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Wisconsin
Chapter DHS 157- Radiation Protection
Regulatory Guide

Guidance for Medical Use of Radioactive Material

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EXECUTIVE SUMMARY

Wisconsin Regulatory Guides (WISREGs) are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of **Wisconsin Administrative Code, Chapter DHS 157**, to delineate techniques used by the Department of Health Services (DHS) staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants or licensees. WISREGs are not substitutes for **Chapter DHS 157**; therefore, compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the DHS, Radiation Protection Section to determine if a radiation protection program meets the current rule and protects health and safety.

Licensees may share comments and suggestions for improvements in this WISREG. This WISREG will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to **Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659** or DHSRadioactiveMaterials@dhs.wisconsin.gov**.**

To request copies of this guide (which may be reproduced) call DHS, Radiation Protection Section at (608) 267-4797 or on DHS's website https://www.dhs.wisconsin.gov/radiation/radioactivematerials/wisregs.htm.

This WISREG, '*Guidance for Medical Use of Radioactive Material'* has been developed to streamline the application process for a Medical Use of Radioactive Material License. A link to Form F-45008, '*Application for Radioactive Material License for Medical Use*' is located in Appendix A of this guide. This form is available at https://www.dhs.wisconsin.gov/library/collection/f-45008.

Appendices D through **Z** provide examples, models and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in ***DHS 157.10(3)*** for:

Category 7A: Teletherapy, HDR, or stereotactic radiosurgery (including mobile)
Category 7B: Broad scope except Teletherapy, HDR or stereotactic radiosurgery
Category 7C: Mobile Nuclear Medicine
Category 7D: Medical-all others

In summary, the applicant will need to do the following to submit an application for a Medical Use license:

- Use this regulatory guide to prepare the Form F-45008, '*Application for Radioactive Material License for Medical Use*' (Appendix A).
- Complete Form F-45008, '*Application for Radioactive Material License for Medical Use*' (Appendix A). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments, which should include the applicant's name and license number (if a renewal).

- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments.
- Submit the application fee (for new licenses only).

Retain one copy of the license application and attachments for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

If you have any questions about the application process, please contact DHS Radiation Protection Section at (608) 267-4797 or email DHSRadioactiveMaterials@dhs.wisconsin.gov.

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ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ANSI	American National Standards Institute
ARSO	Associate Radiation Safety Officer
AU	Authorized User
bkg	background
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	centimeter cubed
cm^2	centimeter squared
Co-57	cobalt-57
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
DAC	derived air concentration
DHS	Wisconsin Department of Health Services
DOT	United States Department of Transportation
dpm	disintegrations per minute
FDA	United States Food and Drug Administration
ft	foot
GM	Geiger-Mueller (detector)
GSR	gamma stereotactic radiosurgery
HDR	high dose-rate
I-125	iodine-125
I-131	iodine-131
IN	Information Notice
IND	Investigational New Drug
Ir-192	iridium-192
LDR	low dose-rate
mCi	millicurie
MDA	minimal detectable activity
ml	milliliter
Mo-99	molybdenum-99
mR	milliroentgen
mrem	millirem
mSv	millisievert
NaI(Tl)	sodium iodide (thallium doped)
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSLD	optically stimulated luminescence dosimeters
P-32	phosphorus-32
Pd-103	palladium-103
PDR	pulsed dose-rate
QA	quality assurance
Ra-226	radium-226
RG	Regulatory Guide
RIS	Regulatory Issue Summary
RSC	Radiation Safety Committee

RSO	Radiation Safety Officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unites)
Sr-90	strontium-90
SSDR	Sealed Source and Device Registration
Sv	Sievert
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeter
WD	written directive
Y-90	yttrium-90
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant in preparing a license application for medical use of radioactive materials. It also provides guidance on DHS's criteria for evaluating the application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of sources in devices.

The term "patient" is used to represent "patient" or "human research subject" throughout this guide. The term "applicant" is used when describing the application process and the term "licensee" is used when describing a regulatory requirement.

This guide addresses the wide variety of radionuclides used in medicine. Uses are:

- Diagnostic studies with unsealed radionuclides;
- Therapeutic administrations with unsealed radionuclides;
- Manual brachytherapy with sealed sources; and
- Therapeutic administrations with sealed sources in devices (e.g., remote afterloaders and gamma stereotactic radiosurgery units).

This guide describes the information needed to complete Form F-45008, *'Application for Radioactive Material License for Medical Use'* (Appendix A). This guide does not directly address complete radiation safety and licensing guidance for uses specified under ***DHS 157.70***, '*Other Medical Uses of Radioactive Material or Radiation from Radioactive Material.'* For guidance on these uses, see the NRC Medical Uses Licensee Toolkit at https://www.nrc.gov/materials/miau/med-use-toolkit.html. Contact DHS Radiation Protection Section staff with questions regarding information not provided.

The format for each item number in this guide is as follows:

- **Rule** – lists the requirements of Chapter DHS 157 that are applicable to the item;
- **Criteria** – outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** – provides additional information on the topic; and
- **Response from Applicant** – indicates what information must be provided by applicants to address that topic.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of Wisconsin according to DHS guidelines. Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established.

Chapter DHS 157 requires the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the rule. Appendices H, I, L, N, O, Q, R, T, U, V, and X describe sufficient radiation protection procedures for compliance of various aspects of the radiation protection program. Each applicant should read the rule carefully and then decide if a procedure from an appendix addresses specific radiation protection program needs at the

applicant's facility. Applicants may adopt a procedure from an appendix or they may develop their own procedures to comply with the applicable rule.

In this guide, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in ***Chapter DHS 157, Subchapter I.*** Rem and Sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because ***Chapter DHS 157, Subchapter III***, sets dose limits in terms of rem--not rad or roentgen. Furthermore, radioactive materials commonly used in medicine emit beta and photon radiation, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem. For alpha and neutron emitting radioactive materials, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles and neutrons requires the use of an appropriate quality factor (Q) value. Tables 1004(b)(1) and (2) in 10 CFR 20.1004, "Units of radiation dose," address the Q values for alpha and neutrons.

This WISREG is modeled on the Nuclear Regulatory Commission's (NRC) NUREG 1556, Volume 9. The WISREG shows the requirements in terms of ***Chapter DHS 157***.

Applicants and licensees should be aware of other WISREGs that provide useful information for medical use licensees. For example, WISREG-1556, Vol. 11, 'Guidance for Licenses of Broad Scope' provides additional licensing guidance on medical use programs of broad scope.

LICENSES

DHS regulates the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects for medical use. DHS issues three types of licenses for the use of radioactive material in medical practices and facilities. These are the general *in vitro* license, the specific license of limited scope, and the specific license of broad scope. These licenses are issued pursuant to ***Chapter DHS 157, Subchapter II***.

DHS usually issues a single radioactive material license to cover activities by a single radiation safety program. Although DHS may issue separate licenses to individual programs for different medical uses, it does not usually issue separate licenses to different departments in a medical institution. Applicants with multiple facilities should consider the number of licenses needed for all facilities. A single license may only be shared across multiple facilities if each facility shares a single radiation safety program and a unified organizational structure where the applicant has direct control over all licensed operations. If medical use of licensed material at different facilities will be managed independently, then each facility should obtain a separate radioactive materials license.

DHS expects applicants to provide requested information on specific aspects of their proposed radiation protection program in attachments to the application. When necessary, DHS may ask the applicant for additional information to gain reasonable assurance that an adequate radiation protection program has been established.

Because a radioactive materials license is a legally binding agreement, only the applicant's senior-level management may sign the license application.

After a license is issued, the licensee must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with DHS;
- Terms and conditions of the license; and
- ***Chapter DHS 157***.

GENERAL *IN VITRO* LICENSE

In ***DHS 157.11(2)(f)***, '*General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing'***,** DHS issues a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use small quantities of certain radioactive material for *in vitro* clinical or laboratory tests not involving "medical use" (i.e., not involving administration to humans). If the general license alone meets the applicant's needs, only Form F-45011, *'Certificate – In Vitro Testing with Radioactive Material Under General License'*, needs to be filed. Medical-use licensees authorized pursuant to ***Chapter DHS 157, Subchapter VI***, do not need to file the form.

DHS limits possession to a total of 200 microcuries of photon-emitting materials listed in ***DHS 157.11(2)(f)*** at any one time, at any one location of storage or use. The use of materials listed in ***DHS 157.11(2)(f)*** within the inventory limits of that section is subject only to the requirements of that section and not to the requirements of ***Chapter DHS 157, Subchapter III*** and ***Subchapter X***, except as set forth in ***DHS 157.11(2)(f)***.

An applicant needing more than 200 microcuries of these materials must apply for a specific license and may request the increased inventory limit as a separate line item on Form F-45008, '*Application for Radioactive Material License for Medical Use'*. This type of applicant generally requests an increased limit of 3 millicuries. If requesting an increased inventory limit, the applicant will be subject to the requirements of ***Chapter DHS 157, Subchapter III***, including the requirements for waste disposal and ***Chapter DHS 157, Subchapter X***.

SPECIFIC LICENSE OF LIMITED SCOPE

DHS issues specific medical licenses of limited scope to private or group medical practices and to medical institutions. A medical institution is an organization in which more than one medical discipline is practiced. In general, individual physicians or physician groups located within a licensed medical facility (e.g., hospital) may not apply for a separate license because ***DHS 157.13(2)(b)*** refers to the applicant's facilities. Since a physician group does not normally have control over the facilities, the hospital remains responsible for activities conducted on its premises and must apply for the license. On specific licenses of limited scope, the authorized users are individually listed in the license.

Radioactive material may be administered to patients on an inpatient or outpatient basis. For patients to whom radioactive material is administered, who are not releasable under ***DHS 157.62(8)***, inpatient facilities are required.

A specific license of limited scope may also be issued to an entity requesting to perform mobile medical services [***DHS 157.62(9), DHS 157.67(13)***]. A medical institution or a private or group practice may apply for authorization to use radioactive material in a mobile medical service.

SPECIFIC LICENSE OF BROAD SCOPE

Medical institutions that provide patient care and conduct research programs that use radionuclides for *in vitr*o, animal, and medical procedures may request a specific license of broad scope in accordance with ***Chapter DHS 157, Subchapter II***. The criteria for the various types of broad scope licenses are found in ***DHS 157.13(3)(c) through (f).*** Generally, DHS issues specific licenses of broad scope for medical use (i.e., licenses authorizing multiple quantities and types of radioactive material for unspecified uses) to institutions that (1) have experience successfully operating under a specific license of limited scope; and (2) are engaged in medical research and routine diagnostic and therapeutic uses of radioactive material. ***WISREG-1556, Vol. 11***, offers additional guidance to applicants for a specific license of broad scope.

THE 'AS LOW AS REASONABLY ACHIEVABLE' (ALARA) CONCEPT

DHS 157.21, Radiation protection programs, states that *"each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities"* and *"the licensee 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...ALARA."* This section also requires that licensees review the content of the radiation protection program and its implementation annually.

The following documents contain information, methods, and references useful to those who are establishing radiation protection programs to maintain radiation exposures at ALARA levels in medical facilities and provide DHS's position:

- *NRC's RG 8.10, 'Operating Philosophy for Maintaining Occupational Radiation Exposures ALARA'*
- *NRC's RG 8.18, 'Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be ALARA.'*

Information directly related to radiation protection standards in ***Chapter DHS 157, Subchapter III***, is contained in:

- NRC's NUREG-1736, *'Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation.'*
- NRC's RG 8.29, *'Instruction Concerning Risks from Occupational Radiation Exposure'*

Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

RESEARCH INVOLVING HUMAN SUBJECTS

DHS 17.03(211) defines "*medical use*" to include the administration of radioactive material to human research subjects. Furthermore, ***DHS 157.59(2)***, 'Provisions for the protection of human research subjects' addresses the protection of the rights of human subjects involved in research conducted by limited specific medical use licensees and broad scope medical use licensees.

Prior DHS approval is not necessary if the research is conducted, funded, supported, or regulated by federal agencies that have implemented the 'Federal Policy for the Protection of Human Subjects'. Otherwise, the licensee must apply for a specific amendment and receive approval for the amendment before conducting such research. Whether or not a license amendment is required, licensees must obtain informed consent from human subjects and prior review and approval of the research activities by an 'Institutional Review Board' or equivalent under the meaning of these terms as defined and described in the 'Federal Policy for the Protection of Human Subjects'. In accordance with ***DHS 157.59(2)(b)***, research involving human subjects shall be conducted only with radioactive materials listed in the license for the uses authorized in the license.

Licensees conducting human research using radioactive drugs, sealed sources, and/or devices are responsible for ensuring that, in addition to complying with ***DHS 157.59(2)***, they comply with all other applicable DHS requirements and license conditions. Therefore, it is a licensee's responsibility to ensure that:

- It is authorized to possess the materials and devices needed to participate in the research studies;
- The materials and devices to be used in the research are included in the specific medical uses authorized in the license;
- The procedures in the research protocols do not conflict with DHS regulatory and license requirements; and
- It is in compliance with ***DHS 157.59(2)***, its license, and any other DHS and other federal regulatory requirements.

WHO REGULATES FACILITIES IN WISCONSIN?

In the special situation of work at federally controlled sites in Wisconsin, it is necessary to know the jurisdictional status of the land to determine whether Nuclear Regulatory Commission (NRC) or DHS has regulatory authority. The NRC has regulatory authority over land determined to be under "exclusive federal jurisdiction," while DHS has jurisdiction over non-exclusive federal jurisdiction land (see **Table 1**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. DHS recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with DHS or NRC regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 1: Who Regulates the Activity?

Applicant and Proposed Location of Work	**Regulatory Agency**
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [*10 CFR 30.12*])	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or Tribal member on Indian Tribal land	NRC
Non-federal entity in Wisconsin at non-federally controlled site	DHS
Non-federal entity in Wisconsin at federally controlled site not subject to exclusive federal jurisdiction	DHS
Non-federal entity in Wisconsin at federally controlled site subject to exclusive federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials **not** directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	DHS

Reference: A current list of Agreement States (States that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their borders), including names, addresses, and telephone numbers of responsible officials, may be found at https://scp.nrc.gov/.

MANAGEMENT RESPONSIBILITY

DHS endorses the philosophy that effective radiation protection program management is vital to safe operations that comply with DHS regulatory requirements [***DHS 157.61(1)***].

> "Management" refers to the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities or that person's delegate or delegates.

To ensure adequate management involvement in accordance with ***DHS 157.13*** and ***DHS 157.61(1)***, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for the following:

- Radiation protection, security, and control of radioactive materials, and compliance with rule;
- Knowledge about the contents of the license application;
- Compliance with current DHS and United States Department of Transportation (DOT) regulations and the licensee's operating, emergency, and security procedures;
- Provision of adequate financial and other resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, the public, and workers are protected from radiation hazards and that compliance with regulations is maintained;
- Appointment of a qualified individual to serve as the radiation safety officer (RSO), who has agreed in writing, to be responsible for implementing the radiation protection program. The RSO shall have independent authority to stop unsafe operations and shall be given sufficient time to fulfill radiation safety duties and responsibilities;
- To report defects, non-compliances, or reportable events, including medical events in accordance with regulations;
- To ensure that radiation workers have adequate training; and
- Approval of qualified individual(s) to serve as Authorized Medical Physicists (AMPs), Authorized Nuclear Pharmacists (ANPs), and Authorized Users (AUs) for licensed activities.

Management may delegate individuals (i.e., a RSO or other designated individual) to submit amendment requests to DHS. A correspondence delegation letter must be completed, signed by management and submitted to DHS. A sample letter has been included in **Appendix F**.

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read, and follow ***Chapter DHS 157***.

The following subchapters of ***Chapter DHS 157*** contain requirements applicable to medical use licensees:

- Subchapter I: General Provisions
- Subchapter II: Licensing of Radioactive Material
- Subchapter III: Standards for Protection from Radiation
- Subchapter VI: Medical Use of Radioactive Material
- Subchapter X: Notices, Instructions and Reports to Workers
- Subchapter XI: Inspection By the Department
- Subchapter XII: Enforcement
- Subchapter XIII: Transportation

HOW TO FILE

APPLICATION PREPARATION

Applicants for a materials license should do the following:

- Use the most recent guidance from DHS in preparing an application;
- Complete Form F-45008 '*Application for Radioactive Material License for Medical Use*' (Appendix A);
- For each separate sheet submitted with the application, other than Form F-45008, identify and key it to the item number on the application or the topic to which it refers;
- Provide sufficient detail for DHS to determine that equipment, facilities, training, experience, and the radiation safety program are adequate to protect health and safety and minimize danger to life and property;
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit the application with the appropriate signature by a representative from senior-level management; and
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of responses as shown in this WISREG or submission of alternative procedures will require a more detailed review.

Personal employee information (i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information) should not be submitted.

WHERE TO FILE

Applicants wishing to possess or use radioactive material in Wisconsin are subject to the requirements of ***Chapter DHS 157*** and must file a license application. Applications should be submitted in electronic form to DHSRadioactiveMaterials@dhs.wisconsin.gov. Alternatively, a hard copy of the application may be sent to:

Department of Health Services

Radiation Protection Section

P.O. Box 2659

Madison, WI 53701-2659

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LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to ***DHS 157.10*** to determine the amount of the fee. DHS will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of DHS's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to ***DHS 157.10***.

Direct all questions about fees or completion of Item 11 of Form F-45008 '*Application for Radioactive Material License for Medical Use*' (Appendix A) to DHS, Radiation Protection Section at (608) 267-4797 or DHSRadioactiveMaterials@dhs.wisconsin.gov.

CONTENTS OF AN APPLICATION

This section explains, item by item, the information requested on Form F-45008 '*Application for Radioactive Material License for Medical Use*' (Appendix A). **Items 9.1 through 9.23** on the application form request specific information about the proposed radiation safety program. To assist the applicant in submitting complete information on these items, the applicable rule citations are referenced in the discussion of each item.

Applicants must provide detailed information about the following:

- Proposed facilities and equipment;
- Training and experience of radioactive material users and the RSO;
- Delegation of authority to RSO;
- Financial assurance (if applicable);
- Mobile use of radioactive material (if applicable); and
- Procedures as indicated by this WISREG and Form F-45008 '*Application for Radioactive Material License for Medical Use*' (Appendix A).

Procedures should include:

- Instruction of individuals in the procedures;
- Discussion of timeliness and frequency;
- Periodic verification through observation, records review, or some other audit method, that individuals know the procedures and follow them; and
- Updating the procedures as necessary to accommodate changes in the license program, such as the introduction of new modalities (i.e., manual brachytherapy, remote afterloaders, gamma stereotactic units).

Several appendices in this report present model procedures that applicants may commit to follow or use to develop site specific procedures.

Application Certification

Individuals acting in a private capacity are required to sign and date Form F-45008 *'Application for Radioactive Material for Medical Use*'. Otherwise, a senior representative of the corporation or legal entity filing the application should sign and date Form F-48008 *'Application for Radioactive Material for Medical Use'*. **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant.** As discussed previously in 'Management Responsibility,' signing the application acknowledges management's commitment and responsibilities for the radiation protection program. The department will return all unsigned applications for proper signature**.**

DHS generally only accepts license correspondence from a senior representative of the applicant or licensee. If the representative would like to delegate authority to another individual (e.g., the Radiation Safety Officer) to submit routine amendment requests on behalf of the licensee or respond to DHS requests for information, the representative should

complete and sign the optional Correspondence Authority box on the first page of the license application, designating one or more individuals for this purpose. **A representative of the licensee's senior management must sign all license renewal applications.**

Note:

- It is a violation of ***Chapter DHS 157*** to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Item 1: Type of Application

On the application check the appropriate box and list the license number for renewal and amendments.

Item 2: Applicant's Name and Mailing Address

Rule: ***DHS 157.13(5)(c); DHS 157.13(10)***

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address.

Note*:* DHS must be notified and the transfer approved before control of the license is transferred. DHS must also be notified when bankruptcy proceedings are initiated. See below for more details. NRC's IN 97-30, *'Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises,'* dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

Item 3: Person to be Contacted about this Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, but the applicant may name a different person as the contact. DHS will contact this individual if there are questions about the application.

Note: Contact information provided should not contain Personally Identifiable Information (PII) (e.g., personal phone number or home email address). Additional information on PII can be found in:

- *"Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission,"* dated March 9, 2007

- *"Recent Licensing Submittals Containing Personally Identifiable Information,"* dated November 15, 2013.

Notify DHS of changes of contact name or telephone number so that DHS can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

The individual named in **Item 3** on the application form may or may not be the same individual who signs the application as the "certifying officer" on behalf of the licensee with the authority to make commitments to DHS (see **Item 12** on Form F-45008 '*Application for Radioactive Material License for Medical Use*' (Appendix A). Any commitments the applicant makes should be signed by the individual named in **Item 12** since only that individual is considered by DHS to have the authority to make commitments on behalf of the applicant. DHS will not accept license renewals signed by the individual identified in **Item 3** if they do not have the authority to make legally binding agreements on behalf of the applicant. The individual named in **Item 12** may delegate the authority to submit license amendments and to respond to letters from DHS to an assigned individual such as the licensee contact named in Item 3, the RSO, or an authorized user by providing the authorization to DHS in writing. **Appendix F** contains sample text which may be used to delegate correspondence authority to a designated individual.

DHS recognizes that licensees may use a consultant to help prepare the license application and provide support to the radiation protection program. However, DHS reminds licensees that regardless of the role of the consultant in radiation protection program management, the licensee remains responsible for all aspects of the licensed program, including the services performed by the consultant.

Item 4: Address(es) Where Radioactive Material Will Be Used or Possessed

Rule: ***DHS 157.13(2)(b); DHS 157.13(5)(a)***

Pursuant to ***DHS 157.13(2)(b)***, specify the street address, city, state and zip code where licensed material will be used or stored. A post office box address is not acceptable as a location of use or storage. If radioactive material is to be used or stored at more than one location under the license, the specific address (e.g., street and building) must be provided for each facility.

If applying for a license for a mobile medical service as authorized pursuant to ***DHS 157.13(5)(a)***, the applicant should refer to **Item 9.17**, *'Mobile Medical Service'* and **Appendix V** of this report for specific licensing guidance.

A DHS license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

As discussed in **Item 7.2** '*Recordkeeping for Decommissioning and Financial Assurance'*, licensees must maintain permanent records on where the licensed material was used or stored while the license was in effect. These records are

important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For medical use licensees, acceptable records include sketches and written descriptions of the specific locations where material has been used or stored and all information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread), damaged devices, or leaking radioactive sources.

Item 5: Individual(s) Responsible for Radiation Safety Program and their Training and Experience

Rule: ***DHS 157.13(2)(a); DHS 157.61(1); DHS 157.61(7); DHS 157.61(8); DHS 157.61(9); DHS 157.61(10); DHS 157.63(4); DHS 157.63(5); DHS 157.63(6); DHS 157.64(4); DHS 157.64(5); DHS 157.64(6); DHS 157.64(7); DHS 157.64(8); DHS 157.65(8); DHS 157.65(9); DHS 157.65(10); DHS 157.66(2); DHS 157.67(17); DHS 157.67(18)***

Criteria: Licensees must ensure adequate oversight of their radioactive material program, and the RSO, ARSO, AUs, AMPs, and ANPs must have adequate training and experience as defined in the rule.

Discussion: ***DHS 157.61(1)*** provides the requirements regarding the authority and responsibilities for the radiation protection program, including those of the licensee's management and the RSO appointed by licensee management. Other personnel who have a role in the radiation protection program include the ARSO, AUs, AMPs, ANPs, and members of the Radiation Safety Committee (RSC) as applicable. ***DHS 157.13(2)(a)*** requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. ***DHS 157.61, DHS 157.63, DHS 157.64, DHS 157.65, DHS 157.66 and DHS 157.67*** give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, the ARSO, and the AMPs.

Applicants should ensure that they submit the specific training information required by DHS. A résumé or curriculum vitae will be insufficient because such documents do not supply all the information needed to evaluate an individual's radiation safety training and experience for DHS purposes. Appendix B contains forms which provide acceptable formats for submitting training, experience and preceptor information for radiation safety officers for medical use, authorized users, authorized medical physicists and authorized nuclear pharmacists. **Appendix G** provides detailed instructions on completing the training, experience and preceptor forms.

Licensees are responsible for their radiation protection programs; it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. The licensee's management must appoint an RSO, who agrees in writing to be responsible for implementing the radiation protection program, and must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding DHS rule and license provisions, including: identifying radiation safety problems; initiating, recommending and providing corrective actions; stopping unsafe operations; and verifying the implementation of corrective actions. Nevertheless, the licensee retains the ultimate responsibility for the conduct of licensed activities.

Licensees authorized for either two or more different types of uses of radioactive material under ***DHS 157.64, DHS 157.65, DHS 157.67,*** or two or more different types of units under ***DHS 157.67***, must establish a Radiation Safety

Committee to oversee all uses of radioactive material permitted by the license. Membership to the committee must include an AU of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor the RSO. The committee may include other members the licensee considers appropriate. ***DHS 157*** does not specify the number of meetings required per year or what constitutes a quorum. In accordance with NRC's NUREG-1516 *'Management of Radioactive Materials Safety Programs at Medical Facilities'*, the Department recommends quarterly RSC meetings and a quorum of at least 50% of the membership. Licensees are reminded that all Radiation Safety Committee members should participate regularly at RSC meetings. Agenda items should address all therapy modalities.

Licensees may contract for medical use services, including those involving patient services. However, the licensee should not assume that by hiring a contractor to provide certain services it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation protection program, including training of contracted staff, is effectively implemented by the appropriate individuals.

Item 5.1: Radiation Safety Officer (RSO) and Associate Radiation Safety Officer (ARSO)

Rule: ***DHS 157.13(2)(a); DHS 157.13(5)(c); DHS 157.61(1); DHS 157.61(7); DHS 157.61(10); DHS 157.61(11); DHS 157.71(1)***

Criteria: The licensee must establish, in writing, the authority, duties, and responsibilities of the RSO and ARSO. RSOs and ARSOs must have adequate training and experience. The training and experience requirements for the RSO and ARSO are described in ***DHS 157.61(7)*** and allow for the following training pathways:

- Certification as provided in ***DHS 157.61(7)(a)*** by one of the professional boards recognized by DHS and written attestation signed by a preceptor RSO as provided in ***DHS 157.61(12)***.
- Classroom and laboratory training (200 hours) and 1 year of work experience as described in ***DHS 157.61(7)(b)*** and written attestation signed by a preceptor RSO as provided in ***DHS 157.61(12)***.
- For medical physicists, certification by a specialty board whose certification process has been recognized by DHS under ***DHS 157.61(8)(a),*** experience in radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities and written attestation signed by a preceptor RSO as provided in ***DHS 157.61(12).*** A list of approved specialty boards can be found on NRC's Medical Use Toolkit website.
- Identification on the license as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

Appendix F contains typical duties and responsibilities of the RSO and a Model Delegation of Authority.

Discussion: The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with ***DHS 157.61(1)***, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in ***DHS 157.61(1)*** to ensure that radioactive materials are used in a safe manner. DHS

requires the name of the RSO on the license and an agreement in writing between the RSO and upper management to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

DHS recognizes that radiation safety programs are often complex, and RSOs typically delegate performance of day-to-day radiation safety duties to radiation workers. Such delegation is normal and does not require license action. In cases where a license is of sufficient breadth that radiation safety oversight requires significant support from more than one individual, a licensee may choose to appoint one or more ARSOs to support the RSO. ARSOs are never required and, in general, ARSOs do not provide value for smaller radiation safety programs. If a licensee proposes an ARSO, the ARSO must be appointed in writing by licensee management, and the written agreement between management and the licensee's ARSO must assign specific duties to each ARSO. This agreement must be submitted to DHS for review and, if approved, will be incorporated into the license via license condition. Although DHS allows ARSO(s) to be listed on licenses, it is generally discouraged as radiation safety tasks may be delegated to licensee personnel without listing individuals on the license. The addition of ARSO(s) to a license will be evaluated on a case-by-case basis. If a licensee's request for ARSO(s) is approved, the RSO still retains radiation safety oversight responsibilities for all sections of the program. The ARSO position should not be used to appoint a "backup" RSO, and ARSO positions may not be assigned to consultants.

Experienced RSOs or ARSOs that do not have experience with each modality listed on the license shall receive supplemental training on the modality(ies) in which they lack experience. The training should be supervised by a RSO, ARSO, AMP, ANP, or AU who is authorized for the type of use for which the individual is seeking approval. The supplemental training should include relevant radiation safety topics, regulatory issues, and emergency procedures specific to each type of use in which supplemental training is required.

Applicants are reminded of recentness of training requirements described in ***DHS 157.61(11)***. Specifically, the proposed RSO or ARSO must have successfully completed the applicable training and experience criteria described in ***Chapter DHS 157, Subchapter VI*** within 7 years preceding the date of the application. If the proposed RSO or ARSO completed the required training 7 years or more prior to the date of the application, then the individual must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant:

- Name of the proposed RSO (RSO is required for all licenses)
- Names(s) of each proposed ARSO, if desired, and identify the types of use of radioactive material for which each ARSO may be assigned duties and tasks under the licensee's program
- Documentation of training and experience for the RSO and each proposed ARSO. If the RSO and/or ARSOs were previously listed on another NRC or Agreement State license, submit a copy of the license for review.
- Usually, the RSO is a full-time employee of the licensed facility. DHS has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO. If a licensee or applicant is requesting a RSO that is not employed by the licensee, DHS will request additional information including:

1. A description of how the licensee or applicant will provide the proposed RSO with sufficient organizational freedom to perform RSO functions.
2. A description of how the proposed RSO will allocate time in order to fulfill his or her duties as RSO, including the hours expected to be devoted to RSO duties over a specified time period, such as "per month."
3. A commitment for the minimum amount of time the proposed RSO will be onsite. In order to fulfill the duties and responsibilities, the RSO should be on-site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy requirements of ***DHS 157.61(1)***.
4. A description of the proposed RSO's typical and maximum response time to provide emergency response support both by telephone and in person.
5. A description of whom the RSO will report to for acquiring or utilizing financial resources to manage radiation safety issues.
6. The name, phone number, and email address of an in-house representative who will serve as the point of contact during the RSO's absence.

Notes:

- Form F-45010A '*Training and Experience and Preceptor Attestation for Radiation Safety Officer for Medical Use'* may be used to document training and experience for RSOs and ARSOs; see Appendix B. Detailed instructions for completing this form are found in **Appendix G.**
- The licensee must notify DHS within 30 days if an RSO or ARSO permanently discontinues his or her duties under the license **[*DHS 157.13(5)(c)*]** and must request an amendment to change an RSO **[*DHS 157.13(5)(b)*]**.
- The licensee must notify DHS within 30 days if an RSO has a name change **[*DHS 157.13(5)(c)*]**.
- An AU, AMP, or ANP may be designated as the RSO on the license if the individual has training and experience with the radiation safety aspects of similar types of radioactive material use for which he or she would have RSO responsibilities and, as required by ***DHS 157.61(1)(f)***, has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.
- Descriptions of training and experience will be reviewed using the criteria listed above. DHS will review the documentation to determine if the applicable criteria in ***DHS 157.61*** are met. If the RSO training and experience do not appear to meet the criteria in ***DHS 157.61***, DHS may request additional information from the applicant.
- The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.

Item 5.2: Medical Authorized Users (AUs)

Rule: ***DHS 157.13(2)(a); DHS 157.13(5)(c); DHS 157.61(3); DHS 157.61(10); DHS 157.61(11); DHS 157.63(4); DHS 157.63(5); DHS 157.63(6); DHS 157.64(4); DHS 157.64(5); DHS 157.64(6); DHS 157.64(7); DHS 157.64(8); DHS 157.65(8); DHS 157.65(9); DHS 157.65(10); DHS 157.66(2); DHS 157.67(4); DHS 157.67(17); DHS 157.67(18)***

Criteria: Training and experience requirements for AUs are described in ***DHS 157.63(4); DHS 157.63(5); DHS 157.64(4); DHS 157.64(5); DHS 157.64(6); DHS 157.65(8); DHS 157.65(9); DHS 157.66(2); DHS 157.67(17)***.

Discussion: An AU is defined in ***DHS 157.03(34)*** 'Definitions.' The responsibilities of AUs involved in medical use include the following:

- Radiation safety commensurate with use of radioactive material;
- Administration of a radiation dose or dosage and how it is prescribed;
- Direction of individuals under the AU's supervision in the preparation of radioactive material for medical use and in the medical use of radioactive material; and
- Preparation of written directives, if required.

DHS 157.61(10) provides that experienced AUs who are named on a DHS, NRC or another Agreement State license or permit in the preceding seven years are not required to comply with the training requirements in ***DHS 157.63-67*** to continue performing those medical uses.

Technologists, therapists, or other personnel may use radioactive material for medical use under an AU's supervision in accordance with ***DHS 157.61(3)***, '*Supervision*,' and in compliance with applicable FDA, other Federal, and State requirements (***DHS 157.59(2)(c)***). Examples include FDA requirements for conduct of certain types of clinical research after submission of applications for Investigational New Drugs (INDs) and under the auspices of a Radioactive Drug Research Committee (***21 CFR 361.1***).

There is no DHS requirement that an AU must provide an interpretation of a diagnostic image or results of a therapeutic procedure. DHS recognizes that the AU may or may not be the physician who interprets such studies. Additionally, ***Chapter DHS 157*** does not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

Each medical use approved on the license must have an authorized user associated with it. The applicant should specify which user(s) will be involved with each requested medical use by referring to **Item 5.2** of the application and providing the user's training and experience. Applicants for uses authorized by ***DHS 157.67(1)*** (HDR and gamma knife) must ensure that training in the operating and emergency procedures for the specific device model used by the licensee is administered prior to first use of the device. It is the applicant's responsibility to ensure that documentation submitted to support a proposed authorized user's training and experience is accurate. *NRC Information Notice 2007-38* contains additional information on an applicant's responsibility to verify information provided on an application and is available at www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/index.html.

Applicants are reminded of recentness of training requirements described in ***DHS 157.61(11)***. Specifically, AU applicants must have successfully completed the applicable training and experience criteria described in ***Chapter DHS 157, Subchapter VI*** within 7 years preceding the date of the application. If a proposed AU completed the required training 7 years or more prior to the date of the application, then the AU applicant must submit documentation of additional related

continuing education and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant:

1. Name of each proposed medical AU.
2. A description of the types of use that the licensee is requesting authorization for the proposed medical AUs.
3. Documentation of training and experience for each proposed medical AU. If medical AU was previously listed on another NRC or Agreement State license for the same type(s) of use, submit a copy of the license for review.

Notes:

- Licensees should designate at least one authorized user for each type of radioactive material requested in **Item 7.1**.
- Forms F-45010B through F-45010E '*Training and Experience and Preceptor Statement*' may be used to document training and experience; see Appendix B. Forms are available for different types of radioactive material use. Detailed instructions for completing these forms are found in **Appendix G.**
- Licensees must notify DHS within 30 days if an AU permanently discontinues his or her duties under the license or has a name change under ***DHS 157.13(5)(c)***.
- Descriptions of training and experience will be reviewed using the criteria listed above. DHS will review the documentation to determine if the applicable criteria in ***Chapter DHS 157, Subchapter VI*** are met. If the training and experience do not appear to meet the criteria, DHS may request additional information from the applicant.
- The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page http://www.nrc.gov/materials/miau/med-use-toolkit.html.
- See NRC Information Notice 23-05 "*Discontinuation of the U.S. Nuclear Regulatory Commission's Recognition of the American Board of Radiology's Certification Processes*" for information regarding American Board of Radiology certificates.

Item 5.3: Authorized Medical Physicist (AMP)

Rule: ***DHS 157.13(2)(a)***; ***DHS 157.13(5)(c); DHS 157.61(8)***; ***DHS 157.61(10); DHS 157.61(11)***

Criteria: Training and experience requirements for AMPs are described in ***DHS 157.61(8)***.

Discussion: An AMP is defined in ***DHS 157.03(32m)***, "*Definitions*." At many licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants for uses authorized by ***DHS 157.67(1)*** (HDR and gamma knife) must also submit documentation of training in the operating and emergency procedures for the specific device model used by the licensee.

Applicants are reminded of recentness of training requirements described in ***DHS 157.61(11)***. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in ***Chapter***

DHS 157, Subchapter VI within 7 years preceding the date of the application. If a proposed AMP completed the required training 7 years or more prior to the date of the application, then the individual must submit documentation of additional related continuing education and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant:

1. Name of each proposed AMP.
2. A description of the types of use and devices that the licensee is requesting authorization for the proposed AMPs.
3. Documentation of training and experience for each AMP. If an AMP was previously listed on another NRC or Agreement State license for the same type(s) of use, submit a copy of the license for review.

Notes:

- Form F-45010G '*Training, Experience and Preceptor Attestation for Authorized Medical Physicist'* may be used to document training and experience; see Appendix B. Detailed instructions for completing this form are found in **Appendix G.**
- Licensees must notify DHS within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change under ***DHS 157.13(5)(c)***.
- Descriptions of training and experience will be reviewed using the criteria listed above. DHS will review the documentation to determine if the applicable criteria in ***DHS 157.61*** are met. If the training and experience do not appear to meet the criteria in ***DHS 157.61***, DHS may request additional information from the applicant.
- The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.

Item 5.4: Authorized Nuclear Pharmacist (ANP)

Rule: ***DHS 157.13(2)(a); DHS 157.13(5)(c); DHS 157.61(3); DHS 157.61(9); DHS 157.61(10); DHS 157.61(11)***

Criteria: Training and experience requirements for ANPs are described in ***DHS 157.61(9)***.

Discussion: An ANP is defined in ***DHS 157.03(33)***. At some licensed medical facilities, an ANP is directly involved with the preparation and administration of radiopharmaceuticals. DHS acknowledges that medical facilities rarely have an ANP. Please contact DHS at DHSRadioactiveMaterials@dhs.wisconsin.gov for more information about how to submit ANP credentials for a medical use license.

Response from Applicant:

- Name of each proposed ANP.
- Documentation of training and experience for each ANP. If an ANP was previously listed on another NRC or Agreement State license, submit a copy of the license for review.

Item 5.5: Non-Medical Authorized Individuals (AUs)

Rule: ***DHS 157.13(2)(a); DHS 157.13(5)(c); DHS 157.61(11)***

Criteria: Training and experience requirements for non-medical authorized individuals are not standardized in DHS 157, for more common types of non-medical use (e.g. shielding verification and instrument calibrations) DHS has established internal policies to evaluate training and experience of proposed non-medical authorized individuals. Each proposed non-medical authorized individual will be reviewed on a case-by-case basis.

Discussion: Authorized Individuals for Non-Medical Uses: For *in vitro* studies, animal research, calibration of survey instruments, shielding verification, and other uses that do not involve the intentional exposure of humans, the list of proposed authorized individuals should include the individuals who will actually be responsible for the safe use of the radioactive material for the requested use. The training should be appropriate in scope for the requested activities and include at a minimum: hands-on training, training on specific operating and emergency procedures, and any pertinent safety and regulatory issues.

Response from Applicant:

- Name of each proposed non-medical authorized individual.
- A clear description of each type of use being requested for each proposed non-medical authorized individual.
- Documentation of training and experience for each non-medical authorized individual. If a non-medical authorized individual was previously listed on another NRC or Agreement State license for the same type(s) of use, submit a copy of the license for review.

Item 6: Training for Individuals Working in or Frequenting Restricted Areas

Rule: ***DHS 157.88(2)***; ***DHS 157.64(2)***; ***DHS 157.65(4)***; ***DHS 157.67(4); DHS 157.71(15)***

Criteria: Individuals working with or in the vicinity of licensed material must have received adequate safety instruction as required by ***Chapter DHS 157, Subchapter VI*** and ***Subchapter X***. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 mSv (100 mrem), the licensee must provide annual safety instructions as required in ***DHS 157.88(2)***. Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in ***DHS 157.64(2), DHS 157.65(4)***, ***DHS 157.67(4),*** *and* NRC's *Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance*, Revision 10.2 dated April 20, 2021. Records of safety instruction provided must be maintained in accordance with ***DHS 157.71(15)***. ***DHS 157.61(3)*** requires the licensee's AUs and ANPs to provide safety instruction to all personnel using radioactive material under their supervision.

Discussion: All individuals working with or around licensed materials should receive safety instruction commensurate with their assigned duties, and, if it is likely that they could receive doses over 1 mSv (100 mrem) in a year, the employee(s) must receive annual instruction as specified by ***DHS 157.88(2)***. AUs, ANPs, AMPs, and their supervised

employees such as NMTs are most likely to receive doses in excess of 1 mSv (100 mrem) in a year. However, licensees also must evaluate potential radiation doses received by any individual working in or frequenting restricted areas. For example, a licensee might determine that housekeeping staff, while not likely to receive doses over 1 mSv (100 mrem), should be informed of the nature of the licensed material and the meaning of the radiation symbol, and instructed not to touch the licensed material and to remain out of the room if the door to the licensed material storage location is open. Providing minimal instruction to ancillary staff (e.g., housekeeping, security, etc.) may assist in avoiding abnormal events, such as loss of radioactive material or unnecessary exposures.

In addition to safety instruction required by ***DHS 157.88(2)*** and in accordance with ***DHS 157.64(2)***, ***DHS 157.65(4)***, and ***DHS 157.67(4)***, the licensee must provide radiation safety instruction to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy or implant therapy who cannot be released in accordance with ***DHS 157.62(8)***. This safety instruction must be commensurate with the duties of the personnel and include safe handling, patient control, visitor control, contamination control, waste control, and notification of the RSO and the AU if the patient has a medical emergency or dies.

In accordance with ***DHS 157.61(3)(a),*** individuals working with licensed material under the supervision of an AU must receive instruction on the licensee's written radiation protection procedures, written directive procedures, and DHS rule and license conditions with respect to the use of radioactive material.

In accordance with ***DHS 157.61(3)(b)***, a licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an ANP or an AU shall instruct supervised individuals in the preparation of radioactive material for medical use and require the individuals to follow their instructions, the licensee's written radiation protection procedures, the license conditions, and DHS rule. ***DHS 157.61(3)(c)*** states that a licensee that permits supervised activities under paragraph ***DHS 157.61(3)(a)*** and ***(b)*** is responsible for the acts and omissions of the supervised individuals.

Procedures describing the training programs are provided in **Appendix H**.

Response from Applicant:

- Commit to follow the training programs described in Appendix H of WISREG 'Guidance for Medical Use of Radioactive Material' Revision 3.

OR

- Submit a description of a training program that will meet the criteria in the section titled 'Training for Individuals Working in or Frequenting Restricted Areas' of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Item 7: Radioactive Material

Rule: ***DHS 157.13(1)*; *DHS 157.13(2)*; *DHS 157.13(9)(b)***; ***DHS 157.13(10)*; *DHS 157.15*; *DHS 157.13(5)(a)***; ***DHS 157.13(12)*; *DHS 157.13(13)*; *DHS 157.62(4)*; *DHS 157.63(1); DHS 157.63(2)*; *DHS 157.64(1)*; *DHS 157.65(1)***; ***DHS 157.66(1)***; ***DHS 157.67(1); DHS 157.70***

Criteria: ***Chapter DHS 157, Subchapter VI*** divides radioactive material for medical use into the following types of use:

DHS 157.63(1)	Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
DHS 157.63(2)	Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required
DHS 157.64(1)	Use of Unsealed Radioactive Material for Which a Written Directive is Required
DHS 157.65(1)	Use of Sealed Sources for Manual Brachytherapy
DHS 157.66(1)	Use of Sealed Sources for Diagnosis
DHS 157.67(1)	Use of a Sealed Source(s) in a Device for Therapy-Remote Afterloader Unit or Gamma Stereotactic Radiosurgery Unit
DHS 157.70	Other Medical Uses of Radioactive Material or Radiation from Radioactive Material (Emerging Technology)

Discussion: This section contains four subsections:

- **Item 7.1: Radioactive Material, Chemical & Physical Form, Possession Limit & Type of Use**
  This subsection provides a discussion of the various types of use that can be authorized under a license for medical use of radioactive material and detailed instructions for requesting authorization for each type of use.
- **Item 7.2: Recordkeeping for Decommissioning and Financial Assurance**
  This subsection details information that all licensees are required to maintain that is important to decommissioning and discusses methods for determining whether financial assurance is required.
- **Item 7.3: Sealed Sources and Devices**
  This subsection describes the information required to be submitted in order to have a sealed source or device approved for use on the license.
- **Item 7.4: Disposition of Material and Termination of License**
  This subsection provides instructions on how to terminate licensed activities and properly document the disposition of the radioactive material.

Item 7.1: Radioactive Material, Chemical & Physical Form, Possession Limit & Type of Use

Rule: ***DHS 157.11(2)(f)***; ***DHS 157.13(1); DHS 157.13(2); DHS 157.63(1); DHS 157.63(2); DHS 157.64(1); DHS 157.65(1); DHS 157.66(1); DHS 157.67(1) DHS 157.70***

Criteria: ***Chapter DHS 157, Subchapter VI*** divides radioactive material for medical use into seven types of use ***DHS 157.63(1)***, ***DHS 157.63(2), DHS 157.64(1), DHS 157.65(1), DHS 157.66(1), DHS 157.67(1), DHS 157.70.***

Discussion: Applicants should select the desired types of uses of licensed material by marking the checkbox next to the desired use(s). Additional information to be provided in support of specific uses is described below.

The use of unsealed material for diagnostic studies in amounts that do not require a written directive is approved under ***DHS 157.63(1)*** for uptake, dilution, and excretion studies and ***DHS 157.63(2)*** for imaging and localization studies. Applicants who desire to use licensed material for diagnostic purposes in amounts less than the written directive threshold should select these boxes as appropriate to the type(s) of studies they will perform. Licensees who use strontium (Sr) -82/rubidium (Rb) -82 generators should contact DHS at DHSRadioactiveMaterials@dhs.wisconsin.gov for sample commitments for the use of Sr-82/Rb-82 Generators.

The use of unsealed radioactive material in therapy is approved under ***DHS 157.64(1)*** and involves administering a radiopharmaceutical, either orally or by injection, to treat or palliate a disease. The most common radiopharmaceutical therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Other therapeutic procedures include ablation of thyroid cancer metastasis, treatment of neuroendocrine tumors, and palliation of bone pain in cancer patients (see **Table 2**). For use approved under ***DHS 157.64(1)***, the applicant should select the box and enter the maximum quantity (in curies) of radioactive material to be possessed.

Table 2: Radiopharmaceuticals Used in Therapy

Radiopharmaceutical	Form	Route of Administration	Therapeutic Use
Ac-225 PSMA	solution	IV	Prostate cancer
I-131 sodium iodide	solution/ capsules	oral	Hyperthyroidism Thyroid carcinoma Whole body scan for thyroid metastasis (diagnostic)
I-131 tositumomab	solution	IV	Non-Hodgkin's lymphoma
Lu-177 PSMA	solution	IV	Prostate cancer
Lu-177 dotatate	solution	IV	Neuroendocrine tumors
Ra-223 dichloride	solution	IV	Prostate cancer
Y-90 Ibritumomab tiuxetan	solution	IV	Non-Hodgkin's lymphoma

The use of sealed sources for therapeutic purposes that involve the direct placement of licensed material on or in a patient is approved under ***DHS 157.65(1)***. Examples of manual brachytherapy under ***DHS 157.65(1)*** include:

- Interstitial Treatment of Cancer using I-125, Pd-103, or Cs-131 as a sealed source seed used for permanent implants.
- Eye Plaque Implants using I-125 or Sr-90.

- Intracavitary Treatment of Cancer using Cs-137 needles.

Topical (Surface) Applications for ***DHS 157.65(1)*** material, the applicant should select the box, and provide the following information:

- the maximum quantity (in curies) of radioactive material to be possessed;
- the sealed source and device registration number for each sealed source and/or device;
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

The use of sealed sources for diagnostic purposes is approved under ***DHS 157.66(1)***. One example is gadolinium-153 as a sealed source in quantities exceeding 30 millicuries. For ***DHS 157.66(1)*** material, the applicant should select the box, and provide the following information:

- the maximum quantity (in curies) of radioactive material to be possessed;
- the sealed source and device registration number for each sealed source and/or device;
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

The use of a sealed source for therapeutic purposes other than manual brachytherapy is regulated under ***DHS 157.67(1)***. The most common type of use in this section is high dose rate brachytherapy using a remote afterloading device.
For ***DHS 157.67(1)*** material, the applicant should select the box(es) for each desired modality and provide the following information:

- the maximum quantity (in curies) of radioactive material to be possessed;
- the sealed source and device registration number for each sealed source and/or device;
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

For sealed sources used in devices, an applicant may wish to request two sources, one to be used in the device and one to be stored in its shipping container, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity allowed in the device at installation is limited by the device's SSDR. The maximum activity at time of patient treatment is limited by the FDA.

DHS 157.70: Other Medical Uses of Radioactive Material or Radiation from Radioactive Material (e.g., Emerging Technology)

Applicants must apply for authorization to use radioactive material, or radiation from radioactive material in medical applications under ***DHS 157.70*** when the desired type of use isn't covered elsewhere in ***Chapter DHS 157, Subchapter VI.*** Use of radioactive material in a source or device after approval by the U.S. Food and Drug Administration (e.g., under an investigational device exemption or an investigational new drug exemption) does not preclude the need for applicants to obtain a DHS license for the radioactive material. For ***DHS 157.70*** material, the applicant should attach a detailed

description of the radioactive material (i.e., radionuclide, form, and maximum quantity in curies) and intended use along with the following information required by ***DHS 157.13(5)(a):***

- Radiation safety precautions and instructions;
- Training and experience of proposed users;
- Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
- Calibration, maintenance and repair of instruments and equipment necessary for radiation safety.

If the material is a sealed source, also provide the following:

- the sealed source and device registration number for each sealed source and/or device,
- the sealed source manufacturer or distributor model number, and
- the device manufacturer or distributor model number.

The NRC has published licensing guidance for a number of emerging technologies which should be used to guide your submittal. This guidance is available on the NRC's web page at: www.nrc.gov/materials/miau/med-use-toolkit.html. Contact DHS at DHSRadioactiveMaterials@dhs.wisconsin.gov for sample commitments for the use of Radioactive Seed Localization, Germanium-68/Gallium-68 generators, and Y-90 microspheres.

Type A broad scope licensees are exempted under ***DHS 157.13(5)(d)*** from selected requirements in ***DHS 157.13(5)*** regarding emerging technologies. However, broad scope licensees should ensure that the quantity of radioactive material needed for the proposed use is authorized on their license or apply for an increase if it is not. Broad scope licensees should refer to NRC's IN 99-024, *'Broad-Scope Licensees Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices.'*

Non-Medical Use of Radioactive Material

If the applicant desires to possess or use radioactive material for non-medical uses, then they should check the "Other radioactive material" box and provide a detailed description including the isotope, form, possession limit, and use. Examples of non-medical use of licensed material by medical use licensees include calibrating survey meters with NIST traceable sources, and radiation shielding verification using technetium-99m or cobalt-57.

Sources that are authorized by ***DHS 157.62(4)***, '*Authorization for calibration and references sources'*, should *not* be listed.

Note: When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included:

- materials in use or possessed,
- material used for shielding, and
- materials classified as waste awaiting disposal or held for decay-in-storage.

Response from Applicant: Provide the information as described above.

Item 7.2: Recordkeeping for Decommissioning and Financial Assurance

Rule: ***DHS 157.13(5)(b)2.*****;** ***DHS 157.15***

Criteria: All licensees are required to maintain records important to decommissioning. In addition, licensees must determine, based on their requested possession limits, whether financial assurance for decommissioning is required. If licensees are authorized to possess licensed material in excess of the limits specified in ***DHS 157.15,*** they must provide evidence of financial assurance for decommissioning.

Discussion: All licensees are required under ***DHS 157.15(7)*** to maintain records important to decommissioning in an identified location. These records must, in part, identify all areas where licensed material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is a reasonable likelihood that contaminants may have spread) and leaking sealed sources. As an alternative to the potential need for site characterizations, some licensees prefer to maintain information on surveys and leak tests on an ongoing basis and as a low-cost means of providing evidence and assurance of an appropriate decommissioning status upon the termination of licensed activities and/or release of a site for non-licensed use. Licensees must transfer the records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with ***DHS 157.13(5)(c)2.***, or to DHS before the license is terminated.

Financial assurance requirements apply to licensees who possess radioactive material with half-lives exceeding 120 days, in amounts that exceed the limits specified in ***DHS 157.15***. Although unsealed radioisotopes for medical use rarely have half-lives exceeding 120 days, impurities or contaminants in the material may have longer half-lives (e.g., Lu-177m, Ac-227). It is the licensee's responsibility to identify and manage long-lived contaminants in their inventory. Licensees may not possess these long-lived radioactive impurities or contaminants in amounts that require financial assurance unless they have posted financial assurance for decommissioning.

Applications for authorization to possess and use unsealed radioactive material with a half-life exceeding 120 days must be accompanied by a decommissioning funding plan or certification of financial assurance when the trigger quantities given in ***DHS 157.15*** are exceeded. Acceptable methods of providing financial assurance include trust funds, escrow accounts, government funds, certificates of deposit, deposits of government securities, surety bonds, letters of credit, lines of credit, insurance policies, parent company guarantees, self-guarantees, statements of intent, special arrangements with government entities, and standby trust funds. NRC's NUREG-1757, Volume 3, *Financial Assurance, Recordkeeping, and Timelines* dated February 2012 contains acceptable wording for mechanisms used to guarantee or secure funds.

Response from Applicant: No response is required from most applicants. If FA is required, applicants must submit evidence of FA following the guidance of NUREG-1757, Volume 3 *"Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness,"* February 2012.

Item 7.3: Sealed Sources and Devices

Rule: ***DHS 157.13(1)(h)*; *DHS 157.13(2)(b)***

Criteria: In accordance with ***DHS 157.13(1)(h)***, applicants must provide the manufacturer's name and model number for each requested sealed source and device (except for calibration and reference sources authorized by ***DHS 157.62(4))***. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Discussion: The NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSDR Certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that DHS can verify that they have been evaluated in an SSDR Certificate or specifically approved on a license. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor.

An applicant should consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SSDR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SSDR Certificates without obtaining DHS's prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the registration certificates, applicants should obtain copies of the certificates and discuss them with the manufacturer.

Reference: NRC Information Notices and NUREGs including NUREG-1556, Vol. 3, Rev. 2, *Applications for Sealed Source and Device Evaluation and Registration* dated September 2015.

Note*:* SSDR Certificates are also available by calling DHS at (608) 267-4797.

Item 8: Facilities and Equipment

Rule: ***DHS 157.13(2)(b)***

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: In ***DHS 157.13(2)(b)***, DHS states that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta-emitters.

Item 8.1: Facility Diagram

Rule: ***DHS 157.03*; *DHS 157.21; DHS 157.22(1)*; *DHS 157.23(1)*; *DHS 157.23(2)*; *DHS 157.26(1)*; *DHS 157.26(2)*; *DHS 157.29(1)*; *DHS 157.29(2)*; *DHS 157.31(2)*; *DHS 157.13(1); DHS 157.13(2)(b); DHS 157.13(1), (5) (12), & (13); DHS 157.13(5)(c); DHS 157.62(8)*; *DHS 157.65(5)*; *DHS 157.67(5)***

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Applicants must describe the proposed facilities and equipment as required by ***DHS 157.13(1), (5) (12), & (13).*** The facility diagram should include the rooms and adjacent areas where radioactive material is prepared, used, administered, and stored that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property (see **Figure 1**).

For types of use permitted by ***DHS 157.63(1) & (2),*** applicants should provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., "hot labs"). When information regarding an area or room is provided, adjacent areas and rooms should be described. Licensees who perform PET studies should submit information regarding rooms above and below the rooms of use.

For types of use permitted by ***DHS 157.64*** and ***DHS 157.65.*** applicants should provide the above information and the locations where sources are stored. Describe the rooms and locations where patients will be housed if they cannot be released under ***DHS 157.62(8)***. Operating rooms should be identified as a location of use for licensees performing permanent brachytherapy. The discussion should include a description of shielding, if applicable.

For types of use permitted by ***DHS 157.66,*** the applicant should provide the room numbers of use.

For types of use permitted by ***DHS 157.67,*** the applicant should provide all of the information discussed above and describe rooms or areas above and below the treatment room(s). In addition to the above, for GSR facilities, applicants should provide the directions of primary beam usage for unit or, in the case of an isocentric unit, the plane of beam rotation.

Applicants for uses approved under ***DHS 157.70*** should review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

DHS 157.13(5)(b) requires licensees to obtain a license amendment before adding to or changing an area of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with ***DHS 157.63(1) & (2).*** Licensees are required by ***DHS 157.13(5)(c)*** to notify DHS within 30 days following changes in areas of use for ***DHS 157.63(1) & (2)*** radioactive material.

Regulatory requirements, the principle of ALARA, medical care, and access control should be considered when determining the location of the therapy patient's room or a therapy treatment room.

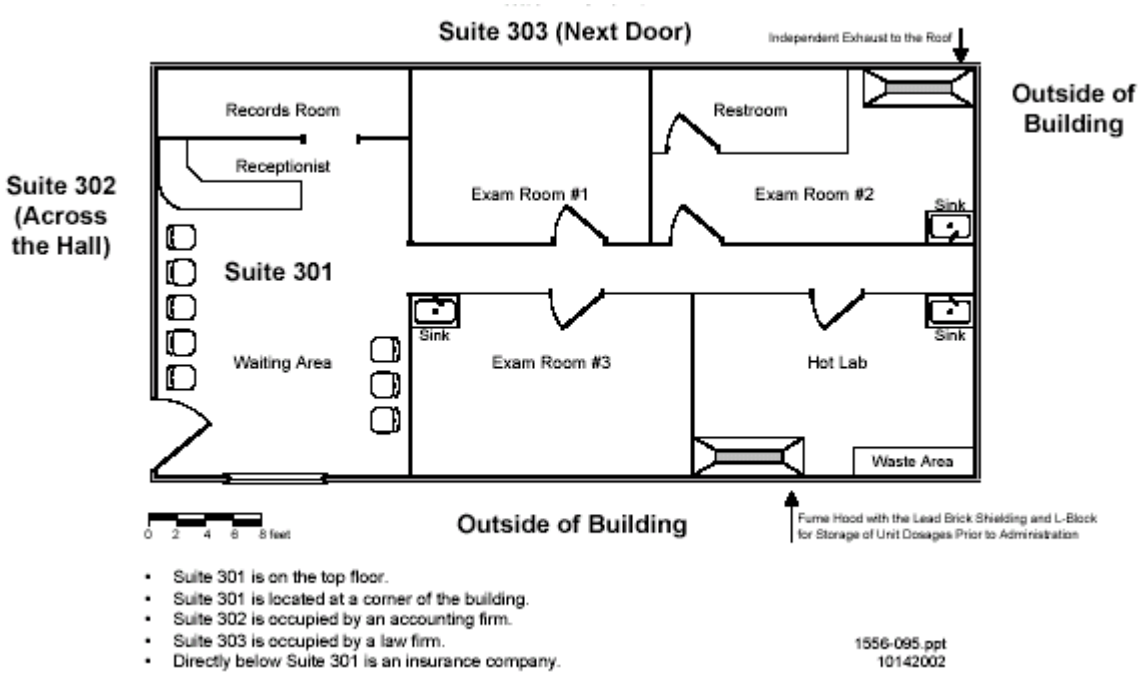

Figure 1: Facility Diagram for Nuclear Medicine Suite

The applicant should demonstrate that the limits specified in ***DHS 157.23(1)*** will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.
- Requesting prior DHS authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements of ***DHS 157.23(1)*** will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits specified in ***DHS 157.23(1)***. A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA must be developed.

Applicants who wish to perform studies with PET radiopharmaceuticals are reminded that rooms in which patients will rest (e.g., "quiet rooms") may require additional shielding to achieve the public dose limits specified in ***DHS 157.23(1)***, particularly if more than one patient will be present at the same time.

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the equipment and administrative procedures they propose to use for evaluation and approval by DHS. If applicants elect to use portable shielding, they should commit to having administrative procedures to control configuration management to maintain doses within regulatory limits.

Response from Applicant: Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used;

- Location, room numbers, and principal use of each room or area where radioactive material is prepared, used or stored, as provided above under the heading 'Discussion;'
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in ***DHS 157.03***; and
- Provide shielding calculations and include information about the type, thickness and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

References: National Council on Radiation Protection and Measurements (NCRP) Report 147, '*Structural Shielding Design for Medical X-Ray Imaging Facilities*'; Report 151, '*Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities*'; and Report 40, '*Protection Against Radiation from Brachytherapy Sources*' may be helpful in responding to the items above. In addition, NRC's NUREG/CR-6276, '*Quality Management in Remote Afterloading Brachytherapy*' and NRC's NUREG/CR-6324, '*Quality Assurance for Gamma Knives'* may also be helpful in responding to the items above. However please note that references to ***10 CFR Part 35*** in these NRC NUREGs may be outdated because NRC's rule was amended after these documents were published.

Item 8.2: Radiation Monitoring Instrumentation

Rule: ***DHS 157.21; DHS 157.25(1); DHS 157.31(2); DHS 157.31(3); DHS 157.13(2)(b); DHS 157.61(3); DHS 157.62(2); DHS 157.71(7)***

Criteria: All licensees shall possess calibrated radiation detection and measuring instruments for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of shielding, radioactive materials containment, and contamination control.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with ***DHS 157.21*** must include provisions for survey instrument calibration **[*DHS 157.25(1)*]**. Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments must be available for use at all times when radioactive material is in use. The licensee must possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

Survey meter calibrations must be performed by persons, including licensed personnel, who are specifically authorized by DHS, NRC or another Agreement State to perform calibrations. Licensees may have their instruments calibrated by a service provider who holds a DHS, NRC or another Agreement State license to perform these activities. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an

alternative method for calibrations. **Appendix I** provides guidance regarding appropriate instrumentation and survey instrument calibration procedures.

Response from Applicant:

- Submit a description of the instrumentation that will be sued to perform required surveys or leak testing and analysis. Additionally, if only one survey instrument is to be used, describe what is done when the survey instrument is being calibrated or repaired.

AND

- Reserve the right to upgrade our instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used for.

AND ONE OF THE FOLLOWING

- Commit to the use of radiation monitoring instruments that will be calibrated by a person authorized by DHS, the NRC or an Agreement State to perform survey meter calibrations.

OR

- Commit to follow survey meter calibration procedures in accordance with Appendix I of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

References: NUREG-1556, Vol. 18, Revision 1, *'Program-Specific Guidance About Service Provider Licenses,'* dated August 2017.

Item 8.3: Dose Calibrator and other Equipment used to Measure Dosages of Unsealed Radioactive Material

Rule: ***DHS 157.13(2); DHS 157.61(3); DHS 157.61(5); DHS 157.62(1); DHS 157.62(3); DHS 157.71(6); DHS 157.71(8)***

Criteria: In ***DHS 157.62(1)*** and ***DHS 157.62(3)***, DHS describes requirements for the use, possession, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages.

Discussion: As described in ***DHS 157.62(3)***, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages prepared by a manufacturer or preparer licensed under ***DHS 157.13(4)(i)*** the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees who receive unit dosages of radioactive material and do not split the dosages may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.
- However, pursuant to ***DHS 157.62(1)***, if the licensee performs direct measurements of dosages in accordance with ***DHS 157.62(3)*** (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or measures unit dosages) the licensee is required to calibrate all instruments used for measuring patient dosages.

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The measurement equipment may be a well ion chamber, a liquid scintillation counter,

etc., as long as the instrument can be calibrated appropriately for the type and energy of radiation emitted and is both accurate and reliable.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for some radionuclides used. Licensees should develop and maintain procedures for beta-emitting radionuclides which specify, for each therapy protocol, the volume and material of the vial or syringe to be used in the dose calibrator. Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers.

Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.

The inherent technical difficulties in measuring alpha emitting radionuclides are even greater than those of measuring beta emissions. In the absence of an additional photon, gamma, or beta particle emission that can be measured with traditional instrumentation used in nuclear medicine (e.g., ion chambers) and quantified in relation to the alpha-particle emissions, most alpha-measuring instruments (e.g., gas-proportional counters and LSC) will require preparation and measurement of an aliquot of the unsealed byproduct material. Measurement of aliquots introduces additional uncertainties associated with removing precise and reproducible volumes from homogeneous samples. For example, NRC issued Information Notice (IN) 2016-03, *"Revision to the National Institute of Standards and Technology Standard for Radium-223 and Impact on Dose Calibration for the Medical Use of Radium-223 Dichloride,*" January 12, 2016, to notify licensees of a correction in measuring radium-223, which is primarily an alpha emitter. To avoid these difficulties, the best method is to use unit dosages and the manufacturer's or commercial nuclear pharmacy's dose label for measurement of the dosage and decay-correct the dosage to the time of administration. These difficulties can also be avoided when not using unit dosages by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation. Applicants requesting an authorized medical use that includes unsealed alpha emitting isotopes should commit to determining the efficiency for the instrument(s) to be used to make quantitative measurements of the alpha emitting isotope.

Response from Applicant: No response required.

Item 8.4: Dosimetry Equipment – Calibration and Use

Rule: ***DHS 157.13(2)(b); DHS 157.61(3); DHS 157.61(5); DHS 157.65(6); DHS 157.67(6)***; ***DHS 157.67(7)***; ***DHS 157.67(8); DHS 157.67(9); DHS 157.67(10); DHS 157.67(11); DHS 157.67(12); DHS 157.71(18); DHS 157.71(20); DHS 157.71(21); DHS 157.71(22); DHS 157.71(23)***; ***DHS 157.71(24)***

Criteria: The above rule references contain DHS requirements for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment. For manual brachytherapy sources and LDR remote afterloader sources licensees may use source activity or output determined by the manufacturer, provided that the manufacturer's measurements meet applicable requirements. For sealed sources used in therapy, and in particular, for new types of use, licensees should select dosimetry equipment that will accurately measure the output or the activity of the source.

See NRC's Medical Uses Licensee Toolkit Web page for calibration equipment requirements for each specific emerging technology.

Discussion: Manual brachytherapy sources and LDR remote afterloader sources are often measured by the manufacturer for source output or activity. If the manual brachytherapy source output or activity is not determined by the manufacturer, the licensee must perform a calibration prior to medical use. Manual brachytherapy sources must be calibrated only initially, prior to use. For all other sealed sources used in a therapy unit, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to ***DHS 157.67(6)***. The licensee must maintain records of calibrations for the duration of the license.

Licensees must perform full calibrations before first medical use and at intervals as defined in ***DHS 157.67(7)***, ***DHS 157.67(8)***, and ***DHS 157.67(9)***. In addition, licensees must perform full calibrations whenever one of the following conditions are met:

- Spot-check measurements (if required) indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for decay.
- Following replacement of the sources or reinstallation of the unit in a new location not previously described in the license.
- Following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly.

If the licensee seeks authorization for medical use under ***DHS 157.70,*** the licensing guidance on *NRC's Medical Use Licensee Toolkit web page* should be reviewed to determine if calibration and use procedures need to be submitted for that ***DHS 157.70*** medical use.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols accepted by nationally recognized bodies (e.g., AAPM, ANSI). Calibration by an AMP is not required for manual brachytherapy sources, except for calculating the activity of Sr-90 sources. In accordance with ***DHS 157.65(6m)***, the licensee's AMP or ophthalmic physicist must calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic therapy. The calibration procedures should address, in part, the method used to determine the exposure rate (or activity) under specific criteria (e.g., distances used for the measurement, whether the

measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).

In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (***DHS 157.67(10), DHS 157.67(11)***, and ***DHS 157.67(12)***). These procedures must be submitted in accordance with ***DHS 157.13(5)(a)2.*** The calibration procedures described by AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used.

In accordance with ***DHS 157.67(14)***, licensees must perform surveys around therapy devices to ensure that the maximum radiation levels and the average radiation levels from the surface of the main source safe with the sources in the shielded position do not exceed the levels stated in the SSD registry.

Response from Applicant: Complete this section only if you are requesting license authorization for HDR, Gamma Stereotactic Radiosurgery unit, Teletherapy or Brachytherapy Use.

- Commit to a written calibration procedure for a therapy sealed source that meets the requirements in ***DHS 157.65(6)*** and ***DHS 157.67(6-12)*** (as applicable to the type of medical use requested).

AND

- Submit the dosimetry system, manufacturer, and model number.

Note: Spot check and full calibration procedures are not required to be submitted with the application; they may be reviewed during inspections.

References: Copies of AAPM Task Group No. 21, '*A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams*', AAPM Task Group No. 40, '*Comprehensive QA for Radiation Oncology*', AAPM Report No. 54, '*Stereotactic Radiosurgery*', AAPM Task Group No. 56, '*Code of Practice for Brachytherapy Physics*', may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740-3843 or by ordering electronically from http://www.aapm.org.

Item 8.5: Other Equipment and Facilities

Rule: *DHS 157.21; DHS 157.13(2)(b); DHS 157.13(9)(b) & (10); DHS 157.13(1), (5) (12), & (13); DHS 157.64(3); DHS 157.65(5); DHS 157.65(7); DHS 157.67(5); DHS 157.67(13); DHS 157.67(16)*

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: The applicant must describe other equipment and facilities available for safe use and storage of radioactive material listed in **Item 7.1** of the application (e.g., fume hoods, xenon traps, emergency response equipment, area monitors, remote handling tools, source transport containers, patient viewing and intercom systems, interlock systems).

For PET radionuclide use: Applicants should focus on remote handling devices and storage containers that may be needed when handling and storing materials with higher energy emissions (e.g., PET specific syringe shields or vial shields).

For radiopharmaceutical therapy: The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (i.e., private room with private bath). I-131 sodium iodide is the most widely used source of radiopharmaceutical therapy. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (i.e., a fume hood) and consider the hazards from airborne I-131. Additionally, for both liquid and capsule form of I-131, applicants should recognize sources of potential contamination from I-131found in the patient's urine, perspiration, saliva, and other secretions.

For manual brachytherapy: The applicant should describe the emergency response equipment and its availability.

For GSR and HDR facilities: The applicant should focus on facilities and equipment necessary to comply with ***DHS 157.67(4)*** and ***DHS 157.67(5)***:

- Appropriate radiation monitors to be used by any individual entering the treatment room to ensure that radiation levels have returned to ambient levels. One method of meeting this requirement is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source;

- Equipment or methods to be used to prevent dual operation of more than one radiation-producing device (e.g., linear accelerator, X-ray machine) in a treatment room, if applicable;

- Methods used to ensure that console keys will be inaccessible to unauthorized persons when the device is not in use or is unattended;

- Except for LDR remote afterloaders, a system for continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used shall be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions shall be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again;

- Except for LDR afterloaders, a system for continuous observation of the patient in the event of medical difficulties. An open microphone system is recommended to allow communication without requiring the patient to move to activate controls; and

- An electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Additionally, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the source(s) on-off control is reset at the console.

For pulsed dose-rate (PDR) remote afterloaders: The applicant should focus on the alarm system because of the unique characteristics and the lack of constant surveillance of their operation. A more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment;
- An AU or someone working under the supervision of an AU checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
    - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;
    - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;
    - The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment;
    - The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times; and
    - No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. No engineering controls that disable this alarm circuit or silence the alarm for periods in excess of 1 minute should be used.

If the alarm circuit is inoperative for any reason, licensees shall prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

For LDR and PDR remote afterloaders: Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

For LDR remote afterloaders: The applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

Response from Applicant: Submit a detailed description of additional equipment and facilities available for the safe use and storage of radioactive materials requested.

Note: For manual brachytherapy facilities, provide a description of the emergency response equipment. For GSR and remote afterloader facilities provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- Steps taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons, and
- Emergency response equipment.

Item 9: Radiation Protection Program

Each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of ***Chapter DHS 157, Subchapter III***. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material.

Item 9.1: Audit Program

Rule: ***DHS 157.21; DHS 157.31(2)***

Criteria: Under ***DHS 157.21***, licensees must annually review the content and implementation of the radiation protection program. The review should ensure the following:

- Compliance with DHS and applicable DOT regulations and the terms and conditions of the license.
- Occupational doses and doses to members of the public are ALARA (***DHS 157.21***).

Records of audits and other reviews of radiation protection program content are maintained for 3 years from the date of the record.

Discussion: The applicant should develop and implement procedures for reviewing the radiation protection program's content and implementation. **Appendix K** contains a suggested model for medical licensee audit. Some sections of **Appendix K** may not apply to every licensee and may not need to be addressed during each audit. Licensees do not need to address items that do not apply to their activities, and activities that have not occurred since the last audit need not be

reviewed at the next audit. Audits of the radiation protection program shall be conducted at intervals not to exceed 13 months.

DHS encourages licensee management to conduct performance-based audits by observing work in progress, interviewing staff about the radiation protection program, and spot-checking required records. As part of their audit programs, licensees should consider performing unannounced audits of authorized and supervised users.

It is essential that once identified, violations and radiation safety concerns are corrected comprehensively and in a timely manner. The following three-step corrective action process has proven effective:

- Conduct a complete and thorough review of the circumstances that led to the violation;
- Identify the root cause of the violation; and
- Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violation.

DHS will review the licensee's audit results during inspections and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. Depending on the significance of the violation, if the violation was identified by the licensee and sufficient corrective steps are taken, DHS may exercise discretion and elect not to cite a violation. DHS's goal is to encourage prompt identification and prompt comprehensive correction of violations and deficiencies.

Under ***DHS 157.31(2)***, licensees must maintain records of audits and other reviews of radiation protection program content and implementation for 3 years from the date of the record. Audit records should describe areas of the program that were reviewed and contain audit findings, noted deficiencies, and corrective actions.

Response from Applicant: No response required. The audit program will be examined during an inspection

References: NRC Information Notices including NRC's IN 96-28, *'Suggested Guidance Relating to Development and Implementation of Corrective Action'* dated May 1, 1996.

Item 9.2: Occupational Dose

Rule: *DHS 157.21; DHS 157.22(1); DHS 157.22(2); DHS 157.22(4); DHS 157.22(7); DHS 157.22(8); DHS 157.25(1); DHS 157.25(2); DHS 157.31(2); DHS 157.31(7); DHS 157.61(3)*

Criteria: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. Applicants must:

- Demonstrate that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 % of the allowable limits as shown in **Figure 2.**

OR

- Monitor external and/or internal occupational radiation exposure **[*DHS 157.25(2)*]**.

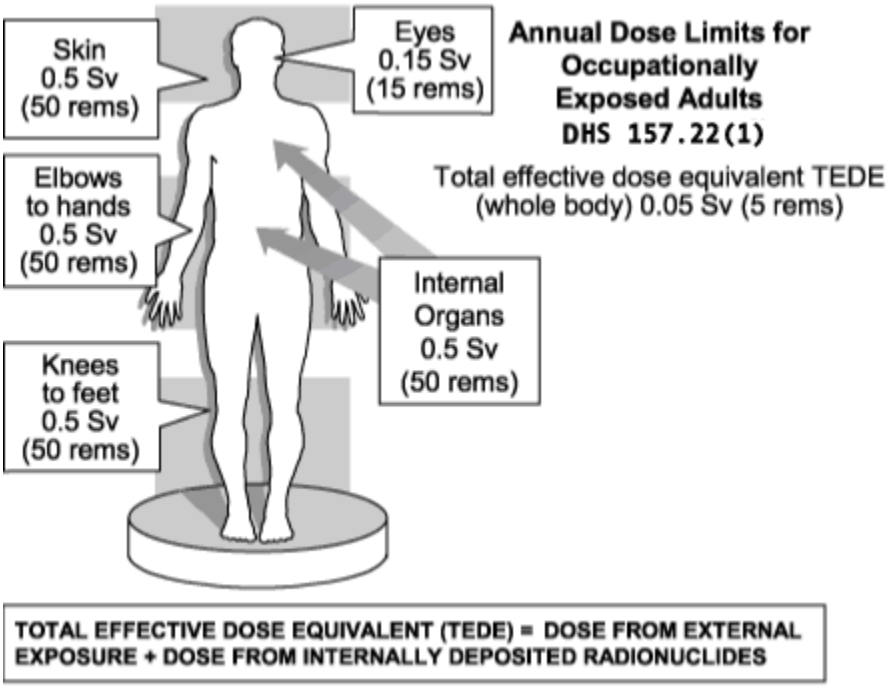

Figure 2: Annual Occupational Dose Limits for Adults

Discussion: The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required to demonstrate compliance with ***DHS 157.25***. If an adult radiation worker is likely to receive in 1 year a dose greater than 10 percent of any applicable limit (see Figure 2 for annual dose limits), monitoring for occupational exposure is required. Licensees must consider the internal and external dose and the occupational workers' assigned duties when evaluating the need to monitor occupational radiation exposure. Review of dosimetry histories for workers previously engaged in similar duties may be helpful in assessing potential doses.

When evaluating external dose from xenon gas or aerosols, the licensee may take credit for the reduction of dose resulting from the use of xenon or aerosol traps. Additionally, periodic checks of the trap effluent may be used to ensure proper operation of the trap. Licensees may vent xenon gas or aerosols directly to the atmosphere as long as the effluent concentration is within ***Chapter DHS 157, Subchapter III*** limits**.**

If the prospective evaluation shows that the individual adult is likely to exceed 10 percent of an applicable limit, then monitoring is required, regardless of the actual dose received. Licensees must provide individual radiation exposure data to each worker as required by ***DHS 157.32(6)***. Monitoring is required for minors and declared pregnant women.

If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as optically stimulated luminescence dosimeters (OSLD), and thermoluminescent dosimeters (TLDs) that personnel will use. **Appendix L** provides a model procedure for monitoring external occupational exposure. If occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors. The use of extremity monitors is required if workers are likely to receive a dose in excess of 0.05 Sv (5 rem) shallow-dose equivalent (SDE). Additionally, applicants should ensure that their personnel dosimetry program contains provisions that personnel monitoring devices be worn so that the part of the body likely to receive the greatest dose will be monitored.

Licensees using dosimetry requiring processing must verify that the dosimetry processor is accredited by National Voluntary Laboratory Accreditation Program (NVLAP) for the type of radiation for which monitoring will be performed. Consult the NVLAP-accredited processor for its recommendations for exchange frequency and proper use.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with ***DHS 157.22(4)*** and ***DHS 157.25(2)***. If internal dose monitoring is necessary, the applicant must measure at least one of the following:

- Concentrations of radioactive material in air in work areas;
- Quantities of radionuclides in the body; or
- Quantities of radionuclides excreted from the body.

The applicant should describe in its procedures the criteria used to determine the type of bioassay and the frequencies at which bioassays will be performed to evaluate intakes. The criteria also should describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments (i.e., the empirical models used to interpret raw bioassay data). The bioassay procedures should provide for baseline, routine, emergency, and follow-up bioassays. If a commercial bioassay service will be used, the applicant must ensure that the service is licensed to perform these activities by DHS, NRC or another Agreement State. Applicants should perform bioassays whenever liquid I-131 is handled.

NRC's RG 8.9, Revision 1, *'Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program'*, and RG 8.20, Revision 2, *'Applications of Bioassay for I-125 and I-131'* and NUREG/CR-4884, *'Interpretation of Bioassay Measurements,'* outline acceptable criteria that applicants may use in developing their bioassay programs.

NRC Regulatory Issue Summary (RIS) 2002-06, *"Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays,"* provides guidance for evaluating occupational dose when some exposure is due to X-rays and dosimeters are used to measure exposure behind lead aprons and elsewhere.

DHS 157.22(2) describes the requirements for summing external and internal doses. Applicants must ensure that their occupational monitoring procedures include criteria for summing external and internal doses.

Response from Applicant:

- Submit a description of facilities and equipment used for monitoring occupational exposure.

AND ONE OF THE FOLLOWING

- Commit to following procedures in Appendix L of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3 for monitoring occupational dose.

OR

- Submit procedures for monitoring occupational dose in accordance with ***DHS 157.21*** and that meet the requirements in ***Chapter DHS 157, Subchapter III.***

References:

- NRC Regulatory Issue Summary 2021-02, "*Recent Issues Associated with Monitoring Occupational Exposure to Radiation from Licensed and Unlicensed Radiation Sources*"
- National Institute of Standards and Technology (NIST) Publication 810, '*National Voluntary Laboratory Accreditation Program Directory*,' is published annually.
- Copies of ANSI N322 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically from http://www.ansi.org.
- NUREG/CR-4884, '*Interpretation of Bioassay Measurements*' and NRC Regulatory Guide 8.9, Revision 1, '*Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program.*'
- NRC Regulatory Issue Summary 2002-06, *'Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays'* and NRC Regulatory Issue Summary 2002-10, *'Revision of the Skin Dose Limit in 10 CFR Part 20.'*

Item 9.3: Public Dose

Rule: *DHS 157.23(1); DHS 157.23(2); DHS 157.28(1)(a); DHS 157.28(1)(b); DHS 157.31(8)*

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations;
- Ensure air emissions of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from these emissions; and
- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include persons who are not radiation workers. This includes licensee staff who work or may otherwise be located near areas where licensed material is used or stored and whose duties do not involve the use of radioactive material.

"Public dose" is defined in ***DHS 157.03*** as "the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes occupational dose, doses received from background radiation, medical procedures the individual has received, exposure to patients released in accordance with ***DHS 157.62(8)***, and voluntary participation in medical research programs. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) where the individual is when he or she receives the dose.

Public dose is controlled, in part, by ensuring that licensed material is secure (e.g., located in a locked area) to prevent unauthorized access or use by individuals coming into the area. Some medical use devices containing licensed material

are usually restricted by controlling access to the keys needed to operate the devices and/or to keys to the locked storage area. Only AUs and personnel using radioactive material under their supervision should have access to these keys.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security. For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD), are often used to show compliance.

Dose to members of the public in waiting rooms was addressed in the NRC *Information Notice (IN) 94-09*. The provisions of ***DHS 157.23(1)*** should not be applied to radiation received by a member of the general public from patients released under ***DHS 157.62(8)***. If a patient is released pursuant to ***DHS 157.62(8)***, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room or individuals near a PET "quiet room") from a patient to 0.02 mSv (2 mrem) in any one hour. Patient waiting rooms and "quiet rooms" need only be controlled for those patients who have not been released, per the release criteria in ***DHS 157.62(8).***

DHS 157.23(1) allows licensees to permit visitors to a patient who cannot be released under ***DHS 157.62(8)*** to receive a dose greater than 1 mSv (0.1 rem) provided the dose does not exceed 5 mSv (0.5 rem) and the authorized user has determined before the visit that it is appropriate. NRC Regulatory Issue Summary 2005-24 *'Control of Radiation Dose to Visitors of Hospital Patients'* discusses some of the measures that may be used to maintain control and minimize doses to visitors. RIS 2006-18, "Requesting Exemption from the Public Dose Limits for Certain Caregivers of Hospital Patients," August 31, 2006, describes dose limits for members of the public that are designated as caregivers. Caregiver dose limits may be established on a case-by-case basis by the licensee. The justification for incurring the exposure is that it is beneficial, or possibly essential, to the wellbeing of the patient, and may, therefore, be considered an extension of the patient's medical treatment.

The licensee must control emissions of radioactive material to air such that the individual member of the public likely to receive the highest total effective dose equivalent (TEDE) does not exceed the constraint level of 0.10 mSv (10 mrem) per year from those emissions. If exceeded, the licensee must report this in accordance with ***DHS 157.32(3)*** and take prompt actions to ensure against recurrence.

Response from Applicant: No response required. The licensee's evaluation of public dose will be examined during an inspection.

Item 9.4: Minimization of Contamination

Rule: ***DHS 157.13(2)(b); DHS 157.62(5)***

Criteria: Applicants for new licenses must describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed radioactive material. As described in **Item 9.14**, '*Spill Procedures*,' cleanup procedures should be implemented for contamination events. Recommended limits for acceptable levels of surface contamination in restricted and unrestricted areas are provided in **Appendix R**, **Tables 8** and **9**.

Sealed sources and devices that are approved by the NRC or an Agreement State and located and used according to their SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and stored, repaired, or disposed of according to DHS requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant:

- Commit to following clean up procedures from Appendix R, Tables 8 and 9, of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

OR

- Submit procedures to minimize the amount of radioactive contamination and radioactive waste generated at your facility.

Item 9.5: Operating and Emergency Procedures

Rule: ***DHS 157.88(1)(a)3.***; ***DHS 157.21; DHS 157.26(1); DHS 157.26(2); DHS 157.28(1)(a); DHS 157.28(1)(b); DHS 157.29(6); DHS 157.31(2); DHS 157.32; DHS 157.13(9)(b); DHS 157.13(17); DHS 157.61(3); DHS 157.61(5); DHS 157.62(8); DHS 157.64(2); DHS 157.64(3); DHS 157.65(2); DHS 157.65(3); DHS 157.65(4); DHS 157.65(5); DHS 157.67(4); DHS 157.67(5); DHS 157.72(1); DHS 157.72(2); DHS 157.73(3)***

Criteria: This section summarizes operating and emergency procedures. Many of these procedures are covered in greater detail in other sections of this document.

The licensee shall develop, implement, and maintain specific operating and emergency procedures which encompass the scope of the radiation protection program. Operating and emergency procedures may contain the following elements:

- Instructions for opening packages containing licensed material;
- Instructions for using licensed material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements;
- Instructions for conducting area radiation level and contamination surveys;
- Instructions for administering licensed material in accordance with the WD;

- Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred: (a) leaking or damaged source, (b) device malfunction and/or damage, (c) licensed material spills, (d) theft or loss of licensed material, (e) releases of xenon-133, or (f) any other incidents involving licensed material;
- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s);
- Steps to ensure that patient release is in accordance with ***DHS 157.62(8)***;
- Steps to take if a therapy patient undergoes emergency surgery or dies;
- Instructions for calibration of survey and dosage measuring instruments;
- Periodic spot checks of therapy device units, sources, and treatment facilities; and
- Instructions for radioactive waste management.

AND

The licensee should:

- Make operating procedures, including emergency procedures, available to all users (e.g., post the procedures or the location of the procedures);
- Maintain a current copy of the procedures at each location of use or, if this is not practicable, post a notice describing the procedures and state where they may be examined;
- Use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA; and
- Secure or control radioactive material at all times.

DHS 157.88(1)(b) requires licensees to post their emergency procedures in a conspicuous location.

Discussion: Sealed sources and radiopharmaceuticals used for therapy can deliver significant doses in a short time. The same may be true for high-activity PET radiopharmaceuticals, if not shielded. For these reasons, unauthorized access to licensed material by untrained individuals could lead to a significant radiological hazard. Therefore, operating procedures must address access control. Many licensees achieve access control by permitting only trained individuals to have access to licensed material (e.g., keys, lock combinations, security badges). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

If a therapy patient treated with unsealed radionuclides or permanent implant brachytherapy undergoes emergency surgery or dies, it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. When an operation or autopsy is to be performed, there should be an increased awareness of the possible exposure of the hands and face to relatively intense beta radiation. Additional care for patients recently treated with medium- to high-energy gamma emitters, such as I-131, and high-energy beta emitters, such as Y-90, should be observed. Procedures for emergency surgery or autopsy can be found in NCRP Report No. 155, "Management of Radionuclide Therapy Patients," December 2006. **Appendix N** also provides procedures for responding to emergency surgery or death of a therapy patient.

Applicants must develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking source, medical events, interlock failure, stuck source). After its occurrence becomes known to the licensee, DHS must be notified when an incident involving licensed material occurs. Refer to **Appendix Z** for a description of when notifications are required.

Response from Applicant: No response required. The licensee's operating and emergency procedures will be examined during an inspection.

Reference: Copies of NCRP Report No. 155, "*Management of Radionuclide Therapy Patients*," NCRP Report No. 105, "*Radiation Protection for Medical and Allied Health Personnel*," 1989, and NCRP Report No. 107, "*Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel*," 1990, may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095, or ordered electronically at http://www.ncrponline.org.

Item 9.6: Material Receipt and Accountability

Rule: ***DHS 157.28(1)(a); DHS 157.28(1)(b); DHS 157.29(6); DHS 157.32(1); DHS 157.13(9)(b); DHS 157.15(7)(a)2.; DHS 157.13(15); DHS 157.06(1) & DHS 157.13(18); DHS 157.61(3); DHS 157.62(5); DHS 157.71(9)***

Criteria: To maintain accountability of licensed material, licensees must do the following:

- Secure licensed material;
- Maintain records of receipt, transfer, and disposal of licensed material;
- Conduct physical inventories at required frequencies to account for licensed material. Ensure that material received does not exceed license possession limits;
- Update transactions in the NSTS, including an annual inventory reconciliation; and
- Conduct physical inventories at semi-annual intervals (not to exceed 6 months) to account for all sealed sources containing radioactive material and retain records for 3 years.

Discussion: Licensed materials must be tracked from "cradle to grave" to ensure accountability, to identify when licensed material may be lost, stolen, or misplaced, and to ensure that possession limits listed on the license are not exceeded.

Licensees are required under ***DHS 157.28*** to secure radioactive material from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material not in storage. Receipt, inventory, transfer, and disposal records must be maintained.

Response from Applicant:

- Commit to conducting physical inventories not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

OR

- Submit a description of the frequency and procedures for ensuring that no radioactive material has been lost, stolen or misplaced.

Item 9.7: Ordering and Receiving

Rule: ***DHS 157.28(1)(a); DHS 157.28(1)(b); DHS 157.29(6); DHS 157.13(9)(b); DHS 157.06(1) & DHS 157.13(18)***

Criteria: ***DHS 157.29(6)*** contains the requirements for receiving packages containing licensed material. Additionally, the security of licensed material, required by ***DHS 157.28(1)(a) & (b),*** must be considered for all receiving areas. ***DHS 157.06(1) & DHS 157.13(18)*** requires licensees, in part, to maintain records showing the receipt of radioactive material.

Discussion: Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized.

Appendix O contains procedures for ordering and receiving licensed material.

Response from Applicant:

- Submit ordering and receiving procedures that will meet the criteria in the section entitled "Ordering and Receiving" of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

OR

- Commit to follow procedures for ordering and receiving in accordance with Appendix O of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Item 9.8: Opening Packages

Rule: ***DHS 157.29(6); DHS 157.31(3); DHS 157.61(3)***

Criteria: Licensees must ensure that packages are opened safely and that the requirements of ***DHS 157.29(6)*** are met. Licensees must retain records of package surveys in accordance with ***DHS 157.31(3)***.

Discussion: Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of ***DHS 157.29(6)*** are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA. **Appendix P** contains model procedures for safely opening packages containing radioactive materials. Applicants are reminded that ***DHS 157.29(6)(b)*** requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day, if it is received after working hours.

Response from Applicant: No response required. The licensee's package opening procedure will be examined during an inspection.

Item 9.9: Leak Tests

Rule: ***DHS 157.24*; *DHS 157.32(7)*; *DHS 157.25(1); DHS 157.31(3); DHS 157.06(3)*; *DHS 157.62(5)*; *DHS 157.71(9); DHS 157.73(3)***

Criteria: DHS requires testing to determine if there is any radioactive leakage from sealed sources. Records of test results must be maintained for 3 years.

Discussion: Licensees must perform leak testing of any sealed source or brachytherapy source in accordance with ***DHS 157.62(5)***. **Appendix Q** provides model leak-testing procedures. ***DHS 157.62(5)*** requires licensees to perform leak tests at six-month intervals or at other intervals approved by DHS, NRC or another Agreement State and specified in the SSDR certificate and before first use unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 μCi) of radioactivity on the sample. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The leak test may be performed in-house or by a contractor who is authorized by the NRC or an Agreement State to perform leak tests as a service to other licensees. If the licensee chooses to analyze their own leak tests, provide a description of the instrumentation that will be used to perform leak tests in **Item 8.2** *'Radiation Monitoring Instruments'* of the application form.

The licensee does not need to leak test sources if:

- Sources contain only radioactive material with a half-life of less than 30 days;
- Sources contain only radioactive material as a gas;
- Sources contain 3.7 MBq (100 μCi) or less of beta-emitting or gamma-emitting material, or 0.37 MBq (10 μCi) or less of alpha-emitting material; or
- Sources contain Ir-192 seeds in nylon ribbon.

Except for brachytherapy sources, sources that are stored and not being used must be leak tested at least every five years **[*DHS 157.24; DHS 157.62(5)*]**. The licensee, shall, however, test each such source for leakage before any use or transfer unless it has been leak-tested within 6 months before the date of use or transfer.

Response from Applicant:

- Commit to leak tests being performed by an organization authorized by DHS, the NRC, or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by DHS, the NRC or an Agreement State to provide leak test kits to other licensees according to the kit supplier's instructions.

OR

- Commit to performing your own leak tests and sample analysis following the procedures in Appendix Q of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

OR

- Submit alternative procedures.

Note: An alternate organization may be used to perform or analyze leak test, without amending the license, provided the organization is specifically authorized by DHS, NRC or an Agreement State.

References: NRC's NUREG-1556, Vol. 18, Revision 1*, 'Program-Specific Guidance About Service Provider Licenses,'* dated August 2017

Item 9.10: Radiation Surveys

Rule: ***DHS 157.03; DHS 157.21; DHS 157.22(1); DHS 157.23(1) & (2); DHS 157.25(1); DHS 157.28(1)(a) & (b); DHS 157.31(2) & (3); DHS 157.31(8); DHS 157.61(3); DHS 157.62(7); DHS 157.71(10)***

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. For example, licensees must perform surveys to:

- Ensure that radioactive material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations;
- Ensure that radioactive material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in ***DHS 157.22(1)***; and
- Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in ***DHS 157.21***.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with ***DHS 157.21*** must include provisions for area surveys. Surveys are evaluations of radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments ensure that surveys accurately assess radiological conditions. Licensees should also use surveys to plan work in areas where radioactive material or radiation exists and to evaluate doses to workers and individual members of the public. In certain cases, environmental monitoring may be required to demonstrate compliance with ***Chapter DHS 157, Subchapter III***. To meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, or gamma) and compared to the appropriate regulatory limits.

There are many different kinds of surveys performed by licensees:

- Contamination (fixed and removable)
- Personnel (during use, transfer, or disposal of licensed material)
- Air effluent
- Water effluent

- Leak test
- Bioassays
- Air sample
- External radiation exposure levels
- Restricted areas

Unrestricted areas: Surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the appropriate regulations. Typical surveys may include:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could cause workers to inhale radioactive material (e.g., radioiodine) or where radioactive material is or could be released to unrestricted areas (Refer to RG 8.25 *'Air Sampling in the Workplace,'* June 1992, and NUREG-1400 *'Air Sampling in the Workplace,'* September 1993, for further guidance on air sampling);
- Bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe;
- Surveys of external radiation exposure levels in both restricted and unrestricted areas; and
- Surveys of incoming and outgoing radiopharmaceutical packages (e.g., from suppliers and to return radiopharmaceuticals to the supplier, respectively).

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific facilities, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. Also, the frequency of the survey depends on the type of survey. **Appendix R** contains procedures with suggested survey frequencies for ambient radiation level and contamination surveys.

For example, in accordance with ***DHS 157.62(7)***, licensees are required to perform daily area surveys in all areas where a written directive (WD) is required for preparation and administration of radiopharmaceuticals (i.e., diagnostic activities exceeding 30 μCi of I-131 and all therapy treatments). However, if the licensee administers radiopharmaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey if the patient is not released. In this case, the licensee should perform adequate surveys of patients' rooms after the patient is released and prior to the release of the room for unrestricted use.

Therapy sealed sources (including applicators and catheters) may become dislodged during implantation or after surgery and inadvertently lost or removed. These sources may have the potential to exceed public and occupational dose limits in a short period of time. Therefore, the following surveys shall be performed in accordance with ***DHS 157.65(2)***.

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

In addition, licensees should consider surveying the following:

- The therapy patient's bed linens before removing them from the patient's room;
- The operating room and the patient's room after source implantation (e.g., radiation level and/or visual check);
- All trash exiting the patient's room or surgical recovery room; and
- Areas of public access in and around the patient's room.

Not all instruments can measure a given type of radiation (e.g., alpha, beta, and gamma). The correct selection, calibration, and use of radiation detection instruments are important aspects of any radiation safety program. Licensees who perform permanent prostate brachytherapy should use a survey instrument with a probe specifically calibrated to measure low energy gamma radiation. Additionally, applicants are reminded that probe movement speeds and surface-to-probe distances greatly affect ambient exposure rate results.

Response from Applicant:

- Submit procedures for radiation surveys that will meet the criteria in the section titled 'Area and Radiation Surveys' in WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

OR

- Commit to follow the procedures for radiation surveys published in Appendix R of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Item 9.11: Procedures for Administration of Radioactive Material Requiring a Written Directive

Rule: ***DHS 157.61(3-5); DHS 157.71(3)***

Criteria: ***DHS 157.61(4)*** sets forth the requirements for the contents of written directives. ***DHS 157.61(5)*** requires medical use licensees to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users.

Discussion: A medical use licensee preparing WDs must develop, implement, and maintain written procedures to provide high confidence that, among other things, each administration is in accordance with the WD, and the patient's identity is verified. Therefore, licensees should have checks in place to ensure that the correct patient is treated and each component of the WD is met. Many licensees perform extensive imaging and dosimetry to prescribe and evaluate doses to not only intended tissue (e.g., prostate), but also to nearby tissue (e.g., rectum, bladder, or urethra). Therefore, licensees are reminded that procedures should correctly document the program currently in place. Licensees are required to

determine if a medical event, as defined in ***DHS 157.72(1)*** has occurred. For purposes of determining whether medical event reporting is required, licensees should also provide definitive criteria for evaluating the adequacy of the dose delivered or activity implanted to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive. For permanent implant brachytherapy, licensees are required to determine, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

Additionally, under ***DHS 157.65(7)*** and ***DHS 157.67(16)*** the licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies.

The written directive procedures do not need to be submitted to DHS. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining DHS approval. Under ***DHS 157.61(5)***, the procedures must address the following as applicable:

- Verifying the patient's identity using more than one method;
- Verifying the specific details of the procedure are under the treatment plan and the written directive;
- Checking both manual and computer-generated dose calculations;
- Determining a medical event;
- For uses authorized under DHS 157.67 or DHS 157.70, verifying that computer generated dose calculations are correctly transferred to the console for the therapeutic device; and
- For manual brachytherapy, determining the total source strength administered outside the treatment site and comparison to the source strength administered to the target as documented on the post-implantation portion of the written directive.

Appendix S provides guidance on developing written directive procedures.

Response from Applicant: If applicable,

- Commit to develop, implement, and maintain procedures for administration of radioactive material requiring a written directive that will meet the criteria in the section entitled 'Procedures for Administrations Requiring a Written Directive' in WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

AND IF APPLICABLE

- Request the approval to use electronic documents and signatures for written directives, quality assurance, and treatment planning.

Item 9.12: Safe Use of Unsealed Licensed Material

Rule: *DHS 157.21; DHS 157.23(1) & (2); DHS 157.31(2) & (3); DHS 157.13(2)(b); DHS 157.61(3); DHS 157.62(6) & (7); DHS 157.64(2)*

Criteria: Before using radioactive material, the licensee must develop and implement a radiation protection program that includes safe use of unsealed radioactive material.

Discussion: Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all radioactive material from the time it arrives at their facilities until it is used, transferred, and disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use radioactive material without undue hazard to themselves, other workers, or members of the public.

In addition, licensees must develop, implement, and maintain procedures for protective measures to be taken by occupational workers to maintain their doses ALARA. Protective measures may include:

- Use of syringe shields and/or vial shields specific to the energy emitted (e.g., PET shields should be used when handling fluorine-18);
- Wearing laboratory coats and gloves when handling unsealed radioactive material;
- Monitoring hands after handling unsealed radioactive material; and
- Designing equipment and facilities to protect health and minimize danger to life or property in accordance with ***DHS 157.13(2)(b)***.

Appendix R contains model procedures for completing area and personnel surveys.

Appendix T contains model procedures for safe use of unsealed radioactive material.

Response from Applicant: If applicable,

- Submit procedures for the safe use of unsealed radioactive material that will meet the criteria in the section titled 'Safe Use of Unsealed Radioactive Material' in WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

OR

- Commit to follow the procedures for safe use of unsealed radioactive material in Appendix T of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Item 9.13: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

Rule: ***DHS 157.21; DHS 157.13(1); DHS 157.13(9)(b); DHS 157.67(3); DHS 157.67(15); DHS 157.71(9); DHS 157.71(27)***

Criteria: In accordance with ***DHS 157.67(3)*** and ***DHS 157.67(15)***, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted by approved individuals according to the manufacturers' written recommendations and instructions and according to the SSDR. In addition, ***DHS 157.67(15)*** requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years for teletherapy units and 7 years for GSR units, to ensure that the source exposure mechanism and other safety components function

properly. Maintenance is necessary to ensure that source integrity and safety components are not compromised and that the device functions as designed. Similar provisions are included in licensing guidance for certain therapy 10 CFR 35.1000 medical uses. See the NRC's Medical Uses Licensee Toolkit Web page for specific information.

Discussion: Maintenance and repair include installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also include any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s).

DHS requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by DHS, NRC or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review ***DHS 157.67(3)*** before responding to this item. ***DHS 157.67(3)*** allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Note: For applicants wishing to perform in-house maintenance and repair of therapy devices, the applicant shall specify the desired installation, maintenance, inspection, adjustment, and repair functions to be performed in-house and provide the name and qualifications of the individual who would perform those functions. The applicant shall provide a training certificate or letter from the manufacturer that specifies the proposed individual's training in the requested repair or maintenance function(s).

Response from Applicant: If applicable:

- Commit to contracting with personnel who are licensed by DHS, the NRC or an Agreement State to perform maintenance and repair services on the specific therapy device(s) possessed by the licensee.

Item 9.14: Spill Procedures

Rule: *DHS 157.88(1); DHS 157.21; DHS 157.13(2)(b); DHS 157.31(2); DHS 157.32(2); & (3); DHS 157.13(9); DHS 157.15; DHS 157.13(17); DHS 157.06(1); DHS 157.13(18); DHS 157.61(3)*

Criteria: Before using radioactive material, the licensee must develop, document, and implement a radiation protection program that includes proper response to spills of radioactive material.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with ***DHS 157.21*** must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material. Spill procedures should address all types and forms of radioactive material used (e.g. unsealed and gases) and should be posted in restricted areas where radioactive materials are used or stored. Spill procedures should include provisions for identifying and reporting spills of radioactive material in excess of the limits in DHS 157.32(2. The names and telephone numbers of the person to be notified of a spill or contamination event (e.g., RSO, staff, local authorities, and DHS, when applicable) do not need to be included in the version of the spill procedures

submitted to DHS. However, these names and telephone numbers should be included in the posted spill procedures at your facility. Additionally, the instructions should contain procedures for evacuation of the area, containment of spills and other releases, appropriate methods for re-entering, and for decontaminating facilities (when necessary).

Appendix N contains emergency response procedures including model spill procedures.

Response from Applicant: If applicable:

- Submit procedures for the response to spills of radioactive material.

OR

- Commit to follow the procedures for response to spills of radioactive material in accordance with Appendix N of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Note: The Department of Health Services Radiation Protection Section office number is (608) 267-4797 during regular business hours (7:45 a.m. to 4:30 p.m.). For spills requiring immediate notification after normal business hours, DHS's 24-hour emergency telephone number is (608) 258-0099. Identify the emergency as radiological.

Item 9.15: Emergency Response for Therapy Devices Containing Sealed Sources

Rule: ***DHS 157.88(1); DHS 157.21; DHS 157.31(2); DHS 157.32(1-3); DHS 157.13(9); DHS 157.13(17); DHS 157.06(1); DHS 157.13(18); DHS 157.61(3); DHS 157.65(4); DHS 157.67(4); DHS 157.71(15); DHS 157.13(2)***

Criteria: Before handling therapy devices containing sealed sources, the applicant must develop, document, and implement written procedures for emergency response. DHS requires that written procedures shall be developed, implemented, and maintained for responding to an abnormal situation involving manual brachytherapy, a remote afterloader unit, or a gamma stereotactic radiosurgery unit. The procedures must be submitted to DHS with your application and should include as appropriate:

- Steps to take if brachytherapy seeds are lost;
- Steps to take if a brachytherapy seed is breached;
- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
- The names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

For ***DHS 157.67*** modalities, a copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position or remove the patient from the radiation field using controls from outside the treatment room.

Discussion: The applicant must establish and follow written procedures for emergencies that may occur (e.g., a manual brachytherapy source becomes dislodged, a therapy source fails to retract or return to the shielded position, or a GSR

couch fails to retract). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. Practice drills, using nonradioactive (dummy) sources (when possible), must be practiced annually or more frequently, as needed. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for removing the patient from the radiation field. Team practice is important for adequate emergency coordination. These procedures, designed to minimize radiation exposure to patients, workers, and the general public should address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation;
- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing safety of the patient;
- Process for identifying and decontaminating equipment if a brachytherapy source ruptures;
- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event;
- Location of emergency source recovery equipment and specification of what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device;
- Radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position);
- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation or areas contaminated with radioactive material;
- Specifying who is to be notified; and
- Requirements to restrict access to (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Model procedures for responding to manual brachytherapy emergencies are provided in **Appendix J**.

Response from Applicant: If applicable:

- Submit procedures for emergency response for sealed sources or devices containing sealed sources.

Item 9.16: Release of Patients or Human Research Subjects

Rule: ***DHS 157.61(3); DHS 157.62(8); DHS 157.71(11)***

Criteria: Licensees may release from its control patients or human research subjects (patients) who have been administered radioactive material if the TEDE to any other individual from exposure to the released patient is not likely to

exceed 5 mSv (0.5 rem). Licensees must provide written radiation safety instructions to patients released (or their parent or guardian) if the TEDE to the maximally exposed individual or the TEDE delivered to a child or infant through breastfeeding is likely to exceed 1 mSv (0.1 mrem) in accordance with ***DHS 157.62(8)***.

Discussion: ***DHS 157.62(8)*** requires that the licensee provide the released individual (patient) with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or a child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breast-feeding, the instructions also shall include:

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

In addition, ***DHS 157.62(8)*** and ***DHS 157.71(11)*** require that the licensee maintain a record of the basis for authorizing the release of an individual for 3 years after the release date, if the TEDE is calculated by:

- Using the retained activity rather than the activity administered;
- Using an occupancy factor less than 0.25 at 1 meter;
- Using the biological or effective half-life; or
- Considering the shielding by tissue.

In ***DHS 157.62(8)*** and ***DHS 157.71(11)***, the licensee is required to maintain a record for 3 years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 mSv (0.5 rem).

Appendix U refers applicants to NRC Regulatory Guide 8.39 for guidance when:

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material; and
- Instructions to the patient are required by ***DHS 157.62(8)***.

NRC Regulatory Guide 8.39 lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in ***DHS 157.62(8)***.

The NRC has published additional information on controlling exposures to members of the public. Licensees should review RIS 2011-01 “NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences” (January 2011) and NRC RIS 2008-11 “Precautions to Protect Children Who May Come In Contact with Patients Released After Therapeutic Administration of Iodine-131,” (May 2008).

Response from Applicant: If applicable:

- Submit procedures for release of patients or human research subjects in Nuclear Regulatory Commission’s Regulatory Guide 8.39 “Release of Patients Administered Radioactive Material” Revision 1. References in the Regulatory Guide to the NRC’s regulations (Title 10 of the Code of Federal Regulations) shall be interpreted as the respective DHS Administrative Code (DHS 157). Where the Regulatory Guide says “should” we will implement this as saying “shall.”

OR

- Submit procedures for release of patients or human research subjects that will address the considerations in the Nuclear Regulatory Commission's Regulatory Guide 8.39 "Release of Patients Administered Radioactive Material" Revision 1.

Reference: NRC's RG 8.39, Revision 1, *'Release of Patients Administered Radioactive Materials'*, dated April 2020.

Item 9.17: Mobile Medical Service

Rule: ***DHS 157.21; DHS 157.13(15); DHS 157.06(1); DHS 157.13(18); DHS 157.03; DHS 157.13(5)(a); DHS 157.62(9); DHS 157.67(13); DHS 157.71(12); DHS 157.71(25); DHS 157.92(3); DHS 157.93(4-6); DHS 157.14; 49 CFR Parts 171-178***

Criteria: In addition to the requirements in ***DHS 157.62(9)***, mobile medical service licensees must comply with all other applicable regulations.

Discussion: Applicants for licensure of mobile medical services should review this guide for information to be submitted as part of their applications; many of the requirements in these sections are relevant to use of radioactive material by mobile medical service providers with details being dependent upon the scope of such programs. "Temporary job site" means a location, other than specific location(s) of use authorized on the license, where mobile medical services are conducted for limited periods of time. Any client addresses where the mobile medical service stores radioactive material is not considered a temporary job site and must be explicitly identified on the mobile medical license.

Mobile medical service licensees may transport licensed material and equipment into a client's building or may bring patients into the mobile coach/van. In either case, the coach/van should be located on the client's property that is under the client's control. Mobile PET medical service licensees must consider a "quiet room" as an area of use if the patients in the "quiet room" cannot be released under the provisions of ***DHS 157.62(8)***.

Self-contained mobile medical service involves a mobile treatment or administration facility that provides ready-to-deliver mobile medical services on arrival at a client's site. Companies providing transportation only will not be licensed for medical use ***Chapter DHS 157, Subchapter VI***. Before using a remote afterloader for this type of service, the device should be installed in an appropriately shielded treatment room.

The general types of services provided as mobile medical services are:

- Mobile medical services (radioactive material, trained personnel, and facility) that provide the device/facility (e.g., in-coach/van use) and treatment of (or administration to) patients at the client site. These mobile medical service providers are responsible for all aspects of radioactive material use and authorized patient treatments (or administrations); and
- Mobile medical service providers (radioactive material and trained personnel) that provide the transportation to and use of the radioactive material within the client's facility. These mobile medical service providers are also responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).

Mobile medical service licensees must ensure that the criteria in ***DHS 157.62(8)*** are met before releasing patients in their facilities.

Refer to **Appendix V** for additional guidance on information to provide in applications.

Note: NRC licensees and Agreement State licensees that request reciprocity for activities conducted in the State of Wisconsin are subject to the general license provisions described in ***DHS 157.14***. This general license authorizes persons holding a specific license from the NRC or an Agreement State to conduct the same activity in the State of Wisconsin if the specific license issued by the NRC or an Agreement State does not limit the authorized activity to specific locations or installations.

Response from Applicant: If applicable:

- Submit information requested, along with any procedures mentioned in Appendix V of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Item 9.18: Transportation

Rule: ***DHS 157.21; DHS 157.13(15); DHS 157.06(1); DHS 157.13(18); DHS 157.92(3); DHS 157.92(2)(c); DHS 157.93(4-6); 49 CFR Parts 171-178***

Criteria: Applicants who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with DHS and DOT regulations.

Discussion: Most packages of radioactive material for medical use contain quantities of radioactive material that require use of Type A packages. Additionally, packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the "Limited Quantity" criteria described in ***49 CFR 173.421*** and are therefore excepted from certain DOT requirements, provided certain other less restrictive requirements are met (e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.005 mSv per hour (0.5 mrem per hour)).

The general license in ***DHS 157.93(4)***, '*General license: NRC-approved package*,' provides the authorization used by most licensees to transport, or to deliver to a carrier for transport, radioactive material in a package for which a license, certificate of compliance, or other approval has been issued by NRC. This general license is subject to certain conditions. ***DHS 157.92(3)*** sets forth the requirements for transportation of radioactive material. ***DHS 157.92(2)(c)*** exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under ***Chapter DHS 157, Subchapter VI***, or the equivalent NRC or Agreement State regulations from the requirements in ***DHS 157.92(3)***. This exemption applies to transport by the physician of radioactive material for use in the practice of medicine.

Some medical use licensees (e.g., teletherapy or GSR) may need to ship licensed material in Type B packages. The Type B package requirements for transporting or delivering the package to a carrier for transport are set forth in 10 CFR Part

71. These include registration as a user of the package and the requirement to have an NRC-approved quality assurance (QA) plan. Consequently, most medical use licensees that ship Type B quantities of radioactive material choose to transfer possession of radioactive materials to a manufacturer (or service licensee) with a DHS, NRC or another Agreement State license, who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of ***DHS 157.93(4)*** or ***DHS 157.93(6),*** as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with DHS and DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the radioactive material at temporary job sites (e.g., the licensee's facilities); and
- Actually takes possession of the radioactive material under its license.

Additionally, for Type B package shipments, the licensee should verify that the manufacturer (or service licensee) is authorized to possess the material at temporary job sites (e.g., the licensee's facilities).

For each shipment, it must be clear who possesses the radioactive material and who is responsible for proper packaging of the radioactive materials and compliance with DHS, NRC and DOT regulations.

During an inspection, DHS uses the provisions of ***DHS 157.92(3)*** to examine and enforce various DOT requirements applicable to medical use licensees. **Appendix W** lists major DOT regulations that apply to medical licensees.

Response from Applicant: No response required. Transportation issues will be reviewed during inspection.

Reference: *U.S. Department of Transportation's 'Radioactive Material Regulations Review'*

Item 9.19: Records of Dosages and Use of Brachytherapy Sources

Rule: ***DHS 157.06(1) & DHS 157.13(18); DHS 157.71(8); DHS 157.71(14); DHS 157.71(17)***

Criteria: Licensees must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for 3 years.

Discussion: Licensees are required to make and maintain records of each dosage activity prior to medical use. The records must include:

- Radiopharmaceutical;
- Patient's or human research subject's name or identification number (if one has been assigned);
- Prescribed dosage, determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);
- Date and time of dosage determination; and
- Name of the individual who determined the dosage.

Dosage determination for unit dosages may be made either by direct measurement or by a decay correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed under ***DHS 157.13(4)(i)*** or equivalent

NRC or Agreement State requirements or an NRC or Agreement State medical use licensee authorized under ***DHS 157.13(1)(j)*** to produce PET radioactive drugs.

If molybdenum or strontium concentration is measured under ***DHS 157.63(3)***, records of concentration must be made and must include, for each measured elution:

- For Mo-99/Tc-99m generators, ratio of the measurements expressed as kBq (mCi) of molybdenum-99 per MBq (mCi) of technetium-99m;
- For Sr/Rb generators, ratio of the measurements expressed as kBq (mCi) of strontium-82 per MBq (mCi) of rubidium-82 and kBq (mCi) of strontium-85 per MBq (mCi) of rubidium-82;
- Date and time of the measurement; and
- Name of the individual who made the measurement.

If the licensee uses manual brachytherapy sources, the following records of use must be kept:

- When temporary implant brachytherapy sources are removed from storage, a record will include the number and activity of sources removed, the time and date they were removed from storage, the location of use, and the name of the individual who removed them from storage;
- When temporary implant brachytherapy sources are returned to storage, a record will include the number and activity of sources returned, the time and date they were returned to storage, and the name of the individual who returned them to storage; and
- For permanent implants, a record will be made and will include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

Response from Applicant: No response required.

Item 9.20: Safety Procedures for Treatments Where Patients are Hospitalized

Rule: ***DHS 157.21; DHS 157.25(1); DHS 157.28(1)(a); DHS 157.31(3); DHS 157.64(3); DHS 157.65(2); DHS 157.67(2) ; DHS 157.65(5); DHS 157.67(5); DHS 157.71(16)***

Criteria: Applicants must develop and implement procedures to ensure that access to therapy treatment rooms, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the public ALARA.

Discussion: ***DHS 157.64(3); DHS 157.65(5)***, and ***DHS 157.67(5)*** require the licensee to take certain safety precautions regarding radiopharmaceutical therapy, manual brachytherapy, remote afterloader brachytherapy, or emerging technologies involving patients hospitalized in accordance with ***DHS 157.62(8)***. This section does not include teletherapy

or GSR outpatient treatments. The precautions described below are to ensure compliance with the exposure limits in ***Chapter DHS 157, Subchapter III.***

DHS 157.65(2) and ***DHS 157.67(2)*** require licensees to perform a radiation survey of the patient (and the remote afterloader unit) immediately after removing the last temporary implant source from the patient and prior to releasing the patient from licensee control. This is done to confirm that all sources have been removed and accounted for. A record of the patient survey must be maintained for 3 years.

In addition, applicants must take the following steps for patients who cannot be released under ***DHS 157.62(8)***:

- Provide a private room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (**Note:** ***DHS 157.64(3)*** allows for a room shared with another radiopharmaceutical therapy patient);
- Provide a private room for patients implanted with brachytherapy sources (**Note:** ***DHS 157.65(5)*** allows for a room shared with another brachytherapy patient);
- Visibly post a '*Radioactive Materials'* sign on the patient's door and note on the door or in the patient's chart stating where and how long visitors may stay in the patient's room [***DHS 157.64(3) and DHS 157.65(5)***];
- Either monitor material and items removed from the patient's room (e.g., patient linens, surgical dressings) with a radiation detection survey instrument set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be distinguished from the natural background radiation level or to confirm that they do not contain brachytherapy sources, or handle them as radioactive waste [***DHS 157.64(3) and DHS 157.25(1)***]; and
- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies [***DHS 157.64(3), DHS 157.65(5), and DHS 157.67(5)***].

DHS 157.25(1) requires licensees to perform adequate surveys to evaluate the extent of radiation levels. Therefore, licensees must evaluate the exposure rates around patients who are hospitalized in accordance with ***DHS 157.62(8)*** following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

DHS 157.28(1)(a) requires licensees to secure radioactive material in storage from unauthorized access or removal. Therefore, licensees must ensure that access to rooms where patients are hospitalized, in accordance with ***DHS 157.62(8)***, is limited to authorized personnel. Access control and appropriate training of authorized personnel may prevent unauthorized removal of radioactive material and unnecessary personnel exposures.

In order to control exposures to individuals in accordance with ***Chapter DHS 157, Subchapter III***, the licensee should consider briefing patients on radiation safety procedures for confinement to bed, visitor control, identification of potential problems, notification of medical staff in the event of problems, and other items as applicable and consistent with good medical care.

Response from Applicant: No response required.

Note: NRC Regulatory Issue Summary 2005-24 *'Control of Radiation Dose to Visitors of Hospital Patients'* provides guidance to licensees on methods that may be used to estimate and control radiation doses to visitors of hospitalized patients who have been administered radioactive material.

Item 9.21: Recordkeeping

Rule: ***DHS 157.31; DHS 157.06(1); DHS 157.13(18); DHS 157.71***

Criteria: Licensees must maintain records as provided in ***DHS 157.31***; ***DHS 157.06(1); DHS 157.13(18);*** and ***DHS 157.71.***

Discussion: The licensee must maintain certain records to comply with ***Chapter DHS 157***, the conditions of the license, and commitments made in the license application and correspondence with DHS. Operating procedures should identify which individuals in the organization are responsible for maintaining which records.

A table of recordkeeping requirements appears in **Appendix Y**.

Response from Applicant: No response required.

Item 9.22: Reporting

Rule: ***DHS 157.32; DHS 157.13(17); DHS 157.72***

Criteria: Licensees are required to report to DHS via telephone, written report, or both, in the event that the safety or security of radioactive material may be compromised. The specific events that require reporting are explained in ***DHS 157.72, DHS 157.32***; and in ***DHS 157.13(17)***. The timing and type of report are specified within these parts. Licensees are also required in ***DHS 157.72(1)*** and ***DHS 157.72(2)*** to report information to referring physicians and certain individuals. They are also required under ***DHS 157.72(4)*** to report to generator distributors that an eluate exceeded the permissible concentration listed in ***DHS 157.63(3)*** at the time of generator elution.

Discussion: DHS requires licensees to report incidents that might compromise the health and safety of patients, health care providers, or the public. Therefore ***Chapter DHS 157, Subchapter II, Subchapter III,*** and ***Subchapter VI*** include provisions that describe reporting requirements associated with the medical use of radioactive material.

A table of reporting requirements appears in **Appendix Z**.

Response from Applicant: No response required.

Item 10: Waste Management

Rule: ***DHS 157.21; DHS 157.23(1); DHS 157.25(1); DHS 157.29(4); DHS 157.30(1-7); DHS 157.31(2) & (3); DHS 157.31(8) & (9); DHS 157.13(2)(b); DHS 157.13(15); DHS 157.06(1); DHS 157.13(18); DHS 157.11(2)(f); DHS 157.61(3); DHS 157.62(10); DHS 157.71(13); DHS 157.92(3)***

Criteria: Radioactive materials must be disposed of in accordance with DHS requirements by:

- Transfer to an authorized recipient;
- Decay-in-storage;
- Release in effluents within the limits in ***DHS 157.23(1)***; or
- As authorized under ***DHS 157.30(2)*** through ***DHS 157.30(5)***.

Appropriate records must be maintained.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with ***DHS 157.21*** must include provisions for waste disposal of radioactive material. **Appendix X** contains model procedures for decay-in-storage,return of radioactive material to authorized recipients, and disposal of liquids into sanitary sewer.

All radioactive waste must be stored in appropriate containers until its disposal, and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. The NRC requires medical licensees to dispose of radioactive waste generated at their facilities in accordance with regulations in ***DHS 157.30*** and ***DHS 157.62(10)***. Generally, medical licensees dispose of radioactive waste by decay-in-storage or transfer to an authorized recipient.

Decay-in-storage: Materials with half-lives of less than or equal to 120 days are appropriate for DIS and interim storage. The holding time of the waste should be based on the radionuclide(s), half-life, and the activity present when the waste was placed into storage. Such waste may be disposed of as in-house trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without any interposed shielding. In accordance with ***DHS 157.29(4)(b)***, all radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released in accordance with ***DHS 157.62(10)***. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed. Applicants must maintain accurate records of such disposals.

Except for material suitable for decay-in-storage and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with ***DHS 157.30(1)(b)*** and ***DHS 157.30(6)***, or in applicable regulations in ***DHS 157.02*** or ***10 CFR 61.3***. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.

When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location and appropriately posted in accordance with ***DHS 157.29(2)***. In addition, all storage containers must be appropriately labeled in accordance with ***DHS 157.29(4)***.

Note: Some short half-life radionuclide products (e.g., samarium-153, Tc-99m/Mo-99 generator columns and Y-90 microspheres) may contain long half-life contaminants that may preclude disposal by decay-in-storage. Long-lived contaminants need not be listed on an NRC license; however, licensees need to perform surveys and dispose of the material in accordance with ***Chapter DHS 157, Subchapter III*** and ***Subchapter VI*** requirements. Licensees using Y-90 microspheres should review NRC Information Notice 2007-10, "Yttrium-90 Theraspheres® and Sirspheres® Impurities," for guidance.

Transfer to an Authorized Recipient: Licensees may transfer radioactive waste to an authorized recipient for disposal. Check and calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153) may not be held for DIS and must be disposed of in accordance with ***DHS 157.30***. It has been DHS's experience that most medical licensees only dispose of radioactive waste with half-lives greater than 120 days by transfer to authorized recipients (e.g., low-level radioactive waste disposal facilities or manufacturers). Because of the difficulties and costs associated with disposal of sealed sources, licensees should preplan the disposal. Licensees may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Before transferring radioactive material, a licensee must verify that the recipient is authorized to receive the material using one of the methods described in ***DHS 157.13(15)***. Records of the transfer must be maintained as required by ***DHS 157.13(17)***.

Licensees should promptly dispose of unused sealed sources to minimize potential problems such as access by unauthorized individuals, use for inappropriate purposes, and improper disposal. **Other Waste Management Issues:**

- Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under ***DHS 157.23(2)*** and ***DHS 157.30(3)***, respectively.
  - Requirements for disposal in the sanitary sewer appear in ***DHS 157.30(3)***. Material must be readily soluble or dispersible in the water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. (Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations; see ***DHS 157.30(3)***). Make a record of the disposal in accordance with ***DHS 157.31(9)***.
  - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in **Table II of Chapter DHS 157, Appendix E**. These limits apply at the boundary of the restricted area. Make a record of the release in accordance with ***DHS 157.31(3)*** and ***DHS 157.31(8)***.
  - Liquid scintillation-counting media containing up to 1.85 kBq (0.05 µCi) of H-3, I-125 or C-14 per gram of medium used may be disposed of without regard to its radioactivity (***DHS 157.30(5)***). Make a record of the disposal in accordance with ***DHS 157.31(9)***.
- Waste from *in vitro* kits (except mock iodine-125) that are generally licensed under ***DHS 157.11(2)(f)*** is exempt from waste disposal requirements in ***Chapter DHS 157, Subchapter III***, as set forth in ***DHS 157.11(2)(f)***. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.
- If applicants propose to treat or dispose of radioactive material by incineration, they must receive specific approval from DHS. Contact DHS for guidance on treatment or disposal of material by incineration.

- Applicants who wish to use waste volume reduction operations (e.g., compactors) must provide a detailed description (as outlined below), along with their response to **Item 8.1** *'Facilities Diagram'*:
  - Describe the compactor to demonstrate that it is designed to safely compact the waste generated during licensed operations
  - Provide manufacturer's specifications, annotated sketches, photographs, and other information about the compactor design;
  - Describe the types, quantities, and concentrations of the waste to be compacted;
  - Provide an analysis of the potential for airborne release of radioactive material during compaction activities;
  - Provide the location of the compactor(s) in the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors, and procedures for monitoring filter blockage and exchange;
  - Discuss the methods used to monitor worker breathing zones and/or exhaust systems;
  - Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area;
  - Discuss the instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

Response from Applicant:

- Commit to follow the waste procedures published in Appendix X of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

OR

- Submit procedures for waste collection, storage and disposal by any of the authorized methods described in Item 10 'Waste Management' of WISREG "Guidance for Medical Use of Radioactive Material" Revision 3.

Notes:

- Contact DHS to obtain approval of any method(s) of waste disposal other than those discussed in Item 10 'Waste Management' of WISREG "Guidance for Medical Use of Radioactive Material."
- NRC Information Notices can be accessed at the NRC's website www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/index.html.

Item 11: License Fees

On Form F-45008 *'Application for Radioactive Material for Medical Use*', enter the fee category and the amount for a new application. There is no fee for license renewals. Direct all questions about fees to the Radioactive Materials Program general email box, DHSRadioactiveMaterials@dhs.wisconsin.gov.

Timely Submittals of Amendments and Renewals

Rule: ***DHS 157.13(5)(c)***

Criteria: It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is no in effect until the amendment has been issued. Also, to continue the license after its expiration date, the license must submit an application for a license renewal at least 30 days before the expiration date.

Discussion: In accordance with ***DHS 157.13(5)(b)*** a licensee is required to apply for and receive a license amendment before several activities can occur, including:

- receiving or using byproduct material for a type of use permitted by ***Chapter DHS 157 Subchapter VI***, but not authorized on the licensee's current license;
- permitting anyone to work as an authorized user (AU) for medical uses, authorized medical physicist (AMP), ophthalmic physicist, or authorized nuclear pharmacist (ANP), unless the individual meets one of the exceptions listed in ***DHS 157.13(5)(b)1.d.***;
- changing the RSO;
- permitting an individual to work as an ARSO or before the RSO assigns a current ARSO duties and tasks in the oversight for a new section of the radiation protection program;
- receiving byproduct material in excess of the authorized quantity, or receiving radionuclides or forms different than currently authorized by the NRC license;
- receiving a sealed source from a different manufacturer or of a different model number than authorized by the license unless the sealed source is used in manual brachytherapy, is listed in the SSD registry, for the quantity and for an isotope authorized by the license;
- changing an area or address of use identified in the application or on the license; includes additions and relocations, unless exempt (e.g., for certain ***DHS 157.63*** and ***DHS 157.64*** areas of use at previously authorized addresses); and
- revising procedures required by ***DHS 157.67(4), DHS 157.67(10), DHS 157.67(11)***, and ***DHS 157.67(12)***, when the revision reduces the level of radiation safety.

A licensee requesting a license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request;
- Submit either a DHS Form F45008 or a letter requesting an amendment or renewal; and
- For renewals, provide a complete and up-to-date application, including all required program elements outlined in this WISREG. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application as long as the material and uses for each individual are the same as currently authorized on the license.

Timely Notification of Transfer of Control

Rule: ***DHS 157.13(5)(c)***

Criteria: Licensees must provide full information and obtain DHS's written consent before transferring control of the license, or, as some licensees refer to the process, "transferring the license."

Discussion: Control may be transferred as a result of mergers, buyouts, or majority stock transfers. Although it is not DHS's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain DHS written consent before transferring control of the license. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid DHS licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the material; and
- Public health and safety are not compromised by the use of such materials.

As provided in ***DHS 157.13(5)(c)2,*** if the licensee's name or mailing address changes, and the name change does not constitute a transfer of control of the license as described in ***DHS 157.13(5)(c)2,*** a licensee must file a written notification with DHS no later than 30 days after the dates of the change(s). Otherwise, DHS's written consent must be given prior to the transfer.

Appendix D identifies the information to be provided about transferring control of a license.

Reference: NRC's Regulatory Issue Summary Regulatory Issue Summary (RIS) 2014-08, Rev. 1 "*Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses,*" dated May 5, 2016

Timely Notification of Bankruptcy Proceedings

Rule: ***DHS 157.13(10)***

Criteria: ***DHS 157.13(10)(e)*** states: "A licensee shall notify DHS in writing within 10 days of the filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, identifying the bankruptcy court in which the petition was filed and the date of filing".

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for compliance with all regulatory requirements. DHS needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). DHS shares the results of its determinations with other entities involved (e.g., trustees) so that health and safety issues can be resolved before bankruptcy actions are completed.
Licensees must notify DHS within 10 days of the filing of a bankruptcy petition.

Reference: NRC's NUREG–1556, Volume 1*5, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses."*

Disposition of Material and Termination of License

Rule: *DHS 157.33(1); DHS 157.33(2); DHS 157.33(3); DHS 157.33(4); DHS 157.13(2)(b); DHS 157.13(5)(c)2.; DHS 157.15; DHS 157.13(11); DHS 157.06(1); DHS 157.13(18); DHS 157.13(11)(d)*

Criteria: Pursuant to the rule requirements described above, the licensee shall do the following:

- Notify DHS, in writing, within 30 days of:
  - Decision to permanently discontinue all activities involving materials authorized under the license;
- Notify DHS, in writing, within 60 days of:
  - The expiration of its license;
  - A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to DHS requirements;
  - No principal activities have been conducted at the entire site under the license for a period of 24 months; and
  - No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to DHS requirements;
- Submit a decommissioning plan, if required by ***DHS 157.13(11)(f)***;
- Conduct decommissioning, a required by ***DHS 157.13(11)(j)*** and ***DHS 157.13(11)(L)***;
- Submit to DHS, a completed Form F-45007 '*Certificate of Disposition of Materials'* and demonstrate that the premises are suitable for release for unrestricted use (e.g., results of final survey); and
- Before a license is terminated, send the records important to decommissioning to DHS. If licensed activities are transferred or assigned in accordance with ***DHS 157.13(5)(c) 2***, transfer records important to decommissioning to the new licensee.

Discussion: Useful guidance and other aids related to decommissioning are:

- NUREG-1757, Volume 2, Revision 2, '*Consolidated NMSS Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria,*' dated July 2022, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses.
- NUREG-1757, Volume 2, includes a table (Table H.1) of acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination. NUREG-1757, Volume 2, also contains methods for conducting site-specific dose assessment for facilities with contamination levels above those in the table.
- *'Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)'* Revision 1, dated August 2000, should be reviewed by licensees who have large facilities to decommission.
- An acceptable computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is D and D, Version 2.1.0, (McFadden and others, 2001).

Note: The licensee's obligations are to undertake the necessary decommissioning activities, to submit Form F-45007 *'Certificate of Disposition of Materials' (*Appendix C), and to perform any other actions as summarized in the 'Criteria.'

References:

- A copy of Form F-45007, *'Certificate of Disposition of Materials'* is located in Appendix C and also on the DHS website *Certificate of Disposition of Materials | Wisconsin Department of Health Services*.
- McFadden, K., D.A. Brosseau, W.A. Beyeler, and C.D. Updegraff, 'Residual Radioactive Contamination from Decommissioning - User's Manual D and D Version 2.1,' NUREG/CR-5512, Volume 2, U.S. Nuclear Regulatory Commission, Washington, D.C., April 2001.

Appendix A

Form F-45008
‘*Application for Radioactive Material License for Medical Use*’

To access Form F-45008 *'Application for Radioactive Material License for Medical Use'*, visit the Department's website at: http://dhs.wisconsin.gov/forms/F4/F45008.pdf

A form-fillable version of this document may be accessed from the Department's website at https://www.dhs.wisconsin.gov/radiation/radioactivematerials/medicaluse.htm

If you need assistance locating or completing the form, contact the Radiation Protection Section by telephone at 608-267-4797 or email DHSRadioactiveMaterials@dhs.wisconsin.gov.

Appendix B

Forms F-45010A-F-45010G
‘*Training, Experience and Preceptor Attestation’*

To access Forms F-45010A through F-45010G *'Training, Experience and Preceptor Attestation'*, visit the Department's website at:

F-45010A (Radiation Safety Officer): http://dhs.wisconsin.gov/forms/F4/F45010A.pdf

F-45010B (Authorized User, No Written Directives): http://dhs.wisconsin.gov/forms/F4/F45010B.pdf

F-45010C (Authorized User, Written Directives Required): http://dhs.wisconsin.gov/forms/F4/F45010C.pdf

F-45010D (Authorized User, Manual Brachytherapy): http://dhs.wisconsin.gov/forms/F4/F45010D.pdf

F-45010E (Authorized User, Remote Afterloader, Gamma Knife, or Teletherapy): http://dhs.wisconsin.gov/forms/F4/F45010E.pdf

F-45010F (Authorized Nuclear Pharmacist): http://dhs.wisconsin.gov/forms/F4/F45010F.pdf

F-45010G (Authorized Medical Physicist): http://dhs.wisconsin.gov/forms/F4/F45010G.pdf

Form-fillable versions of these documents may be accessed from the Department's website at https://www.dhs.wisconsin.gov/radiation/radioactivematerials/medicaluse.htm

If you need assistance locating or completing the forms, contact the Radiation Protection Section by telephone at 608-267-4797 or email DHSRadioactiveMaterials@dhs.wisconsin.gov..

Appendix C

Form F-45007
'Certificate of Disposition Materials'

To access Form F-45007 *'Certificate of Disposition of Materials*, visit the Department's website at: http://dhs.wisconsin.gov/forms/F4/F45007.pdf

A form-fillable version of this document may be accessed from the Department's website at https://www.dhs.wisconsin.gov/radiation/radioactivematerials/medicaluse.htm

If you need assistance locating or completing the form, contact the Radiation Protection Section by telephone at 608-267-4797 or email DHSRadioactiveMaterials@dhs.wisconsin.gov.

Appendix D

Information Needed for Transfer of Control

Definitions

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of a DHS-licensed operation.

Transferor: A transferor is a DHS licensee selling or otherwise giving up control of a licensed operation.

Discussion: Licensees must provide full information and obtain DHS's *prior written consent* before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact whom DHS may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to DHS, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Appendix C of NUREG-1556, Vol. 15 "*Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses"* contains examples of changes of control which may be useful to licensees in determining whether structural organizational changes constitute a transfer of control. Licensees may also refer to NRC Information Notice 89-25, Revision 1, *"Unauthorized Transfer of Ownership or Control of Licensed Activities."*

Appendix E

Reserved

Appendix F

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with DHS and DOT regulations and the conditions of the license. Typically, these duties and responsibilities include the following:

- Stopping unsafe activities involving licensed material;
- Ensuring that radiation exposures are kept ALARA;
- Overseeing all activities involving radioactive material, including monitoring and surveying all areas in which radioactive material is used or stored;
- Developing, implementing, maintaining, and distributing up-to-date operating, emergency, and security procedures;
- Ensuring that possession, use, and storage of licensed material is consistent with the limitations in the license, the rule, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;
- Ensuring individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by a DHS, NRC or another Agreement State license;
- Ensuring personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Maintaining documentation to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- Ensuring personnel monitoring devices are used by appropriate individuals and exchanged at the proper intervals. Monitoring, reviewing, and maintaining personnel radiation exposure and bioassay records. Notifying individuals when radiation exposures are approaching established limits and appropriate corrective actions are taken;
- Properly security licensed material from unauthorized use or access;
- Ensuring documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Notifying proper authorities of incidents such as loss or theft of licensed material, fire, damage to or malfunction of sealed sources, and excess breakthrough values for radionuclide generators;
- Serving as a point of contact for DHS and licensee management during routine operations, emergencies, or incidents;
- Investigating and reporting medical events and precursor events to DHS, identify cause(s) and appropriate corrective action(s), and ensuring timely corrective action(s) are taken;
- Ensuring that the results of audits, identification of deficiencies, and recommendations for change are documented and provided to management for review; ensuring that prompt action is taken to correct deficiencies;
- When violations of the rule, license conditions, or program weaknesses are identified, ensuring that effective corrective actions are developed, implemented, and documented;
- Ensuring that licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;

- Ensuring that radioactive waste is disposed of in accordance with DHS regulations and license conditions. Supervising and coordinating the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records. Overseeing the storage of radioactive material not in current use, including waste;
- Overseeing the inventory and leak testing on all sealed sources;
- Supervising decontamination operations;
- Maintaining up-to-date copies of DHS regulations, the license, revised licensee procedures, and ensuring that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to DHS during the licensing process; and
- Submitting amendment and renewal requests in a timely manner.

Sample Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe and secure use of radiation and radioactive material. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the rule. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Department of Health Services at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____
Signature of Management Representative

I accept the above responsibilities,

_____
Signature of Radiation Safety Officer

cc: Affected department heads.

Sample Correspondence Delegation

[*date*]

Department of Health Services
Radiation Protection Section
P.O. Box 2659
Madison, WI 53701-2659

To Radioactive Material Program Supervisor:

As [*job title*] of [*name of licensee*], I have delegated authority for all matters pertaining to our Radioactive Material License to [*name of designee*]. [*Name of designee*] has management approval to sign and submit amendment requests to the Department of Health Services on behalf of [*name of licensee*]. I understand that license renewals must still be signed by a representative of upper management.

[This document must be signed by a management representative who has independent authority to reassign job duties and provide finances, if necessary, to support an effective radiation safety program.]

_____ _____ _____

Signature Title Date

_____

Print Name

Appendix G

Documentation of Training and Experience for Authorized User (AU), Radiation Safety Officer (RSO), Associate Radiation Safety Officer (ARSO), Authorized Nuclear Pharmacist (ANP), or Authorized Medical Physicist (AMP)

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, Radiation Safety Officer, or Associate Radiation Safety Officer

An applicant or licensee that is adding an experienced authorized user, authorized medical physicist, authorized nuclear pharmacist, radiation safety officer, or associate radiation safety officer to its medical use license needs to provide evidence that the individual is listed on: a) a medical use license issued by DHS, NRC or another Agreement State, b) a permit issued by a NRC master material licensee, c) a permit issued by a DHS, NRC or another Agreement State medical broad scope licensee, or d) a permit issued by a NRC master material broad scope permittee before October 25, 2005. The individual must be authorized for the same types of use(s) requested in the application under review and meet the recentness of training criteria described in ***DHS 157.61(11)***.

When adding an experienced ANP to the license, the applicant may also provide evidence that the individual is listed on: a) an NRC or Agreement State commercial nuclear pharmacy license or b) identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad scope license, or master materials license medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. New Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist, Radiation Safety Officer, or Associate Radiation Safety Officer Recognition by DHS.

Applicants should complete the appropriate form to document that the individuals meet the appropriate training and experience criteria in ***DHS 157.61, 157.63, 157.64, 157.65, 157.66, 157.67,*** or ***157.70***. Forms are available for the following:

Radiation Safety Officer or Associate Radiation Safety Officer	Form F-45010A
Authorized User for DHS 157.63(1)&(2)	Form F-45010B
Authorized User for DHS 157.64(1)	Form F-45010C
Authorized User for DHS 157.65(1)	Form F-45010D
Authorized User for DHS 157.67(1)	Form F-45010E
Authorized User for DHS 157.70	Consult the NRC Medical Licensee Toolkit for current training requirements for new technologies
Authorized Nuclear Pharmacist	Form F-45010F
Authorized Medical Physicist	Form F-45010G

Forms are available on the Department's website located at http://dhs.wisconsin.gov/dph_beh/RadioactiveMat/Index.htm. The NRC Medical Licensee Toolkit may be accessed at http://www.nrc.gov/materials/miau/med-use-toolkit.html.

There are two different training and experience routes recognized to qualify an individual as an AU, AMP, ANP, RSO, or ARSO. The first route is by means of certification by a professional board recognized by DHS and meeting preceptor attestation requirements. The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements. Training and experience requirements are found in ***DHS 157.61(7), DHS 157.61(8), DHS 157.61(9); DHS 157.63(4), DHS 157.63(5), DHS 157.64(4), DHS 157.64(5), DHS 157.64(6), DHS 157.64(7), DHS 157.65(8), DHS 157.66(2)*** and ***DHS 157.67(17).***

The following chart summarizes the training and experience requirements for applicants who are not previously listed on a Department, NRC, or another Agreement State radioactive materials license and who are not using board certification to meet DHS training requirements for the medical use of radioactive material.

Authorization Sought (Authorized Users)	Training and Experience Requirements			Case Studies / Clinical Experience	Preceptor Attestation
	Total Hours	Classroom and Laboratory	Work Experience		
DHS 157.63(1)	60 hours	at least 8 hours			required
DHS 157.63(2)	700 hours	at least 80 hours			required
DHS 157.64(1)	700 hours	at least 200 hours		clinical case studies as listed in DHS 157.64(4)(b)2.g.	required
• DHS 157.64(1), only sodium iodide I-131 ≤ 33 millicuries		80 hours		3 clinical case studies	required
• DHS 157.64(1), only sodium iodide I-131 > 33 millicuries		80 hours		3 clinical case studies	required
• DHS 157.64(1), limited to parenteral administration only		80 hours		3 clinical case studies	required
DHS 157.65(1)		200 hours	500 hours	3 years of supervised clinical experience in radiation oncology	required
• DHS 157.65(1), limited to Sr-90 for ophthalmic use		24 hours		5 clinical case studies	required
DHS 157.66(1)		8 hours			not required
DHS 157.67(1)		200 hours	500 hours	3 years of supervised clinical experience in radiation therapy	required

Authorization Sought	Training and Experience Requirements			Preceptor Attestation
	Total Hours	Classroom and Laboratory	Work Experience	
ANP (DHS 157.62(9))	700 hours	200 hours		required

RSO* (DHS 157.62(7))		200 hours	1 year	required
AMP (DHS 157.62(8))	M.S. or Ph.D. in appropriate discipline and 1 year full-time formal training and 1 year full-time work experience			required

*An AU, AMP, or ANP who seeks to be named as RSO on a medical license must document experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities. The duration of the training is not specified by regulation.

III. Recentness of Training

The required training and experience described in ***Chapter DHS 157, Subchapter VI*** must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use;
- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization;
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization; and
- For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

IV. Instructions and guidance for filling out Training, Experience and Preceptor Attestation Form.

It is the licensee's responsibility to verify the completeness and accuracy of the information provided by individuals seeking authorization for medical use. Licensees must take reasonable steps to ensure that information provided to the Department is complete and accurate in all material aspects. See NRC IN 2007-38 *'Ensuring Complete and Accurate Information in the Documentation of Training and Experience for Individuals Seeking Approval as Medical Authorized Users.'*

Note: Individuals who have been certified by boards recognized by the DHS need only complete the sections entitled 'Name of Individual', 'State licensure' (physicians and pharmacists only), and 'Certification'. Information for all other individuals to be listed on the license as an AU, AMP, ANP or RSO must be provided in the remaining sections of the applicable training and experience form.

Part I. Training and Experience

Provide information for each individual for whom authorization is sought. Authorized Medical Physicists should specify the type of authorization being requested.

Name of individual

Provide the individual's complete name so that DHS can distinguish the training and experience received from that received by others with a similar name. Do not include personal or private information (e.g., date of birth, social security number) as part of your qualification documentation.

State licensure

DHS requires physicians and pharmacists to be licensed by the state of Wisconsin to prescribe drugs in the practice of medicine or of pharmacy, respectively (see ***DHS 157.03*** '**Definitions**'). For AUs, attach a copy of the license to practice medicine in the state of Wisconsin. For ANPs, attach a copy of the license to practice pharmacy in the state of Wisconsin.

Certification

The applicant should provide the complete name of the specialty board and the category (or subspecialty) if the board recognizes more than one certification specialty. The month and year certified is used to establish recentness of training, to confirm that DHS recognizes that board's certifications, and to verify that the applicant meets the training requirements. The applicant should also provide a copy of the board certification. Board certifications which are accepted by DHS are listed on NRC's website at http://www.nrc.gov. Board-certified applicants do not need to submit the preceptor attestation in Part II of the appropriate training and experience form.

Medical Physicist – Formal Training

This section is used to document that the medical physicist has received one full year of full-time training and one full year of work experience. Both years are required to be under the supervision of an authorized medical physicist but they do not have to be under the same authorized medical physicist.

Classroom and Laboratory Training, Supervised Work Experience, and Supervised Clinical Experience

Because the applicant is not required to receive the classroom and laboratory training at one location or at one time, space is provided to identify each location and date of training. The clock hours must be indicated for those individuals that must meet a minimum number of training and work experience hours. The specific number of hours needed for each training element will depend upon the type of approval sought. Medical physicist applicants are not required to specify the type of classroom and laboratory training they received, but they must document completion of one year of full-time training in medical physics.

All applicants will complete "Supervised Work Experience," and most individuals (e.g., under ***DHS 157.64; DHS 157.65(9))*** are required to have specific clinical case experience and will complete "Supervised Clinical Experience". Applicants should list radionuclide and treatment method for each type of clinical case in which they participate. A Radiation Safety Officer who is using the training and experience route must document one full year of work experience.

Note: Classroom and Laboratory Training may be provided at medical teaching or university institutions. In some cases, a course may be provided for that particular need and taught in consecutive days; in others, the period may be a semester or quarter as part of the formal curriculum. The required "structural educational programs" or "training" may be obtained in any number of settings, locations, and educational situations. If the applicant is seeking authorization under the requirements of ***DHS 157.61, 157.63, 157.64, 157.65, or 157.67***, applicants must submit a written attestation signed by a preceptor. The preceptor is responsible for the initial determination of the adequacy of the training (and work experience) to permit the individual to function independently.

Supervising Individual

Applicants should identify the individual who supervised their work experience and/or clinical case studies. If the individual had more than one supervisor, the names of all supervising individuals must be listed.

A supervisor that is authorized for the same uses as the applicant is seeking provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of radioactive material. Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice. However, work experience for sealed source therapy, as described in ***DHS 157.65(8)(b)2., DHS 157.65(9)(b)*** and ***DHS 157.67(17)(b)2.*** must have been gained at a medical institution. When the supervised work experience is complete, the applicant should provide documentation of it and written attestation from the preceptor using the appropriate training and experience form that indicates that the applicant has obtained all required experience elements.

Note: The ANP applicant is required to have supervised practical experience in a nuclear pharmacy but the individual(s) providing the supervision are not specified. Therefore, the ANP applicant does not need to identify a supervising individual.

Part II Preceptor Attestation

DHS defines the term "preceptor" in ***DHS 157.03,*** '*Definitions,'* to mean "an individual who provides, directs or verifies training and experience requirements" for an individual to become an AU, AMP, ANP or RSO. While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an AU, AMP, ANP or RSO (pursuant to ***DHS 157.61, 157.62, 157.63, 157.64, 157.65, or 157.67***) and attest that the individual has satisfactorily completed the appropriate training and experience criteria and has achieved a level of competence or a level of radiation safety knowledge sufficient to function independently. The preceptor attests that that they are an Authorized Nuclear Pharmacist or Radiation Safety Officer or meets the requirements to be a preceptor AU or AMP. The preceptor shall sign the attestation.
Note: ***DHS 157.66***, '*Sealed Sources for Diagnosis*' does not require a preceptor statement.

Appendix H

Training Programs

Procedures for describing the training programs appear below. These procedures include examples of training topics, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and the background knowledge of the audience. These procedures also may be used to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these procedures or develop an alternative program to meet DHS requirements. Guidance on requirements for training and experience for AMPs and AUs who engage in certain specialized practices is also included.

Training Program for Medical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the date of the instruction or training, a brief outline of subjects covered, and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Who Use of Radioactive Material

Training for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures (e.g., AU, AMP, ANP, RSO, nurse, dosimetrist, technologist, therapist) may contain the following elements, commensurate with their duties:

- Basic radiation biology, e.g., interaction of ionizing radiation with cells and tissues [***DHS 157.88(2)***];
- Basic radiation protection to include concepts of time, distance, and shielding [***DHS 157.88(2)***];
- Concept of maintaining exposure ALARA [***DHS 157.88(2), DHS 157.21***];
- Risk estimates, including comparison with other health risks [***DHS 157.88(2)***];
- Posting requirements [***DHS 157.22(2)***];
- Proper use of personnel dosimetry (when applicable) [***DHS 157.22(1)***];
- Access control procedures [***DHS 157.26(1), DHS 157.28(1)(b)***];
- Proper use of radiation shielding, if used [***DHS 157.88(2)***];
- Patient release procedures [***DHS 157.62(8)***];
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care [***DHS 157.88(2), DHS 157.64(2), DHS 157.65(4), DHS 157.67(4)***];
- Occupational dose limits and their significance [***DHS 157.22(1)***];
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy [***DHS 157.22(8)***];
- Worker's right to be informed of occupational radiation exposure [***DHS 157.88(3)***];

- Each individual's obligation to report unsafe conditions to the RSO [***DHS 157.88(2)***];
- Applicable regulations, license conditions, information notices, bulletins, etc. [***DHS 157.88(2)***];
- Where copies of the applicable rules, the DHS license, and its application are posted or made available for examination [***DHS 157.88(1)***];
- Proper recordkeeping required by DHS rules [***DHS 157.88(2)***, ***DHS 157.61(3)***];
- Appropriate surveys to be conducted, including surveys of all material leaving radioactive material areas [***DHS 157.25(1)***];
- Proper use of required survey instruments [***DHS 157.25(1)***];
- Emergency procedures [***DHS 157.88(2)***];
- Decontamination and release of facilities and equipment [***DHS 157.13(2)(b)***, ***DHS 157.13(11)***];
- Dose to individual members of the public [***DHS 157.23(1)***];
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing); and
- Hazardous materials (HAZMAT) training for preparing shipments of radioactive material (49 CFR Part 172).

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Therapeutic Quantities of Radioactive Material (including greater than 30 microcuries of I-131), or Therapeutic Treatment Planning

In addition to the topics identified above, the following topics must be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist), as applicable, commensurate with their duties:

- Leak testing of sealed sources [***DHS 157.62(5)***];
- Emergency procedures (including emergency response drills) [***DHS 157.64(2)***, ***DHS 157.65(4), DHS 157.67(4)***];
- Operating instructions [***DHS 157.61(3), DHS 157.67(4)***];
- Computerized treatment planning system [***DHS 157.67(16)***];
- Dosimetry protocol [***DHS 157.67(4)***];
- Detailed pretreatment quality assurance checks [***DHS 157.61(3), DHS 157.67(4)***];
- Safe handling of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources [***DHS 157.64(2), DHS 157.65(4)***];
- Patient control procedures [***DHS 157.64(2), DHS 157.65(4), DHS 157.67(4)***];
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) [***DHS 157.64(2), DHS 157.65(4), DHS 157.67(4)***];
- Licensee's written directive procedures, to ensure that each administration is in accordance with the written directive, patient identity is verified, and where applicable, attention is paid to correct positioning of sources, applicators, and collimators to ensure that treatment is to the correct site [***DHS 157.61(5)***];
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) [***DHS 157.65(4), DHS 157.67(4)***];

- Size and appearance of different types of sources and applicators [***DHS 157.65(4), DHS 157.67(4)***];
- Previous incidents, events, and/or accidents [***DHS 157.64(2), DHS 157.65(4), DHS 157.67(4)***]; and
- Licensee operational radiation safety training (to new staff and annually to all individuals operating the unit) that is device model-specific and includes [***DHS 157.67(4), DHS 157.70***]:
  - Vendor training (prior to first use of a new unit or after manufacturer upgrades that affect operation and safety of the unit)
  - Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;
  - Hands-on training in actual operation of the device under the direct supervision of an experienced user including "dry runs" (using dummy sources) of routine patient set-up and treatment and implementation of the licensee's emergency procedures;
  - A method of determining each trainee's competency to use the device for each type of proposed use, such as practical examinations.

Additional Training for Authorized Medical Physicists

Applicants for licenses to include AMPs who plan to engage in certain tasks requiring special training should address the sections of ***Chapter DHS 157, Subchapter VI*** listed in ***DHS 157.61(8)(b)1.*** Note that additional training requirements apply to AMP planning tasks such as remote afterloader therapy, gamma stereotactic radiosurgery therapy and the use of the relevant treatment planning system(s). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in ***DHS 157.61(8).***

Additional Training for Therapy Authorized Users

Applicants for licenses should carefully consider the type of radiation therapy that is being considered. In addition to the training and experience requirements of ***DHS 157.64(4), DHS 157.64(6), DHS 157.65(8), DHS 157.65(9), DHS 157.67(17),*** and ***DHS 157.70***, attention should be focused on the additional training and experience required for treatment planning, quality control systems, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in ***DHS 157.64(4), DHS 157.65(8), DHS 157.67(17),*** and ***DHS 157.70***.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and housekeeping duties, dietary, laboratory, security and life-safety services. The training program for ancillary staff who perform duties that are likely to result in a dose in excess of 1 mSv (100 mrem) will include instruction commensurate with potential radiological health protection problems present in the workplace. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. Topics of instruction should include the following:

- Storage, transfer, or use of radiation and/or radioactive material [***DHS 157.88(2)***];

- Potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) [***DHS 157.88(2)***];
- The applicable provisions of **Chapter DHS 157** and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) [***DHS 157.88(2)***];
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of **Chapter DHS 157** and licenses or unnecessary exposure to radiation or radioactive material (e.g., notification of the RSO regarding radiation protection issues) [***DHS 157.88(2)***];
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material [***DHS 157.88(2)***]; and
- Radiation exposure reports that workers may request [***DHS 157.88(3)***].

Appendix I

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Model procedures for describing the specifications for monitoring instruments and a program for calibration of survey instruments appear below. Applicants may either adopt these model procedures or adopt alternative procedures.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present; and
- Individuals conducting calibrations will wear assigned dosimetry, if required.

Equipment Selection

Licensees should possess and use calibrated and operable radiation detection and measurement instruments that are sufficiently sensitive to detect and measure the type and energy of the radiation used. Applicants should determine the number and type of instruments necessary to support licensed activities by considering the scope of activities that will be performed at their facilities. Licensees typically possess one or more portable or handheld instruments to monitor radiological conditions, detect contamination, and perform package preparation and receipt surveys. Portable instrumentation includes ionization chambers as well as other instrumentation, such as count-rate meters that are supported by a variety of handheld probes or detectors that can be used to detect various types of radiation. These include Geiger-Mueller (GM) detectors, sodium iodide [NaI(Tl)] scintillation detectors, and plastic scintillation detectors. Additionally, licensees may possess stationary or fixed instrumentation, such as well type scintillation counters (LSCs), area monitors, stack monitors, or continuous air monitors.

When deciding which types of instruments are appropriate for the intended use, licensees may wish to consult with the instrumentation or equipment manufacturer or vendor to obtain specifications. The instrument should be capable of detecting the type of radiation (e.g., beta or gamma) and be sensitive to the energy or energy range of the radiation to be measured (e.g., keV, MeV). The characteristics of the instrument, including principles of operation and expected efficiency for the type and energy of the radiation being measured, should be understood by the licensee before use.

- Low-energy beta emitters are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2% for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys;
- Medium-to-high energy beta emitters, such as yttrium-90, can be detected with a pancake GM. The efficiency ranges from 15-40%, depending on beta energy;
- Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels; and

- Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.

The following table (except for items marked with a *), extracted from '*The Health Physics & Radiological Health Handbook*,' Revised Edition, 1992, may be helpful in selecting instruments:

Table 3: Typical Survey Instruments

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Meters	Gamma, X-ray	mR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate

Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Training

Before independently calibrating radiation survey instruments, an individual shall have sufficient training and experience to perform independent radiation survey instrument calibrations in accordance with ***DHS 157.62(2).***

Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and the use of radiation detection instruments
- Mathematics related to the use and measurement of radioactivity
- Biological effects of radiation

On-the-job training will be considered complete if the individual has completed both of the following:

- Observing authorized personnel performing radiation survey instrument calibration
- Conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations

Facilities and Equipment for Calibration of Dose and Dose Rate Measuring Instruments

To reduce doses received by individuals not calibrating radiation survey instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.

The calibration source should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.

The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use.

Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR 20, “Precautionary Procedures.”

Individuals conducting radiation survey instrument calibrations will wear assigned dosimetry.

Individuals conducting calibrations will use a calibrated and operable radiation survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Frequency of Calibration of Radiation Measurement Instruments and Equipment

A licensee committed to a routine or emergency radiation survey program should perform an acceptable calibration of all radiation measurement instruments and equipment at the frequency specified in U.S. Nuclear Regulatory Commission (NRC) regulations, annually, or at the frequency recommended by the manufacturer, whichever period is shorter.

Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a radiation measurement instrument have changed, by repair or alteration, or whenever system performance is observed to change significantly. (Battery changes are not considered as a repair or alteration.)

Routine maintenance of radiation measurement instruments should be performed as recommended by the manufacturer.

Primary or secondary standard instruments used to calibrate radiation measurement instruments should be inspected frequently for consistency of performance.

Calibration Sources for Dose and Dose Rate Measuring Instruments

Radiation survey instruments will be calibrated with a radioactive source in accordance with ***DHS 157.62(2)***. Electronic calibrations alone are not acceptable. Radioactive sealed sources will be used for calibrating dose and dose rate measuring radiation survey instruments; these sources will have the following characteristics:

- The sources should approximate a point source;
- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 microGray/h (µGy)/h [0.1 millirad (mrad)/h] and 10 percent for dose rates less than 1.0 µGy/h [0.1 mrad/h]; and
- The sources should contain a radionuclide that emits radiation of identical or similar type and energy [e.g., cesium-137 (Cs-137), cobalt-60] as the environment in which the calibrated device will be used. • The sources should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour [30 milliroentgen per hour] at 100 centimeters [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of cobalt-60].

Note: Inverse square and radioactive decay laws should be used to correct for changes in exposure rate due to changes in distance or source decay.

Calibration of Dose or Dose Rate Measuring Instruments

There are three kinds of scales frequently used on dose or dose-rate survey meters. These are calibrated as follows:

- **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, check the response of the instrument at approximately 20 percent and 80 percent of full scale. Instrument readings shall be within ± x (noted below) of the conventionally true value for the following ranges:
  - Background to 10 µGy/h [1.0 mrad/h]; ±x = ±30%
  - 10 µGy/h [1.0 mrad/h] to 1.0 milliGray (mGy)/h [100 mrad/h]; ±x = ±20%
  - 1.0 mGy/h [100 mrad/h] to 10 Gray/h [1,000 Rad/h]; ±x = ±10%
- **Logarithmic readout instruments**, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for linear readout instruments. K–5

- **Digital readout instruments** should be calibrated the same as linear readout instruments. Digital readout instruments without scale switching for indicating exposure rates shall be checked at two points on each decade.
- **Integrating instruments** shall be checked at two dose rates at approximately 20 percent and 80 percent of the stated dose rate range. Instrument readings shall be within the same ± x of the conventionally true value as described for linear readout instruments.

Note:

- Readings above 2.58 × 10−4 coulomb/kilogram/hour [1R/h] need not be calibrated, unless the licensee expects to make measurements at higher dose rates; regardless, such scales may be checked for operation and response to radiation.
- Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured.

Calibration of Surface Contamination Measurement Instruments

Instruments used to detect surface contamination usually consist of a count-rate meter and a detector that is appropriate for the type of radiation(s) being measured.

The efficiency of radiation survey meters must be determined by using radiation sources with similar energies and types of radiation that users of the radiation survey instrument intend to measure.

If each scale has a calibration potentiometer, the reading should be adjusted to respond to the calibration source at approximately 80 percent of full scale, and the response at approximately 20 percent of full scale should be observed. If only one calibration potentiometer is available, the response should be adjusted at mid-scale on one of the scales, and response on the other scales should be observed. The instrument efficiency factor [e.g., counts per minute (cpm)/disintegrations per minute (dpm)] thus obtained should have a signal-to-noise ratio, including the compilation of source and instrument uncertainties, of ±x for the following ranges:

- Alpha measurement
  0.01 Bq/cm^2 to 2.0 Bq/cm^2 [60 to 12,000 dpm/100 cm^2]; ±x = ±20%
  2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 dpm/100 cm^2]; ±x = ±10%

- Beta measurement
  0.05 Bq/cm^2 to 2.0 Bq/cm^2 [300 to 12,000 dpm/100 cm^2]; ±x = ±20%
  2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 dpm/100 cm^2]; ±x = ±10%

Calibration of Analytical Instruments Such as Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

Analytical instruments used to determine radioactivity in a sample may be specialized equipment according to the type of samples to be analyzed and the types and quantities of radioactivity to be measured. Typically, the sample sizes and activities are very small, and can be difficult to measure. Sample collection and preparation may differ for the various analytical K–6 instruments, so manufacturer procedures and industry standard practices should be followed. Such

analytical instruments should be calibrated in accordance with the manufacturer's instructions. Analytical instruments typically require routine maintenance and verification procedures to ensure that they are operating properly when used.

As with calibration of other radiation measurement instruments, calibration of analytical instruments use a radioactive sealed source(s). These should be suitable for the geometry of the sample(s) to be analyzed. The calibration source(s) should have a known activity(ies) and be of similar type and energy as the radioactive materials to be analyzed. The analysis should be sensitive enough to detect the lowest levels of radioactivity desired. Correction of results for quenching, self-absorption, and other factors may be required, depending on the analytical instrument, the samples type, and other environmental conditions.

Model procedures for the calibration of LSC, well-type LSC, gas-flow proportional counters, and single or multi-channel analyzers are not provided in this document. For compliance with ***DHS 157.25(1)(b)***, users should refer to manufacturers' instructions and/or nationally recognized standards for instrument calibration information. In general, manufacturers' instructions typically specify that for these types of instruments, calibration is expected to produce readings within plus or minus 20 percent of the actual values over the range of the instrument. The minimum detectable activity (MDA) for instruments used should be a fraction (10 to 50 percent) of the criteria that is to be met.

Calibration Records

A record must be made of each radiation survey instrument calibration and retained for 3 years after each record is made (***DHS 157.31(3)(a)*** and ***DHS 157.71(7)***).

Calibration records for all radiation survey instruments should indicate the procedure used and the results of the calibration. The records should include the following:

- the owner or user of the radiation survey instrument
- a description of the radiation survey instrument that includes the manufacturer's name, model number, serial number, and type of detector
- a description of the calibration source, including the exposure rate at a specified distance or activity on a specified date
- for each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the radiation survey instrument
- the efficiency of the radiation survey instrument, for each radionuclide the instrument will be used to measure (if efficiency is not calculated before each use) the exposure reading indicated with the radiation survey instrument in the "battery check" mode (if available on the instrument)
- for radiation survey instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular) K–7

- for radiation survey instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument
- for radiation detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure
- the exposure rate or count rate from a check source, if used • the name and signature of the individual who performed the calibration and the date on which the calibration was performed

The following information will be attached to the radiation survey instrument as a calibration sticker or tag:

- for dose and dose rate measuring instruments, the source radionuclide that was used to calibrate the instrument (with correction factors) for each scale
- for surface contamination measurement instruments, the efficiency of the radiation survey instrument, for each radionuclide the instrument will be used to measure (if efficiency is not calculated before each use)
- the proper deflection in the battery check mode, unless this is clearly indicated on the instrument
- special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated)
- for each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
- the date of calibration and the next calibration due date
- the apparent exposure rate or count rate from the check source, if used
- sensitivity of counting system

Follow the procedures in **Appendix Q** of this WISREG to determine MDA, if there is a question concerning the ability to measure small quantities of radioactivity.

Procedure for Calibrating Survey Instruments

This provides acceptable procedures for survey instrument calibrations. You may either adopt these model procedures or develop your own procedures to meet the requirements of ***DHS 157.21*** and ***DHS 157.62(2)***. (Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1997, *'Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.'* Copies may be obtained from the American National Standards Institute at 1430 Broadway, New York, NY 10018 or by ordering electronically from http://www.ansi.org.)

Procedures for calibration of survey instruments:

- Radiation survey instruments will be calibrated with a radioactive source in accordance with ***DHS 157.62(2)***. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually, before first use and after servicing or repairs that may affect calibration. Battery changes are not considered "servicing." Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured. An ideal calibration source

would emit the applicable radiation (e.g., alpha, beta, or gamma) with an energy spectrum similar to that to be measured and have a suitably long half-life.

- Use radioactive sealed source(s) that:
  - Approximates a point source;
  - Is certified, NIST-traceable, standard source that has an activity or exposure rate is accurate to within 5%; if the activity or exposure rate is determined by measurement, document the method used to make the determination and traceability to NIST;
  - Emit the type of radiation measured;
  - Approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed; and
  - Provide a radiation dose rate sufficient to reach the full scale (<1000 mR/hr) of the instrument calibrated.
- Use the inverse square and radioactive decay laws, as appropriate, to correct for changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made [***DHS 157.31(3)(a)*** and ***DHS 157.71(7)***].
- Before use, perform daily operational-calibration (with a dedicated check source) and battery checks.
- Instrument readings should be within ± 10% of known radiation values at calibration points; however, readings within ± 20% are acceptable if a calibration chart or graph is prepared and made available with the instrument.
- The kinds of scales frequently used on radiation survey meters are calibrated as follows:
  - Linear Readout Instruments must be calibrated at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20% and 80%).
  - Logarithmic Readout Instruments must be calibrated at one point (the midpoint) on each decade.
  - Digital Readout Instruments with either manual or automatic scale switching for indicating exposure rates must be calibrated at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20% and 80% of each scale).
  - Digital readout instruments without scale switching for indicating exposure rates must be calibrated at one point (the midpoint) on each decade.
  - Integrating instruments must be calibrated at two dose rates (at approximately 20% and 80% of the dose rate range).
- Readings above 1000 mR/hr need not be calibrated; however, such scales may be checked for operation and approximately correct response.
- Include in survey meter calibration records the procedure used and the data obtained. Record the following:
  - A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
  - A description of the NIST-traceable calibration source, including the calibration procedure, exposure rate, distance at which is was measured and date of measurement;

- For each calibration point, the calculated exposure rate, the indicated exposure rate, the calculated correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
- The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument);
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
- For instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
- The exposure rate from a check source, if used;
- The name of the person who performed the calibration and the date it was performed.

- The following information will be attached to the instrument as a calibration sticker or tag:
  - The source that was used to calibrate the instrument;
  - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
  - Special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated);
  - The date of calibration and the next calibration due date;
  - The apparent exposure rate from the check source, if used.

Determining the Efficiency of NaI(Tl) Uptake Probes

Sodium iodide (thallium doped) [NaI(Tl)] uptake probes are commonly used for bioassays of personnel administering I-131. Refer to **Chapter DHS 157, Appendix E** for the Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) for occupational exposure to radionuclides. Convert count rates (e.g., in cpm) to units of activity (dpm, µCi) when performing bioassays to determine thyroid burdens of radioiodine.

Use the following procedure to calibrate probe for uptake measurements:

- Frequency: perform calibrations annually, before first use and after repairs that affect calibrations.
- Check the instrument's counting efficiency using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example:

$$Eff_a = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{(\text{activity of std in microcurie})}$$

Where:

Eff_a = efficiency

cpm = counts per minute

std = standard, and

bkg = background

Note: The absolute efficiency is dependent on the counting geometry. Applicants may elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and has much less of a dependence on the counting geometry.

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test will be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due
- Results of efficiency calculation(s)

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed radioactive material is prepared, administered, or stored. Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. Calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and after repair, using the following procedure:

- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

  For example:

$$Eff = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{(\text{activity of std in microcurie})}$$

Where:

Eff = efficiency, in cpm / microcurie,

cpm = counts per minute

std = standard, and
bkg = background

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test will be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due
- Results of efficiency calculation(s)

Reference:

- Detailed information about portable radiation survey instrument calibration may be obtained by referring to American National Standards Institute (ANSI) N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments," 2013. Copies may be obtained from the ANSI eStandards Store.
- National Council on Radiation Protection and Measurements (NCRP) Report No. 112, "Calibration of Survey Instruments Used in Radiation Protection for the Assessment of Ionizing Radiation Fields and Radioactive Surface Contamination," 1991.
- NRC's NUREG-1556, Vol. 18, *'Program Guidance About Service Provider Licenses'* dated August 2017

Appendix J

Model Emergency Procedures for Manual Brachytherapy Permanent Implants

Applicants may either adopt Appendix J or develop alternative procedures to meet the requirements of ***DHS 157.21***.

Lost Implant Seeds in the Operating Room

1. A calibrated and operable survey meter appropriate to the energy of the sources being used (i.e., low energy gamma detector), shielded container and forceps/reverse-action tweezers shall be available in the operating room during seed implantation.
2. A representative of Radiation Oncology must be present during seed implantation.
3. Once a source is known to be missing, no one shall leave the operating room until further notice.
4. Ensure that all known radiation sources are shielded.
5. Survey the room, including personnel and equipment, with a survey meter. Persons who have been surveyed and are free of contamination may be released from the operating room.
6. If the missing source is not found, notify the Radiation Safety Officer immediately.
7. If the missing source is found, use forceps/reverse-action tweezers to pick up the source and place it into the shielded container. Continue to survey the room to ensure that all sources have been found.

Note: A report to DHS may be required pursuant to ***DHS 157.32(1)***.

Rupture of a Manual Brachytherapy Source

Manual brachytherapy sources for permanent implants are contained in titanium tubes and are susceptible to damage through improper handling (e.g., stepping on a source, cutting a source, or bending it with forceps or tweezers). AAPM recommends the use of reverse action tweezers to prevent damage or rupture of brachytherapy seeds.

1. A calibrated and operable survey meter appropriate to the energy of the sources being used (i.e., low energy gamma detector), shielded container and forceps shall be available in the operating room during seed implantation.
2. If a source rupture is suspected, ensure that no one leaves the operating room.
3. Notify Radiation Safety Officer.
4. Shield all known sources of radiation. Use forceps to pick up source fragments and place in the shielded container.
5. Ensure that the patient and linens are not contaminated before removing patient from operating room.
6. Survey room including personnel and equipment, with a survey meter. Persons who have been surveyed and are free of contamination may be released from the operating room.
7. Decontaminate personnel and equipment as needed. Bag waste and hold for decay-in-storage.

Note: A report to DHS may be required pursuant to ***DHS 157.13(17)(b)***.

RSO	WORK PHONE NUMBER	EMERGENCY NUMBER

Appendix K

Suggested Medical Licensee Audit

Suggested Medical Licensee Audit

Annual Radiation Protection Medical Licensee Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit:_____ Date of Last Audit: _____

Next Audit Date:_____

Auditor: _____ Date: _____
(Signature)

Management Review: _____ Date: _____
(Signature)

License

A. License number:

B. Current amendment number:

C. Are all of the tie-down documents on file?

D. Has the legal entity having control over license operations changed since the last audit?

E. Are materials, uses, and locations of use confined to those specifically described in the license?

Audit History

A. Were previous audits conducted annually [***DHS 157.21(3)***]?

B. Are records of previous audits being maintained for three years after they were made [***DHS 157.31(2)***]?

C. Were any deficiencies identified during previous audit?

D. Were corrective actions taken? (Note: Look for repeated deficiencies).

E. What corrective actions from previous audits, if any, are still in progress?

Organization and Scope of Program

A. Radiation Safety Officer:

1. If the RSO position has changed, was license amended ***DHS 157.13(5)(b)***]?

2. Does the new RSO meet the department's training requirements [***DHS 157.61(7), DHS 157.61(10), and DHS 157.61(11)***]**?**

3. Is the RSO fulfilling all duties [***DHS 157.61(1)***]?

4. If the scope of the program expanded, have the RSO duties been updated to reflect the scope of the program?

5. Was DHS notified about a temporary RSO?

6. Was a written agreement in place for temporary RSO [***DHS 157.61(1)(b)***]?

B. Multiple places of radioactive material use? If yes, list all locations of use.

C. Are all locations of use listed on the license?

D. Were annual audits performed at each location [***DHS 157.21(3)***]? If no, explain.

E. Describe scope of the program (staff size, number of procedures performed, etc.).

F. Licensed Material:

1. The isotope, the chemical forms, the quantity and authorized use is listed. [**L/C**]

2. Does the total amount of radioactive material possessed require financial assurance [***DHS 157.15***]? If so, is financial assurance current with standards in NUREG-1757, Vol. 3 [***DHS 157.15(4)***]?

3. Calibration, transmission, and reference sources [***DHS 157.62(4)***]?

   a. Sealed sources manufactured and distributed by a person licensed pursuant to the department [***DHS 157.13(4)(j)***], NRC, or equivalent Agreement State regulations who is authorized to redistribute sealed sources that do not exceed 1.11GBq (30 mCi) each [***DHS 157.62(4) (a) and (b)***].

   b. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceeding 0.555 GBq (15 mCi) [***DHS 157.62(4)(b)***]**?**

   c. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200uCi) or 10^3 times the quantities in **Chapter DHS 157, Appendix F** [***DHS 157.62(4)(c)***]?

   d. Technetium-99m or fluorine-18 in amounts as needed [***DHS 157.62(4)(d)***]?

   e. Calibration sources are not bundled or aggregated over 30 millicuries?

4. Unsealed materials used under ***DHS 157.63(1), DHS 157.63(2)***, and ***DHS 157.64(1)*** are:

   a. Obtained from a manufacturer or preparer licensed under [***DHS 157.13(4)(i)***]?

   OR

   b. Obtained from a producer of Positron Emission Tomography radioactive drugs?

   OR

   c. Prepared by a physician authorized user, an authorized nuclear pharmacist, or an individual under the supervision of an authorized nuclear pharmacist or physician authorized user?

   OR

   d. Obtained and prepared for research in accordance with ***DHS 157.63(1), DHS 157.63(2),*** and ***DHS 157.64(1)***, as applicable?

G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate [***DHS 157.61(1), DHS 157.66(2),*** and ***DHS 157.67(1)***]? Are copies of (or access to) SSDR Certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?

H. Are the actual uses of medical devices consistent with the authorized uses listed on the license?

I. If places of use or storage changed, was the license amended?

J. If control of the license was transferred or bankruptcy filed, was the department's prior consent obtained or notification made, respectively [***DHS 157.13(9)(b)*** and ***DHS 157.13(10)***]?

K. Is radioactive material regulated under ***DHS 157.70*** used in accordance with the license conditions and tie-down commitments?

Radiation Safety Program

A. Minor changes or revision to radiation safety program [***DHS 157.61(2)***]?

B. Records of changes maintained for 5 years [***DHS 157.71(2)***]?

C. Radiation Safety Committee meetings and attendance [***DHS 157.61(1)(e)***]?

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

A. Authorized User [***DHS 157.61(10), DHS 157.61(11), and DHS 157.63(4), DHS 157.63(5), DHS 157.64(4), DHS 157.64(5), DHS 157.64(6), DHS 157.65(8), DHS 157.65(9), DHS 157.66(2) or DHS 157.67(17)***]

1. Listed on current facility license
2. Each AU only uses material for which they are authorized?

B. Authorized Medical Physicist [***DHS 157.61(8), DHS 157.61(10), DHS 157.61(11)***]:

1. Listed on current facility license
2. Each AMP only uses material for which they are authorized?

C. Non-medical authorized individuals are on the license for the licensed tasks they perform/supervise?

Mobile Medical Service:

A. Operates services per [***DHS 157.62(9), DHS 157.67(13)***]?
B. Compliance with public dose limits [***DHS 157.23(1)***] has been evaluated and met?

C. Are all base locations listed on the license?
D. Letter signed by management of each client [***DHS 157.62(9)(a)1.***]**?**

D. Licensed material was not delivered to client's address (unless the client is licensed to receive radioactive materials) [***DHS 157.62(9)(b)***]?

D. Dosage measuring instruments are checked for proper function before used at each address of use or on each day of use, whichever is more frequent [***DHS 157.62(9)(a)2.***]**?**

F. Survey instruments are checked for proper operation before used at each address of use [***DHS 157.62(9)(a)3.***]?

F. Survey of all areas of use prior to leaving each client address [***DHS 157.62(9)(a)4.***]?
G. Adequate security maintained for mobile trailer? Keypad codes changes or keys retrieved when an employee terminates employment?

H. Additional technical requirements for mobile remote afterloaders are per [***DHS 157.67(13)***]?

Amendments Since Last Audit:

A. Any amendments since last inspection [***DHS 157.13(5)(b)***]?

Notifications Since Last Audit:

A. Any notifications since last audit [***DHS 157.13(5)(c)***]?

B. Appropriate documentation provided to the department for Authorized Nuclear Pharmacist (ANP), Authorized Medical Physicists (AMP), or Authorized User (AU) no later than 30 days after the individual starts work [***DHS 157.13(5)(c)1.***]?

C. DHS notified within 30 days after: authorized user, authorized nuclear pharmacist, authorized medical physicist, or RSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for ***DHS 157.63(1)*** or ***DHS 157.63(2)*** use [***DHS 157.13(5)(c)2.***]?

Training, Retraining, And Instructions to Workers

A. Is the individual worker understanding of current procedures and DHS rules adequate?

B. Training program implemented?

1. Operating procedures [***DHS 157.61(3), DHS 157.64(2), DHS 157.65(4), DHS 157.67(4)***]?
2. Emergency procedures [***DHS 157.61(3), DHS 157.64(2), DHS 157.65(4), DHS 157.67(4)***]?
3. Periodic training required and implemented [***DHS 157.64(2), DHS 157.65(4), DHS 157.67(4)***]?
4. Have workers who prepare packages for shipment received DOT Hazardous Materials training within the past three years ***[49 CFR 172.704]***?
5. Were all workers who are likely to exceed 1.0 mSv (100 mrem) in a year instructed, and was refresher training provided [***DHS 157.88(2)***]?
6. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [***DHS 157.61(3)***]?
7. Are initial and periodic training records maintained for each individual for three years [***DHS 157.71(15)***]?
8. Briefly describe training program:

C. Additional therapy device instructions/training:

1. Unit operation, inspection, associated equipment, survey instruments?
2. License conditions applicable to the use of the unit [**L/C**]?
3. Emergency drills for HDR and gamma knife include participation by all AUs and AMPs [***DHS 157.67(4)***]?
4. Vendor operational and safety training provided to AUs and AMPs prior to first patient treatment of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit?

D. Workers cognizant of requirements for:

1. Radiation Safety Program [***DHS 157.61(1), DHS 157.61(2), DHS 157.21***]?
2. Annual dose limits [***DHS 157.22(1), DHS 157.23(1), DHS 157.23(2)***]?

3. Form F-45003 *'Occupational Exposure Record Per Monitoring Period'*

4. 10% monitoring threshold [***DHS 157.25(2)***]?

5. Dose limits to embryo/fetus and declared pregnant worker [***DHS 157.22(8)***]?

Note: WISREG 8.13 *'Instructions Concerning Prenatal Radiation Exposure'* is a useful reference.

6. Extreme Danger/Grave Danger Posting [***DHS 157.29(2)(c)***]?

7. Procedures for opening packages [***DHS 157.29(6)***]?

E. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with ***DHS 157.61(3)***?

Manual Brachytherapy and Unsealed Therapy Training

A. Safety instruction to personnel provided include [***DHS 157.64(2), DHS 157.64(4)***]:

1. Control of patient and visitors?

2. Routine visitation to patients in accordance with ***DHS 157.23(1)***?

3. Contamination control and size/appearance of sources?

4. Safe handling and shielding instructions?

5. Waste control?

6. RSO and AU notification in emergency or patient death?

7. Records of training retained for three years [***DHS 157.71(15)***]?

Facilities

A. Facilities as described in license application [**L/C**]?

B. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights [***DHS 157.67(5), DHS 157.26(1)***]?

C. Emergency source recovery equipment available [***DHS 157.65(5), DHS 157.67(5)***]?

D. Storage areas:

1. Materials secured from unauthorized removal or access [***DHS 157.28(1)(a)***]?

2. Licensee controls and maintains constant surveillance of licensed material not in-storage [***DHS 157.28(1)(b)***]?

3. Locations appropriately shielded to control public and occupational exposures in accordance with ***DHS 157.22*** and ***DHS 157.23***?

E. Therapy unit operation:

1. Unit, console, console keys, and treatment room controlled adequately [***DHS 157.28(1)(a), DHS 157.67(4)***]?

2. Restricted to certain source orientations and/or gantry angles?

3. Ceases to operate in restricted orientation(s)?

4. Only one radiation device can be operated at a time within the treatment room [***DHS 157.67(4)(a)3.***]?

Dose or Dosage Measuring Equipment

A. Possession, use, calibration, and check of instruments to measure activities of unsealed radionuclides [***DHS 157.62(1)***]:

1. List type of equipment used:

2. Approved procedures for use of instrumentation followed?

3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?

4. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., ±10%)?

5. Records maintained and include required information [***DHS 157.71(6)***]?

B. Determination of dosages of unsealed radioactive material [***DHS 157.62(3)***]?

1. Each dosage determined and recorded prior to medical use [***DHS 157.62(3)(a)***]?

2. Measurement of unit dosages made either by direct measurement or by decay correction [***DHS 157.62(3)(b)***]**?**

3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [***DHS 157.62(3)(c)***]**?**

C. Licensee uses generators?

1. First eluate after receipt tested for Mo-99 breakthrough [***DHS 157.63(3)(b)***]?

2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 µCi per mCi of Tc-99m [***DHS 157.63(3)***]?

3. Before first patient use of day eluate tested for strontium (Sr)-82 and strontium-85 (Sr-85) when eluting rubidium (Rb)-82 [***DHS 157.63(3)(b)3***]?

4. No radiopharmaceuticals administered with Sr-82 concentrations over 0.02 kBq per MBq [0.02 µCi per mCi] of Rb-82 or Sr-85 concentrations over 0.2 kBq per MBq [0.2 µCi per mCi] of Rb-82 [***DHS 157.63(3)(a)2 and 3***]?

5. Each breakthrough measurement that exceeds the limits was reported to DHS and the distributor of the generator in accordance with ***DHS 157.72(4)***?

6. Records of breakthrough concentrations maintained for 3 years [***DHS 157.71(14)***]?

D. Dosimetry Equipment [***DHS 157.67(6)***]:

1. Calibrated system available for use [***DHS 157.67(6)(a)***]?

2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [***DHS 157.67(6)(a)1.***] or calibrated by inter-comparison per ***DHS 157.67(6)***?

3. Calibrated within the previous 4 years [***DHS 157.67(6)(a)2.***]?

4. Licensee has available for use a dosimetry system for spot-check measurements [***DHS 157.67(6)(b)***]?

5. Record of each calibration, inter-comparison, and comparison maintained [***DHS 157.71(20)***]?

Radiation Protection and Control of Radioactive Material

A. Use of radiopharmaceuticals:

1. Protective clothing worn?

2. Personnel routinely monitor their hands?

3. No eating/drinking in use/storage areas?

4. No food, drink, or personal effects kept in use/storage areas?

5. Proper dosimetry worn?

6. Radioactive waste disposed of in proper receptacles?

7. Syringe shields and vial shields used?

8. Proper use of remote-handling tools and radiation shields?

B. Leak tests and Inventories:

1. Leak test performed on sealed sources and brachytherapy sources [***DHS 157.62(5)(b)***]?

2. Inventory of sealed sources and brachytherapy sources performed semiannually [***DHS 157.62(5)(g)***]?

3. Records maintained for three years [***DHS 157.71(9)***]?

Radiation Survey Instruments

A. Survey instruments used to show compliance with ***DHS 157.21*** and ***DHS 157.13(2)(b)***:

1. Appropriate operable survey instruments possessed or available [***DHS 157.62(1)***]

2. Calibrations [***DHS 157.62(2)(a) and (b)***]

    a. Before first use, annually and after repairs?

    b. Within 20% on each scale or decade of interest?

    c. Instrument sent to a licensed instrument service provider or calibrated according to approved in-house procedures?

3. Records maintained for three years [***DHS 157.71(7)***]?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [***DHS 157.25(1), DHS 157.67(7)***]?

1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [***DHS 157.62(7)***]?

2. Weekly in all areas where radiopharmaceuticals or waste is stored?

3. Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?

4. Trigger levels established?

5. Corrective action taken and documented if trigger level exceeded?

6. Techniques can detect 0.1 mR/hr, 2000dpm?

7. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry [***DHS 157.67(14)*** and records maintained [***DHS 157.71(26)***]?

    a. After new source installation?

    b. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic and mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose

A. Is licensed material used in a manner to keep doses below 1 mSv (100 mrem) in a year [***DHS 157.23(1)***]?

B. Has a survey or evaluation been performed per ***DHS 157.25(1)***?

C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour [***DHS 157.23(1)(a)2.***]?

E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [***DHS 157.28(1)(a)***]?

F. Records maintained ***DHS 157.31(3), DHS 157.31(8)***]?

Patient Release

A. Individuals released when TEDE less than 5 mSv (500 mrem) [***DHS 157.62(8)(a)***]?

B. Instructions to the released individual, including breast-feeding women, include required information [***DHS 157.62(8)(b)***]?

C. Release records maintained for three years [***DHS 157.71(11)(a)***]?

D. Records of instructions given to breast-feeding women maintained, if required for three years [***DHS 157.71(11)(b)***]?

Radiopharmaceutical Therapy

A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [***DHS 157.64(3)(a)***]?

B. RSO and AU promptly notified if patient died or had a medical emergency [***DHS 157.64(3)(b)***]?

Brachytherapy

A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [***DHS 157.65(5)***]?

B. Survey immediately after implant [***DHS 157.65(2)(a)***]?

C. Patients surveyed immediately after removing the last temporary implant source [***DHS 157.65(2)(b)***]?

D. RSO and AU promptly notified if patient died or had a medical emergency [***DHS 157.65(5)(c)***]?

E. Records maintained for three years [***DHS 157.71(16)***]?

Radioactive Waste

A. Disposal:

1. Decay-in-storage [***DHS 157.62(10)(a)***]

2. Procedures followed [***DHS 157.62(10)(a)1.***]?

3. Labels removed or defaced [***DHS 157.29(4)***, ***DHS 157.62(10)(a)2.***]?

B. Special procedures performed as required [**L**/**C**]?

C. Improper/unauthorized disposals [***DHS 157.30(1)***]?

D. Records maintained [***DHS 157.31(3), DHS 157.31(9), DHS 157.71(13)***]?

E. Effluents:

1. Release to sanitary sewer [***DHS 157.30(3)***]?

    a. Material is readily soluble or readily dispersible [***DHS 157.30(3)(a)1.***]?

    b. Monthly average release concentrations do not exceed **Chapter DHS 157, Appendix E, Table III** values?

    c. No more than 185 GBq (5.0 Ci) of H-3, 37GBq (1.0 Ci) of C-14 and 37 GBq (1.0 Ci) of all other radionuclides combined released in a year [***DHS 157.30(3)(a)3.***]?

    d. Procedures to ensure representative sampling and analysis implemented [***DHS 157.25(1)***]?

2. Waste incinerated?

    a. License authorizes [***DHS 157.30(4)***]?

    b. Directly monitor exhaust?

    c. Airborne releases evaluated and controlled [***DHS 157.23(2), DHS 157.25(1)***]?

3. Air effluents and ashes controlled [***DHS 157.21, DHS 157.22(1), DHS 157.23(1), DHS 157.25(1), DHS 157.30(1)***]?

Note: Useful references are *NRC Inspection Procedure 87102* and *NRC Regulatory Guide 8.37*.

a. Air effluent less than 10-mrem constraint limit [***DHS 157.21***]?

b. If no, reported appropriate information to DHS.

i. Corrective actions implemented and on schedule?

c. Description of effluent program:

i. Monitoring system hardware adequate?

ii. Equipment calibrated, as appropriate?

iii. Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?

F. Waste storage:

1. Protection from elements and fire?

2. Control of waste maintained [***DHS 157.28(1)(a)***]?

3. Containers properly labeled and area properly posted [***DHS 157.29(2), DHS 157.29(4)***]?

4. Package integrity adequately maintained?

G. Waste disposal:

1. Sources transferred to authorized individuals [***DHS 157.30(1), DHS 157.06(1), DHS 157.13(1)***]?

2. Name of organization: _____.

H. Records of surveys and material accountability are maintained [***DHS 157.31(3), DHS 157.31(9), DHS 157.71(13)***]?

Receipt and Transfer of Radioactive Material

A. Describe how packages are received and by whom.

B. Written package opening procedures established and followed [***DHS 157.29(6)***]?

C. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [***DHS 157.29(6)(b)1.***]?

D. Incoming packages surveyed [***DHS 157.29(6)(b)1.***]?

E. Monitoring in (C) and (D) performed within time specified [***DHS 157.29(6)(d)***]?

F. Transfer(s) performed per [***DHS 157.13(15)***]?

G. All sources surveyed before shipment and transfer [***DHS 157.25(1), 49 CFR 173.475(i)***?

H. Records of surveys and receipt/transfer maintained [***DHS 157.31(3), DHS 157.06(1), DHS 157.13(18)***]?

I. Package receipt/distribution activities evaluated for compliance with ***DHS 157.23(1)***?

Transportation [*DHS 157.91(3)(a) and 49 CFR 171-189]*

A. Shipments are:

1. Delivered to common carriers;
2. Transported in own private vehicle;
3. Both;
4. No shipments since last audit.

B. Return radiopharmacy doses or sealed sources?

1. Licensee assumes shipping responsibility?
2. If no, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

C. Packages:

1. Authorized packages used?
2. Performance test records on file?
    a. DOT-7A packages
    b. Special form sources
3. Two labels (White-I, Yellow-II, or Yellow-III) with TI, Nuclide, Activity, and Hazard Class?
4. Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee)?
5. Closed and sealed during transport?

D. Shipping Papers:

1. Prepared and used?
2. Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable)?
3. Readily accessible during transport?

Gamma Stereotactic Radiosurgery Servicing

A. Inspection and servicing performed following source replacement or at intervals not to exceed 7 years [***DHS 157.67(15)(a)***]?

B. Needed service arranged for as identified during the inspection?

C. Service performed by persons specifically authorized to do so [***DHS 157.67(15)(b)***]?

D. Were security requirements implemented, if applicable? [***DHS 157, Subchapter XV***]

Full Calibration-Therapeutic Medical Devices

A. Proper protocol(s) used (e.g., TG-21, AAPM 54, TG-56, TG-40, etc.)?

B. Performed prior to first patient use [***DHS 157.67(7)(a)1., DHS 157.67(8)(a)1., DHS 157.67(9)(a)1***?

C. At intervals not to exceed one year for teletherapy, gamma stereotactic, and LDR remote afterloader; at intervals not exceeding one quarter for HDR, MDR, and PDR remote afterloaders [***DHS 157.67(7)(a)3., DHS 157.67(8)(a)3.*** and ***4, DHS 157.67(9)(a)3.***]?

D. Whenever spot-checks indicate output differs from expected by ±5% [***DHS 157.67(7)(a)2., DHS 157.67(9)(a)2.***]?

E. After source exchange, relocation, major repair or modification [***DHS 157.67(7)(a)2., DHS 157.67(8)(a)2., DHS 157.67(9)(a)2***]?

F. Performed with properly calibrated instrument [***DHS 157.67(7)(c), DHS 157.67(8)(c), DHS 157.67(9)(c)***]?

G. Includes

1. For remote afterloaders:

    a. Output measured within ±5% of expected [***DHS 157.67(8)(b)1.***]?

    b. Source positioning accuracy within ±1 millimeter [***DHS 157.67(8)(b)2.***]?

    c. Source retraction with backup battery upon power failure [***DHS 157.67(8)(b)3.***]?

    d. Length of source transfer tubes [***DHS 157.67(8)(b)4.***]?

    e. Timer accuracy and linearity over the typical range of use [***DHS 157.67(8)(b)5.***]?

    f. Length of the applicators [***DHS 157.67(8)(b)6.***]?

    g. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [***DHS 157.67(8)(b)7.***]?

    h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [***DHS 157.67(8)(j)***]?

2. For gamma stereotactic radiosurgery:

    a. Output measured within ±3% of expected [***DHS 157.67(9)(b)1.***]?

    b. Helmet factors [***DHS 157.67(9)(b)2.***]?

    c. Isocenter coincidence [***DHS 157.67(9)(b)3.***]?

    d. Timer accuracy and linearity over the range of use [***DHS 157.67(9)(b)4.***]?

    e. On-off error [***DHS 157.67(9)(b)5.***]?

    f. Trunnion centricity [***DHS 157.67(9)(b)6.***]?

g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [***DHS 157.67(9)(b)7.***]?

h. Helmet microswitches [***DHS 157.67(9)(b)8.***]?

i. Emergency timing circuit [***DHS 157.67(9)(b)9.***]?

j. Stereotactic frames and localizing devices (trunnions) [***DHS 157.67(9)(b)10.***]?

3. For Leksell Gamma® Knife Perfexion™, Icon™, or Elekta Esprit *(Leksell Gamma Knife® Perfexion™, Icon™, and Elekta Esprit Licensing Guidance, Revision 2)*:

a. Surveys completed at installation of a new source and following repairs to the sources shielding, the sector drive unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the sources, or compromise the radiation safety of the unit or the sources [***DHS 157.67(14)****]*

b. Follow the applicable full calibration requirements of ***DHS 157.67(9)*** except for those requirements which are not applicable

c. The docking device is securely mounted to the table and that the frame adapter can be correctly docked in the docking device

d. Proper functioning source exposure indicator light in the treatment room

e. The frame adapter functions correctly and can be attached correctly to the patient's frame

f. The location of the radiation focal point, with respect to the table position, is within the specifications provided by the manufacturer

g. The location of the table at a number of off-center positions is within the collision specifications provided by the manufacturer. Performed monthly and during full calibrations

h. Each sector moves correctly to each position within appropriate tolerance limits. Performed every 6 months and during full calibration.

i. The vendor verified the location of the radiation focal point, with respect to the table position, is within the specifications using measurements conducted in an off-centered position. Performed every 6 months and during full calibration.

4. For the Icon™ and Elekta Esprit *(Leksell Gamma Knife® Perfexion™, Icon™, and Elekta Esprit Licensing Guidance, Revision 2)*:

j. The precision of the CBCT system is within the specifications provided by the manufacturer

k. The mask adapter functions correctly and can be attached correctly to the docking device

l. Verify that a movement of the patient marker is accompanied by a shift of the HDMM response curve.

m. Confirm the HDMM system is working properly by performing a test without a patient present with the aim to check the HDMM system's quantitative output. Performed monthly and during full calibration.

n. Confirm the CBCT image quality is satisfactory. Performed monthly and during full calibration.

H. Output corrected mathematically for decay [***DHS 157.67(7)(e), DHS 157.67(8)(g), DHS 157.67(9)(e)***]?

I. Records maintained for three years [***DHS 157.71(21)***]?

Periodic Spot Checks for Therapeutic Devices

A. Performed at required frequency [***DHS 157.67(10)(a), DHS 157.67(11)(a), DHS 157.67(12)(a)***]?

B. Procedures established by authorized medical physicist [***DHS 157.67(10)(b), DHS 157.67(11)(b), DHS 157.67(12)(b)***]?

C. Procedures are being followed?

D. Medical Physicist reviews results within 15 days [***DHS 157.67(10)(c), DHS 157.67(11)(f), DHS 157.67(12)(b)2.***]?

E. Performed with properly calibrated instrument [***DHS 157.67(10), DHS 157.67(12)***]?

F. Output and safety spot checks include:

1. For remote afterloaders:

    a. Interlock systems [***DHS 157.67(11)(c)1.***]?

    b. Source exposure indicator lights [***DHS 157.67(11)(c)2.***]?

    c. Viewing and intercom systems, except for LDR [***DHS 157.67(11)(c)3.***]?

    d. Emergency response equipment [***DHS 157.67(11)(c)4.***]?

    e. Radiation monitors used to indicate source position [***DHS 157.67(11)(c)5.***]?

    f. Timer accuracy [***DHS 157.67(11)(c)6.***]?

    g. Clock (date and time) in the unit's computer [***DHS 157.67(11)(c)7.***]?

    h. Decayed source(s) activity in the unit's computer [***DHS 157.67(11)(c)8.***]?

2. For gamma stereotactic radiosurgery:

    a. Treatment table retraction mechanism [***DHS 157.67(12)(c)1.***]?

    b. Helmet microswitches [***DHS 157.67(12)(c)1.***]?

    c. Emergency timing circuits [***DHS 157.67(12)(c)1.***]?

    d. Stereotactic frames and localizing devices [***DHS 157.67(12)(c)1.***]?

    e. The output for one typical set of operating conditions [***DHS 157.67(12)(c)2.a.***]?

    f. Difference between measured and expected output [***DHS 157.67(12)(c)2.b.***]?

    g. Source output compared against computer calculation of output [***DHS 157.67(12)(c)2.c.***]?

    h. Timer accuracy and linearity over the range of use [***DHS 157.67(12)(c)2.d.***]?

    i. On-off error [***DHS 157.67(12)(c)2.e.***]?

j. Trunnion centricity [***DHS 157.67(12)(c)2.f.***]?

k. Interlock systems [***DHS 157.67(12)(d)1.***]?

l. Source exposure indicator lights [***DHS 157.67(12)(d)2.***]?

m. Viewing and intercom systems [***DHS 157.67(12)(d)3.***]?

n. Timer termination [***DHS 157.67(12)(d)4.***]?

o. Radiation monitors used to indicate room exposures [***DHS 157.67(12)(d)5.***]?

p. Emergency off buttons [***DHS 157.67(12)(d)6.***]?

3. For Leksell Gamma® Knife Perfexion™, Icon™, or Elekta Esprit *(Leksell Gamma Knife® Perfexion™, Icon™, and Elekta Esprit Licensing Guidance, Revision 2)*:

   a. Follow the applicable spot check requirements of ***DHS 157.67(12)*** except for those requirements which are not applicable

   b. The docking device is securely mounted to the table and that the frame adapter can be correctly docked in the docking device

   c. Proper functioning source exposure indicator light in the treatment room

   d. Frame adapter is functioning correctly and can be attached correctly to the patient's frame

4. For the Icon™ and Elekta Esprit

   a. The precision of the CBCT system is within the specifications provided by the manufacturer

   b. Before each patient use, and when the patient is immobilized with a mask, we confirm that the mask fits the patient's head, the mask adapter is functioning correctly and can be attached correctly to the docking device

   c. Verify that a movement of the patient marker is accompanied by a shift of the HDMM response curve

G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [***DHS 157.67(10)(e), DHS 157.67(11)(d), DHS 157.67(12)(f)]?***

H. Records maintained for three years [***DHS 157.71(22), DHS 157.71(23), DHS 157.71(24)***]?

Installation, Maintenance, and Repair of Therapy Devices

A. Only authorized individuals perform installations, maintenance, adjustment, repair, and inspections [***DHS 157.67(3), DHS 157.67(15)***]? Name of organization/individual: .

B. Records maintained for three years [***DHS 157.71(19), DHS 157.71(27)***]?

Operating Procedures for Therapy Devices

A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console [***DHS 157.67(4)(c)***]?

B. Copy of the entire procedures physically located at the device console [***DHS 157.67(4)(b)***]?

C. Procedures include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [***DHS 157.67(4)(a)4.a.***]?

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [***DHS 157.67(4)(a)4.b.***]?

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally [***DHS 157.67(4)(a)4.c.***]?

D. Radiation survey of patient is performed to ensure source is returned to shielded position [***DHS 157.67(2)(a)***]?

E. Records of radiation surveys maintained for 3 years [***DHS 157.71(16)***]?

F. Authorized medical physicist and authorized user:

1. Physically present during initiation of patient treatment with remote afterloaders for MDR and PDR, an appropriately trained physician under the supervision of the authorized user may be physically present instead of the AU) [***DHS 157.67(5)(f)1.a., DHS 157.67(5)(f)1.b.***]?

2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device (***DHS 157.67(5)(f)3.***), except for the Perfexion™, Icon™, and Elekta Esprit units, for which an AMP and a physician under the supervision of an AU are present throughout the duration of all treatments (*NRC's Leksell Gamma Knife® Perfexion™ Icon™, and Elekta Esprit Licensing Guidance*)?

Personnel Radiation Protection

A. Exposure evaluation performed [***DHS 157.25(1)***]?

B. ALARA program implemented [***DHS 157.21(2)***]?

C. External Dosimetry

1. Monitor workers per ***DHS 157.25(2)***?

2. External exposures account for contributions from airborne activity [***DHS 157.22(3)***]?

3. Dosimetry supplier/Exchange frequency: .

4. Supplier is NVLAP-approved [***DHS 157.25(1)(c)1.***]?

5. Dosimeter frequency exchanged as recommended by the supplier.

D. Internal Dosimetry:

1. Monitor workers per ***DHS 157.25(2)(a)***?

2. Briefly describe program for monitoring and controlling internal exposures [***DHS 157.27(1)*** & ***(2)***]?

3. Monitoring/control program implemented (includes bioassays)?

E. Review of Records and Reports:

1. Reviewed by Frequency

2. Auditor reviewed personnel monitoring records for period to

3. Prior dose determined for individuals likely to receive doses [***DHS 157.22(5)***]?

4. Maximum exposures TEDE: Other:

5. Maximum CDEs: Organ(s):

6. Maximum CEDE:

7. Internal and external summed [***DHS 157.22(2)***]?

8. Were occupational limits met [***DHS 157.22(1)***]?

9. DHS forms or equivalent used [***DHS 157.22(5)(d)1., DHS 157.31(7)(c)***]?

    a. Form F-45003 *'Occupational Exposure Record Per Monitoring Period'*

10. If a worker declared her pregnancy in writing during audit period, then was the dose in compliance [***DHS 157.22(8)***] and were the records maintained [***DHS 157.31(7)***]?

11. Were annual occupational exposure reports provided to workers? [***DHS 157.88(3)(a)***]

F. Records of exposures, surveys, monitoring, and evaluations maintained [***DHS 157.31(2), DHS 157.31(3), DHS 157.31(7)***]?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events

1. Review a sampling of records for administrations requiring a WD. The number of patient cases to be sampled should be representative of each treatment modality performed in the institution.

2. Conduct a review of each applicable program area (e.g., radiopharmaceutical therapy, high dose-rate brachytherapy, implant brachytherapy, teletherapy, and emerging technologies). If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work.

3. Review the procedures developed in accordance with ***DHS 157.61(4)*** to ensure that the procedures for administrations requiring a WD are effective.

4. Determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. Determine if a medical event, as defined in ***DHS 157.72(1)***, has occurred, and for permanent implant brachytherapy, that within 60 calendar days from the date the implant was performed the total source strength administered outside of the treatment site was compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented in accordance with ***DHS 157.61(4)***. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

If medical events [criteria as in ***DHS 157.72(1)***] have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.

1. Event date _____ Information Source _____

2. Notifications

   - Wisconsin Department of Health Services
   - The referring physician
   - Patient in writing/by telephone
   - If notifications did not occur, why not?

3. Written Reports submitted to DHS within 15 days [***DHS 157.72(1)(d)***] ?

Notification and Reports

A. In compliance with [***DHS 157.88(3), 157.13(17)***] (reports to individuals; public and occupational doses monitored to show compliance with **Chapter DHS 157, Subchapter III 'Standards for Protection from Radiation'**?

B. In compliance with [***DHS 157.32(1), DHS 157.13(17)***] (theft or loss)?

C. In compliance with [***DHS 157.32(2), DHS 157.13(17)***] (incidents)?

D. In compliance with [***DHS 157.33(3), DHS 157.13(17)***] (overexposures and high radiation levels)?

E. Aware of the Radiation Protection Section phone numbers [Office: (608) 267-4797, 24-hour: (608) 258-0099]

F. In compliance with [***DHS 157.32(3)***] (Constraint on air emissions)?

Posting and Labeling

A. Form F-45027*, 'Notice to Employees'* is posted [***DHS 157.88(1)***]?

B. **Chapter DHS 157, Subchapters III and Subchapter X** license documents, operating procedures applicable to activities under the license or registration are posted or post a notice indicating where documents may be examined. [***DHS 157.88(1)***]?

C. Emergency procedures that apply to activities conducted under the license is posted? [***DHS 157.88(1)(a)6.***]

D. Other posting and labeling per ***DHS 157.29(1), DHS 157.29(4)*** and not exempted by ***DHS 157.29(3)*** or ***DHS 157.29(5)***?

Recordkeeping for Decommissioning

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [***DHS 157.15(7)(a) 2***]?

B. Records include all information outlined in ***DHS 157.15(7)***?

Information Notices and Regulatory Issue Summaries

A. DHS Information Notices, etc., received?

B. Appropriate action in response to DHS Information Notices, etc.?

Special License Conditions or Issues

A. Special license conditions or issues to be reviewed:

B. Evaluation:

Audits and Findings

A. Summary of findings:

B. Corrective and preventive actions:

Appendix L

Model Procedures for an Occupational Dose Program

This procedure provides acceptable methods for an external occupational dose program and references for developing an internal occupational dose program. Applicants may either adopt these procedures for an external occupational dose program or develop alternative procedures to meet the requirements of ***DHS 157.21*** and ***Chapter DHS 157, Subchapter III.*** The procedure includes guidance as well as discussion of rule requirements that are to be reflected in the elements of an occupational dose program.

"Dosimetry" is broad term commonly applied to those methods used to measure or otherwise quantify radiation doses to individuals. A dosimetry program is required for individuals likely to receive in 1 year a dose in excess of 10% of the applicable regulatory limits in ***DHS 157.22(1)***. The Total Effective Dose Equivalent (TEDE) is the sum of the deep-dose equivalent (external exposure) and the committed effective dose equivalent (internal exposure). The definition of the terms TEDE, deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in ***DHS 157.03***, '*Definitions*.' To demonstrate that dosimetry is not required, the licensee needs to have available for inspection an evaluation to demonstrate that the workers are not likely to exceed 10% of the applicable annual limits (***DHS 157.25(1)***).

If an individual is likely to receive more than 10% of the annual dose limits, DHS requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his/her dose.

The As Low As Reasonably Achievable "ALARA" Program

DHS 157.21 states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities…" and "the licensee 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 (ALARA)." Additionally, ***DHS 157.21*** requires that licensees periodically review the content of the radiation protection program and its implementation.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels. Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in ***DHS 157.22(1)*** that apply to external exposure: deep dose to the whole body (5 rem or 0.05 Sv), shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). According to the definitions in ***DHS 157.03***, the (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm^2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm^2), and eye dose equivalent at 0.3 cm (300 mg/cm^2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses (leaded glasses).

Monitoring an individual's external radiation exposure is required by ***DHS 157.25(2)*** if the external occupational dose is likely to exceed 10% of the dose limit appropriate for the individual (i.e., adult, minor, or the fetus of a declared pregnant

woman). External radiation monitoring is also required by ***DHS 157.25(2)*** for any individual entering a high or very high radiation area.

The use of individual monitoring devices for external exposure is required for the following:

- For adults who are likely to receive an annual dose in excess of any of the following:
  - 0.5 rem (0.005 Sv) DDE
  - 1.5 rem (0.015 Sv) eye dose equivalent
  - 5 rem (0.05 Sv) shallow-dose equivalent to the skin
  - 5 rem (0.05 Sv) shallow-dose equivalent to any extremity
- For declared pregnant women who are likely to receive an annual dose from occupational exposure in excess of 0.1 rem (1.0 mSv) DDE, although the dose limit applies to the entire gestation period.
- For individuals entering a high or a very high radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, DHS does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10% of rule limits:

- Prior Experience: Review of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits;
- Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys (e.g., using a survey meter or area thermoluminescent dosimeters (TLDs)) in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable ‘accident’ scenarios should also be evaluated); and
- The licensee performs a reasonable calculation based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as optically stimulated luminescence dosimeters (OSLs) or TLDs. Dosimeters requiring processing must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-approved, as required by ***DHS 157.25(1)***. Acceptable exchange frequencies are every 3 months for TLDs and OSLs, provided the individual does not exceed 10% of the occupational limits. If the individual exceeds 10% of the occupational dose limits, ***DHS 157.25*** requires the device to be exchanged monthly.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year (***DHS 157.22(1)***). When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly non-uniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate

to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

An acceptable alternative approach for highly non-uniform radiation fields is to use more than one dosimeter to separately track doses to different parts of the whole body. At the end of the year, each of the doses for each location is summed. The deep-dose equivalent recorded is that of the dosimeter location receiving the highest dose.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees shall be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and add it to the employee's dose record. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose. If the individual is not likely to exceed 10% of the occupational limits, dose evaluation is not required.

DHS 157.31(7) requires that the recording for individual monitoring be done on Form F-45003 *'Occupational Exposure Record Per Monitoring Period'* or equivalent. Form F-45003 *'Occupational Exposure Record Per Monitoring Period'* is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years. Additionally, ***DHS 157.88(3)(a)*** requires licensees to provide written annual occupational exposure reports to workers.

Investigational Levels – External Dose Monitoring

DHS emphasizes that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, *'Recommendations of the International Commission on Radiological Protection,'* investigational levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's or a group of workers' doses need to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in **Table 4** (i.e., 10% of the annual limit for occupational exposure), the RSO or the RSO's designee should investigate the exposure and review the

actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II in **Table 4** (i.e., 30% of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Table 4: Investigational Levels

Part of Body	Investigational Level I (mrem per year)	Investigational Level II (mrem per year)
Whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
Hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
Lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Review and record on Form F-45003 *'Occupational Exposure Record Per Monitoring Period'*, or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring. Take the actions listed below when the investigation levels listed in **Table 4** are reached:

- Personnel dose less than Investigational Level I: Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken if an individual's dose is less than **Table 4** values for the Investigational Level I;
- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II: When the dose of an individual equals or exceeds Investigational Level I, the RSO or the RSO's designee will conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements additional safety measures are needed to reduce exposures. Evaluate in the context of ALARA program quality and record the results of investigations and evaluations;
- Personnel dose equal to or greater than Investigational Level II: The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. A consideration of actions should be taken by the RSO to reduce the probability of recurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation; and
- Re-establishment of Investigational Level II to a level above that listed in **Table 4**.

Declared Pregnancy and Dose to Embryo/Fetus

DHS 157.22(8) states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to

avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. When a pregnancy is declared in writing, and includes the worker's estimated date of conception, the dose to an embryo/fetus shall be taken as the sum of:

- The deep-dose equivalent to the declared pregnant woman; and
- The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

References: Methods for calculating the radiation dose to the embryo/fetus can be found in NRC's Regulatory Guide 8.36, *'Radiation Dose to the Embryo/Fetus.'*

Internal Exposure

With respect to internal exposure, you are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from intakes in 1 year. ***Chapter DHS 157, Subchapter III*** provides terms for radionuclide intakes by means of inhalation and ingestion, i.e., derived air concentration (DAC) and ALI.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in μCi/ml that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in ***Chapter DHS 157, Appendix E.***

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. **Chapter DHS 157, Appendix E,** ALI and DAC numbers reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (W_T), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." Per **Chapter DHS 157, Appendix E**, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities require particular caution. To monitor

internal exposures from such operations, establish a routine bioassay program for workers who handle liquid iodine-131. Perform bioassay measurements within 72 hours of handling liquid iodine-131 . Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the iodine in sealed form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed).

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program must be established. The program should include:

- adequate equipment to perform bioassay measurements;
- procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units;
- the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue);
- the interval between bioassays;
- action levels; and
- the actions to be taken at those levels.

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to NRC Regulatory Guide 8.9 Revision 1, *'Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program*' dated July 1993, NRC Regulatory Guide 8.20 Revision 2, *'Applications of Bioassay for I-125 and I-131'* dated September 2014, and NRC Regulatory Guide 8.34, *'Monitoring Criteria and Methods to Calculate Occupational Radiation Doses'* dated August 2022.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by ***DHS 157.22(4)***, ***DHS 157.31(3)***, and ***DHS 157.31(7)***. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Revision 1 of NRC Regulatory Guide 8.7, *'Instructions for Recording and Reporting Occupational Radiation Exposure Data'* dated May 2018.

Summation of External and Internal Doses

Pursuant to ***DHS 157.22(1)***, the external and internal doses must be summed if required to monitor both under ***DHS 157.25(2)***.

Two documents that contain helpful information regarding occupational doses are:

- NRC Regulatory Issue Summary 2002-06, *'Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;'*
- NRC Regulatory Issue Summary 2002-10, *'Revision of Skin Dose Unit in 10 CFR Part 20.'*

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Appendix M

RESERVED

Appendix N

Model Emergency Procedures

Spill Procedures – Low and High Activity Unsealed Sources

These procedures provide acceptable responses to emergencies. Applicants may either adopt Appendix N or develop alternative procedures to meet the requirements of ***DHS 157.21***.

Spilled Gas Procedure

1. Notify persons in the room that a spill has occurred and ask them to leave the room.
2. Remove the patient from the room.
3. Close door to room.
4. Remain outside the room for ___ minutes (see below for clearance time calculation).
5. Report the incident to the RSO.

RSO	WORK PHONE NUMBER	EMERGENCY NUMBER

This spilled gas procedure shall be posted in the room(s) where gas is used.

Clearance Time Calculation

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the following calculations should be done to determine for how long a room should be cleared in case of a gas spill.

1. Collect the following data:
   a. A, the highest activity of gas in a single container, in microcuries;
   b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;
   c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;
   d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-5} µCi/ml in restricted areas and 3×10^{-7} µCi/ml in unrestricted areas. For other gases, see Appendix B to DHS 157; and
   e. V, the volume of the room in milliliters.

2. For each room in which radioactive gases are used, make the following calculation:
   a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
   b. The evacuation time $t = \frac{-V}{Q} \times \ln\left(\frac{CV}{A}\right)$

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a "caution radioactive material" labeled bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.

5. Report the incident to the RSO.

Reminders to RSO

1. Follow up on the decontamination activities and document the results.

2. As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.

3. If necessary, notify the State.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with "caution radioactive material" labeled absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.

3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the RSO immediately.

6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

Reminders to RSO

1. Supervise and confirm decontamination of personnel. If decontamination of personnel was not successful, consider including perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

2. Document decontamination results, including all surveys, locations of surveys, and decontamination results.

3. Evaluate and determine personnel radiation exposure. Beta emitting radionuclides could have a potential for resulting in a shallow-dose exposure in excess of regulatory limits from µCi quantities of contamination.

4. Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.

5. If necessary, notify the State.

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated and radiotoxicity of the spilled material. For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest ALI, an alternative spill procedure may be to restrict access pending complete decay.

RSO	WORK PHONE NUMBER	EMERGENCY NUMBER

Note: A report to DHS may be required pursuant to ***DHS 157.13(17)***.

Use **Table 5** as general guidance to determine whether a major spill procedure or a minor spill procedure will be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these millicurie amounts are considered major, and below these levels are considered minor.

Table 5: Relative Hazards of Common Medical Radionuclides

Radionuclides	Millicurie	Radionuclide	Millicurie
N-13	100	Tc-99m	100
C-14	10	In-111	10
O-15	100	I-123	10
F-18	100	I-125	1
P-32	1	I-131	1
Ga-67	10	Sm-153	10
Rb-82	10	Yb-169	10
Sr-82	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100
Y-90	1	Alpha emitters	*
Lu-177	10		

* For radiopharmaceuticals where the primary emission is alpha, consider implementing major spill precautions

Note: For medical isotopes not listed in the table, the licensee will need to evaluate a major spill threshold prior to first use. The threshold should be at or below five times the lowest ALI for that isotope.

Spill Kit

Assemble a spill kit that contains the following items:

- disposable gloves and housekeeping gloves
- disposable lab coats
- disposable head coverings
- disposable shoe covers
- roll of absorbent paper with plastic backing
- masking tape
- plastic trash bags with twist ties
- "Radioactive Material" labeling tape
- marking pen
- pre-strung "Radioactive Material" labeling tags
- contamination wipes
- instructions for "Emergency Procedures"
- clipboard with copy of Radioactive Spill Report Form
- pencil
- appropriate survey instruments, including batteries

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

The following procedures should be followed:

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.
2. Protective eye wear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).
3. The Radiation Safety Staff will direct personnel in methods to keep doses ALARA during surgical procedures.
4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

The following procedures should be followed:

1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.
2. An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
3. Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high energy beta rays in cases involving therapy with P-32 and Y-90.
4. Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accord with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.

5. If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

Reference: NRCP Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities," 1991, contains helpful information. It is available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

Autopsy or Cremation of Patients Who Have Permanent Implants

If an autopsy or cremation is to be performed:

1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient
2. Consult and get permission from the RSO
3. Instruct pathologist to excise tissue containing radioactive seeds. Make pathologist aware seeds may have migrated and additional tissue may need to be removed. Instruct pathologist to consult with RSO about the possibility of slicing through a seed and contaminating the facility.
4. Seek municipal approval, if required, because the very high temperatures used in modern crematoria may cause seeds to burst, releasing radioactivity into the plume.

Nuclear Pacemakers

Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases, and when the licensee is not responsible for control or disposal of the pacemaker, notify the NRC and attempt to contact the hospital where the pacemaker was implanted to arrange for explanation. The licensee that implanted the device is responsible for the follow-up, explanation, and return of the pacemaker to the manufacturer for proper disposal. Information Notice (IN) 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," April 3, 1998, provides additional information.

Appendix O

Procedures for Ordering and Receiving Packages

This procedure provides acceptable methods for ordering and receiving packages containing licensed material. Applicants may either adopt this procedure or develop alternative procedures.

Guidance

- Authorize, through a designee (e.g., RSO), each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting AU and that possession limits are not exceeded.

- Establish and maintain a system for ordering and receiving radioactive material; include the following information:

  - Records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier;

  - Confirmation, through the above records, that material received was ordered through proper channels.

- For deliveries during normal working hours, inform carriers to deliver radioactive packages directly to a specified area.

- For deliveries during off-duty hours, inform security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided below. Develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty will accept delivery of radioactive material that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Division, Room ___. Unlock the door, place the package _____, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, at extension _____.

Title	Name	After Hours Telephone Number
Radiation Safety Officer		
Director of Nuclear Medicine		
Nuclear Medicine Technologist Supervisor		
Nuclear Medicine Technologist on call		
Nuclear Medicine Physician on Call		

Appendix P

Model Procedure for Safely Opening Packages Containing Radioactive Material

This model provides acceptable procedures for opening packages containing radioactive material. Applicants may either adopt this model procedure or develop an alternative procedure to meet the requirements of ***DHS 157.29(6)***.

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in ***49 CFR 173.435*** or **Chapter DHS 157, Appendix O** (e.g., 16 curies of Mo-99, 54 curies of Cs-137, 27 curies of Ir-192; 11 curies of Co-60). Such packages must be received expeditiously when the carrier offers it for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages for which monitoring is required, check for external radiation levels and surface contamination within 3 hours of receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of ***DHS 157.29(6)***.

DHS and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of ***DHS 157.94(1)*** [i.e. 22 dpm/cm^2 of beta or gamma emitting photons or 2.2 dpm/cm^2 of alpha]; and
- External radiation levels exceed the limits of ***49 CFR 173.441*** (200 mR/hr on contact)

Implement the following procedure for opening each package containing radioactive material received under your DHS license:

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO immediately.
3. Monitor the external surfaces of a labeled package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in ***DHS 157.03***. (**Note**: Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations, ***49 CFR 172.403 and 172.436-440***.)
4. Monitor the external surfaces of a labeled package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in ***DHS 157.03 and*** **Chapter DHS 157, Appendix O**. (**Note**: Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations, ***49 CFR 172.403*** and ***49 CFR 172.436-440***.)
5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify that the contents agree with the packing slip.
9. Check the integrity of the final source container. Notify the RSO of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
10. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example,

a NaI(T1) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute (**Note:** a dose calibrator is not sufficiently sensitive for this measurement). Take precautions against the potential spread of contamination.

11. Check the user request to ensure that the material received is the material that was ordered.
12. Monitor the packing material and the empty packages for contamination with radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
13. Make a record of the receipt.
14. If applicable, comply with the National Source Tracking System reporting requirement, as described in ***10 CFR 20.2207***, "Reports of Transactions Involving Nationally Tracked Sources."

For packages received under the general license in ***DHS 157.11(2)(f)***, implement the following procedure for opening each package:

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO immediately.
2. Check to ensure that the material received is the material that was ordered.

Appendix Q

Leak Test Program

Procedures for leak testing appear below. Applicants may either adopt these procedures or develop alternative procedures.

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak testing and sample analysis independently in accordance with ***DHS 157.13(2)(a)***. Records for training on the applicable leak test procedures should be maintained. See Appendix Y or recordkeeping requirements.

Classroom training may be in the form of lecture, online, video, or self-study, and should cover the following subject areas:

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and using instruments
- mathematics and calculations used for measuring radioactivity
- biological effects of radiation

Appropriate on-the-job training consists of the following:

- observing authorized personnel collecting and analyzing leak test samples
- collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak test and sample analysis

Facilities and Equipment

- To ensure the required sensitivity of measurements, leak tests should be analyzed in a low-background area;
- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured (e.g., sodium iodide well-counter system for gamma emitters, liquid scintillation detector for beta emitters, or gas-flow proportional counters for alpha emitters); and
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 μCi) of radioactivity.

If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). The MDA may be determined using the following formula:

$$\mathrm{MDA} = \frac{2.71 + 4.65\sqrt{\mathrm{bkg} \times \mathrm{t}}}{\mathrm{t} \times \mathrm{E}}$$

Where:

MDA = minimum detectable activity in disintegrations per minute (dpm)
bkg = background count rate in counts per minute (cpm)
t = background counting time in minutes
E = detector efficiency in counts per disintegration

For example:

Where:

bkg = 200 cpm
E = 0.1 counts per disintegration (10 percent efficient)
t = 2 minutes

$$\text{MDA} = \frac{2.71 + 4.65\sqrt{200\ \text{cpm} \times 2\ \text{minutes}}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{400}}{0.2}$$

$$= \frac{2.71 + 4.65(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

$$= \frac{478.55\ \text{disintegrations}}{\text{minute}}$$

$$\text{becquerels (Bq)} = \frac{1\ \text{disintegration}}{\text{second}}$$

$$\text{MDA} = \frac{478.55\ \text{disintegration}}{\text{minutes}} \times \frac{\text{minute}}{60\ \text{seconds}} = 7.976\ \text{Bq}$$

Note: The MDA equation shown assumes that counting times for the background measurement and for the sample will be equal. MDA equations for nonequal counting times, as well as derivations of equations and discussions of limitations, can be found in "Decommissioning Health Physics—A Handbook for MARSSIM Users," Eric W. Abelquist, published by Taylor & Francis Group, 2001.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective Sealed Source and Device registration certificate. If a sealed source is not registered, leak tests should be conducted at 6-month intervals, unless a different interval is established during the licensing process. Leak testing of sealed sources may be required by license condition.

Procedure for Performing Leak Testing and Analysis (on all sealed sources except individual Ra-226 sealed sources)

This procedure provides acceptable procedures for sealed source leak testing and analysis. Applicants may either adopt this procedure or develop alternative procedures.

- Follow the manufacturer's instructions for performing the leak test.
- For each source to be tested, list identifying information, such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking but do not wipe the surface of a plated or foil source.

Procedure for Performing Gaseous Emanation Test for Individual Ra-226 Sealed Sources

- For each source to be tested, list identifying information, such as sealed source serial number, manufacturer, model number, radionuclide, and activity.
- Number each container to correlate information for each source.
- Wear gloves.
- Put each Ra-226 sealed source into a separate small, gas-tight container with activated carbon or two cotton filters.
  - Leave source in an airtight container for 24 hours.
  - Remove source.
  - Close container.
- Measure immediately the activity of the Absorber. (See "Model Procedure for Analysis of Gaseous Emanation and Leak Test" below for (i) how to analyze the absorber, (ii) required records, (iii) leakage determination, and (iv) required response to a leaking source.)
- If the wipe test reveals 37 Bq [1 nanocurie (nCi)] or greater of radon or daughter products
  - Notify the RSO.
  - Immediately withdraw the sealed source from use and store it, dispose of it, or cause it to be repaired in accordance with the requirements in ***Chapter DHS 157, Subchapter I*** and ***Subchapter III*** and
  - File a report within 5 days of the leak test, in accordance with ***DHS 157.32(7)***, "Report of a leaking or contaminated sealed sources," or standard license condition.

Procedure for Analysis of Leak Test and Gaseous Emanation

- Select an instrument that is sensitive enough to detect 185 Bq [0.005 μCi] of the radionuclide and ensure that its calibration is current.
- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5% of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- Calculate efficiency of the instrument.

$$\text{Efficiency in cpm/microcurie} = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in microcurie}}$$

Where:

cpm = counts per minute
std = standard
bkg = background

- Count each wipe sample to determine net count rate.
- For each sample, calculate the activity in microcurie and record.

$$\text{Microcurie on wipe sample} = \frac{(\text{cpm from wipe sample}) - (\text{cpm from bkg})}{\text{efficiency in cpm/microcurie}}$$

- Leak test records will be retained in accordance with ***DHS 157.71(9)*** for 3 years. Include the following in records:
  - The model number and serial number (if assigned) of each source tested;
  - The identity of each source radionuclide and its estimated activity;
  - The measured activity of each test sample expressed in microcurie;
  - A description of the method used to measure each test sample;
  - The date of the test; and
  - The name of the individual who performed the test.
- If the wipe test reveals 185 Bq (0.005 μCi) or greater:
  - Notify the RSO
  - Immediately withdraw the sealed source from use and either store the source, dispose of the source, or cause the source to be repaired, in accordance with the requirements in ***Chapter DHS 157, Subchapters II and III.***
  - File a report within 5 days of the leak test with DHS.

Appendix R

Model Procedure for Area and Personnel Surveys

This procedure provides acceptable methods for radiation surveys. Applicants may either adopt this procedure or develop alternative procedures to meet the requirements of ***DHS 157.21, DHS 157.23(1), DHS 157.25(1),*** and ***DHS 157.62(7).*** **Table 3** in Appendix I provides examples of appropriate portable and stationary survey instruments.

Exposure Rate Surveys

Ambient exposure rate surveys shall be performed to identify areas that may result in radiation doses to workers or the public. See **Table 7** for locations and frequencies of surveys. Perform surveys with a meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour. Before use of survey instrumentation, check for operability (e.g., check battery, check response with a dedicated check source). Area surveys should be completed to evaluate doses to members of the public when process or procedures have changed.

Notify RSO immediately of radiation levels that exceed trigger levels. Trigger levels for restricted and unrestricted areas are presented in **Table 6.**

Table 6: Exposure Rate Trigger Levels

Area Surveyed	Trigger Level
Unrestricted	0.1 mR/hr
Restricted	5.0 mR/hr

Contamination Surveys

Contamination surveys shall be performed using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Contamination surveys are performed in areas where unsealed forms of radioactive materials are used to evaluate radioactive contamination that could be present:

- on surfaces of floors, walls, laboratory furniture, and equipment
- after any spill or contamination event
- when procedures or processes have been changed
- the immediate work area when licensed material is used
- in unrestricted areas at frequencies consistent with the types and quantities of material in use
- in areas adjacent to restricted areas and in all areas through which licensed material is transferred or temporarily stored

Removable contamination can be detected and measured by conducting a wipe test of the surface using methods that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in **Table 8** for restricted areas and **Table 9** for unrestricted areas (e.g., 200 dpm/100 cm^2 for isotopes of iodine-131 in unrestricted areas). Wipe tests shall be measured in a low-background area and recorded in dpm.

Area surveys shall consist of ambient exposure rate surveys and removable contamination surveys according to Table 7. See **Table 7** for areas and frequencies.

Table 7: Area Survey Frequency

Area Surveyed	Radiation Level Survey (mR/h)**	Removable Contamination Survey (dpm)
Radiopharmaceutical elution, preparation, assay, and administration areas when using radiopharmaceuticals requiring a written directive	Day of use	Weekly
All areas where unsealed alpha emitters are handled	Day of use	Day of use
Radionuclide use (not requiring a written directive)*, storage, and waste storage	Weekly	Weekly

*If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed. For radiopharmaceutical administrations requiring a written directive, unrestricted areas will be surveyed at the end of the therapy prior to releasing the area for unrestricted use.

** Licensees are required to perform radiation level surveys at the frequency specified, these surveys can act as a qualitative assessment of contamination in areas of use and on personnel. If trigger levels are exceeded, licensees must evaluate the presence of fixed versus removable contamination and follow appropriate emergency procedures.

Before releasing an area for unrestricted use after therapy, the licensee shall evaluate the need for the following contamination surveys, using a handheld survey instrument, and perform as necessary;

- the area of administration
- all trash exiting the patient's room or surgical recovery room
- the therapy patient's bed linens before removing them from the patient's room
- areas of public access in and around the patient's room

If trigger levels are exceeded, follow your emergency procedures for responding and investigating what caused the trigger to be tripped. Trigger levels for contamination are found in **Table 8 and 9** below. If trigger levels are exceeded:

- Unrestricted areas should be immediately decontaminated to background levels using appropriately sensitive equipment. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in **Table 9**;
- Any contaminated area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated. **Note:** A report to DHS may be required under ***DHS 157.13(17)***; and
- Follow internal procedures for responding and investigating what caused the trigger to be tripped.

Table 8: **Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)**

Area, clothing	**Alpha emitters**	**P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198**	**Cr-51, Co-57, Ga-67, Tc-99m, F-18, Tl-201**

Restricted areas, protective clothing used only in restricted areas	200	2,000	20,000

Table 9: Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)

Nuclide [1]	Average [2,3,4]	Maximum [2,4,5]	Removable [2, 4, 6]
U-nat, U-235, U-238, and associated decay products	5,000	15,000	1,000
Transuranics, I-125, I-129, Ra-226, Ra-228, Pa-231, Ac-227, Th-230	100	300	20
I-126, I-131, I-133, Ra-223, Ra-224, Sr-90, U-232, Th-nat, Th-232	1,000	3,000	200
Other alpha emitters[1]	500	1,500	100
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5,000	15,000	1,000

1. Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.
2. As used in this table, disintegrations per minute (dpm) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
3. Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.
4. The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/h at 1 cm and 1.0 millirad/h at 1 cm, respectively, measured through not more than 7 milligram/cm^2 of total absorber.
5. The maximum contamination level applies to an area of not more than 100 cm^2.
6. The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with a filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally, and the entire surface should be wiped.

Personnel Surveys

Personnel should be surveyed to minimize the spread of contamination. Personnel surveys are necessary following the use of unsealed forms of radioactive materials, licensees shall survey:

- at the end of each day of use;
- hands, clothing, and shoes for contamination of personnel involved in a contamination event; and

Contents of Survey Records

Each survey record should include the following:

- a diagram of the area surveyed
- a list of items and equipment surveyed
- specific locations on the survey diagram where wipe tests were taken
- exposure rate levels with appropriate units
- contamination levels with appropriate units
- make, model, and serial number of instruments used
- background levels

- name or initials of the person making the evaluation and recording the results and date

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

Licensees must maintain records of surveys required by ***DHS 157.25(1)(a)*** and ***DHS 157.62(7)***. Licensees must retain these records for 3 years after the record is made as required by ***DHS 157.31(3)*** and ***DHS 157.71(10).***

Appendix S

Model Procedure for Developing, Maintaining, and Implementing Written Directives

This model provides acceptable procedures for administrations that require written directives. You may either adopt this model procedure or develop your own procedure to meet the requirements of ***DHS 157.61(4)*** & ***DHS 157.61(5)***.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require WDs. This model does not restrict your use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in ***DHS 157.61(5)*** will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μCi), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from radioactive material. The WD must contain the information described in ***DHS 157.61(4)*** and be retained in accordance with ***DHS 157.71(3)***.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the AU prescribes a remote afterloader treatment, the delivery process may involve a team of medical professionals such as an AMP, a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities, e.g., radiopharmaceutical therapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and emerging technologies. For each such modality for which ***DHS 157.61(4)*** requires a written directive, the licensee shall develop, implement, and maintain written procedures for WDs to meet the requirements and objectives of ***DHS 157.61(4), DHS 157.61(5) & DHS 157.62(3),*** outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in ***DHS 157.61(4)***, including the patient or human research subject's name;
- Verify the patient's or human research subject's identity prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- Check both manual and computer-generated dose calculations;

- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices;
- Determine if a medical event, as defined in ***DHS 157.72(1)***, has occurred;
- Determine, for permanent implant brachytherapy, within 60 calendar days from the date of implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implant portion of the written directive; and
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or any Dosage of Quantities Greater than 30 Microcuries of Sodium Iodide I-131

Develop, maintain and implement the following procedures to meet the objectives of ***DHS 157.61(4)*** and ***DHS 157.61(5)***:

- An AU must date and sign a WD prior to the administration of any dose or dosage;
- Prior to administering a dose or dosage, the patient's or human research subject's identity will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or social security card. Asking or calling the patient's name does not constitute positive patient identity verification; and
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

Licensees are required under ***DHS 157.61(4) & (5)*** to have a Written Directive (WD) for certain administrations of doses and to have procedures for administrations for which a WD is required. Model procedures for meeting these requirements appear below.

Complete the WD in accordance with ***DHS 157.61(4)***. For temporary implants, before implantation, record the treatment site, radionuclide, and dose, as required by ***DHS 157.61(4)(b)6.a.,*** and after implantation but before completion of the procedure, record the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose), and date, as required by ***DHS 157.61(4)(b)6.b.***. For permanent implants, before implantation, record the treatment site, radionuclide, and total source strength, as required by ***DHS 157.61(4)(b)5.a.***, and after implantation but before the patient leaves the post-treatment recovery area, record the treatment site, the number of sources implanted, the total source strength implanted, and the date, as required by ***DHS 157.61(4)(b)5.b.*** The WD may be maintained in the patient's chart

To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.

For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the non-radioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

1. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).

2. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).

3. For manually generated dose calculations, verifying:
    a. No arithmetic errors;
    b. Appropriate transfer of data from the WD, treatment plan, tables and graphs;
    c. Appropriate use of nomograms (when applicable); and
    d. Appropriate use of all pertinent data in the calculations.

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing

will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.

Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:

1. An individual who did not perform the full calibration (the individual will meet the requirements specified in ***DHS 157.61(8)***) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in ***DHS 157.67(6)***); or
2. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.

For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

For emerging technologies (e.g., Yttrium-90 Microsphere Brachytherapy, Leksell Gamma Knife Perfexion), the licensee should review the applicable guidance on the NRC's Medical Uses Licensee Toolkit Web page to ensure the written directive contains all necessary components.

A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes (i) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (ii) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

As required by ***DHS 157.61(5)*** , determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable, and whether a medical event, as defined in ***DHS 157.72(1)***, has occurred. For permanent implant brachytherapy, determine, within 60 calendar days from the date the implant was

performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implant portion of the WD, to evaluate whether a medical event, as defined in ***DHS 157.72(1)***, has occurred. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified

Conduct periodic reviews of each applicable program area, e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, gamma stereotactic radiosurgery, and emerging technologies. The number of patient cases to be sampled will be based on the principles of statistical acceptance sampling and will represent each treatment modality performed in the institution, e.g., radiopharmaceutical, brachytherapy and gamma stereotactic radiosurgery.

If feasible, the persons conducting the review will not review their own work. If this is not possible, two people will work together as a team to conduct the review of that work. We will regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective. As required by ***DHS 157.61(5)***, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. For each patient case reviewed, deviations from the WD, the cause of each deviation, and the action required to prevent recurrence will be identified.

Reports of Medical Events

Notify by telephone DHS no later than the next calendar day after discovery of the medical event and submit a written report to DHS Office within 15 days after the discovery of the medical event, as required by ***DHS 157.72(1)***. Also notify the referring physician and the patient as required by ***DHS 157.72(1)***. (**Note*:*** The telephone number of the DHS Office is (608) 267-4797, daytime; (608) 258-0099 after-hours.)

Appendix T

Model Procedure for Safe Use of Licensed Material

This procedure provides acceptable methods for safe use of licensed material. You may either adopt this procedure or develop your own procedure to meet the requirements of ***DHS 157.21, DHS 157.23(1),*** and ***DHS 157.62(6)***.

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area using an appropriate survey instrument.
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle.)
- Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the workplace in a designated low-background area.
- Wear extremity dosimeters, if required, when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled (including bearing the radiation symbol and the words CAUTION, “RADIOACTIVE MATERIAL" or “DANGER, RADIOACTIVE MATERIAL”), and properly shielded receptacles.
- Never pipette by mouth.
- Wipe-test unsealed radioactive material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
- Survey all areas of licensed material use, including the generator storage, kit preparation, and injection areas, for contamination using a survey instrument at the required frequency. If necessary, decontaminate the area.
- Store radioactive solutions in shielded containers that are clearly labeled.
- Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with ***DHS 157.62(6)*** and ***DHS 157.29(4)***. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical).
- Syringes and unit dosages must be labeled in accordance with ***DHS 157.62(6)*** and ***DHS 157.29(4)***. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in **Chapter DHS 157, Appendix F**, the syringe or vial need only be labeled to identify the radioactive drug (***DHS 157.62(6)***). To avoid mistaking patient dosages, label the syringe with the type of study and the patient’s name.
- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (***DHS 157.62(3)***).

- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an authorized user.
- When measuring the dosage, licensees need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
- Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified, and the administration must be in accordance with the written directive (***DHS 157.61(5)***).
- Always keep calibration, transmission, and reference sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all licensed material when not under the constant surveillance and immediate control of an authorized user or person working under the supervision of an authorized user.

Appendix U

Model Procedures for Release of Patients or Human Research Subjects Administered Radioactive Materials

DHS 157.62(8) permits a licensee to "authorize the release from its control any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)."

An applicant committing to follow this appendix shall follow the guidance provided in NRC's RG 8.39, Revision 1, *'Release of Patients Administered Radioactive Materials'*, dated April 2020. References in the RG to the NRC's regulations (Title 10 of the Code of Federal Regulations) shall be interpreted as the respective DHS Administrative Code (DHS 157). Where the RG says "should" we will implement this as saying "shall."

Appendix V

Guidance for Mobile Medical Services

Mobile medical service providers must comply with all applicable sections of ***Chapter DHS 157, Subchapter VI*** as well as DOT regulations with regard to approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training. For example, mobile medical service providers offering remote afterloaders must comply with ***DHS 157.67(1)***.

Type and Location of Use

In general, there are two types of mobile medical service. One type is to transport and use radioactive material within a transport vehicle (e.g., in-coach/van use). A second type is to transport radioactive material to a client's facility and use within a client's facility by the mobile medical service's employees.

For the first and second types, which include material use by the service provider, the service provider must apply for full service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transportation of the radioactive material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the radioactive material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the radioactive material use and patient treatments upon transfer of the radioactive material to their possession.

For all types, licensed activities must be conducted in accordance with the rules for compliance with ***DHS 157.62(9)(a)1.*** which states that the licensee will obtain a letter signed by the management (i.e., chief executive officer or delegate) of each of its clients for which services are rendered. The letter will permit the use of radioactive material at the client's address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service, as required by ***DHS 157.62(9)(c)*** and ***DHS 157.71(12).*** Additionally, as required by ***DHS 157.62(9)(a)4***. the licensee will survey to ensure compliance with the requirements in ***Chapter DHS 157, Subchapter III*** (e.g., ensure that all radioactive material, including radiopharmaceuticals, sealed sources, and all associated wastes have been removed) before leaving a client's address.

The location of use for mobile medical services is of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary job site at client facilities. The following section describes the required information necessary for base locations and temporary job sites.

Base Location and Client Site(s)

The base location (e.g., the central radiopharmaceutical laboratory or the storage location for the remote afterloader) for the mobile medical service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, commercial facility, or the mobile coach/van. You must specify in what type of facility the proposed base facility is located. As required by ***DHS 157.15*** and ***DHS 157.13(1)*** you must submit a detailed description and diagram(s) of the proposed base facility and associated equipment in accordance with **Items 8.1 through 8.5** of this WISREG. The description and diagram of the proposed facility must demonstrate that the building (or coach/van) is of

adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with ***DHS 157.23(1)***. Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within the coach/van, the description of the coach/van must address radiation levels in the driver's compartment to demonstrate compliance with ***DHS 157.22(1)***,*'Occupational dose limits for adults.'*

- You may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Base locations can include the use of a mobile coach/van. When the base facility is in the coach/van, and there is no permanent structure for the radioactive material storage, the service must provide for the following:
  - Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
  - Secured storage facilities available for storage of radioactive material and radioactive waste if the coach/van is disabled; and
  - Radioactive material can be delivered directly to the coach/van only if the coach/van is occupied by licensee's personnel at the time of delivery.
- If a base facility is located in a residential area, the following information must be provided:
  - Justification of the need for a private residence location rather than for a commercial location.
  - Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the facility in the event of contamination. Provisions for decontamination of the mobile medical service coach/van, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the client and the mobile medical service.
  - A description of the program demonstrating compliance with ***DHS 157.23(1)*** '*Dose limits for individual members of the public.'*
  - Verification that restricted areas does not contain residential quarters.
- Perform surveys necessary to show that the exposure rate does not exceed 2 mrem in any one hour or TEDE does not exceed 100 mrem per year. Restrict access to members of the public if these limits cannot be met (e.g., cones, ropes and signs).

If you will provide transportable services to the client's site for use within the client's facility by the mobile medical service's employees, you must provide the following client facility information and commitment:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with **Items 8.1 through 8.5** of this WISREG. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with ***DHS 157.23(1)***. You must include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.

- A commitment, as delineated in the letter required by ***DHS 157.62(9)(a)1.*** that the mobile medical service licensee has full control of the treatment room during radioactive material use for each client.
- ***DHS 157.62(9)(b)*** prohibits radioactive material from being delivered directly to a non-licensed client site when mobile medical staff are not present. If the mobile service provider wishes to have radioactive material delivered when staff is not present, provide the following information:
  - Commitment from client that radioactive material will be secured from unauthorized access;
  - Diagram of storage location if separate from use location;

Mobile Therapy Services

This section applies only to therapeutic uses of radioactive material. For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

For self-contained radioactive material services (e.g., in-coach/van) you must provide the following additional facility information:

- For therapy treatments with radioactive material (e.g., high dose-rate remote afterloader), a separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public;
- A signed agreement, as delineated in the letter required by ***DHS 157.62(9)(a)1.***, that the location of the device/vehicle will be on client-owned or controlled property;
- The protection from vehicular traffic that could adversely affect patient treatment(s), that could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided;
- A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient; and
- If you will provide transportable services to the client's site for use within the client's facility by the mobile medical service's employees, you must provide the initial installation records and function checks of a remote afterloader device for each site of use, as required by [***DHS 157.67(8), DHS 157.67(11),*** and ***DHS 157.67(13)***].

For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, you must ensure the following:

- Each client is properly licensed for medical use of radioactive material. If applicable, you must ensure that each client has received the necessary initial and recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader device to the client;
- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of radioactive material for patient treatments. This includes such activities as dosage

measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the radioactive material for patient treatments. The responsibilities for supervising individuals who use the radioactive material, set forth in ***DHS 157.61(3)*** transfer to the client's Authorized Users (AUs) upon transfer of the device to the client by the mobile medical service provider;

- The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site); and
- As required by ***DHS 157.06(1)*** **and** ***DHS 157.13(18)*** a formal record of the transfer of control of the radioactive material from the mobile medical service provider to the client, and from the client back to the mobile medical service provider, must be made for each transfer of radioactive material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

You must have an authorized user designated to supervise mobile medical staff for each location of use. The supervising authorized user must commit to periodically observe supervised individual(s) or you must provide an alternate method to ensure that the supervised individual(s) follows policies and procedures.

In addition to the requirements in ***DHS 157.88(2)*** you will instruct supervised individuals in your written radiation protection procedures, written directive procedures, department rules, and license conditions with respect to the use of radioactive material. Additionally, you will require the supervised individual to:

- Follow the instructions of the supervising authorized user for medical uses of radioactive material;
- Follow the instructions of the supervising authorized nuclear pharmacists or supervising authorized user for preparation of radioactive material for medical uses; and
- Follow the written radiation protection procedures and written directive procedures established by the licensee.

Although you may add new client locations without receiving an amendment to your radioactive materials license, you are required to notify DHS of the supervising individual(s) at a new client location within 30 days of using radioactive material at the new location [***DHS 157.13(5)(c)1.***]. This notification does not require a fee.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of ***DHS 157.88(2), DHS 157.64(2), DHS 157.65(4),*** and ***DHS 157.67(4)*** as applicable. The training for these individuals will include, at a minimum, DOT HAZMAT general and security awareness (also see **Item 9.18** and **Appendix W** for DOT regulations), shielding, ALARA, and basic radiation protection.

Survey Instrument and Dose Measurement Instrument Checks

As required by ***DHS 157.62(9)(a)3.***, you will check survey instruments for proper operation with a dedicated check source before use at each address of use. You will check dose measurement instruments before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Radioactive Material

A supplier will deliver radioactive material to the base location or to the client's address if the client is licensed to receive the type of radioactive material ordered. You may request an exception for a dedicated location of use within a non-licensed client's facility. Delivery of radioactive material to a coach/van that is not occupied by the mobile medical service personnel is prohibited. Alternatively, you may pick up the radioactive material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

Develop, implement, and maintain emergency procedures, in accordance with your radiation protection program required by ***DHS 157.21***. You should indicate typical response times of the RSO and AU in the event of an incident and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as, wind, water, or fire that results in damage to exterior or interior portions of the vehicle or the radioactive material used in the mobile medical service. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous material-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

- A 24-hour emergency contact telephone number for the mobile medical service provider's emergency response personnel.
- The emergency contact numbers for the Department of Health Services / Radiation Protection Section. (During office hours: 7:45 a.m. to 4:30 p.m. (608) 267-4797; After hours (608) 258-0099.
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist.
- Procedures for retrieving and securing any radioactive material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers.
- Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios.
- Preplanned decontamination procedures, including ready access to all necessary materials.

- A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys.
- Security of the transport vehicle against unauthorized access, including the driver's compartment.
- Procedures to ensure that following any accident, no patient treatments with remote afterloaders will occur until all systems pertaining to radiation safety have been tested and confirmed to be operational by the RSO or an AMP. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with ***DHS 157.13(17)*** will be provided to clients following any accident in which there is actual or possible damage to the client's facility or the device.

Note: The type of response should be consistent with the level of the incident. The response may range from phone contact for minor spills to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

Develop, document, and implement procedures to assure that the following take place:

- Radioactive material is transported in accordance with DOT ***49 CFR Parts 170–189***. Procedures will include:
  - Use of approved packages;
  - Use of approved labeling;
  - Conduct of proper surveys;
  - Complete and accurate shipping papers;
  - Bracing of packages;
  - Security provisions; and
  - Written emergency instructions.
- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
- Licensed material is secured during transport and use at the client's facilities.
- Radioactive waste is handled properly during transport. You will describe the method of storage and final disposal.
- The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Note: The necessary DOT Type 7A package certification for remote afterloader devices is established by prior approval of the appropriate sealed source and device sheets. However, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT Type 7A packaging may be compromised. The device must not be used or transported until checked by the vendor and certified as retaining its integrity as a Type 7A package.

Radioactive Waste Management

If waste will be stored in coach/vans, the vehicle will be properly secured and posted as radioactive material storage locations. You will ensure that the coach/van will be secured against unauthorized access and that the waste storage location will be posted as a radioactive material storage area.

Develop, document, and implement final waste disposal procedures in accordance with **Item 10** of this guide.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewerage system, in accordance with ***DHS 157.30(3)***. However, collecting excreta from patients in a coach/van restroom with a holding tank is not considered direct disposal into the sanitary sewerage system.

If a restroom facility is provided in the coach/van for patient use, submit the following information for department review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the coach/van, and the driver of the coach/van; a description of procedures to assess the tank for possible leakage and a description of any restroom ventilation if any I-131 will be held in the tank;
- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in ***DHS 157.22(1)*** and ***DHS 157.23(1)*** that the external surfaces of the coach/van do not exceed 2 mrem/hour, and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet; and
- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Medical Services with Remote Afterloader Devices

Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that proper operation of the device be fully checked after each such relocation. Therefore, develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Safety checks conducted on a remote afterloader device and facility. The procedure must include the periodic spot checks required by ***DHS 157.67(11)*** and the additional spot checks required by ***DHS 157.67(13)*** before use at each address of use. Additionally, the procedure should include provisions for prompt repair of any system not operating properly;
- The pretreatment operational function checks after each device move should include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages;
- Such tests should be performed in accordance with written procedures;
- You must maintain records, as described in ***DHS 157.71(23)*** **and** ***DHS 157.71(25)***, showing the results of the above safety checks for DHS inspection and review for a period of 3 years; and

- Perform surveys of the source housing and areas adjacent to the treatment room following relocation of a HDR unit. These surveys should include the source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position.

Appendix W

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Licensed Material

Licensed material must be transported in accordance with DOT regulations. The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:

- Table of Hazardous Materials and Special Provisions ***49 CFR 172.101***, and **App. A, Table 2**: Hazardous materials table, list of hazardous substances, and reportable quantities;

- Shipping Papers ***49 CFR 172.200-204:*** Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper's certification;

- Package Markings ***49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.310, 49 CFR 172.324:*** Applicability, general marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;

- Package Labeling ***49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406 49, CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440:*** General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;

- Placarding of Vehicles ***49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556:*** Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;

- Emergency Response Information ***49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604:*** Applicability and general requirements, emergency response information, emergency response telephone number;

- Training, Subpart H, ***49 CFR 172.700***, ***49 CFR 172.702-704*** purpose and scope, applicability and responsibility for training and testing, and training requirements;

- Security Plans ***49 CFR 172.800***, ***49 CFR 172.802, 49 CFR 172.802:*** Purpose and applicability, components of a security plan;

- Shippers – General Requirements for Shipments and Packaging ***49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.443, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476:*** Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the

listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limit, requirements for U.S. NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and

- Carriage by Public Highway ***49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842.*** Driver training, shipping paper, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

For additional transportation information, licensees may consult DOT's *"A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials"*, http://hazmat.dot.gov/pubtrain/ramreview.pdf or visit the DOT's Office of Hazardous Materials Safety web site at http://hazmat.dot.gov

Appendix X

Procedure for Waste Disposal by Decay-In-Storage, Generator Return, Licensed Material Return, and Disposal of Liquids into Sanitary Sewerage

These procedures provide acceptable methods for waste disposal. Most licensees will dispose of material that fall within these procedures. Note that some short half-life radionuclide products [e.g., technetium (Tc)-99m/molybdenum (Mo)-99 generator columns and some yttrium (Y)-90 microspheres] may contain long half-life contaminants that may preclude disposal by decay-in-storage and may require disposal by alternate methods, such as return to the manufacturer. Applicants may either adopt these procedures or develop alternative procedures to meet the requirements of ***DHS 157.30, DHS 157.21,*** and ***DHS 157.62(10)***.

Procedure for Decay-In-Storage

DHS 157.62(10) describes the requirements for decay-in-storage. Applicants should ensure that adequate space and facilities are available for the storage of waste for decay-in-storage (DIS). Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
- Waste should be stored in suitable well-marked containers, and then containers should provide adequate shielding.
- Liquid and solid waste should be stored separately.
- If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material.
- When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container. The container may then be transferred to the decay-in-storage area. When large quantities are held for DIS, measurable activities may be present event after many half-lives and person performing surveys should be aware of the potential for measurable radiation.
- The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.
- Prior to disposal as ordinary or biomedical waste, monitor and record the results of monitoring of each container as follows:
  - Use a survey instrument that is appropriate for the type and energy of the radiation being measured;
  - Check the radiation detection survey meter for proper operation and current calibration status;
  - Monitor in a low-level radiation (<0.05 millirem per hour) area away from all sources of radioactive material, if possible;
  - Remove any shielding from around the container or generator column;
  - Monitor, at contact, all surfaces of each individual container;
  - Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in ***DHS 157.62(10)***);

- Discard as in-house waste ordinary or biomedical waste only those containers that cannot be distinguished from background. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal;
- Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized radioactive material recipient.
- Shote half-life radionuclide products, such as samarium-153 (Sm-153), Tc-99m/Mo-99 generator columns, and Y-90 microspheres may contain long half-life contaminants that may preclude disposal by decay-in-storage. Licensees need to perform surveys and dispose of long half-life contaminants in accordance with ***DHS 157 Subchapter III*** and ***DHS 157 Subchapter VI***.

Note: Check for any calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153), as these may not be held for decay-in-storage and must be disposed of in accordance with ***DHS 157 Subchapter III*** and ***DHS 157 Subchapter II***.

Procedure for Returning Generators to the Manufacturer

Used Mo-99/Tc-99m, strontium-82/rubidium-82, or germanium-68/gallium-68 generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with DHS transportation requirements in ***DHS 157.03*** '*Definitions'* **and *Chapter DHS 157, Subchapter XIII*** and DOT regulations (incorporated by reference). Perform the following actions when returning generators:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions; and
- Retain records of receipts and transfers in accordance with ***DHS 157.06(1)*** and ***DHS 157.13(18)***.

Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

- In accordance with ***DHS 157.13(15)***, confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's DHS license, NRC or Agreement State license that authorizes the radioactive material);
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions; and
- Retain records of receipts and transfers in accordance with ***DHS 157.06(1)*** and ***DHS 157.13(18)***.

Procedure for Disposal of Liquids into Sanitary Sewerage

- Confirm that the sewer system is a public system, not a private sanitary system, septic system or leach field.
- Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.
- Calculate the amount of each radio nuclide that can be discharged by using information from prior, similar discharges and the information in ***DHS 157 Appendix E***.
- Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in ***DHS 157.30(3)(a)3.c.*** and ***DHS 157, Appendix E, Table 3***.
- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of each radionuclide to the corresponding limit for each radionuclide in ***DHS 157, Appendix E, Table 3*** must not exceed unity.
- Confirm that the total quantity of licensed material and other radioactive material released into the sanitary sewerage system in a year does not exceed 185 gigabecquerel (GBq) [5 Curies (Ci)] of tritium (H-3), 37 GBq [1 Ci] of carbon (C)-14, and 37 BGq [1 Ci] of all other radioactive materials combined. **Note:** ***DHS 157.30(3)(a)3.c.*** further limits the disposal of H-3, C-14 and "other radioactive material" to the limits noted above even when sewerage totals determined under ***DHS 157.30(3)(a)3.c.***, and as noted in the bullet above, may have allowed a higher sanitary sewerage disposal activity.
- Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks, toilets, or other release points.
- Discharge liquid waste slowly, to minimize splashing, with water running to be sure that the material moves out of the sink and into the sewer system.
- Survey the sink and the surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Decontaminate all areas or surfaces if found to be contaminated.
- Maintain records of releases of licensed material to the sanitary sewer system. These records should include, for each release, the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual discharging the waste. For the licensed facility as a whole, records should be maintained of the quantity and concentration of radionuclides that are released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Appendix Y

Recordkeeping Requirements

Record	Survey Requirement	Record Requirement	Retention Period
Results of surveys and calibrations	***DHS 157.25; DHS 157.29(6)***	***DHS 157.31(3)(a)***	3 years
Results of surveys to determine dose from external sources		***DHS 157.31(3)(b)***	Duration of license
Results of measurements and calculations used to determine individual intakes		***DHS 157.31(3)(b)***	Duration of license
Results of air samplings, surveys and bioassays	***DHS 157.27(3)(a)3***	***DHS 157.31(3)(b)***	Duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		***DHS 157.31(3)(b)***	Duration of license
Determination of prior occupational dose		***DHS 157.31(5)***	Duration of license
Planned special exposure	***DHS 157.22(6)***	***DHS 157.31(6)***	Duration of license
Individual monitoring results	***DHS 157.25(2)***	***DHS 157.31(7)***	Duration of license
Dose to declared pregnant woman	***DHS 157.25(2)(a)3***	***DHS 157.31(7)(d)***	Duration of license
Dose to individual members of the public	***DHS 157.23(2)***	***DHS 157.31(8)***	Duration of license
Waste Disposal	***DHS 157.30***	***DHS 157.31(9)***	Duration of license
Records of information important to the decommissioning of a facility			Duration of license
Receipt, transfer and disposal of radioactive material	***DHS 157.06(1)***	***DHS 157.06(1)***	Duration of possession and 3 years thereafter
Authority and responsibilities of radiation protection program	***DHS 157.61(1)***	***DHS 157.71(1)***	5 years
Radiation protection program changes	***DHS 157.61(2)***	***DHS 157.71(2)***	5 years
Written directives	***DHS 157.61(4)***	***DHS 157.71(3)***	3 years
Calibrations of instruments used to measure activity of unsealed radioactive material	***DHS 157.62(1)***	***DHS 157.71(6)***	3 years
Radiation survey instruments calibrations	***DHS 157.62(2)***	***DHS 157.71(7)***	3 years
Dosages of unsealed radioactive material for medical use	***DHS 157.62(3)***	***DHS 157.71(8)***	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	***DHS 157.62(5)***	***DHS 157.71(9)***	3 years
Surveys for ambient radiation exposure rate	***DHS 157.62(7)***	***DHS 157.71(10)***	3 years

Release of individuals containing unsealed radioactive material or implants containing radioactive material	***DHS 157.62(8)***	***DHS 157.71(11)***	3 years

Appendix Z

Reporting Requirements

EVENT	TELEPHONE NOTIFICATION	WRITTEN REPORT	DHS 157 REQUIREMENT
Reports to individual workers with doses >100 mrem	None	Annually	***DHS 157.88(3)(a)***
Reports to former individual workers	None	Upon request	***DHS 157.88(3)(c)***
Reports to worker terminating employment	None	Upon request	***DHS 157.88(3)(b)***
Removable radioactive surface contamination exceeds the limits of DHS 157.94(1) [i.e. 22 dpm/cm2 of beta or gamma emitting photons or 2.2 dpm/cm2 of alpha]	immediate [DHS and final delivery carrier must be notified]	None	***DHS 157.94(1)***
Theft or loss of material	Immediate	30 days	***DHS 157.32(1)***
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	***DHS 157.32(2)(a); DHS 157.32(3)***
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	***DHS 157.32(2)(a); DHS 157.32(3)***
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	***DHS 157.32(2)(b); DHS 157.32(3)***
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	***DHS 157.32(2)(b); DHS 157.32(3)***
Doses in excess of specified criteria	None	30 days	***DHS 157.32(3)***
Levels of radiation or concentrations of radioactive material in excess of specified criteria	None	30 days	***DHS 157.32(3)***
Planned special exposures	None	30 days	***DHS 157.32(4)***
Report to individuals who exceed dose limits	None	30 days	***DHS 157.32(6)***
Report of individual monitoring	None	Annually	***DHS 157.32(5)(b)***
Defect in equipment that could create a substantial safety hazard	2 days	30 days	
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	***DHS 157.13(17)(a)***
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	***DHS 157.13(17)(b)***
Unplanned fire or explosion that affects the integrity of any licensed material or device,	24 hours	30 days	***DHS 157.13(17)(b)***

container, or equipment with licensed material			
Licensee permits individual to work as AU, ANP, or AMP	None	30 days	***DHS 157.13(5)(c)***
RSO, AU, ANP, ARSO, or AMP discontinues performance of duties under license or has a name change	None	30 days	***DHS 157.13(5)(c)2.a***
Temporary Radiation Safety Officer	None	30 days	***DHS 157.13(5)(c)2.e***
Licensee's mailing address changes	None	30 days	***DHS 157.13(5)(c)2.b***
Licensee's name changes without constituting a change of control	None	30 days	***DHS 157.13(5)(c)2.c***
Licensee adds or changes areas of 10 CFR 35.100 or 35.200 use of byproduct material identified in application or license if the change or addition did not involve movement of a PET radionuclides production facility or transfer line from a PET radionuclide production facility	None	30 days	***DHS 157.13(5)(c)2.d.***
The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment	None	30 days	***DHS 157.13(5)(c)2.f.***
Unplanned contamination event	24 hours	30 days	***DHS 157.13(17)(b)***
Medical event: dose that differs from the prescribed dose by 5 rem EDE or 50 rem to an organ	24 hours	15 days	***DHS 157.72(1)(a)***
Medical event: patient intervention results in unintended permanent functional damage to an organ	24 hours	15 days	***DHS 157.72(1)(b)***
Notify referring physician and person who is the subject of a medical event	24 hours	Upon request	***DHS 157.72(1)(e)***
Dose to embryo/fetus or nursing child in excess of 5 rem or resulted in unintended permanent damage to an organ of the child	24 hours	15 days	***DHS 157.72(2)***
Leaking sealed source	None	5 days	***DHS 157.32(7); DHS 157.72(3)***

Eluate exceeding permissible molybdenum-99, strontium-82, or strontium-85 concentrations	7 days	30 days	***DHS 157.63(3)(a)***

For licensees who possess category 1 or 2 quantities of material, reporting requirements can be found in *DHS 157.9715*.