 ppm or less.
5. Lack of noticeable odor.

(f) A licensee or registrant shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face to facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(g) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

(4) APPLICATION FOR USE OF HIGHER ASSIGNED PROTECTION FACTORS (a) A licensee or registrant shall obtain authorization from the department before using assigned protection factors in excess of those specified in Appendix D

(b) The department may authorize a licensee or registrant to use higher assigned protection factors on receipt of an application that meets the following criteria: