ADMINISTRATIVE RULES – NOTICE OF PUBLIC HEARING

Health Services
Chapter DHS 157, Radiation Protection

NOTICE IS HEREBY GIVEN that pursuant to ss. 227.11 (2) (a) 254.34)1) (a), 254.365 (4) and 254.37 (3), Stats., and interpreting ss. 254.31 to 254.45, Stats., and 42 USC 2011 to 2114, Stats., the Department of Health Services will hold a public hearing to consider the proposed creation, repeal, renumbering and amendment of portions of ch. DHS 157, Radiation Protection, relating to the regulation of radiation producing devices and radioactive materials, and affecting small businesses.

Hearing Date(s) and Location(s)

Date and Time	Location
October 13, 2009 Tuesday 10:00 - 11:30 am	Medical College of Wisconsin 8701 Watertown Plank Rd. (Rm. H1250) Milwaukee, WI
October 14, 2009 Wednesday 10:00 - 11:30 am	Department of Health Services 1 W. Wilson St. Rm. B139 Madison, WI

Accessibility

English
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Hmong
DHS yog ib tus tswv hauj lwm thiab yog ib qhov chaw pab cuam uas muab vaj huam sib luag rau sawv daws. Yog koj xav tau kev pab vim muaj mob xiam oob qhab los yog xav tau ib tus neeg pab txhais lus los yog txhais ntaub ntawv, los yog koj xav tau cov ntaub ntawv no ua lwm hom lus los yog lwm hom ntawv, koj yuav tau thov kev pab uas yog hu rau Paul Schmidt ntawm 608

267-4792 or paul.schmidt@dhs.wisconsin.gov. Koj yuav tsum thov qhov kev pab yam tsawg kawg 7 hnub ua ntej qhov hauj lwm ntawd.

Analysis Prepared by the Department of Health Services

Statutes interpreted: Sections 254.31 to 254.45, Stats., and 42 USC 2011 to 2114.

Statutory authority: Sections 227.11 (2) (a), 254.34 (1) (a), 254.365 (4) and 254.37 (3), Stats.

Explanation of agency authority:
As specified under s. 254.34 (1), Stats., the Department is the state radiation control agency and is required under ss. 254.34 (1) (a), 254.365 (4), and 254.37 (3), Stats., to promulgate rules pertaining to the use of radiation in Wisconsin. Specifically, the Department is required to promulgate and enforce rules pertaining to sources of ionizing radiation and for registration and licensing sources of ionizing radiation, and enforcement as may be necessary to prohibit and prevent unnecessary radiation exposure. The Department's rules for by-product material, source material, and special nuclear material are required to be in accordance with 42 USC 2021 (o) and be otherwise compatible with the requirements under 42 USC 2011 to 2114 and regulations adopted under 42 USC 2011 to 2114.

Related statute or rule:
Chapter NR 809 incorporates the radioactivity standards for community water systems and the analytical methods established in ss. DHS 157.95 and 157.96. The Department of Natural Resources applies these standards to community drinking water systems.

Chapter DHS 163 establishes requirements for identification, removal and reduction of lead-based paint hazards. Lead in paint analysis requires use of a portable device containing radioactive material which is required to be licensed under ch. DHS 157. Section DHS 157.05 (4) requires that any person providing training for certified lead inspectors or risk assessors to meet the training requirements of s. DHS 163.24 (a) 1. and 3. and to complete an additional 8 hours of radiation safety training.

Plain language analysis:

Under s. 254.34 (1) (a) Stats., the Department is responsible for developing and enforcing rules, including registration and licensing of sources of ionizing radiation, to prohibit and prevent unnecessary radiation exposure. The Department is also responsible for maintaining compliance with the Agreement signed by Governor Doyle in 2003 and the Nuclear Regulatory Commission (NRC) that transferred regulatory authority over certain radioactive materials from the NRC to the state. Under the Agreement, the Department is responsible for licensing and inspecting radioactive materials commonly used in medicine, industry, research and education. NRC staff periodically evaluate the state regulatory program.

One of the requirements of this Agreement is Wisconsin's assurance that it will revise the radioactive material portions of ch. DHS 157 within 3 years of any applicable changes in Title10 Code of Federal Regulations. Title 10 CFR has been revised since ch. DHS 157 was last revised

in 2006. Therefore, the Department proposes to modify the radioactive material requirements in ch. DHS 157.

In addition, the Department proposes to revise the portions of ch. DHS 157 pertaining to x-rays to reflect new diagnostic and therapeutic technologies, experience with implementing the current rule, changes in comparable federal regulations in 21 CFR Part 1020, and input provided to the Department by an advisory group that included representatives of academic and medical facilities, radioactive materials users, x-ray users and large and small businesses.

The proposed revisions to ch. DHS 157 accomplish the following:

- Update the radiation protection and regulatory requirements for radioactive materials to reflect changes in federal regulations in Title 10, Code of Federal Regulations Parts 19, 20, 31, 33-36, 39, 40, 70, 71 and 150 and applicable portions of Title 49 (transportation), Code of Federal Regulations.

- Incorporate new security requirements for certain radioactive materials, initially implemented nationally under order of the Nuclear Regulatory Commission.

- Update the radiation safety requirements for x-ray producing devices to reflect new diagnostic and therapeutic technologies, current federal regulation and the input of an ad hoc advisory group representing a cross-section of regulated users.

- Revise operator qualifications for fluoroscopy machines.

- Incorporate minor corrections to rule language based on the Department's experience administering the current rule.

- Incorporate minor revisions to operator qualification, shielding and quality testing requirements.

Summary of, and comparison with, existing or proposed federal regulations:
Wisconsin's Agreement with the Nuclear Regulatory Commission requires the Department to incorporate relevant changes to federal radioactive material regulations into its radiation protection rules within 3 years of the effective date of the federal regulations. The proposed changes to ch. DHS 157 ensure continued compatibility with new federal radioactive material regulations in 10 CFR Pts. 19, 20, 31, 33-36, 39, 40, 70, 71 and 150 and applicable parts of Title 49 CFR relating to transportation as required by s. 254.34 (1), Stats.

Comparison with rules in adjacent states:

Illinois:
Illinois is an Agreement state with the Nuclear Regulatory Commission. As a result, Illinois law contains radiation protection and regulatory requirements very similar to those in ch. DHS 157

and compatible with equivalent federal regulations in Titles 10 and 49, Code of Federal Regulations.

Iowa:
Iowa is an Agreement state with the Nuclear Regulatory Commission. As a result, Iowa law contains radiation protection and regulatory requirements very similar to those in ch. DHS 157 and compatible with equivalent federal regulations in Titles 10 and 49, Code of Federal Regulations.

Michigan:
Michigan is not an Agreement state with the Nuclear Regulatory Commission. However, Michigan has formally declared its intent to become an agreement state with the Nuclear Regulatory Commission. As a result, Michigan law does not contain regulations equivalent to most of ch. DHS 157. The Nuclear Regulatory Commission is currently responsible for regulating the majority of radioactive material use in Michigan under Titles 10 and 49, Code of Federal Regulations.

Minnesota:
Minnesota is an Agreement state with the Nuclear Regulatory Commission. Minnesota adopted new radiation protection regulations for radioactive materials effective January 1, 2005. As a result, Minnesota law contains radiation protection and regulatory requirements very similar to those in ch. DHS 157 and compatible with equivalent federal regulations in Titles 10 and 49, Code of Federal Regulations.

Summary of factual data and analytical methodologies:
The methods specified in s. 227.114, (2), Stats., for reducing a rule's impact on small business have not been incorporated in the proposed rules because incorporating any methods may be contrary to the explicit state statutory requirements for radiation control, federal regulatory and statutory requirements for radiation control, Agreement state requirements, and the state's public policy on radiation control stated in s. 254.33, Stats. Because of the Department's limited use of discretion in developing the content of the proposed rules, the Department has limited its analysis of the proposed rules affect on the small businesses regulated by ch. DHS 157 to the affect that the proposed revisions in x-ray regulatory requirements will have on those businesses.

The Department referred to all of the following to draft the proposed rules and the small business fiscal impact analysis:

1. The input of an ad hoc rules advisory group that included representatives of academic and medical facilities, radioactive materials users, x-ray users and large and small businesses.

2. An Agreement state rule template called the "Suggested State Regulations for the Control of Radiation" (SSRCR) developed by the Conference of Radiation Control Program Directors, Inc. (CRCPD). The CRCPD is a national organization of primarily state radiation control staff that supports and represents state radiation control programs. The SSRCR is developed with the involvement of federal radiation agencies, such as the Nuclear Regulatory Commission, the Food and Drug Administration and the

Environmental Protection Agency. The SSRCR is also continually updated and used by most of the 35 existing Agreement states to help meet federal requirements.

3. Requirements of Titles 10, 21, and 49 of the Code of Federal Regulations; 42 USC; ss. 254.31 to 254.45, Stats., and the Agreement between Wisconsin and the Nuclear Regulatory Commission.

4. The 2002 Economic Census – Wisconsin Geographic Series, which is compiled by the U.S. census bureau every 5 years for each year ending in "2" and "7". The U.S. census bureau is currently compiling the 2007 census information. This information will not become fully available until 2010. The information provided by the Economic Census includes the North American Industry Classification Codes, information on industries, business revenues, sizes, and employment. The Department used this information to approximate business size and any possible percentage increase in business costs due to the proposed revisions in x-ray regulatory requirements.

5. Criteria adopted by the Department and approved by the Wisconsin Small Business Regulatory Review Board to determine whether the Department's proposed rules have a significant economic impact on a substantial number of small businesses. Pursuant to the Department's criteria, a proposed rule will have a significant economic impact on a substantial number of small businesses if at least 10% of the businesses affected by the proposed rules are small businesses and if operating expenditures, including annualized capital expenditures, increase by more than the prior year's consumer price index (CPI) or reduce revenues by more than the prior year's CPI. For the purposes of this rulemaking, we used 2008 as the index year; the 2008 CPI is estimated to be 3.8%. The consumer price index is compiled by the U.S. Department of Labor, Bureau of Labor Statistics and measures, among other things, the rate of inflation.

6. Section 227.114 (1) (a), Stats., which defines "small business" as a business entity, including its affiliates, which is independently owned and operated and not dominant in its field, and which employees 25 or fewer full-time employees or which has gross annual sales of less than $5,000,000.

Analysis and supporting documents used to determine effect on small business:
The Department is the state's radiation control agency and is required under ss. 254.34 (1) (a), 254.365 (4), and 254.37 (3), Stats., to promulgate rules pertaining to the use of radiation in Wisconsin. Specifically, the Department is required to promulgate and enforce rules pertaining to sources of ionizing radiation, for registration and licensing sources of ionizing radiation, and to prohibit and prevent unnecessary radiation exposure.

The Department's x-ray registration and inspection program, and radioactive materials licensing and inspection program, are both 100% fee supported by the annual fees authorized under ss. 254.35 (3) and 254.365 (5), Stats. There are no fee increases proposed in this rule revision.

The fiscal impact to x-ray registrants relates to proposed requirements in the following sections: ss. DHS 157.74 (2) (L).; 157.76 (11) and (12); 157.80 (2) (a) 2; 157 82 (2) and (5); and 157.85 (13), (14) and (16). The proposed requirements and the fiscal impact on small business are detailed below.

DHS 157.74 (2) (L). This new subsection requires radiation safety committee oversight of all facilities that have 2 or more therapeutic radiation machines, regardless of the type of device (external or internal) used. The requirement for a radiation safety committee already exists for radioactive materials under s. DHS 157.61 (1) (e). The majority of therapeutic radiation machines currently being used in Wisconsin are used at large medical facilities that do not qualify as small businesses under s. 227.114 (1) (a), Stats. and have existing radiation safety committees. In the event that a facility without a radiation safety committee acquires 2 or more therapeutic radiation machines, they can utilize existing staff to form a radiation safety committee required under this section. As a result, the Department expects this new requirement to have minimal impact on any facility, including small business.

DHS 157.76 (11). Fluoroscopy devices, used to obtain continuous x-ray images of the body, produce very high radiation exposure rates with exposure time directly controlled by the device operator. The Department is aware of fluoroscopy operators receiving substantial exposure from use of fluoroscopic devices, indicating a lack of awareness of safety requirements. As a result, the Department is proposing minimum training for all personnel that operate fluoroscopy devices, regardless of the type of facility. This new requirement will impact the small percentage (less than 10%) of medical clinics, chiropractic and veterinary facilities with fluoroscopy devices, all of which are classified as a small businesses under s. 227.114 (1) (a), Stats. The proposed training requirement will also affect all large hospitals and clinics that routinely utilize fluoroscopy by requiring physicians as well as other operators to complete minimum training. The proposed training will take a minimum of 8 hours to complete. This training can be accomplished in a variety of ways, including in house (on site) training and continuing education, and can be rolled into the business'existing training infrastructure. As a result, the Department expects there will be a small cost associated with this training to all facilities using fluoroscopy devices, including small business.

DHS 157.76 (12). The Department is proposing requiring fluoroscopy units to have their radiation output measured annually by a qualified person on staff or under contract. This is consistent with the recommendations of the Conference of Radiation Control Program Directors (CRCPD) in their suggested state regulations. There is minimal effort required to meet this requirement because fluoroscopy units already have either qualified staff or contractors on hand. As a result, the Department anticipates minimal fiscal impact on any facility, including small business.

DHS 157.80 (2) (a) 2. The Department is proposing that operators of computed tomography (CT) x-ray systems for veterinary use be qualified or otherwise trained to use the device. This requirement will apply to all veterinary facilities using CT x-ray systems, which is currently a very small percentage of the total facilities statewide (approximately 4 sites). The small number of veterinary facilities impacted by this requirement are classified as a small business. The proposed training can be obtained from a device vendor or other qualified staff. To the

Department's knowledge, the few veterinary facilities with CT x-ray systems already meet this requirement. Due to the very small number of impacted facilities and the access to training, the Department anticipates minimal fiscal impact to small businesses.

DHS 157.82 (2) and (5). These 2 subsections jointly require all electronic brachytherapy users to receive device specific training prior to operating this new technology. The proposed training is consistent with the requirements for other therapeutic radiation machines in ch. DHS 157. Currently, this new technology is not being used by any facility classified as a small business under s. 227.114 (1) (a), Stats.

DHS 157.85 (13), (14), (16). These subsections establish quality assurance requirements for electronic brachytherapy devices as recommended by a national organization, the American Association of Physicists in Medicine (AAPM). Currently, this new technology is not being used by any facility classified as a small business under s. 227.114 (1) (a), Stats.

Effect on small business:
Pursuant to the foregoing analysis, the Department does not anticipate that the proposed revisions will have a significant economic impact on small businesses.

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Place where comments are to be submitted and deadline for submission:
Comments may be submitted to the agency contact person that is listed above. The deadline for submitting comments is October 21, 2009.

Small Business Regulatory Coordinator
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Fiscal Estimate
Under s. 254.34 (1) (a) Stats., the Department of Health Services is responsible for developing and enforcing rules, including registration and licensing of sources of ionizing radiation. Sources of ionizing radiation include x-ray producing devices. The Department is also responsible for maintaining compliance with an agreement between Wisconsin and the federal Nuclear Regulatory Commission (NRC) that transferred regulatory authority over certain radioactive materials from the NRC to the state.

The current rule revision is intended to bring Wisconsin into compliance with the most recent changes to federal radiation protection and regulatory requirements. No fiscal effect is anticipated as a result of the incorporation of new federal standards into DHS 157.

In addition, the Department proposes to update certain radiation safety requirements. Since the last revision of DHS 157 in 2006, new x-ray technologies with potential for significant radiation exposures to operators and patients have become more prevalent in the state. This rule revision proposes operator qualification and safety requirements for these new technologies. The new x-ray technologies are primarily being used by large, medical facilities not classified as a small business under s 227.114 (1) (a), Stats. In a few cases, they are being used by a small subset of veterinary facilities that are classified as a small business. The training needed to become qualified to operate these new technologies is available and may be accomplished in-house by incorporating into existing radiation safety programs. Some facilities are already providing operator training to meet facility requirements. Any additional training cost will vary by facility, but is not expected to be significant for any facility.

The Department is also proposing new quality assurance requirements for the digital x-ray systems that are being increasingly used in medical, dental, chiropractic and podiatric offices within the state. Digital x-ray systems use a digital (i.e., electronic) image receptor that replaces the use of x-ray film. The Department does not expect a significant cost to any facility from these new requirements.

Finally, the Department is proposing minimum training for all operators of fluoroscopy devices, including physicians. Fluoroscopy devices produce a continuous x-ray image of the body with potential for significant radiation exposure to both the patient and medical personnel. Fluoroscopy devices are used by most hospitals, plus a small subset of medical clinics, chiropractic and veterinary facilities. Although there will be a cost to complete the operator qualification training, either thru formal continuing education or in-house training, it is anticipated that there will be only a minimal fiscal impact to any facility.

The proposed changes to x-ray safety requirements are not the result of the changes in federal standards, although the changes are consistent with safety standards recommended by national organizations, specifically the American Association of Physicists in Medicine (AAPM) and the Conference of Radiation Control Program Directors (CRCPD). The new standards can be incorporated into the training required of most occupations that use radiation producing devices and thus is not expected to be a significant additional cost to any facility or individual. The Department is not proposing a fee increase in this rule revision.

Text of Proposed Rule

SECTION 1. DHS 157.03 (5), (6), (32m) (a), (33) (a), and (50) (intro.) and (a) are amended to read:

DHS 157.03 (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. Particle accelerator is considered an equivalent term.

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

(32m) (a) Meets the training requirements in s. DHS 157.61 (8) (a) and (11).

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

(50) "Byproduct material" means ~~either~~any 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~~using special nuclear material.

SECTION 2. DHS 157.03 (50) (c) to (e), (75r), and (103r) are created to read:

DHS 157.03 (50) (c) Any discrete source of radium-226 that has been produced, extracted or converted after extraction, for use for a commercial, medical or research activity.

(d) Any material that has been made radioactive by use of a particle accelerator, and is produced , extracted, or converted after extraction, for use for a commercial, medical or research activity.

(e) Any discrete source of naturally occurring radioactive material, other than source material, that the NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security, and is extracted or converted after extraction for use in a commercial, medical or research activity.

(75r) "Consortium" means an association of medical use licensees and a positron emission tomography (PET) radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility must be located at an educational institution, a federal facility or a medical facility.

(103r) **"**Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

SECTION 3. DHS 157.03 (191) and (200) are amended to read:

DHS 157.03 (191) “Licensed practitioner” means a chiropractor, dentist, physician, podiatrist, physician’s assistant, nurse practitioner or radiologist’s assistant licensed in the state of Wisconsin.

(200) “Low specific activity − III” or “LSA−III material” means solids, such as consolidated wastes or activated materials, excluding powders, that satisfy the requirements of 10 CFR 71.77, for which all of the following apply:

SECTION 4. DHS 150.03 (221m) is created to read:

DHS 150.03 (221m) “Nationally tracked source” means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix T. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

SECTION 5. DHS 157.03 (222), (374) (a), (c) and (d), (382), (388), (402m), (407), and (413) are amended to read:

(222) “NARM” means any naturally occurring or accelerator−produced radioactive material. ~~It does not include byproduct, source or special nuclear material.~~

(374) (a) For capacitor energy storage equipment, peak tube potential in ~~kV~~ kilovoltage and quantity of charge in ~~mAs~~millamperage-seconds (mAs).

(c) For CT ~~x−ray systems~~equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in ~~mA~~millamperes (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~~equipment 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.

(382) “Therapeutic radiation machine” means x−ray, gamma ray or electron−producing equipment designed and used for external beam or internal radiation therapy.

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

(402m) “Unirradiated uranium” means uranium containing not more than 2 X 10^3 Bq of plutonium per gram of uranium−235, not more than 9 X 10^6 Bq of fission products per gram of uranium− 235, and not more than 5 X 10^{-3} g of uranium−236 per gram of uranium−235.

(407) “Useful beam” means the radiation ~~emanating from~~ which passes through the tube housing port ~~or the radiation head and passing through~~ and the aperture of the beam−limiting device when the exposure ~~controls are in a mode to cause the system to produce radiations~~switch or timer is activated.

(413) “Waste” means those ~~materials having a low level of radioactivity containing 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~~low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in DHS 157.03 (50) (b) to (e).

SECTION 6. DHS 157.03 (430m) is created to read:

DHS 157.03 (430m)“X-ray control” means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stablizers, and similar devices, which control the technique factors on an x-ray exposure.

SECTION 7. DHS 157.05 (5) title is created to read:

DHS 157.05 (5) PHYSICAL CONTROLS.

SECTION 8. DHS 157.09 (2) (a) 2., (c) 2. intro., 3., and (d) title are amended to read:

DHS 157.09 Exemptions. (2) EXEMPTIONS OF RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL. (a) 2. A manufacturer, processor or producer of a product or material is exempt from the requirements of subch. II if they transfer radioactive material contained in a product or material in concentrations not in excess of those in Appendix A and introduced into the product or material by a licensee holding a specific license issued by the department, the NRC or another agreement state expressly authorizing such introduction. 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.

(c) 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:

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~~ the effective date of this section ….[legislative reference bureau inserts date].

(d) (title) *Self−luminous products containing tritium, krypton−85, or promethium−147 ~~or radium−226~~.*

SECTION 9. DHS 157.09 (2) (d) 4. is repealed.

SECTION 10. DHS 157.09 (2) (f) and (g) 3. are amended to read:

DHS 157.09 (2) (f) *Resins containing scandium−46 and designed for sand−consolidation in oil wells.* A person is exempt from this subchapter to the extent that the 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 or initial transfer for sale or distribution of any resins containing scandium−46.

(g) 3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license according to ~~s. DHS 157.13 (4) (i)~~10 CFR 32.21.

SECTION 11. DHS 157.11 (2) (b) 3. b., c., g. and h. are amended to read:

DHS 157.11 (2) (b) 3. 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. Devices containing only krypton need not be tested for leakage of radioactive material.

c. Ensure that the tests required by this subd. par. b. and 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.

g. Except as provided in subd. ~~3.h.~~ pars. h. and j., 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 or

export of the device shall furnish to the department a written report containing identification of the device by manufacturer's or initial transferer's name ~~and~~, model and serial number ~~and~~, the name ~~and~~, address and license number of the person receiving the device, and the date of the transfer. ~~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 and serial number of device transferred, the name and address of the transferee, and the name, phone number and position of an individual who may constitute a point of contact between the department and the transferee.

SECTION 12. DHS 157.11 (2) (b) 3. j. to m. are created to read:

DHS 157.11 (2) (b) 3. j. Not export the device containing byproduct material except as allowed under 10 CFR Part 110.

k. Respond to written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within the same time period, request in writing a longer time period and provide written justification why it cannot comply.

L. Appoint an individual responsible for having knowledge of the appropriate requirements of this chapter and the authority for taking required actions to comply with these requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with the appropriate requirements of this chapter. This appointment does not relieve the general licensee of any of its responsibility under this chapter.

m. May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required under this subd. par. b. need not be performed during the period of storage only. When devices are put back into service or transferred to another person, and have not been tested within the required time interval, they shall be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

SECTION 13. DHS 157.11 (2) (b) 4. is amended to read:

DHS 157.11 (2**)** (b) 4. The general license under this paragraph does not authorize the manufacture or import of devices containing radioactive material.

SECTION 14. DHS 157.11 (2) (h) is created to read:

DHS 157.11 (2) (h) G*eneral license relating to certain items and self-luminous products containing radium-226.* 1. A general license is issued to own, receive, acquire, possess, use or transfer radium-226 contained in the following products:

a. Antiquities originally intended for use by the general public that were manufactured in the 19th and 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts and healing pads.

b. Intact timepieces containing greater than 37 kBq (1 microcurie) of radium-226, nonintact timepieces, and timepiece dials and hands no longer installed in timepieces.

c. Self-luminous items installed in air, marine or land vehicles.

d. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

e. Small radium sources, such as discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations, electron tubes, lightning rods, ionization sources or static eliminators, containing no more than 37 kBq (1 microcurie) of radium 226.

2. The general license in this paragraph is exempt from the requirements of subchs. III and X with the exception of ss. DHS 157.30 (1), 157.32 (1) and (2). This exemption does not apply to any person specifically licensed under this chapter.

3. A person who owns, receives, acquires, acquires, possesses,uses or transfers radium-226 under the general license in subd. 1. shall do all the following:

a. Report to the department under DHS 157.32 any stolen, lost or missing radioactive material.

b. Not abandon the product containing radium-226. The product, and any radioactive material from the product, shall be disposed of according to the requirements of DHS 157.30 (8), by transfer to a person authorized under a specific license to receive the radium-226, or as approved by the department .

c. Not export products containing radium-226 except under 10 CFR 110.

d. Respond to written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request,or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within the same time period, request in writing a longer time period and provide written justification why it cannot comply.

4. The general license in subd. 1. does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

SECTION 15. DHS 157.12 (1) is renumbered DHS 157.12 (1) (a) and as renumbered is amended to read:

DHS 157.12 (1) REGISTRATION REQUIREMENT. (a) 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, 3.7 MBq (0.1 millicurie) of radium-226 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). Each address for a location of use as described in sub. (3) (d) represents a separate general licensee and requires a separate registration.

SECTION 16. DHS 157.12 (1) (b) is created to read:

DHS 157.12 (1) (b) A person in possession of devices that meet the criteria for registration under par. (a) shall notify the department of bankruptcy as specified in s. DHS 157.13 (10) (e) and (f).

SECTION 17. DHS 157.13 (1) (j) is created to read:

DHS 157.13 (1) (j) 1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued by the department, NRC or an agreement state under this chapter or equivalent regulations for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in s. DHS 157.13 (4) (i).

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in s. DHS 157.68.

4. Information identified in s. DHS 157.13 (4) (i) 3. on the PET drugs to be noncommercially transferred to members of a consortium.

SECTION 18. DHS 157.13 (4) (g) 2. b., d. and e., and (i) (title), (intro.) and 2. a. are amended to read:

DHS 157.13 (4) (g) 2. b. Cobalt−57 in units not exceeding 370 ~~MBq~~kBq (10 microcuries) each.

d. Iodine−125 in units not exceeding 370 ~~MBq~~kBq (10 microcuries) each.

e. Mock Iodine−125 in units not exceeding 1.85 ~~MBq~~kBq (0.05 microcurie) of iodine−129 and 185 ~~MBq~~Bq (0.005 microcurie) of americium−241 each.

(i) *Manufacture, preparation, or transfer for commercial distribution or noncommercial transfer to medical use licensees in a consortium 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 or noncommercial transfer to medical use licensees in a consortium drugs containing radioactive material for use by a person authorized under subchapter VI if all the following conditions are satisfied:

2. a. Registered or licensed with the FDA as ~~a drug manufacturer~~the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding or processing of a drug under 21 CFR 207.20 (a).

SECTION 19. DHS 157.13 (4) (i) 2. e. is created to read:

DHS 157.13 (4) (i) 2. e. Registered with a state agency as a positron emission tomography (PET) drug production facility.

SECTION 20. DHS 157.13 (4) (i) 4. a. and b. and 6. a. are amended to read:

DHS 157.13 (4) (i) 4. 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 or noncommercial transfer to medical use licensees in a consortium. 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 or noncommercial transfer to medical use licensees in a consortium. 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.

6. 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 or noncommercial transfer to medical use licensees in a consortium.

SECTION 21. DHS 157.13 (4) (i) 4. d. is created to read:

DHS 157.13 (4) (i) 4. d. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m or strontium-82/rubidium-82 generator, test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, according to s. DHS 157.63 (3), and retain a record of each measurement under s. DHS 157.71 (14).

SECTION 22. DHS 157.13 (4) (j) (intro.) is amended to read:

DHS 157.13 (4) (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, transmission or reference source or for the uses listed in ss. DHS 157.65 (1), 157.66 (1) ~~and~~, 157.67 (1) and 157.70 if all of the following conditions are satisfied:

SECTION 23. DHS 157.13 (17) (b) 4. Note and (c) 2. Note and (19) are created to read:

DHS 157.13 (17) (b) 4. Note: Submit report to the Department via telephone at (608) 267-4797 or via facsimile at (608) 267-3695.

(c) 2. Note: Submit written reports to the Department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701−2659.

(19) SERIALIZATION OF NATIONALLY TRACKED SOURCES. A licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

SECTION 24. DHS 157.22 (1) (c) 1. is amended to read:

DHS 157.22 Occupational dose limits. (1) (c) 1. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a method approved by the department. The assigned deep−dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow− dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. 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.

SECTION 25. DHS 157.25 (2) (a) 6. is repealed.

SECTION 26. DHS 157.29 (6) (e) 1. is amended to read:

DHS 157.29 (6) (e) 1. Removable radioactive surface contamination exceeds the limits of s. ~~DHS 157.94 (1) (h)~~DHS 157.94 (1) (i).

SECTION 27. DHS 157.30 (1) (a) 4. and (6) (b) are amended to read:

DHS 157.30 (1) (a) 4. Dispose of as authorized under ~~sub~~subs. (2), (3), (4) ~~or,~~ (5) or (8).

(6) TRANSFER FOR DISPOSAL AND MANIFESTS. (b) Any licensee shipping radioactive waste or byproduct material as defined in s. DHS 157.03 (50) (c) to (e) intended for ultimate disposal at a licensed land disposal facility shall document the information required in Appendix G, Section I and transfer this recorded information to the intended consignee in accordance with the requirements of Appendix G.

SECTION 28. DHS 157.30 (8) is created to read:

DHS 157.30 (8) DISPOSAL OF CERTAIN BYPRODUCT MATERIAL. (a) Licensed byproduct material as defined in DHS 157.03 (50) (c) to (e) may be disposed of under 10 CFR 61 or equivalent agreement state regulations, even though it is not defined as low level radioactive waste. Any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed by the NRC under 10 CFR 61 or an agreement state with equivalent regulations shall meet the requirements of 10 CFR 20.2006.

(b) A licensee may dispose of byproduct material as defined in s. DHS 157.03 (50) (c) to (e) at a disposal facility authorized to dispose of such material under federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

SECTION 29. DHS 157.32 (9) is created to read:

DHS 157.32 (9) REPORTS OF TRANSACTIONS INVOLVING NATIONALLY TRACKED SOURCES. A licensee who manufactures, transfers, receives, disassembles or disposes of a nationally tracked source shall submit a report to the Nuclear Regulatory Commission that complies with the requirements of 10 CFR 20.2207.

SECTION 30. DHS 157.42 (1) (a) and (b) are amended to read:

DHS 157.42 (1) (a) An entrance control of the type described in s. DHS 157.26 (1) (a) 1. that causes the radiation level upon entry into the area to be reduced. Entrance control devices that reduce the radiation level upon entry shall be tested monthly.

(b) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized. The alarm system shall be tested for proper operation with a radiation source each day before the installation is used for

radiographic operations. The test shall include a check of both the visible and audible signals. ~~Entrance control devices that reduce the radiation level upon entry shall be tested monthly.~~

SECTION 31. DHS 157.53 (1) (a) 1. is amended to read:

DHS 157.53 Requirements for personnel safety. (1) (a) 1. Completed ~~a course recognized by the department, the NRC, another agreement state or a licensing state~~ training incorporating the subjects outlined in Appendix J and demonstrated an understanding of the subject matter by successful completion of a written examination.

SECTION 32. DHS 157.61 (10) (a) is amended to read:

DHS 157.61 (10) (a) An individual identified as a radiation safety officer, a teletherapy or authorized medical physicist, ~~an authorized medical physicist~~ or a nuclear pharmacist on a department, NRC or another agreement state license, the permit issued by a licensee of broad scope or the permit issued by an NRC master material licensee before October 24, 2002 need not comply with the training requirements of subs. (7) to (9), respectively.

SECTION 33. DHS 157.61 (10) (b) is renumbered DHS 157.61 (10) (c).

SECTION 34. DHS 157.61 (10) (b) is created to read:

DHS 157.61 (10) (b) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a department, NRC or another agreement state license, the permit issued by a licensee of broad scope or the permit issued by NRC master material licensee between October 24, 2002 and April 29, 2005 need not comply with the training requirements of ss. DHS 157.61 (7), (8) or (9).

SECTION 35. DHS 157.62 (1) (b) is amended to read:

DHS 157.62 Technical requirements. (1) (b) A licensee shall calibrate the instrumentation required in par. (a) according to nationally recognized standards or the manufacturer's instructions.

SECTION 36. DHS 157.62 (3) (b) 2. c. is created to read:

DHS 157.62 (3) (b) 2. c. A PET radioactive drug producer licensed under s. DHS 157.13 (1) (j) or by NRC or another agreement state.

SECTION 37. DHS 157.62 (3) (c) 3. is amended to read:

DHS 157.62 (3) (c) 3. A combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under s. DHS 157.13 (4) (i), a PET radioactive drug producer licensed under s. DHS 157.13 (1) (j), or equivalent NRC or other agreement state requirements.

SECTION 38. DHS 157.63 (1) (a) is renumbered DHS 157.63 (1) (a) (intro.) and as renumbered is amended to read:

DHS 157.63 (1) (a) Is obtained from ~~a manufacturer or preparer licensed under s. DHS 157.13 (4) (i) or equivalent NRC or other agreement state requirements.~~ either of the following:

SECTION 39. DHS 157.63 (1) (a) 1. and 2. are created to read:

DHS 157.63 (1) (a) 1. A manufacturer or preparer licensed under s. DHS 157.13 (4) (i), or equivalent NRC or other agreement state requirements.

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

SECTION 40. DHS 157.63 (1) (b) (intro.) is amended to read:

DHS 157.63 (1) (b) (intro.) Is prepared by, excluding production of PET radionuclides, any of the following:

SECTION 41. DHS 157.63 (2) (a) is renumbered DHS 157.63 (2) (a) (intro.) and as renumbered is amended to read:

DHS 157.63 (2) (a) Is obtained from ~~a manufacturer or preparer licensed under s. DHS 157.13 (4) (i) or equivalent NRC or agreement state requirements.~~ either of the following:

SECTION 42. DHS 157.63 (2) (a) 1. and 2. are created to read:

DHS 157.63 (2) (a)1. A manufacturer or preparer licensed under s. DHS 157.13 (4) (i), or equivalent NRC or other agreement state requirements.

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

SECTION 43. DHS 157.63 (2) (b) intro., (3) (a) 1. to 3., (5) (a) 1. and (6) (a) are amended to read:

DHS 157.63 (2) (b) (intro.) Is prepared by, excluding production of PET radionuclides, any of the following:

(3) (a) 1. 0.15 kilobecquerel ~~(0.15 microcurie)~~ of molybdenum−99 per megabecquerel of technetium−99m (0.15 microcure of molybdenum-99 per 1 millicure of technetium 99m).

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

3. 0.2 kilobecquerel of strontium−85 per megabecquerel of rubidium−82 chloride injection (0.02 microcurie of strontium-85 per 1 millicurie of rubidium-82 chloride injection).

(5) (a) 1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for ~~uptake, dilution, and excretion~~ imaging and localization studies that includes the topics listed in par. (c) 1. and 2.

(6) WRITTEN ATTESTATION. (a) *Unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.* A licensee shall require an authorized user of unsealed radioactive material for the uses authorized under sub. (1) to have obtained written attestation, signed by a preceptor authorized user who meets the requirements of subs. (4) ~~and~~or (5), s. DHS 157.64 (4), or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements of sub. (4) (a) 1. or (c) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under sub. (1).

SECTION 44. DHS 157.64 (1) (a), (b) (intro.) and (5) (b) are amended to read:

DHS 157.64 (1) (a) Obtained from a manufacturer or preparer licensed under s. DHS 157.13 (4) (i), a PET radioactive drug producer licensed under s. DHS 157.13 (1) (j), or equivalent NRC or other agreement state requirements.

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

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

SECTION 45. DHS 157.67 (8) (b) 1. is amended to read:

DHS 157.67 (8) (b) 1. The output within 5% ~~of the source strength~~.

SECTION 46. DHS 157.68 (1) (intro.) and (2) (e) are amended to read:

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

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

SECTION 47. DHS 157.72 (1) (c) Note and (d) 3. Note are created to read:

DHS 157.72 (1) (c) Note: Submit report to the Department via telephone at (608) 267-4797 or via facsimile at (608) 267-3695.

(d) 3. Note: Submit written reports to the Department at: Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701−2659.

SECTION 48. DHS 157.74 (2) (L) is created to read:

DHS 157.74 (L) A registrant that uses two or more therapy devices for human use shall establish a radiation safety committee consisting of at least three members to oversee the use of all therapeutic radiation machines. The committee shall include an operator authorized by the registrant, a representative of the institution's management, and the radiation safety officer. If the institution has a radiation safety committee established under s. DHS 157.61(1)(e), this committee may be designated to oversee the use of all therapeutic radiation machines, if an operator authorized by the registrant is appointed to this committee.

SECTION 49. DHS 157.74 (3) (title) is amended to read:

DHS 157.74 (3) (title) X−RAY ~~FILM~~IMAGE PROCESSING EQUIPMENT AND PROCESSING PROCEDURES.

SECTION 50. DHS 157.74 (3) (a) title is created to read:

DHS 157.74 (3) (a) *Film.*

SECTION 51. DHS 157.74 (3) (a) to (d) are renumbered DHS 157.74 (3) (a) 1., 2., 3. and 4.

SECTION 52. DHS 157.74 (3) (b) is created to read:

DHS 157.74 (3) (b) *Digital Imaging Systems.* 1. Each installation using a digital radiographic x−ray system for human diagnosis or screening shall have available suitable equipment for handling and processing the radiographic digital image according to the manufacturer's instructions.

2. Quality control and maintenance procedures shall be performed on a regular schedule according to the device manufacturer's recommendations. If analysis shows that the image quality has declined, corrective action shall be taken prior to performing patient examinations.

SECTION 53. DHS 157.76 (11), (12) and Note are created to read:

DHS 157.76 (11) EQUIPMENT OPERATIONS. (a) The facility shall ensure that only a licensed practitioner or a radiologic technologist who is trained in the safe use of fluoroscopic x-ray systems shall be allowed to operate these systems. All fluoroscopic x-ray images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner.

(b). The use of fluoroscopic x-ray systems by radiologic technologists shall be performed under the supervision of a licensed practitioner for the purpose of localization to obtain images for diagnostic purposes.

(c) Radiologic technology students may not operate fluoroscopic x-ray systems except under the direct supervision of a licensed practitioner or radiologic technologist.

(d) Fluoroscopic x-ray systems may not be used as a positioning tool for general purpose radiographic examinations.

(e) The registrant shall require the operator of a fluoroscopic x-ray system to meet either of the following requirements:

1. Is certified by the American Board of Radiology or board eligible.

2. Has completed training to include but not limited to the following:

a. Principles and operation of the fluoroscopic x-ray system.

b. Biological effects of x-ray.

c. Principles of radiation protection.

d. Fluoroscopic outputs.

e. High level control options.

f. Dose reduction techniques for fluoroscopic x-ray systems.

g. Applicable state and federal regulations.

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

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

SECTION 54. DHS 157.77 (2) (g) is amended to read:

DHS 157.77 (2) (g) *Exposure control location.* The x−ray exposure control shall be placed so that the operator may view the patient while making any exposure and at least ~~3 feet~~1 meter (3.3 feet) from the end of the protective barrier.

SECTION 55. DHS 157.79 (2) (c) is amended to read:

DHS 157.79 (2) (c) A ~~deadman~~dead−man type of exposure switch shall be provided with an electrical cord of sufficient length so that the operator or the assistant, may stand out of the useful beam and at least 2 meters (6.5 feet) from the table during all x−ray exposures. A foot operated exposure switch may be used and this switch may be integrated into the table base or the foot switch may be on a 2 meter (6.5 feet) cord.

SECTION 56. DHS 157.80 (2) (a) is renumbered DHS 157.80 (2) (a) 1. and 3. and amended to read:

DHS 157.80 (2) OPERATING PROCEDURES. (a) 1. A CT x−ray system for human use may only be operated for diagnostic procedures by an American registry of radiologic technologists certified person who has been specifically trained in its operation.

3. Combination systems which are designated as PET/CT shall be operated by a person qualified by training in the safe use of radioactive materials and who meets the training requirements of Appendix L.

SECTION 57. DHS 157.80 (2) (a) 2. is created to read:

DHS 157.80 (2) (a) 2. A CT x-ray system for veterinary use may only be operated for diagnostic procedures by a person who is certified by the American registry of radiological technologists or has completed training equivalent to the requirements of Appendix L and has been specifically trained in its operation.

SECTION 58. DHS 157.81 (1) and (2) are amended to read:

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

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

SECTION 59. DHS 157.81 (3) (c) 7. is created to read:

DHS 157.81 (3) (c) 7. The x-ray exposure control shall be located within the shielded area and at least 1 meter (3.3 feet) from the open end of the protective barrier, excluding mammography units.

SECTION 60. DHS 157.82 (2) (c) and (5) (c) are created to read:

DHS 157.82 (2) (c) A registrant for electronic brachytherapy shall require the authorized user to complete device specific instruction from the manufacturer or individual trained by the manufacturer, and training on procedures required by s. DHS 157.85(16)(g) 4. and 5.

(5) (c) A person who will be operating an electronic brachytherapy unit shall complete device specific instruction from the manufacturer or individual trained by the manufacturer, and training on procedures required by s. DHS 157.85 (16) (g) 4. and 5.

SECTION 61. DHS 157.82 (6) is amended to read:

DHS 157.82 (6) SAFETY PROCEDURES. Written safety procedures and rules, including any restrictions required for the safe operation of the particular therapeutic radiation machine, shall be developed by a medical physicist and shall be available in the control area of a therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules. Operators, authorized users and medical physicists for electronic brachytherapy shall participate in drills of the emergency procedures, required by s. DHS 157.85(16)(g) 5., initially and at least annually thereafter.

SECTION 62. DHS 157.83 (1) (a) and (c) are amended to read:

DHS 157.83 (1) (a) Prior to administration, a written directive is prepared for any external beam radiation therapy dose or electronic brachytherapy dose. A written revision to an existing written directive may be made prior to beginning treatment, or prior to delivery of a fractional dose, provided that the revision is dated and signed by an authorized user ~~prior to administration of the external beam radiation therapy dose, or the next external beam radiation therapy fractional dose~~. If, because of the patient's condition, a delay to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 24 hours of the oral revision.

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

SECTION 63. DHS 157.85 (13) (em) is created to read:

DHS 157.85 (13) (em) Full calibration for electronic brachytherapy units shall include all of the following:

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

2. Proper operation of back-up exposure control devices.

3. The output within 2 % of the expected value, if applicable, or determination of the output if there is no expected value.

4. Evaluation that the relative dose distribution about the source is within 5 % of the expected value.

5. Source position accuracy to within 1 millimeter within the applicator.

6. Determination of the proper length of source transfer tubes and applicators.

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

SECTION 64. DHS 157.85 (14) (e) is amended to read:

DHS 157.85 (14) (e) A registrant shall have the medical physicist review and sign the results of each radiation output quality control check and notify the registrant of results within 10 working days of the date that the check was performed.

SECTION 65. DHS 157.85 (14) (fm) is created to read:.

DHS 157.85 (14) (fm) If the results of the quality control checks indicate malfunction of any system, the registrant shall prevent clinical use of the system until repaired.

SECTION 66. DHS 157.85 (14) (g) 4. is amended to read:

DHS 157.85 (14) (g) 4. Viewing and intercom systems, if applicable.

SECTION 67. DHS 157.85 (14) (g) 6. and (gm) are created to read:

DHS 157.85 (14) (g) 6. If applicable, the integrity of all cables, catheters or parts of the device that carry high voltages.

(gm) Daily quality control checks for electronic brachytherapy shall include all the following:

1. The output of the x-ray source falls within 3 % of expected values, which includes output as a function of time or output as a function of setting on a monitor chamber.

2. Verification of the consistency of the dose distribution to within 3 % of that found during calibration.

3. Validation of the operation of positioning methods to assure that the treatment dose exposes the intended location to within 1 mm.

4. Inspection of all treatment components on the day of use.

SECTION 68. DHS 157.85 (16) (g) is created to read:

DHS 157.85 (16) (g) A registrant for electronic brachytherapy shall do all of the following:

1. Ensure the electronic brachytherapy unit is inoperable, either by hardware or password, when unattended by qualified staff or service personnel.

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

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

4. Create a written procedure for safe operation of each device.

5. Develop, implement and maintain written procedures for responding to an abnormal situation. The procedure shall include all the following:

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

b. The names and telephone numbers of the licensed practitioner, the medical physicist, the radiation safety officer and the manufacturer to be contacted if the unit or console operates abnormally.

6. Maintain a copy of the procedures required by subd. 4. and 5. at the unit console.

7. Ensure all of the following is done during treatment:

a. Only individuals approved by the authorized user, radiation safety officer or medical physicist may be present in the treatment room.

b. Protective shielding shall be available for persons in the treatment room.

c. A radiation survey is performed when the unit and/or shielding is portable to verify proper shielding placement immediately upon initiation of treatment.

d. A medical physicist and operator shall be physically present during the initiation and course of patient treatment.

e. A medical physicist or operator shall monitor the position of all persons in the treatment room to prevent unshielded exposure.

f. A medical physicist or operator shall monitor all entrances to prevent entering individuals from unshielded exposure.

g. Only mechanical supporting or restraining devices may be used to hold a patient in position, when applicable.

SECTION 69. DHS 157.88 (3) (a) (intro.) is amended to read:

DHS 157.88 (3) (intro.) NOTIFICATIONS AND REPORTS TO INDIVIDUALS. (a) *Radiation exposure reports.* Every 12 months, a licensee or registrant shall provide a written report of radiation exposure to each employee who is required to be monitored for radiation exposure under s. DHS 157.25 (2) if the employee's annual dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue. The report shall include all of the following:

SECTION 70. DHS 157.92 (2) (c) 5. (intro.) and (3) (a) (intro.)and (b) are amended to read:

DHS 157.92 (2) (c) 5. (intro.) Liquid solutions of uranyl nitrate enriched in uranium−235 to a maximum of two percent by ~~weight~~mass, provided that all the following conditions apply:

(3) TRANSPORT OF LICENSED MATERIAL. (a) A licensee who transports licensed material outside the site of usage, as specified in the department license, or on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR 107, 171 to 180, and 390 to 397, appropriate to the mode of transport and do all the following:

(b) If the regulations of the U.S. department of transportation are not applicable to a shipment of licensed material, a licensee shall comply with the requirements of 49 CFR ~~170 to 189~~107, 171 to 180, and 390 to 397, appropriate to the mode of transport as if the shipment was subject to the regulations. A request for modification, waiver or exemption from these requirements and any notification referred to in these requirements shall be submitted in writing to the department.

SECTION 71. APPENDIX E, List of Elements (page 439) is amended to read:

List of Elements

Name	Symbol	Atomic Number
Actinium	Ac	89
Aluminum	A	13
Americium	Am	95
Antimony	Sb	51
Argon	Ar	18
Arsenic	As	33
Astatine	At	85
Barium	Ba	56
Berkelium	Bk	97
Beryllium	Be	4
Bismuth	Bi	83
Bromine	Br	35
Cadmium	Cd	48
Calcium	Ca	20
Californium	Cf	98
Carbon	C	6
Cerium	Ce	58
Cesium	Cs	55
Chlorine	Cl	17
Chromium	Cr	24
Cobalt	Co	27
Copper	Cu	29
Curium	Cm	96
Dysprosium	Dy	66
Einsteinium	Es	99
Erbium	Er	68
Europium	Eu	63
Fermium	Fm	100
Fluorine	F	9
Francium	Fr	87
Gadolinium	Gd	64
Gallium	Ga	31
Germanium	Ge	32
Gold	Au	79
Hafnium	Hf	72
Holmium	Ho	67
Hydrogen	H	1
Indium	In	49
Iodine	I	53
Iridium	Ir	77
Iron	Fe	26
Krypton	Kr	36
Lanthanum	La	57
Lead	Pb	82
Lutetium	Lu	71
Magnesium	Mg	12
Manganese	Mn	25
Mendelevium	Md	101

List of Elements (cont.)

Name	Symbol	Atomic Number
Mercury	Hg	80
Molybdenum	Mo	42
Neodymium	Nd	60
Neptunium	Np	93
Nickel	Ni	28
Niobium	Nb	41
Nitrogen	N	7
Osmium	Os	76
Oxygen	O	8
Palladium	Pd	46
Phosphorus	P	15
Platinum	Pt	78
Plutonium	Pu	94
Polonium	Po	84
Potassium	K	19
Praseodymium	Pr	59
Promethium	Pm	61
Protactinium	Pa	91
Radium	Ra	88
Radon	Rn	86
Rhenium	Re	75
Rhodium	Rh	45
Rubidium	Rb	37
Ruthenium	Ru	44
Samarium	Sm	62
Scandium	Sc	21
Selenium	Se	34
Silicon	Si	14
Silver	Ag	47
Sodium	Na	11
Strontium	Sr	38
Sulfur	S	16
Tantalum	Ta	73
Technetium	Tc	43
Tellurium	Te	52
Terbium	Tb	65
Thallium	Tl	81
Thorium	Th	90
Thulium	Tm	69
Tin	Sn	50
Titanium	Ti	22
Tungsten	W	74
Uranium	U	92
Vanadium	V	23
Xenon	Xe	54
Ytterbium	Yb	70
Yttrium	Y	39
Zinc	Zn	30

SECTION 72. APPENDIX O, s. II is amended to read:

II. a. For individual radionuclides whose identities are known, but which are not listed in TABLE VI, the determination of the values of A_1 and A_2 requires department approval, except that the values of A_1 and A_2 in TABLE ~~VII~~VIII may be used without obtaining department approval.

b. For individual radionuclides whose identities are known, but which are not listed in Table VII, the exempt material activity concentration and exempt consignment activity values contained in Table VIII may be used. Otherwise, the licensee shall obtain prior department approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table VII, before shipping the material.

c. The licensee shall submit requests for prior approval, described under paragraphs II(a) and II(b) of this Appendix, in writing to the department.

SECTION 73. APPENDIX O, s. IV, par. (a) is amended to read:

(a) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i and A_1(i) is the A_1 value for radionuclide I.

SECTION 74. APPENDIX O, s. IV, par. (b) is renumbered and amended to read:

(b) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i ~~and A_1(i)~~ and A_2(i) ~~are the A_1 and A_2~~ is the ~~values~~ value for radionuclide ~~respectively~~ i.

(c) Alternatively, ~~an~~ the A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \ \underline{for\ mixtures} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity of nuclide ~~I~~ (i) in the mixture and A_1(i) is the appropriate A_1 value for nuclide i.

(d) ~~An~~ Alternatively the A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \ \underline{for\ mixtures} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity ~~of nuclide I~~ for radionuclide (i) in the mixture, and A_2 (i) is the appropriate A_2 value for ~~nuclide~~ radionuclide (i).

SECTION 75. APPENDIX O s. IV pars. (e) and (f) are created to read:

(e) The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide (i) in the mixture, and [A] is the activity concentration for exempt material containing radionuclide (i).

(f) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide (i) in the mixture, and A is the activity limit for exempt consignments for radionuclide (i).

SECTION 76. APPENDIX O, TABLE VII (page 534) is amended to read:

TABLE VII
EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225 (a)	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227 (a)		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (a)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m (a)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (a)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (a)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X1010^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211 (a)	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ba-131 (a)	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (a)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

SECTION 77. APPENDIX O, TABLE IX (page 547) is amended to read:

TABLE IX
ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment* wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.9×10^{-8}	~~5.4~~ 5.0 $\times 10^{-7}$
0.72	2.6×10^{-8}	7.1×10^{-7}
1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.1×10^{-6}	5.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}
Natural thorium	8.1×10^{-9}	2.2×10^{-7}

SECTION 78. APPENDIX P is amended to read:

Quantities of Radioactive Materials Requiring Consideration of the Need for a Contingency Plan for Responding to a Release

Radioactive Material[1/]	Release Fraction	Quantity (GBq)	Quantity (Ci)
Actinium-228	0.001	148,000	4,000
Americium-241	0.001	74	2
Americium-242	0.001	74	2
Americium-243	0.001	74	2
Antimony-124	0.01	148,000	4,000
Antimony-126	0.01	222,000	6,000
Barium-133	0.01	370,000	10,000
Barium-140	0.01	1,110,000	30,000
Bismuth-207	0.01	185,000	5,000
Bismuth-210	0.01	22,200	600
Cadmium-109	0.01	37,000	1,000
Cadmium-113	0.01	2,960	80
Calcium-45	0.01	740,000	20,000
Californium-252	0.001	333	9 (20 mg)
Carbon-14 (Non-CO2)	0.01	1,850,000	50,000
Cerium-141	0.01	370,000	10,000
Cerium-144	0.01	11,100	300
Cesium-134	0.01	74,000	2,000
Cesium-137	0.01	111,000	3,000
Chlorine-36	0.5	3,700	100
Chromium-51	0.01	11,100,000	300,000
Cobalt-60	0.001	185,000	5,000
Copper-64	0.01	7,400,000	200,000
Curium-242	0.001	2,220	60
Curium-243	0.001	110	3
Curium-244	0.001	148	4
Curium-245	0.001	74	2
Europium-152	0.01	18,500	500
Europium-154	0.01	14,800	400

Europium-155	0.01	111,000	3,000
Gadolinium-153	0.01	185,000	5,000
Germanium-68	0.01	74,000	2,000
Gold-198	0.01	1,110,000	30,000
Hafnium-172	0.01	14,800	400
Hafnium-181	0.01	259,000	7,000
Holmium-166m.	0.01	3,700	100
Hydrogen-3	0.5	740,000	20,000
Indium-114m.	0.01	37,000	1,000
Iodine-125.	0.5	370	10
Iodine-131	0.5	370	10
Iridium-192	0.001	1,480,000	40,000
Iron-55	0.01	1,480,000	40,000
Iron-59	0.01	259,000	7,000
Krypton-85	1.0	222,000,000	6,000,000
Lead-210	0.01	296	8
Manganese-56	0.01	2,220,000	60,000

Radioactive Material[1/]	Release Fraction	Quantity (GBq)	Quantity (Ci)
Mercury-203	0.01	370,000	10,000
Molybdenum-99	0.01	1,110,000	30,000
Neptunium-237	0.001	74	2
Nickel-63	0.01	740,000	20,000
Niobium-94	0.01	11,100	300
Phosphorus-32	0.5	3,700	100
Phosphorus-33	0.5	37,000	1,000
Polonium-210	0.01	370	10
Potassium-42	0.01	333,000	9,000
Promethium-145	0.01	148,000	4,000
Promethium-147	0.01	148,000	4,000
Radium-226	0.001	3,700	100
Ruthenium-106	0.01	7,400	200
Samarium-151	0.01	148,000	,000
Scandium-46	0.01	111,000	3,000
Selenium-75	0.01	370,000	10,000
Silver-110m.	0.01	37,000	1,000
Sodium-22	0.01	333,000	9,000
Sodium-24	0.01	370,000	10,000
Strontium-89	0.01	111,000	3,000
Strontium-90	0.01	3,330	90
Sulfur-35	0.5	33,30	900
Technetium-99	0.01	370,000	10,000
Technetium-99m	0.01	14,800,000	400,000
Tellurium-127m	0.01	185,000	5,000
Tellurium-129m	0.01	185,000	5,000
Terbium-160	0.01	148,000	4,000
Thulium-170	0.01	148,000	4,000
Tin-113	0.01	70,000	10,000
Tin-123	0.01	111,000	3,000
Tin-126	0.01	37,000	1,000
Titanium-44	0.01	3,700	100
Vanadium-48	0.01	259,000	7,000
Xenon-133	1.0	33,300,000	900,000
Yttrium-91	0.01	74,000	2,000
Zinc-65	0.01	185,000	5,000
Zirconium-93	0.01	14,800	400
Zirconium-95	0.01	185,000	5,000
Any other beta-gamma emitter	0.01	370,000	10,000
Mixed fission products	0.01	37,000	1,000
Mixed corrosion products	0.01	370,000	10,000
Contaminated equipment, beta-gamma	0.001	370,000.	10,000
Irradiated material, any form other than solid noncombustible	0.01	37,000	1,000
Irradiated material, solid noncombustible	0.001	370,000	10,000
Mixed radioactive waste, beta-gamma	0.01	37,000	1,000
Packaged mixed waste,[2/] beta-gamma	0.001	370,000	10,000
Any other alpha emitter	0.001	74	2
Contaminated equipment, alpha	0.0001	740.	20
Packaged waste, alpha[2/]	0.0001	740	20

[1/] For combinations of radioactive materials, the licensee is required to consider whether an emergency plan is needed if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material above exceeds one.

[2/] Waste packaged in Type B containers does not require an emergency plan.

SECTION 79. DHS 157 APPENDIX T is created to read:

CHAPTER DHS 157

APPENDIX T

NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8.100	3	81