

HOW TO FILE

PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application.
- Complete *DHFS* form#### (*Appendix A*).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 – inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of responses as shown in this document or submission of alternative procedures may require a custom review.

Note: In this document, dose or radiation dose is used as defined in HFS 157.03, i.e., a generic term that means absorbed dose, dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. These latter terms are also defined in HFS 157.03.

WHERE TO FILE

Applicants wishing to process or use radioactive material in Wisconsin are subject to the requirements of *HFS 157* and must file a license application with:

*Department of Health and Family Services
Radiation Protection Section
1 West Wilson Street
P.O. Box 2659
Madison, WI 53701-2659
Phone: (608) 267-4797
Fax: (608) 267-3695*

LICENSEE FEES

The appropriate fee must accompany each application or license amendment request. Refer to *HFS 157.10* to determine the amount of the fee. The department 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 the department's disposition of an application or the withdrawal of an application.

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

Direct all questions about the department's fees or completion of Item 16 of *DHFS Form#### (Appendix A)* to the *Department of Health and Family Services, Radiation Protection Section* at (608) 267-4797.

Contents of an Application

Item 1: License Action Type

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

ITEM 1. TYPE OF APPLICATION (Check All That Apply)

- NEW LICENSE
- RENEWAL License # _____
- AMENDMENT License # _____

Item 2: Applicant's Name and Mailing Address

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.

Note: The department must be notified in the event of change of ownership or control and bankruptcy proceedings; see below for more details.

Timely Notification of Change of Ownership or Control:

Regulations: *HFS 157.13*

Criteria: Licensees must provide full information and obtain the department's **written consent prior** to transferring ownership or control of the license (commonly referred to as "transferring the license").

Discussion: Changes in ownership may be the results of mergers, buyouts, or majority stock transfers. Although it is not the department's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain the department's prior written consent. This is to ensure all the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid **DHFS** 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 disposition of records and radioactive material;
- Public health and safety are not compromised by the use of such materials.

Response from Applicant:

None from an applicant for a new license

Notification of Bankruptcy Proceedings.

Regulations: *HFS 157.13(10)*

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify *DHFS*, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Response from Applicant:

None at time of application for a new license.

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 radiation safety officer, unless the applicant has named a different person as the contact. *DHFS* will contact this individual if there are questions about the application.

Notify *DHFS* if the contact person or his or her telephone number changes so that *DHFS* 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.*

Applicants should note that deviations from the suggested responses and submission of alternative procedures may require custom review.

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

Applicants need to provide the following information:

- Description of storage and use location.

Specify the street address, city and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, WI) for each facility location. The descriptive address should be sufficient to allow a *DHFS* inspector to find the use/storage location. A Post Office Box address is not acceptable.

Obtaining a *DHFS* license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements for storage locations).

Note: As discussed later in the section "Financial Assurance and Record Keeping for Decommissioning," licensees need to maintain permanent records on file describing where radioactive material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of the specific locations or room numbers where radioactive material is

used or stored, and any records of spills or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

Regulations: *HFS 157.13 (2)*

Criteria: The Radiation Safety Officer (RSO), Authorized Users (AUs), and Authorized Nuclear Pharmacists (ANPs) must have adequate training and experience.

Discussion: Individuals responsible for the radiation protection program are licensee senior management, the RSO, ANPs, and AUs. *DHFS* requires that an applicant be qualified by training and experience to use radioactive materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. The minimum training and experience criteria for RSOs and AUs, though not specifically described in the department's rule for radiopharmacy licensees, should include a bachelor's degree in a physical science, or equivalent, and previous experience handling and supervising similar activities. Applicants should note that a résumé or a curriculum vitae does not usually supply all the information needed to evaluate an individual's training and experience.

DHFS holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes underemphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO, in writing, sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding the department's rule and license provisions and to terminate unsafe activities involving radioactive material. The licensee maintains the ultimate responsibility, nevertheless, for the conduct of licensed activities.

Response from Applicant:

Refer to the subsequent sections specific to the individuals described above. Applicants should submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO. Management may delegate authority to the RSO to submit license amendments.

Item 5. Radiation Safety Officer (RSO)

Regulations: *HFS 157.13(2)*

Criteria: Each licensee must appoint a qualified individual to act as the Radiation Safety Officer (RSO). The RSO must have adequate training and experience.

Discussion: *DHFS* requires the name, training, and experience of the proposed RSO to ensure that the applicant has identified a responsible, qualified person to oversee the radiation safety program. When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position, and select an individual who is qualified and has the time and resources to fulfill those duties and responsibilities. Typical duties and responsibilities of a radiopharmacy RSO are included in *Appendix H*.

The RSO needs a level of basic technical knowledge sufficient to understand the work to be performed with radioactive materials at the radiopharmacy and to be qualified by training and experience to perform the duties required for that position. Any individual who has sufficient training and experience to be named as an authorized nuclear pharmacist (ANP) is also considered qualified to serve as the facility RSO. The same is true for an authorized user (AU) who has had adequate training and experience in the radiation safety aspects associated with the use of similar types of radioactive material.

The training and experience requirements for the RSO may be met by any of the following:

- Qualification as an ANP;
- Identification as an AU on the license and experience in the use of the types and quantities of radioactive material for which the individual has RSO responsibilities;
- Didactic and work experience.

In order to demonstrate adequate training and experience, the RSO should have (1) as a minimum, a college degree at the bachelor level, or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include all the following subjects:

- Radiation protection principles;
- Characteristics of ionizing radiation;
- Units of radiation dose and quantities;
- Radiation detection and measurement instrumentation;
- Biological hazards of exposure to radiation (appropriate to types and forms of radioactive material to be used);
- *DHFS* requirements and standards;
- Hands-on use of radioactive materials commensurate with the uses proposed by the applicant.

The length of training and experience will depend upon the type, form, quantity, and proposed use of the radioactive material requested. The proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. The requisite training may be obtained from formal courses consisting of lectures and laboratories designed for RSOs presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not be counted toward the hours documenting length of training unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the department upon request;
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to department upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the institution.

Response from Applicant:

ITEM 5. RADIATION SAFETY OFFICER (RSO) (*Attach evidence of training and experience and check one box*)

NAME: _____ TELEPHONE (Include Area Code): _____

AND

- A copy of the license (*DHFS*, the *NRC* or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an Authorized Nuclear Pharmacist, or an Authorized User or submit documentation of training and experience;

AND

- The duties of the RSO are as outlined in Appendix H of WISREG "Guidance for Commercial Radiopharmacy Licenses."

OR

- We will submit an alternative description of duties and responsibilities of the RSO.

Note: See *Appendix G* for convenient formats to use for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes.

Item 5.1: Authorized Nuclear Pharmacist (ANP)

Regulations: *HFS 157.13(4); HFS 157.03; HFS 157.61.*

Criteria: ANP must be a State-licensed pharmacist with adequate training and experience.

Discussion: Each commercial nuclear pharmacy must have an authorized nuclear pharmacist to prepare or supervise the preparation of radioactive drugs for medical use. Any individual who is not qualified to be an authorized nuclear pharmacist may work under the supervision of an authorized nuclear pharmacist. The criteria for a pharmacist to work as an ANP at a commercial radiopharmacy are described in *HFS 157.13 (4)*. This section of the regulation refers to the definition of an ANP in *HFS 157.03*, "Definitions," the training and experience criteria described in *HFS 157.61*, "Training for an Authorized Nuclear Pharmacist," and recentness criteria described in *HFS 157.61*, "Recentness of Training." Successful completion of training as described in *HFS 157.61*, within 7 years preceding the date of the application, is evidence of adequate training and experience. Additional training and experience may be necessary if the time interval is greater than 7 years. Applicants may find it convenient to present this documentation using formats similar to those found in *Appendix G*. Each hour of training may be listed only once, (i.e., under the most applicable category). The recentness of training requirements applies to board certification as well as to other recognized training pathways.

On-the-job training may not be counted toward the hours listed above unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring facility or institution and can be made available to the department upon request;

- Evidence that the sponsoring facility or institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to the department upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the facility or institution.

Response from Applicant:

ITEM 5.1 AUTHORIZED NUCLEAR PHARMACIST (ANP)

(Attach evidence of training and experience and check all that apply)

NAME: _____ TELEPHONE (Include Area Code): _____

- We will provide a copy of the State pharmacy licensure for each pharmacist; and a copy of the license (*DHFS*, the *NRC* or an Agreement State) on which the individual was specifically named as an ANP

AND ONE OF THE FOLLOWING

- We will provide a copy of the certification(s) for the radiopharmacy board(s) approved by *DHFS*.

OR

- We will provide a description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.

OR

- We will provide a written certification, signed by a preceptor ANP, that the above training and experience as specified in *HFS 157.61 (9)* has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Item 6: Authorized Users (AU)

Regulations: *HFS 157.13 (2)*

Criteria: Authorized users (AUs) must have adequate training and experience with the types and quantities of radioactive material that they propose to use.

Discussion: If the applicant intends to perform functions other than the preparation and distribution of radioactive drugs, the applicant may request that an individual other than an ANP perform and/or supervise those functions. This individual, if approved, would be designated on the license as an AU. These other functions may include leak testing of sealed sources or instrument calibration services for the pharmacy; however, the term Authorized User, as used in this document should not be confused with the definition of an "Authorized User" contained in *HFS 157.03* for medical use.

Licensees must apply for a service license if the applicant wishes to provide services such as leak testing of sealed sources or instrument calibration to their customers or others.

In order to demonstrate adequate training and experience, the proposed AU should have (1) as a minimum, a college degree at the bachelor level, or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation protection principles;
- Characteristics of ionizing radiation;
- Units of radiation dose and quantities;
- Radiation detection and measurement instrumentation;
- Biological hazards of exposure to radiation (appropriate to types and forms of radioactive material to be used);
- *DHFS* requirements and standards; and
- Hands-on use of radioactive materials commensurate with uses proposed by the applicant.

The length of training and experience listed above will depend upon the type, form, quantity, and proposed use of the radioactive material requested. The proposed AU's training and experience should be sufficient to identify and control the anticipated radiation hazards. The above training may be obtained from formal radiation safety courses consisting of lectures and laboratories presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not count toward the hours listed above unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring facility or institution and can be made available to the department upon request;
- Evidence that the sponsoring facility or institution has examined the student's knowledge of the course content is maintained on file at the facility or institution and can be made available to the department upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the facility or institution.

The AU must demonstrate training and experience with the type and quantity of material that is to be used at the pharmacy. For example, someone with training and experience only with microcurie quantities of unsealed radioactive material may not be qualified to use or supervise the use of higher activity sealed radioactive sources for instrument calibration. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

Response from Applicant: For each proposed Authorized User (AU):

ITEM 6. AUTHORIZED USERS (AU) (Check one box)

- We will provide the individuals name and identify types, quantities, and proposed uses of radioactive material.
- AND*
- We will provide a copy of the license (*DHFS*, the *NRC* or an Agreement State) on which the individual was specified as an AU for the types and quantities and proposed uses of radioactive materials.
- OR*
- We will provide a copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of radioactive materials.
- OR*
- We will provide a description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials is attached. Appendix G in WISREG "Guidance for Commercial Radiopharmacy Licenses", may be helpful in describing the training and experience required.

Item 7: Occupationally Exposed Workers and Ancillary Personnel

Regulations: *HFS 157.88 (2); HFS 157.21; and HFS 157.13(2)*

Criteria: Individuals working with radioactive material must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. In addition, those individuals who, in the course of employment, are likely to receive in a year a dose in excess of 100 mrem (1 mSv) must be instructed according to *HFS 157.88 (2)*.

Discussion: *HFS 157.21* requires each licensee to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with Subchapter 3 of HFS 157 'Radiation Protection'. Each individual working with radioactive material must be trained in the radiation safety procedures applicable to their *job before beginning work with radioactive materials*. Licensees should not assume that safety instruction has been adequately covered by prior employment or training. Practical, site-specific training should be provided for all individuals prior to beginning work with, or in the vicinity of, licensed material. Training should also be performed whenever there is a *significant change in duties, procedures, regulations, or terms of the license*.

Each individual that receives greater than 1 mSv (100 mrem) should also *receive annual* training as specified in *HFS 157.88 (2)*. ANPs and others involved in the preparation of radiopharmaceuticals are most likely to receive doses in excess of 1 mSv (100 mrem) in a year; however, potential radiation doses received by all employees must also be evaluated. The evaluation must include consideration of assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during licensed activities.

If individuals making deliveries of radioactive material at the licensees facility are likely to receive a dose in excess of 1 mSv (100 mrem) in a year from the licensees activities, the licensee is responsible for ensuring that the person has received the training specified in Subchapter 10 of HFS 157 'Radiation Protection', regardless of whether that person is an employee of the licensee. If the training has been provided by someone else (such as the shipper or another licensee), the licensee does not have to provide

training except for instruction in site-specific radiation hazards. This issue is discussed in NRC Generic Letter 95-09, "Monitoring and Training of Shippers and Carriers of Radioactive Materials," dated November 3, 1995 which is available from the department.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and should emphasize practical subjects important to the safe use of licensed material. A method should be provided for individuals receiving instructions and training to ask questions. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual (e.g., the RSO, an ANP, AU, or radiation safety professional familiar with the licensee's program).

Licensee personnel who work in the vicinity of, but do not handle radioactive materials (ancillary staff), are not required to have radiation safety training as long as they are not likely to receive 1 mSv (100 mrem) in a year; however, to minimize potential radiation exposure when ancillary staff are working in the vicinity of radioactive material, it is prudent for them to work under the supervision and in the physical presence of an ANP/AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the radioactive material and the meaning of the radiation symbol, and should be instructed not to handle radioactive materials and to keep away from it as much as their work permits.

Some ancillary staff, although not likely to receive doses over 1 mSv (100 mrem), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments in the vicinity of the radioactive material to ensure the control and security of the material.

The guidance in *Appendix N* may be used by the applicant to develop a training program.

Response from Applicant:

ITEM 7 OCCUPATIONALLY EXPOSED WORKERS AND ANCILLARY PERSONNEL (Check one box)

- We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training. (Procedures are Attached)

References: For hard copies of NRC Generic Letter 95-09, "Monitoring and Training of Shippers and Carriers of Radioactive Materials," dated November 3, 1995, contact the department.

Item 8. Personnel Involved in Hazardous Materials Package Preparation and Transport

Regulation: 49 CFR 172.700; 49 CFR 172.702; 49 CFR 172.704.

Criteria: Applicants must train personnel involved in the preparation and transport of hazardous material packages in the applicable DOT regulations.

Discussion: Licensees who prepare packages of radioactive materials or who transport their own packages must provide training to their employees who perform those functions. The training must include:

- General awareness and familiarization training designed to provide familiarity with DOT requirements, and the ability of the employee to recognize and identify hazardous materials;
- Function-specific training concerning the DOT requirements that are specifically applicable to the functions the employee performs, (e.g., if the employee's duties require affixing DOT radioactive labels to packages, the employee must receive training in DOT's regulations governing package labeling); and
- Safety training concerning emergency response information, discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed to in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

The training must be provided initially, and every 3 years thereafter. **Records of training must be maintained.**

Note: The licensee is not responsible for providing DOT-required hazardous materials training to common carriers to whom the pharmacy offers radioactive materials packages for transport.

Response from Applicant:

ITEM 8 PERSONNEL INVOLVED IN HAZARDOUS MATERIALS PACKAGE PREPARATION AND TRANSPORT (Check one box)

- We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in *49 CFR 172.700, 49 CFR 172.702 AND 49 CFR 172.704*, as applicable. (Procedures are Attached)

Item 8.1 Instruction for Supervised Individuals Preparing Radiopharmaceuticals

Regulation: *HFS 157.13 (4); HFS 157.61 (3)*

Criteria: Individuals who prepare radioactive material for medical use under the supervision of an authorized nuclear pharmacist must be instructed in the preparation of radioactive material for medical use, the principles of radiation safety, and the licensee's procedures for the use of radioactive material; follow the instructions given; and must have their work and records kept to reflect their work periodically reviewed by the supervising ANP.

Discussion: The applicant must instruct supervised individuals in the preparation of radioactive material for medical use and require those individuals to follow their instructions, the written radiation protection program, license conditions, and the department rules. The supervising ANP must review the work of supervised individuals in the preparation of radioactive material for medical use and the records kept to reflect that work.

An ANP is considered to be supervising the use of radioactive materials when directing personnel in the conduct of operations involving licensed materials. The ANP need not be present at all times during the

use of such materials; however, the supervising ANP is responsible for ensuring that personnel under supervision have been properly trained and instructed. *The ANP must be physically present during the preparation and dispensing of radiopharmaceuticals by supervised individuals. radiopharmaceuticals.* This will be addressed by a condition on the radiopharmacy license. The supervising ANP is responsible for the supervision of operations involving the use of radioactive materials.

Department rules do not relieve the licensee from complying with applicable Department of Health and Human Services (Food and Drug Administration), other Federal, and State requirements governing radioactive drugs.

Response from Applicant:

No response from the applicant is necessary. Supervision will be reviewed during inspection.

Item 9 Radioactive Material

Part 1 Unsealed And/or Sealed Radioactive Material

Regulations: *HFS 157.13*

Criteria: Applicants must submit information specifying each radionuclide requested; the form; and the maximum activity to be possessed at any one time. For sealed sources, the applicant must also submit the manufacturer and model number of each requested sealed source.

Discussion: Each authorized radioisotope is listed on a department license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit).

The applicant should list each requested radioisotope by its element name and its mass number (e.g., technetium-99m) in item 5. Note in the sample license in *Appendix E* that the *DHFS* provides authorization to permit radiopharmacy licensees flexibility to prepare and distribute a range of radioisotopes as new radioactive drugs are developed. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not generally required.

For unsealed radioactive material, it is also necessary to specify whether requested radioisotopes will be handled in volatile or non-volatile form, since additional safety precautions are required when handling and using material in a volatile form. For example, when requesting authorization to possess and distribute iodine-131, the applicant must specify whether the material will be manipulated at the radiopharmacy in a volatile form (e.g., compounding of iodine-131 capsules) or received in the form in which it will be distributed (e.g., redistribution of sealed, unopened vials of iodine-131). Applicants requesting authorization to manipulate volatile radioactive material must describe appropriate facilities and engineering controls in response to Item 13, "Facilities and Equipment," and radiation safety procedures for handling of such material in specific responses to Item 14.4, "Occupational Dose;" Item 14.5, "Public Dose;" Item 14.6, "Safe Use of Radionuclides and Emergency Procedures;" and Item 14.7, "Surveys."

The anticipated possession limit in becquerels (Bq) or curies (Ci) for each radioisotope should also be specified. Possession limits must include the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for

decommissioning before specifying possession limits of any radioisotope with a half-life greater than 120 days. These requirements are discussed in Item 9, Part two on Financial Assurance and Decommissioning.

Applicants will be authorized to possess and use only those sealed sources, such as calibration and reference sources, that are specifically approved or registered by the department or an Agreement State. A safety evaluation of sealed sources and devices is performed by the NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Information on SSD registration certificates may be obtained by contacting the Registration Assistant by calling NRC's toll-free number, (800) 368-5642, extension 415-7231. Applicants must provide the manufacturer's name and model number for each requested sealed source and device, so that the department can verify that they have been evaluated in an SSD Registration Certificate or specifically approved on a license.

Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the sealed source and device 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 registration certificates, without obtaining the department's prior permission in a license amendment. To ensure that applicants use sources and devices according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer.

A safety evaluation of sealed sources and devices is performed by NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD Registration Certificate. Information on SSD registration certificates is available on the NRC's web site at <http://www.hsr.doe.gov/nrc/ssdrform.htm> and may also be obtained by contacting the Registration Assistant by calling NRC's toll free number, (800) 368-5642, Extension 415-7231. For additional guidance relating to sealed sources and devices, see also NRC NUREG - 1556, Vol. 3., "Applications for Sealed Source and Device Evaluation and Registration."

The applicant must also request authorization to possess depleted uranium if it will be used for shielding of molybdenum-99/technetium-99m generators. Depleted uranium is frequently used as shielding for generators when the molybdenum-99 activity is greater than 148 gigabecquerels (4 curies). **HFS 157.09** exempts depleted uranium from the requirements for a license to the extent that the material is used as a shipping container, such as when molybdenum-99/technetium-99m generators are in transit from their manufacturer to the pharmacy; however, a specific license or authorization from the department is needed to possess and use the depleted uranium as a shield during the time that the pharmacy uses or stores the generator at its facility. The applicant must specify the total amount of depleted uranium, in kilograms, that will be needed.

If an applicant requests quantities of licensed material in excess of values specified in **HFS 157.13 (1) (g); Appendix P "Quantities of radioactive material requiring consideration of the need for an emergency plan for responding to a release," of Chapter HFS 157.**(for example, 10 curies of Iodine 131), the applicant must either submit an emergency plan for responding to a release of radioactive materials or perform an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 10 millisieverts (mSv) (1 rem) effective dose equivalent or 50 mSv (5 rems) to the thyroid.

Licensees must submit a license amendment and receive department authorization before they may make changes in the types, forms, and quantities of materials possessed.

Response from Applicant:

ITEM 9 RADIOACTIVE MATERIAL (ATTACH ADDITIONAL PAGES IF NECESSARY)			
Item 9.1 Radioisotope			
Item 9.2 Chemical/Physical Form			
Are open containers of potentially volatile materials (Iodine-131, PET gases) manipulated at this location? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, process and engineering controls must be described..</i>			
Are sealed sources used at this location? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, please fill out Items 9.3 – 9.5, otherwise proceed to Item 9.6</i>			
Item 9.3 Sealed Source Manufacturer or Distributor and Model Number			
Item 9.4 Device Manufacturer or Distributor and Model Number			
Item 9.5 Sealed Source Device Registration Sheet Number			
Is Depleted Uranium used as a shielding material? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, specify the total amount (in Kilograms) _____</i>			
Item 9.6 Maximum Possession Limit			
Item 9.7 Proposed Use			

Part 2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: HFS 157.13; and HFS 157.15

Criteria: A licensee authorized to possess radioactive material in excess of the limits specified in **HFS 157.15** must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning. Even if a DFP or FA is not required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where radioactive materials are used or stored and related to leaking sources. Pursuant to **HFS 157.15**, licensees must transfer records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned according to *HFS 157.13*; or
- The department before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most commercial radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements, because the vast majority of radioactive materials they possess and redistribute do not have half-lives greater than 120 days and the total inventory of licensed materials with half-lives greater than 120 days do not exceed the thresholds in *HFS 157.15*.

Applicants requesting more than one radionuclide may determine whether financial assurance for decommissioning is required by calculating, for each radionuclide with a half-life greater than 120 days possessed, the ratio between the activity possessed, in curies, and the radionuclide's threshold activity requiring financial assurance, in curies. If the sum of such ratios for all of the radionuclides possessed exceeds "1" (i.e., "unity"), then applicants must submit evidence of financial assurance for decommissioning.

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All commercial nuclear pharmacy licensees need to maintain records of structures and equipment where radioactive material was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. If no records exist regarding structures and equipment where radioactive materials were used or stored, licensees shall make all reasonable efforts to create such records based upon historical information (e.g. employee recollections). In addition, if radiopharmacy licensees have experienced unusual occurrences (e.g., incidents that involve spread of contamination, leaking sources), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For radiopharmacy licensees whose contamination incidents did not involve radioactive materials with half-lives exceeding 120 days and whose sealed sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where radioactive material was used or stored.

Response from Applicant:

No response is needed from most applicants

If financial assurance is required, submit the documentation required under *s. HFS 157.15*. NRC Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each of the mechanisms authorized by the regulation to guarantee or secure funds except for the Statement of Intent for Government licensees. This document is available from the department upon request.

Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with **HFS 157.13** or to the department before the license is terminated.

References: Contact **DHFS** to obtain copies of NRC Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, and Policy & Guidance Directive (P&GD) FC 90-2, Revision 1, "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991.

Contents of an Application: Purpose(s) for Which Radioactive Material Will Be Used

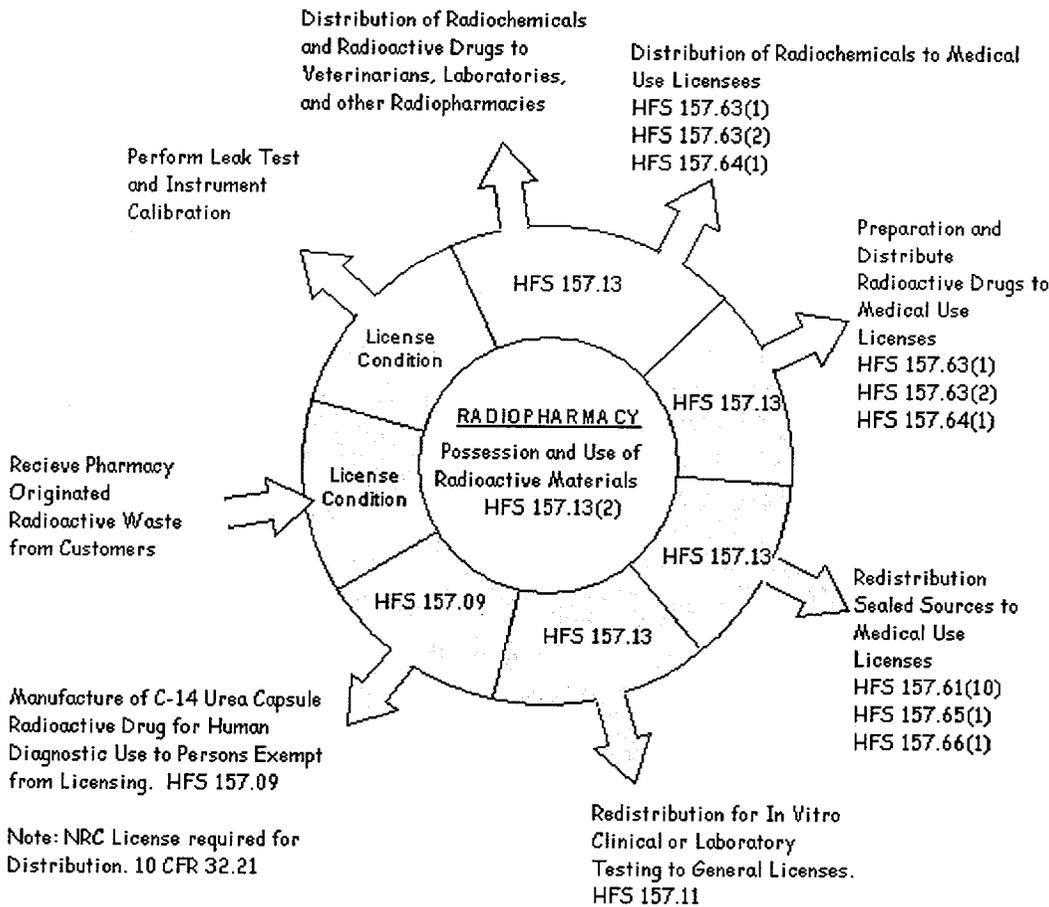


Figure 1. Purpose Wheel. The distribution of radioactive materials by commercial radiopharmacies is authorized by several distinct regulations. The appropriate regulation to refer to depends on the nature of the material, the purpose(s) for which it will be used, and to whom it is sent.

Item 10. Distribution and Redistribution of Radioactive Material

Regulations: *HFS 157.13*

Criteria: The applicant must specify the radioactive material it intends to distribute and redistribute.

Discussion: Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a non- *HFS 157.13* supplier (chemical grade materials). Radioactive drugs are those materials suitable for human use (e.g., monoclonal antibodies and technetium-99m-tagged red blood cells) and radiopharmaceuticals. However, the terms, "radiopharmaceutical" and "radioactive drug" will be used interchangeably in this guidance document, and reference to one is not meant to exclude the other.

Distribution activities are normally classified as either "distribution" or "redistribution." "Distribution" applies to those radioactive drugs and radiochemicals initially prepared by the pharmacy. "Redistribution" refers to those materials received from another person, authorized pursuant to *HFS 157.13*, depending on the product distributed, i.e., *in vitro* kits, other radiopharmaceuticals, or sealed sources for medical use, respectively. The distribution of radioactive materials to other persons requires specific approval from the department, either by the department rule or by a license authorizing the activity. The initial distribution of radioactive drugs for medical use must be prepared by a person licensed pursuant to *HFS 157.13*.

The redistribution of *in vitro* kits and sealed sources containing radioactive material for medical use is authorized pursuant to *HFS 157.13*, respectively, provided that the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to *HFS 157.13*, respectively. The transfer of radioactive materials for non-medical use, including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to *HFS 157.13*.

All radioactive material listed above shall be distributed only to persons authorized by *DHFS*, the **NRC** or Agreement State license to receive such materials, or by a general license (*HFS 157.11*) to receive *in vitro* test materials.

Initial distribution of unsealed radioactive material in the form of radiopharmaceuticals intended for human diagnostic and therapeutic use by medical licensees comprises the bulk of virtually all radiopharmacy activities. Prior to the transfer, distribution, or redistribution of any licensed material, the radiopharmacy must verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. The pharmacy should verify that the address to which radioactive materials are delivered is an authorized location of use listed on the customer's license. *HFS 157.13* lists five methods that can be used to meet the license verification requirement. The most common form of verification is for the radiopharmacy to possess a valid copy of the customer's *DHFS*, **NRC** or Agreement State license or other applicable document (e.g. *in vitro DHFS Form #*).

Response from Applicant: Provide the following, as applicable:

Item 10.1 Radiopharmaceuticals (Check all that apply)

- We will confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to *s. HFS 157.13 (4) (I)*, or under equivalent NRC or Agreement State requirements;
AND
- We will describe all licensed material to be distributed or redistributed.

Item 10.2 Generators (Check all that apply)

- We confirm that the generators will be obtained from a manufacturer licensed pursuant to *ch. HFS 157.13 (4) (j)*, or under equivalent NRC or Agreement State requirements;
AND
- We confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

Item 10.3 Redistribution of Generators (Check all that apply)

- We will submit a description of the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport;
AND
- We confirm that the manufacturer's packaging and labeling will not be altered;
AND
- We confirm that the generator will not be distributed beyond the expiration date shown on the generator label;
AND
- We confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator;
AND
- We confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

NOTE: ALTHOUGH REDISTRIBUTION OF USED GENERATORS MAY BE AUTHORIZED BY DHFS, DHFS APPROVAL DOES NOT RELIEVE THE LICENSEE FROM COMPLYING WITH APPLICABLE FDA OR OTHER FEDERAL OR STATE REQUIREMENTS.

Item 10.4 Redistribution of Sealed Sources – For Brachytherapy or Diagnosis (Check all that apply)

- We confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued in pursuant to *ch. HFS 157.13 (4) (k)*, or under equivalent NRC or Agreement State requirements;
AND
- We confirm that the manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.5 Redistribution of Calibration and Reference Sealed Sources (Check all that apply)

- We confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to *s. HFS 157.13 (4) (k)*, or under equivalent NRC or Agreement State requirements, to initially distribute such sources;
AND
- We confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.6 Redistribution of Prepackaged Units for *In-Vitro* Tests (Check all that apply)

- We confirm that the prepackaged units for *in-vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in-vitro* tests in accordance with a specific license issued pursuant to *ch. HFS 157.13 (4) (g)*, or under equivalent license of an NRC or Agreement State.

Item 10.7 Redistribution to General Licensee (Check all that apply)

- We confirm that the manufacturer's packaging and labeling of the prepackaged units for *in-vitro* tests will not be altered in any way,
- AND*
- We confirm that each redistributed prepackaged unit for *in-vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

Item 10.8 Redistribution to Specific License (Check all that apply)

- We confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in-vitro* test will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license. *ch. HFS 157.11 (2) (f)*
- AND*
- We confirm that the labeling on redistributed prepackaged units for *in-vitro* tests will conform to the requirements of *ch. HFS 157.29 (1) and ch. HFS 157.29 (4)*

Item 11 Preparation of Radiopharmaceuticals

Regulation: *HFS 157.13(4)*

Criteria: The preparation of radiopharmaceuticals for commercial distribution to medical users requires specific authorization.

Discussion: The bulk of radiopharmacy activities involve the preparation of radiopharmaceuticals for commercial distribution to medical users.

Response From Applicant:

ITEM 11 PREPARATION OF RADIOPHARMACEUTICALS (Check one box)

- We will attach a document that indicates the types of radiopharmaceuticals preparation activities we intend to perform (e.g. compounding of Iodine-131 capsules, radioiodination, and technetium-99m kit preparation).

Item 12 Sealed Sources for Calibration and Reference Sources

Regulation: *HFS 157.13(1)(2)*

Criteria: The applicant must specify the uses for sealed sources for reference and calibration.

Discussion: The applicant should describe the intended use of sealed sources. This will normally be for calibration and checks performed only on the applicant's instruments and equipment. Any sources intended for use in a specific instrument calibration device should be identified, along with the manufacturer and model number of the device.

Response from Applicant:

ITEM 12. Sealed Sources for Calibration and Reference Sources (Check one box)

- We will attach a document that indicates isotope, quantity, manufacturer and model number for each calibration and reference source we intend to use.

Facilities and Equipment

Item 13 Facilities and Equipment

Regulations: *HFS 157.13; HFS 157.15; HFS 157.21; and HFS 157.32*

Criteria: Radiopharmacies must demonstrate that they are a pharmacy. Facilities and equipment must be adequate to protect health and minimize danger to life or property, minimize the likelihood of contamination, and keep exposures to workers and the public ALARA.

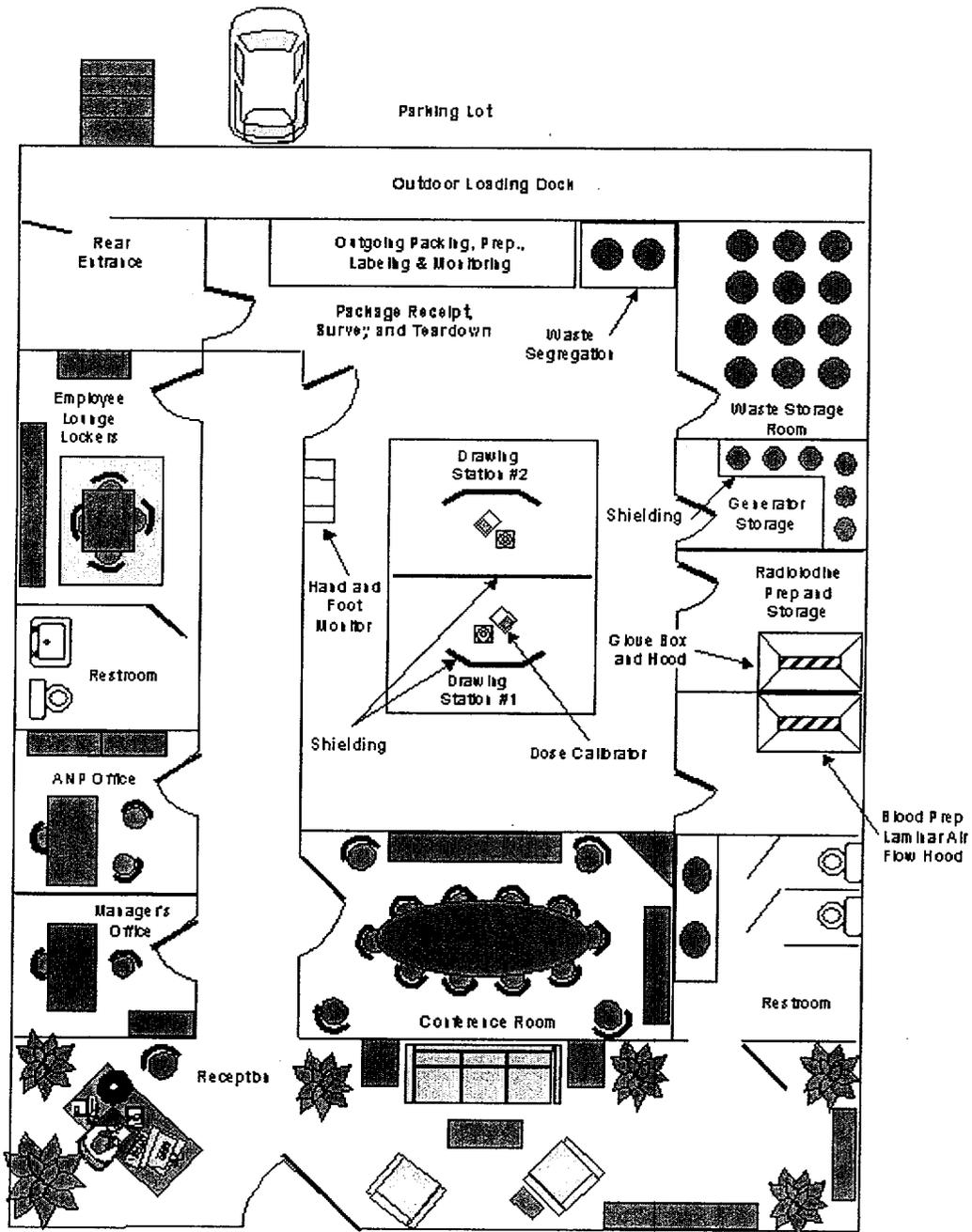
Discussion: Applicants must demonstrate that they are a pharmacy by submitting evidence that they are a licensed as a pharmacy by the State Board of Pharmacy.

If the license has not been issued by the State Board of Pharmacy at the time of application, the applicant may provide it at a later date, but prior to license issuance from the department.

Applicants must provide the department with documentation demonstrating that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees. The facilities and equipment must also keep exposures to radiation and radioactive materials ALARA, and minimize the risks from the uses of the types and quantities of radioactive materials. The applicant should provide clear delineation's between its restricted and unrestricted areas through the use of barriers, postings, and worker instructions.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed, in case changes are required as a result of the application review. This also ensures the adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant cannot possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.

Applicants are reminded that records important to decommissioning are required to be maintained in an identifiable location. For further information, see the section entitled, "Financial Assurance and Record Keeping for Decommissioning."



Scale: 1" = 10'

Figure 2. Typical Facility Diagram.

Response from Applicant:

ITEM 13 FACILITIES AND EQUIPMENT (Check boxes and attach diagram.)

We will provide copies of the license from the State Board of Pharmacy as a pharmacy.

AND

We will provide a description of the facilities and equipment to be made available where radioactive material will be used. A diagram should be submitted showing the entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to specified scale, or dimensions should be indicated. For additional information refer to Item 13 of WISREG "Guidance for Commercial Radiopharmacy Licenses." (Description is Attached)

Item 14 Radiation Safety Program

Item 14.1 Audit Program

Regulations: *HFS 157.21; and HFS 157.31*

Criteria: Licensees must review the content and implementation of their radiation protection programs annually to ensure the following:

- Compliance with department and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (*HFS 157.21*); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: *Appendix I* contain a suggested audit program that is specific to commercial radiopharmacies and is acceptable to *DHFS*. All areas indicated in *Appendix I* may not be applicable to every licensee, and all items may not need to be addressed during each audit. For example, licensees do not need to address areas, which do not apply to their activities, and activities, which have not occurred since the last audit need not be reviewed at the next audit.

Currently, the department's emphasis during inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of the radiopharmacy to observe whether radiation safety procedures are being followed, etc.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; **NRC** Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," provides guidance on this subject, which is available from the department. The department will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, *DHFS* can exercise discretion and will normally elect not to cite a violation. The department's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for three years from the date of the record. Audit records should contain the following information to be

acceptable: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Response from Applicant:

Item 14.1 RADIATION SAFETY PROGRAM -AUDIT

The applicant is not required to, and should not, submit its audit program to the department for review during the licensing phase. This matter will be examined during an inspection.

References: The current version of NRC NUREG - 1600 is available electronically at <http://www.nrc.gov>. INs are available in the "Reference Library" on NRC's Home Page at <http://www.nrc.gov>. For hard copies of NRC NUREG - 1600, IN 96-28, and IP 87117, "Radiopharmacy Programs," contact the department.

Item 14.2 Radiation Monitoring Instruments

Regulations: *HFS 157.31; HFS 157.25; and HFS 157.13*

Criteria: Licensees must possess radiation monitoring instruments to evaluate possible radiation hazards that may be present. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Licensees must possess calibrated radiation detection/measurement instruments to perform, as necessary, the following:

- Package surveys;
- Personnel and facility contamination measurements;
- Sealed source leak tests;
- Air sampling measurements;
- Bioassay measurements;
- Effluent release measurements; and
- Dose rate surveys

For the purposes of this document, radiation monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters;
- Portable or stationary dose rate or exposure rate meters;
- Single or multichannel analyzers;
- Liquid Scintillation Counters (LSC);
- Gamma counters;
- Proportional counters;
- Solid state detectors; and
- Hand and foot contamination monitors.

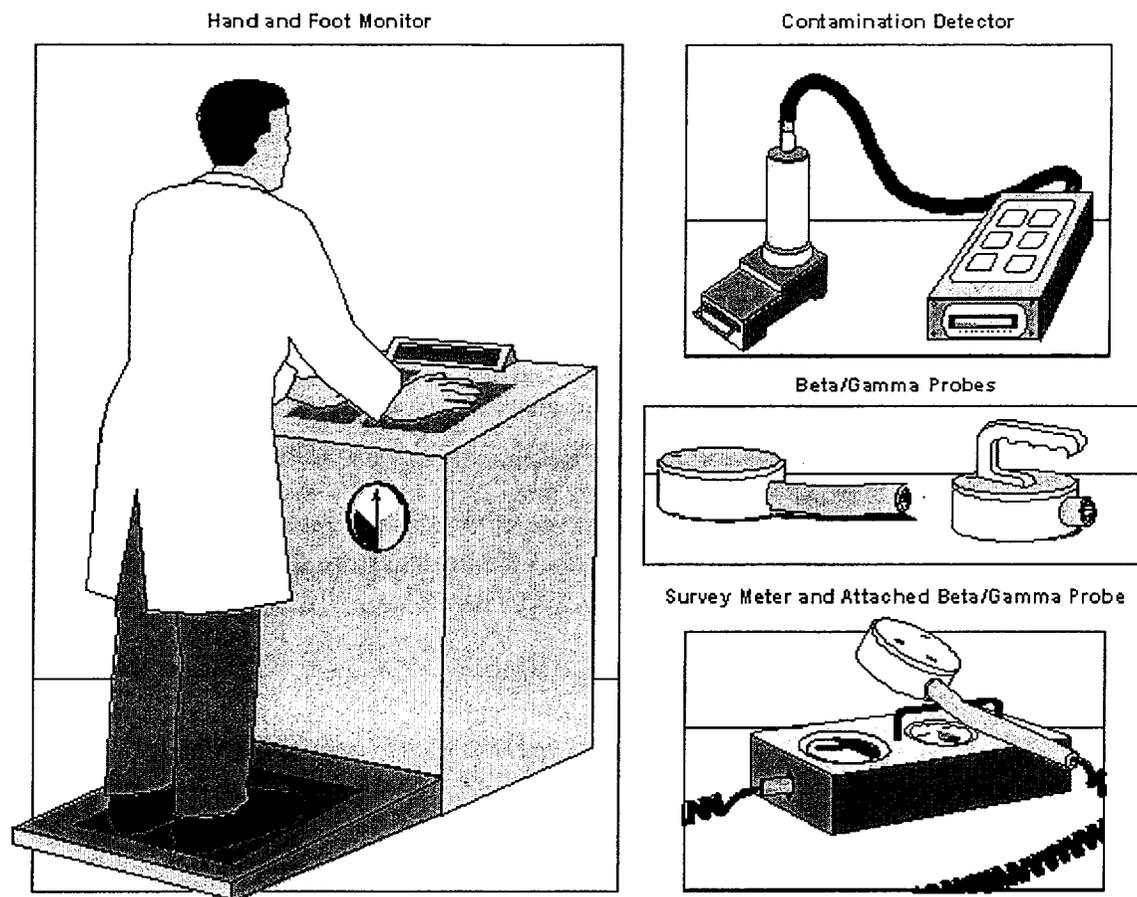


Figure 3. Examples of Portable and Stationary Survey Instruments Used by Radiopharmacies.

The choice of instrument should be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.). Radiopharmacies typically use a broad energy range of gamma and beta radiation emitters and need to use radiation detectors appropriate for those energies. **Figure 3** illustrates some common survey instruments used for contamination surveys. Applicants should discuss the types of instruments to be used for each type of survey to be performed and the availability of a sufficient quantity of these instruments at their facility.

Instrument calibrations may be performed by the pharmacy or by another person specifically authorized by the department, the **NRC**, an Agreement State, or a licensing state to perform that function. If the pharmacy utilizes the services of another person for instrument calibration, the pharmacy should ensure that person has been authorized by either the department, the **NRC**, an Agreement State, or a licensing State to perform that activity. **Appendix J** provides information about instrument specifications and model calibration procedures.

Response from Applicant:

Item 14.2 RADIATION MONITORING INSTRUMENTS (Check one box)

- We will use equipment that meets the radiation monitoring instrument specifications and implement the model survey meter calibration program published in Appendix J of WISREG "Guidance for Commercial Radiopharmacy Licenses."
- OR*
- We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J of WISREG "Guidance for Commercial Radiopharmacy Licenses", and instruments will be calibrated by other licensees authorized by *DHFS*, the *NRC* or an Agreement State, or a Licensing State to perform that service.
- OR*
- We will provide a description of alternative equipment to be used for radiation monitoring and alternative procedures for the calibration of radiation monitoring equipment. (**Procedures are Attached**)

Note: If the applicant intends to provide radiation protection services, including calibration of survey meters, to customers, the applicant must apply for a service license from the department.

Item 14.3 Material Receipt and Accountability

Regulations: *HFS 157.32; HFS 157.31; HFS 157.30; HFS 157.29; HFS 157.28; HFS 157.25; and HFS 157.13*

Criteria: Licensees must ensure the security and accountability of licensed material and must open packages safely.

Discussion: As illustrated in **Figure 4**, radioactive materials must be tracked from receipt to disposal in order to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over radioactive material accountability by including the following items (as applicable) in their radiation protection program:

- Physical inventories of sealed sources at intervals not to exceed 6 months;
- Ordering and receiving licensed material;
- Package opening;
- Maintaining material inventory within license possession limits;
- Transfer of material, including distribution; and
- Disposal of material.

Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with *HFS 157.29*. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

A model procedure for safely opening packages containing licensed materials is included in *Appendix P*. The department rule in *HFS 157.29* states the requirements for monitoring packages containing licensed material. These requirements are described in **Table 1**, below.

Table 1. Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater than Type A	Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Greater than Type A	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less than Type A	None	None
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Less than Type A	Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Not Labeled	Radioactive Material	None	None
Damaged	Radioactive Material	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package.

- ❖ Assume packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has three hours after the beginning of the next work day to perform the required surveys.

HFS 157. 29 requires that the licensee immediately notify the final delivery carrier and **DHFS** when removable radioactive surface contamination exceeds the limit of 22 disintegrations per minute per square centimeter (dpm/cm²) averaged over 300 cm² (6600 dpm/300 cm²); or external radiation levels exceed 2.0 mSv/hr (200 mrem/hr) at the surface.

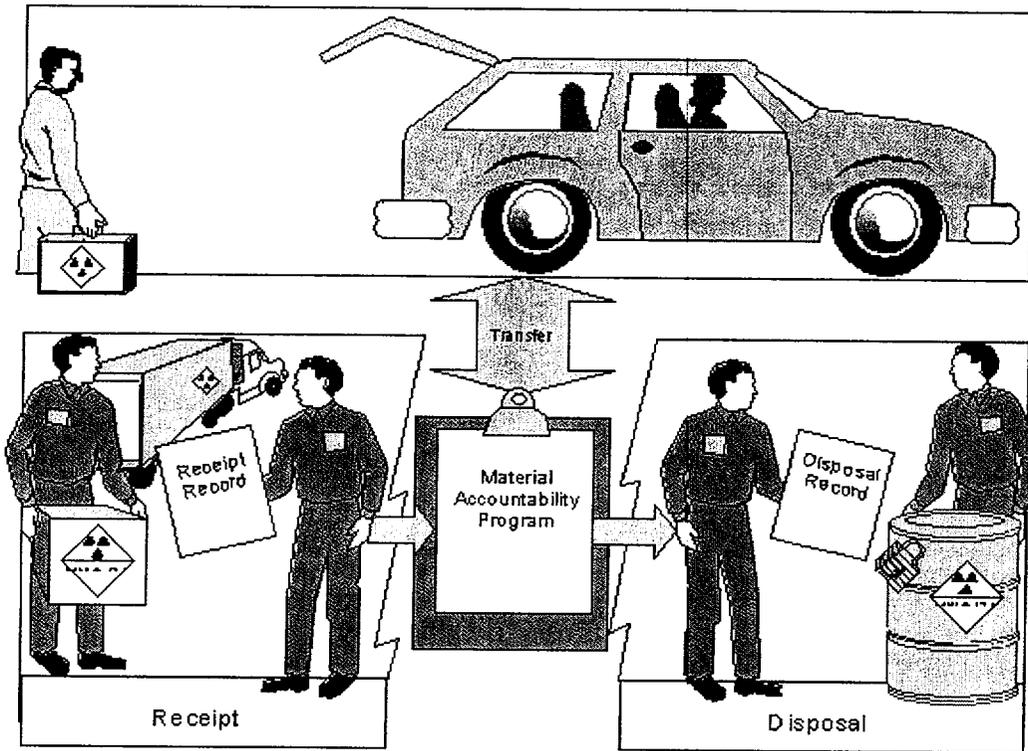


Figure 4. Accountability. Licensees must maintain records of receipt, transfer, and disposal of radioactive material.

Licensees must secure and control licensed material and should have a means of promptly detecting losses of radioactive material. *HFS 157.28* requires licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over radioactive material that is not in storage.

Licenses will normally contain specific conditions requiring the licensee to perform inventories and leak tests of sealed sources every six months (see sample license in **Appendix E**). Since the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program. Sources in storage that are used infrequently may not require leak testing; however, the inventory must still be performed at the specified interval.

With regard to unsealed radioactive material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for receipt, use, transfer, disposal, and radioactive decay. These methods help to ensure that possession limits are not exceeded.

Table 2 list the types and retention times for the records of receipt, use, transfer, and disposal (as waste) of all radioactive material the applicant must maintain. Other records such as transfer records could be linked to radioactive material inventory records.

Table 2. Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until the department terminates the license
Important to decommissioning	Until the site is released for unrestricted use

Material accountability records typically contain the following information:

- Radionuclide and activity (in units of becquerels or curies), and date of measurement of radioactive material;
- For each sealed source, manufacturer, model number, location and, if needed for identification, serial number and as appropriate, manufacturer and model number of device containing the sealed source;
- Date of the transfer and name and license number of the recipient, and description of the radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number); and
- For radioactive materials disposed of as waste, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.).

See the section on "Waste Disposal" for additional information.

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by *HFS 157.15*. See also the section on "Financial Assurance and Record Keeping for Decommissioning."

Response from Applicant:

Item 14.3 MATERIAL RECEIPT AND ACCOUNTABILITY (Check all that apply)

- We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in *ch. HFS 157.29 (6)*.
- AND*
- We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.
- AND*
- We have developed, and will implement and maintain written procedures for radioactive material accountability and control to ensure that: **(Procedures are attached)**
1. License possession limits are not exceeded;
 2. Radioactive material in storage is secured from unauthorized access or removal;
 3. Radioactive material not in storage is maintained under constant surveillance and control; and
 4. Records of receipt, transfer, and disposal of licensed material are maintained.

Item 14.4 Occupational Dosimetry

Regulations: *HFS 157.31; HFS 157.25; and HFS 157.22*

Criteria: Each licensee shall evaluate the potential occupational exposures of all workers and monitor occupational exposure to radiation when required.

Discussion: The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose (prospective evaluation). When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in the prospective evaluation if monitoring was not required at the other facilities. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in NRC Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses, dated July 1992" which is available from the department.

If the prospective evaluation shows that an individual's dose is not likely to exceed 10% of any applicable regulatory limit, the individual is not required to be monitored for radiation exposure and there are no recordkeeping or reporting requirements for doses received by that individual. If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit, monitoring is required.

Licensees shall monitor worker exposures for:

Adults who are likely to receive an annual dose in excess of any of the following:

- 5 mSv (0.5 rem) deep-dose equivalent;
- 15 mSv (1.5 rems) eye dose equivalent;
- 50 mSv (5 rems) shallow-dose equivalent to the skin; and
- 50 mSv (5 rems) shallow-dose equivalent to any extremity.

Minors who are likely to receive an annual dose in excess of any of the following:

- .5 mSv (0.05 rem) deep-dose equivalent;
- 1.5 mSv (0.15 rem) eye dose equivalent;
- 5 mSv (0.5 rem) shallow-dose equivalent to the skin; and
- 5 mSv (0.5 rem) shallow-dose equivalent to any extremity.

Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.

Internal exposure monitoring is required for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable ALIs for ingestion and inhalation; and
- Minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

If an individual is likely to receive in 1 year a dose greater than 10% of any applicable limit (see **Figure 5** for annual dose limits for adults), monitoring for occupational exposure is required. ANPs and radiopharmacy technologists are generally likely to receive 10% of the limits for occupational dose. Most radiopharmacies provide these employees with whole body and extremity monitors.

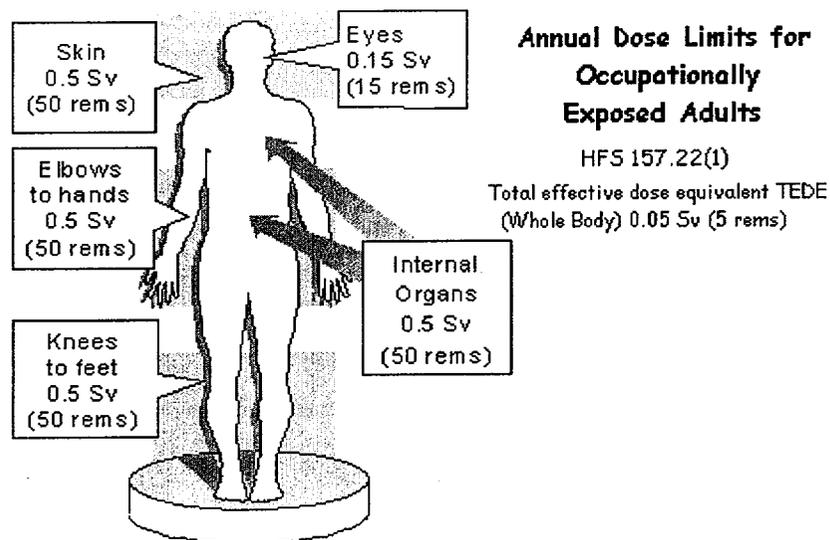


Figure 5. Annual Dose Limits for Occupationally Exposed Adults.

TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE) = DEEP DOSE FROM EXTERNAL EXPOSURE + DOSE FROM INTERNALLY DEPOSITED RADIONUCLIDES

Most licensees use either film badges, OSLs or thermoluminescent dosimeters (TLDs) that are supplied by a NVLAP-approved processor to monitor for external exposure. The exchange frequency for film badges is generally monthly due to technical concerns about film fading. The exchange frequency for TLDs is generally quarterly. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use. If monitoring is required, then the licensee must maintain records of the monitoring regardless of the actual dose received.

The types and quantities of radioactive material used at most commercial radiopharmacies provide a reasonable possibility for an internal intake by ANPs and radiopharmacy technologists. Uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing from vials containing millicurie quantities of radioiodine and other isotopes require particular caution. Precautionary measures for personnel to follow during iodine capsule preparation should involve the use of a fume hood and glove box or shoulder length gloves (see *Appendix Q* for additional guidance on precautionary measures). To monitor internal exposure from such operations, most pharmacies institute a routine bioassay program to periodically monitor these workers.

A program for performing thyroid uptake bioassay measurements 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 and should address the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue). Thyroid bioassay procedures should also specify the interval between bioassays, action levels, and

the actions to be taken at those levels. Generally, thyroid uptake bioassay measurements at radiopharmacies are performed weekly for those workers who routinely handle radioiodine or are in the immediate vicinity when radioiodine is being handled. 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 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses,"** dated July 1992, and **NRC NUREG - 1400, "Air Sampling in the Workplace,"** dated September 1993.

Response from Applicant:

ITEM 14.4 OCCUPATIONAL DOSIMETRY (Check all that apply)

We will maintain for inspection by *DHFS*, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in *ch. HFS 157.22*.

AND/OR

We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

Note: Some licensees choose to monitor their workers for reasons other than compliance with department requirements (e.g., in response to worker requests).

References: National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available electronically at <http://ts.nist.gov/nvlap>. NIST Publication 810 can be purchased from GPO, whose URL is <http://www.gpo.gov>. ANSI N322 may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018. See the Notice of Availability (on the inside front cover of this report) to obtain copies of **NRC Regulatory Guide 8.7, Revision 1, "Instructions for Recording and Reporting Occupational Radiation Exposure Data,"** dated June 1992; **NRC Regulatory Guide 8.9, Revision 1, Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program** dated July 1993; **NRC Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses,"** dated July 1992 and **NRC NUREG - 1400, "Air Sampling in the Workplace,"** dated September 1993.

Item 14.5 Public Dose

Regulations: *HFS 157.32; HFS 157.31; HFS 157.28; HFS 157.23; HFS 157.21; and HFS 157.03*

Criteria: Licensees must do the following:

- Ensure that radioactive material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) (TEDE) in one year from licensed activities;
- Ensure that air emissions of radioactive material 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 those emissions;
- Ensure that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations;
- Prevent unauthorized access, removal, or use of radioactive material.

Discussion: "Public dose" is defined in subchapter three of HFS 157 'Radiation Protection' as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation, sanitary sewerage discharges from licensees, and from medical procedures. 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) the individual is in when the dose is received. For guidance about accepted methodologies for determining dose to members of public, please refer to *Appendix K*.

There are many possible internal dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

1. Airborne radioactive material;
2. Waterborne radioactive material; and
3. External radiation exposure.

The licensee should review these major pathways and decide which are applicable to its operations. The licensee must ensure that the total effective dose equivalent from all exposure pathways arising from licensed activities does not exceed 1.0 mSv (100 mrem) to the maximally exposed member of the public. In addition, the licensee must control air emissions, 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 0.1 mSv (10 mrem) per year from those emissions. If exceeded, the licensee must report this, in accordance with *HFS 157.32*, and take prompt actions to ensure against recurrence.

Licensees should design a monitoring program to ensure compliance with *HFS 157.21 and HFS 157.28*. The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to Item 14.7 "Surveys."

During department inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit and the dose constraint. See *Appendix K* for examples of methods to demonstrate compliance.

Response from Applicant:

ITEM 14.5 PUBLIC DOSE

No response is required, in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

Item 14.6 Safe Use of Radionuclides and Emergency Procedures

Regulations: *HFS 157.88; HFS 157.32; HFS 157.28; HFS 157.21; and HFS 157.13*

Criteria: Licensees are required to do the following:

- Keep radiation doses to workers and members of the public ALARA;

- Ensure security of radioactive material; and
- Make the required notifications of events to *DHFS*.

Discussion: Licensees are responsible for the security and safe use of all radioactive material from the time it arrives at their facility until it is used, transferred, and/or disposed. Licensees should develop written procedures to ensure safe use of radioactive material, and the procedures should also include operational and administrative guidelines. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

General Safety Procedures:

The written procedures should include the following elements:

- Contamination controls;
- Waste disposal practices;
- Personnel and area monitoring (including limits);
- Use of protective clothing and equipment;
- Safe handling of radioactive materials;
- Recording requirements;
- Reporting requirements; and
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Performing molybdenum-99 breakthrough measurements on each elution from a generator;
- Use of appropriate shielding (see **Figure 6**);
- Frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the laboratory; and
- Special procedures for higher risk activities, such as use of radioiodine.

Applicants should also develop radioisotope-specific procedures based on the respective hazards associated with the radioisotopes. General safety guidelines are described in *Appendix Q*. Applicants should use these guidelines to aid in the development of their own procedures for the safe use of radioisotopes.

Licensees should determine if they have areas that require posting in accordance with *HFS 157.29(2)*, unless they meet the exemptions listed in *HFS 157.29(3)*. Also, containers of radioactive material (including radioactive waste) must be labeled in accordance with *HFS 157.29(4)*, unless they meet the exemptions in *HFS 157.29(5)*.



Figure 6. Use of Appropriate Shielding.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their receipt, transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment and unintended radiation exposure to workers and members of the public. In addition, loss or theft of radioactive material, and fires involving radioactive material can adversely affect the safety of personnel and members of the public. Applicants should therefore develop and implement procedures to minimize, to the extent practical, the potential impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of staff and the radiation safety officer. In addition, the licensee should develop procedures for routine contacts with its local fire department to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with step-by-step instructions and clear direction of whom to contact. The licensee should establish clear delineation's between minor contamination events, minor spills, and major spills and events.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary. *Appendix Q* includes model emergency procedures. Applicants may adopt these procedures or develop their own incorporating the safety features included in these model procedures.

Certain incidents and emergencies require notification of *DHFS*. *Appendix T* provides a listing of major *DHFS* reporting and notification requirements relevant to commercial radiopharmacies.

Response from Applicant:

ITEM 14.6 SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES (Check one box)

- We will develop, implement and maintain safe use of radionuclides and emergency procedures that will meet criteria in the section entitled 'Safe Use of Radionuclides and Emergency Procedures' in WISREG "Guidance for Commercial Radiopharmacy Licenses." (**Procedures are Attached**)

Item 14.7 Surveys

Regulations: *HFS 157.31; HFS 157.25; and HFS 157.06*

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. Records of survey results must be maintained.

Discussion: Surveys are evaluations of radiological conditions and potential hazards. 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 is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. In order to meet regulatory requirements for surveying, measurements of radioactivity should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

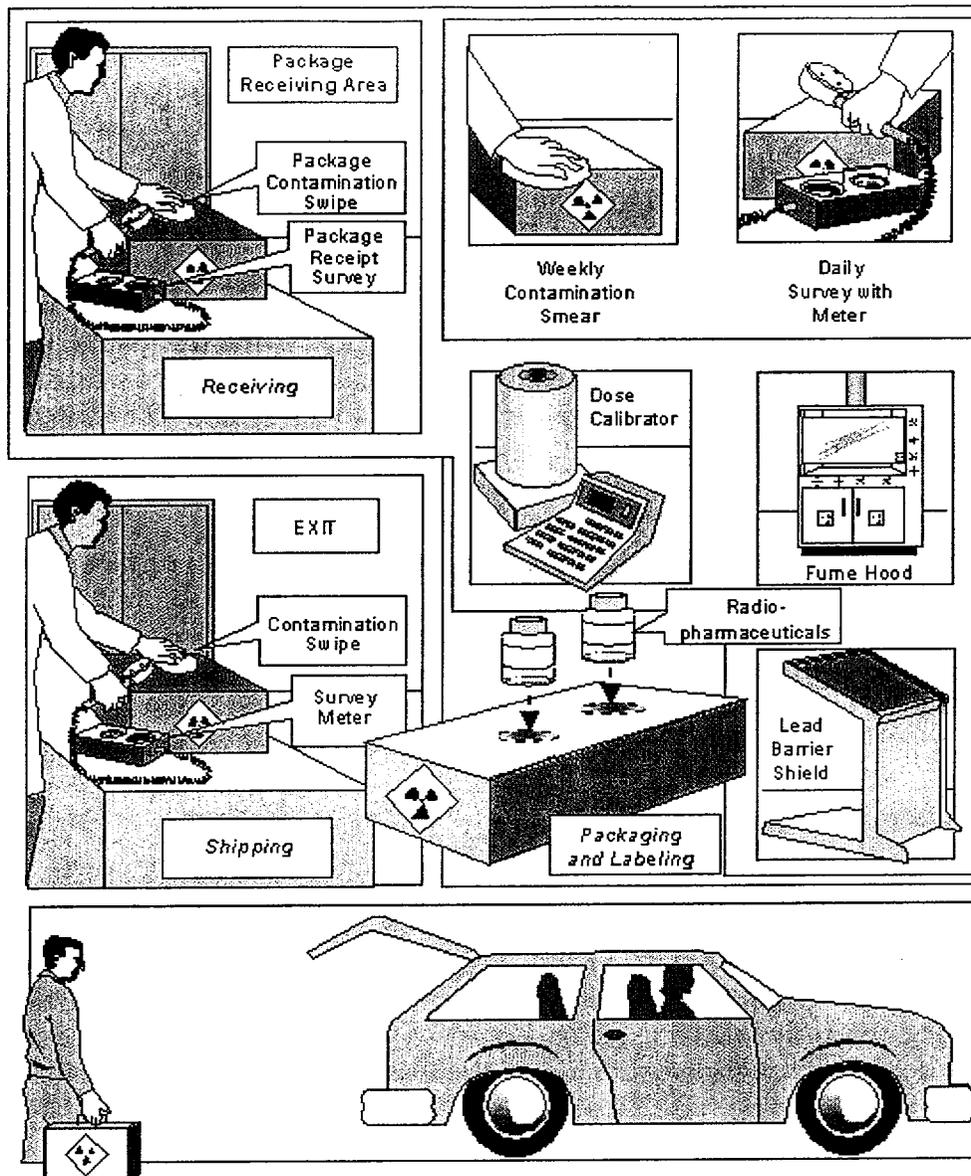


Figure 7. Typical Surveys at Radiopharmacy.

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. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- 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 expose workers to the inhalation of radioactive material (e.g. radioiodine) or where radioactive material is or could be released to unrestricted areas;
- 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 radiopharmaceutical packages entering (e.g., from suppliers and returns from customers) and departing (e.g., prepared radiopharmaceuticals for shipment to customers).

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above. *Appendix R*, "Radiation Surveys," contains a model procedure for radiation survey frequencies.

Not all instruments can measure a given type of radiation (e.g. alpha, beta and gamma). The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. The energy of the radiation may not be high enough to penetrate some detector windows and be counted. The correct selection, calibration and use of radiation detection instruments is an important aspect of any radiation safety program.

Subchapter III of HFS 157 'Radiation Protection' does not specify limits for surface contamination, but it does specify dose limits for unrestricted areas (2 millirem in any one hour) and posting requirements (5 millirem in any one-hour for "Radiation Areas"). Each applicant should propose and justify their removable surface contamination and radiation level action limits that will require action to (1) reduce the contamination or radiation level; or (2) institute additional restrictions on access to the area. See **Table 6** in **Appendix R** for guidance on surface contamination limits acceptable to the department.

Undetected Contamination and Loss of Control of Radioactive Material

Due to the large quantities of radioactive material in liquid form often handled by radiopharmacy personnel, there can be a greater potential for radioactive material contamination. Radiation surveys, if properly conducted as outlined in this section, will normally detect contamination before it leaves the licensee's restricted area (e.g., radiopharmaceutical preparation and packaging areas). If detected within the restricted area during or shortly following radiopharmaceutical preparation, the licensee can normally complete standard decontamination activities to mitigate the spread of the contamination outside the restricted area.

There have been several instances involving licensees, including radiopharmacies, in which contamination has not been detected (usually due to no survey being done, or else an inadequate survey being performed) and which is inadvertently removed from the restricted area. Typically the contamination has been deposited on an outgoing package containing radioactive material, the skin or clothing of a licensee employee leaving the facility, or both. Once the contamination leaves the licensee's restricted area, control of the radioactive material is lost. At this point the contamination has a high probability of reaching public locations outside the radiopharmacy including one or more of its customers (e.g., a hospital). Contamination incidents such as this can create public health, regulatory, and public relations problems for licensees. In virtually all cases, the events could have been avoided if licensee personnel had performed an adequate radiation survey to detect the contamination before leaving the restricted area.

Response from Applicant:

ITEM 14.7 SURVEYS (Check all that apply)

- We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R of WISREG "Guidance for Commercial Radiopharmacy Licenses."

References: Contact the department to obtain copies of NRC Information Notice 98-18, "Recent Contamination Incidences Resulting From Failure to Perform Adequate Surveys," dated May 13, 1998.

Item 14.8 Dose Calibrator and Other Dosage Measuring Equipment

Regulations: *HFS 157.13*

Criteria: Commercial radiopharmacy licensees must possess and use instrumentation capable of accurately measuring the radioactivity in radioactive drugs.

Discussion: Due to the potential for radiopharmacy errors to adversely affect their customers (medical facilities) and their customers' patients, each dosage of a radioactive drug must be measured prior to transfer to provide high confidence that the correct amount of the radioactive drug is transferred in accordance with the customer's request.

The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by combination of measurement and calculation, of the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to their transfer for commercial distribution.

These procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. This is accomplished by performing periodic checks and tests prior to first use, followed by checks at specified intervals, and following repairs that could affect system performance. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured. Currently, no alpha-emitting nuclides are used in unsealed form in medicine; therefore, guidance is not provided in this document on the measurement of these radionuclides. For photon-emitters, activity measurement is a fairly straightforward determination; however, for beta-emitters, a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of beta-correction factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST) traceable standard for all radionuclides currently in use. If radiopharmacies intend to initially distribute, i.e., measure, prepare, and label, beta-emitting radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use beta-correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor. If radiopharmacy applicants intend to only redistribute beta-emitting radionuclides that have been previously prepared and distributed by other persons licensed pursuant to *HFS 157.13* (4)(i) then the correction factor calculation is not required.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, due 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, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate to the system, to ensure correct operation. Typically, all systems must be checked each day of use for constancy to ensure continued proper operation of the system. In addition, other appropriate tests may include

accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers).

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

Appendix O contains a model procedure for dose calibrator testing.

Response from Applicant:

Item 14.8 DOSE CALIBRATOR AND OTHER DOSAGE MEASURING EQUIPMENT (Check all that apply)

- We shall describe the types of systems (measurement or combination of measurement and calculation) that we intend to use for the measurement of alpha, beta, and photon-emitting radioactive drugs;

AND
- We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meet the requirements in *ch. HFS 157.13 (4) (I)*. (Procedures are Attached)

AND
- We will provide, if applicable, a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers;

OR
- We will include, if applicable, a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer, or other entity.

Radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) beta-emitting radionuclides must provide the calculation to demonstrate its ability to accurately dispense such materials; however, a correction factor calculation is not required if radiopharmacy applicants intend to only redistribute beta-emitting radionuclides that were previously prepared and distributed by others who are licensed pursuant to *HFS 157.13 (4) (i)*.

Note: If the applicant intends to provide radiation protection services, including calibration of dose calibrators, to customers, the applicant must apply for a service license from the department.

Item 14.9 Radioactive Drug Labeling for Distribution

Regulations: *HFS 157.29; and HFS 157.13*

Criteria: The labels affixed to radioactive drugs for distribution must have the required color, symbol, and wording.

Discussion: The licensee must label each "transport radiation shield" to show the radiation symbol as described in *HFS 157.29*. The label must also include the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The phrase "transport radiation shield" refers to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. The "transport radiation shield" should be constructed of material appropriate for the isotope to be transferred for commercial distribution. The "transport radiation shield" does not refer to the outer suitcase, packaging, or other carrying device, even though that barrier may provide some radiation shielding.

The licensee must label each syringe, vial, or other container (e.g., generator or ampule) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol, as described in *HFS 157.29*. The label must include the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the "transport radiation shield" label. The identifier must provide a correlation between the syringe, vial, or other container and the information on the label of its "transport radiation shield." Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

Applicants Response:

<p>Item 14.9 RADIOACTIVE DRUG LABELING FOR DISTRIBUTION (Check all that apply)</p> <p><input type="checkbox"/> We will describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g. on the "transport radiation shield" or the container used to hold the radioactive drug); (Description is attached)</p> <p style="text-align: center;"><i>AND</i></p> <p><input type="checkbox"/> We agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.</p>
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Item 14.10 Radioactive Drug Shielding for Distribution

Regulations: *HFS 157.22; and HFS 157.13*

Criteria: The shielding provided for each radioactive drug to be distributed must be adequate for safe handling and storage by the pharmacy's customers to maintain occupational exposures ALARA.

Discussion: The applicant must provide appropriate "transport radiation shields" for the primary container of each radioactive drug that it intends to distribute. The shielding must be adequate for the types and activities of radioactive materials that the applicant intends to distribute. Typically, "transport radiation shields" used by radiopharmacies have included two-piece, shielded syringe and vial containers (or "pigs"). Pharmacies have used lead and tungsten shields for gamma-emitting materials and plexiglass inserts for beta-emitters.

As general guidelines, "transport radiation shields" for technetium-99m products have ensured surface radiation levels of not more than 0.03 milliSievert per hour (mSv/hr) (3 mrem/hr), due to the ease of shielding the low energy gamma emitted. For iodine-131, surface dose rates on "transport radiation shields" have been approved up to 0.5 mSv/hr (50 mrem/hr) for diagnostic dosages and up to 1.5 mSv/hr (150 mrem/hr) for therapeutic dosages. The applicant should select appropriate shielding materials and dimensions to not only ensure that occupational doses are ALARA, but also that the "transport radiation shield" can be easily handled.

Applicants Response:

Item 14.10 RADIOACTIVE DRUG SHIELDING FOR DISTRIBUTION (Check all that apply)

- We will, for each drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):
- Indicate the radionuclide and the maximum activity for each type of container (e.g. vial, syringe);
 - Describe the type and thickness of the "transport radiation shield" provided for each type of container; and
 - Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

NOTE: IT IS NOT ACCEPTABLE TO STATE THAT THE APPLICANT WILL COMPLY WITH DOT REGULATIONS. THE DOSE RATE LIMITS THAT DOT IMPOSES APPLY TO THE SURFACE OF THE PACKAGE, NOT THE SURFACE OF THE "TRANSPORT RADIATION SHIELD."

Item 14.11 Leak Tests

Regulations: *HFS 157.31; HFS 157.25; and HFS 157.06*

Criteria: *DHFS* requires testing to determine whether there is any radioactive leakage from the sealed sources. Records of the test results must be maintained.

Discussion: When issued, the license will require performance of leak tests at intervals approved by the department, the NRC or an Agreement State and specified in the SSD Registration Certificate. 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 microcuries) of radioactivity.

Commercial radiopharmacies may have their sealed sources leak tested by an individual licensed by the department, the NRC or an Agreement State to perform leak testing, or radiopharmacies may perform leak testing of their own sealed sources. *Appendix L* contains a model procedure for performance of leak testing and sample analysis. If the radiopharmacy has its leak testing performed by a licensed leak test provider, the radiopharmacy is expected to take the leak test samples according to the sealed source manufacturer's and the leak test provider's kit instructions and return it to the provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.

Response from Applicant:

ITEM 14.11 LEAK TEST (Check one box)

Leak tests will be performed by an organization authorized by *DHFS*, 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 *DHFS*, the *NRC*

or

an Agreement State to provide leak test kits to other licensees according to kit suppliers instructions.

License number of organization authorized to perform or analyze leak test (Specify whether Department, *NRC*, or other Agreement State): _____

Or

We will perform our own leak testing and sample analysis. We will follow the model procedures in Appendix L of WISREG "Guidance for Commercial Radiopharmacy Licenses."

Or

We will submit alternative procedures. (Procedures are attached)

Note: If the applicant intends to provide radiation protection services, including leak testing, to customers, the applicant must apply for a service license from the department.

Item 15. Waste Disposal and Transfer

Item 15.1 Waste Management

Regulations: *HFS 157.31; HFS 157.30; HFS 157.29; HFS 157.13; and HFS 157.06*

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Discussion: Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, and unusable items contaminated with radioactive material, e.g., absorbent paper, gloves, etc. Licensees may not receive radioactive waste from other licensees for processing, storage or disposal, unless specifically authorized to do so by the department. Commercial radiopharmacies may request to receive certain radioactive waste returned from their customers. For guidance on receiving radioactive waste from customers, refer to the section titled, "Waste Management, Returned Wastes from Customers."

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 department requires commercial radiopharmacy licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Decay-in-Storage (DIS);
- Transfer to an authorized recipient; and
- Release into sanitary sewerage.

Licensees may choose any one or more of these methods to dispose of their radioactive waste. Most commercial radiopharmacies dispose of radioactive waste by decay-in-storage because the majority of radioactive materials used by these facilities have short half-lives.

Applicant's programs for management and disposal of radioactive waste should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Regulations require that licensees maintain all appropriate records of disposal of radioactive waste.

Disposal By Decay-in-Storage (DIS)

DHFS permits radioactive materials with half-lives of less than or equal to 120 days to be disposed by DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. *DHFS* may permit radioactive material with half-lives of up to 300 days (i.e., Co-57) to be disposed by DIS with submittal of additional information. Applicants should assure that adequate space and facilities are available for the storage of such waste. Procedures for management of waste by DIS should include methods of segregation, surveys prior to disposal, and maintenance of records of disposal.

Licensees can minimize the need for storage space, if radioactive waste is segregated according to physical half-life. Segregation of waste is accomplished by depositing radioisotopes of shorter physical half-lives in containers separate from those used to store radioactive waste with longer physical half-lives. Radioactive waste with shorter half-lives will take less time to decay and thus may be disposed in shorter periods of time, freeing storage space.

Used syringes/needles and vials returned from pharmacy customers (medical facilities) are considered both biohazardous and radioactive waste since these items may be contaminated with customer's patients' blood or other body fluids. Following completion of decay-in-storage, such waste may be disposed of as biohazardous waste (medical waste) if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background.

Radioactive material labels on the used syringes/needles cannot be defaced without exposing employees to the risk of injury from the needles. Additionally, exposing employees to the risk of injury from needles would place licensees in violation of the Occupational Safety and Health Administration (OSHA) regulations in 29 CFR 1910.1030(d)(1), which requires precautions to prevent contact with blood or other potentially infectious materials, including recommendations not to manipulate used syringes/needles by hand. Thus, radiopharmacy licensee's do not have to deface or remove radiation labels from individual containers and packages (e.g., syringes, vials) inside waste barrels/containers intended for disposal as medical waste, provided the following conditions are met:

- The radioactive material labels on the outer waste barrels/containers will be defaced or removed prior to transfer to waste disposal firm;
- Waste barrels are sealed prior to delivery to the waste disposal firm;
- Waste barrels/containers will be delivered directly from the licensee's facility to a waste disposal firm for disposal;
- Medical waste is incinerated, and not sent to a medical waste landfill; and
- The waste disposal firm is notified that the barrels must not be opened at any point, and for any reason, prior to incineration.

Other pharmacy radioactive waste that has not been returned from customers and has not otherwise come into contact with blood or body fluids should not have a biohazardous component. Following completion

of decay-in-storage and provided it has been stored separate from radioactive, biohazardous waste and contains no other hazardous components (e.g. needles, hazardous chemicals), such waste may require disposal as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to final disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

Records of DIS should include the date when the waste was put in storage for decay, date when ten half-lives of the longest-lived radioisotope have transpired, date of disposal, results of final survey before disposal as ordinary trash and results of the background survey, identification of the instrument used to perform the survey and the signature or initials of the individual performing the survey.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. Most commercial radiopharmacies only dispose of radioactive wastes with half-lives greater than 120 days to authorized recipients (e.g., low-level radioactive waste disposal facilities). Since radiopharmacy licensees typically possess small quantities of these materials, the volume of materials disposed in this manner would also be minimal, if any. Currently, radiopharmacies use this system for waste disposal infrequently; therefore, detailed guidance is not provided in this document on the specific requirements related to the transfer of wastes to authorized recipients for disposal.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Release Into Sanitary Sewerage

Licensees may dispose of radioactive waste by release into sanitary sewerage if each of the following conditions are met:

- Material is readily soluble (or is easily dispersible biological material) in water;
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in *HFS 157, Appendix E, Table III*;
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in *HFS 157, Appendix E, Table III* cannot exceed unity; and
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed the limits specified in *HFS 157.30*.

Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are indeed readily dispersible in water. NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated January 1994, provides the criteria for evaluating solubility of liquid waste.

Applicants should develop and implement procedures to ensure that all releases of radioactive waste into the sanitary sewerage, if any, meet the criteria stated in *HFS 157.30*. Licensees are required to maintain accurate records of all releases of radioactive material into the sanitary sewerage

Response from Applicant:

ITEM 15.1 WASTE MANAGEMENT (Check all that apply)

- We will use the model waste procedures published in Appendix Z of WISREG "Guidance for Commercial Radiopharmacy Licenses."
- OR
- We will use: Decay-In-Storage, or Disposal of Liquids Into Sanitary Sewerage model waste procedures that are published in Appendix Z of WISREG "Guidance for Commercial Radiopharmacy Licenses."
- OR
- We will provide procedures for waste collection, storage and disposal by any of the authorized methods described in Item 15.1 Waste Management of WISREG "Guidance for Commercial Radiopharmacy Licenses." We will contact *DHFS* for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 15.1 Waste Management of WISREG "Guidance for Commercial Radiopharmacy Licenses."
- OR
- If access to a radioactive waste burial site is unavailable, we will request authorization for extended interim storage of waste. We will refer to NRC IN 90-09 "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses," dated February 1990, for guidance and submit the required information with this application.

NOTE: APPLICANTS DO NOT NEED TO PROVIDE INFORMATION TO *DHFS* IF THEY PLAN TO DISPOSE OF LLW VIA TRANSFER TO ANOTHER AUTHORIZED RECIPIENT OR TO DISPOSE OF LIQUID SCINTILLATION MEDIA OR ANIMALS CONTAINING LOW LEVELS OF H-3 OR C-14 AS AUTHORIZED BY *ch. HFS 157.30 (5)*.

References: Contact the department to obtain copies of the following NRC documents: Policy and Guidance Directive PG 94-05, "Updated Guidance on Decay-In-Storage," dated October 1994; Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994; and Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984. Information Notices are available at <http://www.nrc.gov>.

Item 15.2 Returned Wastes from Customers

Regulations: *HFS 157.92; HFS 157.30; and HFS 157.13*

Criteria: Commercial radiopharmacies may receive radioactive waste from customers. This radioactive waste is limited to items that originated at the radiopharmacy and that contained (or contain) radioactive material delivered for customer use (e.g., pharmacy supplied syringes and vials and their contents).

Discussion: Commercial radiopharmacy licenses contain a license condition that permits radioactive waste, consisting of pharmacy supplied items, to be received from their customers. The customer may return, and the radiopharmacy may accept for disposal, only items originating at the radiopharmacy that contained or contain radioactive material. This is limited to pharmacy-supplied syringes and vials and their contents. It is *not* acceptable for customers to return items originating at their facilities that are contaminated with radioactive material supplied by the pharmacy (e.g., gloves, absorbent material, IV tubing, patient contaminated items). If an applicant wishes a broader authorization for radioactive waste retrieval, the applicant must apply for a separate license as a radioactive waste broker under the general provisions of *HFS 157.30 and HFS 157.13*.

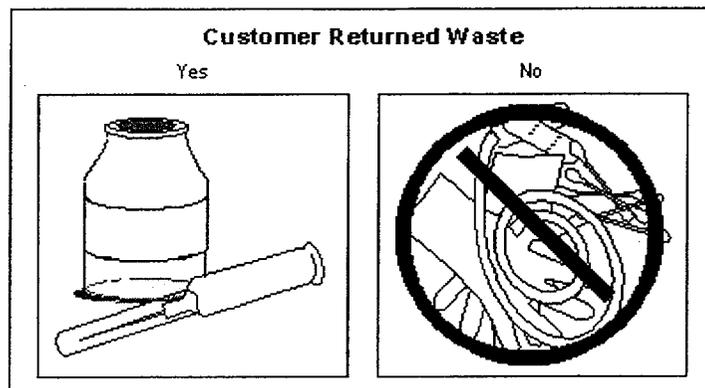


Figure 8. Returned Waste. *Only items that originated at the radiopharmacy (pharmacy supplied syringes and vials and their contents) may be returned to the radiopharmacy for disposal.*

Radiopharmacy customers, who act as the shipper for returned materials, should be supplied with detailed written instructions on how to properly prepare and package radioactive waste for return to the radiopharmacy. These instructions should clearly indicate that only items that contained or contain radioactive materials supplied by the radiopharmacy may be returned. In addition, these instructions should be adequate to ensure that customers comply with Department of Transportation (DOT) and the department rule for the packaging and transport of radioactive materials and for the radiation safety of drivers/couriers. Since customers may return unused syringes and vials, which may contain significant quantities of radioactive material, the radiopharmacy should also include in their instructions methods for determining that the activities of radioisotopes returned to the pharmacy are "limited quantities," or otherwise ensure that customers prepare and offer packages for transport that meet *DHFS* and DOT requirements if the packages contain greater than limited quantities of radioactive material. The radiopharmacy should also have written instructions for pharmacy staff to address pick-up, receipt and disposal of the returnable radioactive waste. *Appendix S* contains a model procedure for return of pharmacy radioactive wastes from customers.

If the pharmacy chooses to take the responsibility to act as the shipper for returned materials, the pharmacy must ensure that its customer follows DOT and the department rule for the packaging and transport of radioactive materials and for the radiation safety of drivers/couriers in the return process.

Response from Applicant:

Item 15.2 RETURNED WASTE FROM CUSTOMERS (Check one)

We will develop, implement and maintain procedures for returned waste from customers, that will meet the criteria in the section entitled 'Returned Waste from Customers' in WISREG "Guidance for Commercial Radiopharmacy Licenses."
(Procedures are attached)

OR

We will develop, implement and maintain procedures for returned waste from customers in accordance with Appendix S of WISREG "Guidance for Commercial Radiopharmacy Licenses."

Note: Retrieval, receipt and disposal of pharmacy supplied syringes and vials from customers is authorized via a license condition.

Item 15.3 Transportation

Regulations: *HFS 157.94; HFS 157.93; HFS 157.92; HFS 157.21; HFS 157.13; HFS 157.06; and 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 those materials to ensure compliance with department and U.S. Department of Transportation (DOT) regulations.

Discussion: The department inspects and enforces DOT's regulations governing the transport of radioactive materials by the department's licensees.

The types and quantities of radioactive materials shipped by commercial radiopharmacy licensees will nearly always meet the criteria for shipment in a "Type A" package, as defined by the DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation and contamination level limits. For radiopharmacies who transport their own packages, the packages must be blocked and braced, and shipping papers must be used and located properly in the driver's compartment.

Packaging used by commercial radiopharmacies typically includes military ammunition boxes, "briefcases," and cardboard/fiberboard boxes. These packages will normally meet the criteria for "Type A" quantities, which must meet specified performance standards to demonstrate that they will maintain the integrity of containment and shielding under normal conditions of transport. Such packages will normally withstand minor accident situations and rough handling conditions. The testing criteria for Type A packages are listed in 49 CFR 173.465. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and maintaining a certificate of testing. Shippers are not required to personally test the packages, but must ensure that the testing was performed before use and maintain a record of the testing.

DOT regulations also require that individuals who perform functions related to the packaging and shipment of radioactive material packages receive training specific to those functions. The training must include a general awareness of DOT requirements, function-specific training for the individuals' duties, and safety training. DOT also specifies the frequency of the training and a record retention requirement for training (see Item 8).

An outline of DOT and department requirements generally relevant to commercial radiopharmacy operations is included for applicant and licensee reference in *Appendix M*.

Response from Applicant:

No response is required. The licensee's program for transportation of radioactive materials will be reviewed during inspection.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials," can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425. The Memorandum of Understanding with DOT on the Transportation of Radioactive Material, signed June 6, 1979, is available from the department upon request.

Item 15.4 Minimization of Contamination

Regulations: *HFS 157.13(2)(b)*

Criteria: Applicants for new licenses must describe 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. In the case of commercial radiopharmacy applicants, these issues usually do not need to be addressed as a separate item, as they are included in responses to other items of the application.

The bulk of unsealed radioactive material utilized by radiopharmacies have short half-lives (under 120 days). These radionuclides do not pose a source of long-term contamination. Additionally, nearly all radioactive waste generated by radiopharmacies is stored for decay rather than transferred to a radioactive waste disposal facility.

The licensee may possess and redistribute sealed sources that contain radionuclides with long half lives. These sealed sources have been approved by **NRC** or an Agreement State and, if used according to the respective SS&D Registration Certificate, usually pose little risk of contamination. Leak tests performed at the frequency specified in the SS&D Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to department requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

Response from Applicant:

No response is required. The department will consider the criteria about met if the applicant meets the criteria in 'Facilities and Equipment; Safe Use of Radionuclides and Emergency Procedures; Surveys; Leaking Testing; and Waste Management.'

The Next Two Items on DHFS Form### are to be completed on the Form itself.

Item 16: Fees

On *DHFS Form* ????, enter the fee category and the amount. Enclose fee with the application.

Item 17: Certification

Individuals acting in a private capacity are required to sign and date **DHFS Form ???**. Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date **DHFS Form ????**. **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.**

Note:

- It is a violation of Wisconsin Administrative Code, Chapter HFS 157 'Radiation Protection' 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.
-

Appendix A:

**State of Wisconsin
Department of Health and Family Services
Radiation Protection Section
Form #####**

**Application for a Radioactive Material License for
Commercial Radiopharmacies**

State of Wisconsin
 Department of Health and Family Services
 Radiation Protection Section
 1 West Wilson Street, Room 150
 P.O. Box 2659
 Madison, WI 53701-2659
 Phone: (608)267-4797
 Fax: (608)267-3695

**APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE
 FOR COMMERCIAL RADIOPHARMACIES**

Instructions – Complete all items if this is an initial application or an application for renewal of a license. Refer to WISREG “Guidance for Commercial Radiopharmacy Licenses.” Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the State of Wisconsin, Department of Health and Family Services (DHFS). DHFS is requesting disclosure of information. Failure to provide any information may result in denial or delay of a radioactive material license.

APPLICATION TYPE

ITEM 1. TYPE OF APPLICATION (Check All Apply)

- NEW LICENSE
- RENEWAL License # _____
- AMENDMENT License # _____

CONTACT INFORMATION

ITEM 2. NAME AND MAILING ADDRESS OF APPLICANT:

ITEM 3. PERSON TO CONTACT REGARDING APPLICATION:

APPLICANT'S PHONE NUMBER (Including Area Code):

CONTACT'S PHONE NUMBER (Including Area Code):

LOCATION OF RADIOACTIVE MATERIAL

ITEM 4. ADDRESS(ES) WHERE RADIOACTIVE MATERIAL WILL BE USED OR POSSESSED (Do Not Use P.O. Box):

(ATTACH ADDITIONAL PAGES IF NECESSARY)

ADDRESS

PHONE NUMBER

RADIATION SAFETY OFFICER AND AUTHORIZED NUCLEAR PHARMACIST

ITEM 5. RADIATION SAFETY OFFICER (RSO) *(Attach evidence of training and experience and check one box)*

NAME: _____ TELEPHONE (Include Area Code): _____

AND

- A copy of the license (*DHFS*, the *NRC* or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an Authorized Nuclear Pharmacist, or an Authorized User;

OR

- A description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to commercial nuclear pharmacies. Appendix G and Appendix H in WISREG "Guidance for Commercial Radiopharmacy Licenses" should be used in documenting and determining required training and experience.

ITEM 5.1 AUTHORIZED NUCLEAR PHARMACIST (ANP)

(Attach evidence of training and experience and check all that apply)

NAME: _____ TELEPHONE (Include Area Code): _____

- We will provide a copy of the State pharmacy licensure or registration for each pharmacist; and a copy of the license (*DHFS*, the *NRC* or an Agreement State) on which the individual was specifically named as an ANP.

OR

- We will provide a copy of the permit maintained by a licensee of broad scope;

AND ONE OF THE FOLLOWING

- We will provide a copy of the certification(s) for the radiopharmacy board(s) approved by *DHFS*.

OR

- We will provide a description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.

OR

- We will provide a written certification, signed by a preceptor ANP, that the above training and experience as specified in *s. HFS 157.61 (9)* has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

AUTHORIZED USERS

ITEM 6. AUTHORIZED USERS (AU) (Check one box)

- We will provide the individuals name and identify types, quantities, and proposed uses of licensed material.

AND

- We will provide a copy of the license (*DHFS*, the *NRC* or an Agreement State) on which the individual was specified as an AU for the types and quantities and proposed uses of licensed materials.

OR

- We will provide a copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials.

OR

- We will provide a description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials is attached. Appendix G in WISREG "Guidance for Commercial Radiopharmacy Licenses", may be helpful in describing the training and experience required.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

ITEM 7 OCCUPATIONALLY EXPOSED WORKERS AND ANCILLARY PERSONNEL (Check one box)

We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training. **(Procedures are Attached)**

ITEM 8 PERSONNEL INVOLVED IN HAZARDOUS MATERIALS PACKAGE PREPARATION AND TRANSPORT (Check one box)

We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in *49 CFR 172.700, 49 CFR 172.702 AND 49 CFR 172.704*, as applicable. **(Procedures are Attached)**

RADIOACTIVE MATERIALS

ITEM 9 RADIOACTIVE MATERIAL (ATTACH ADDITIONAL PAGES IF NECESSARY)

Item 9.1 Radioisotope			
Item 9.2 Chemical/Physical Form			

Are open containers of potentially volatile materials (Iodine-131) manipulated at this location? Yes No
If yes, process and engineering controls must be described..

Are sealed sources used at this location? Yes No
If yes, please fill out Items 9.3 – 9.5, otherwise proceed to Item 9.6

Item 9.3 Sealed Source Manufacturer or Distributor and Model Number			
Item 9.4 Device Manufacturer or Distributor and Model Number			
Item 9.5 Sealed Source Device Registration Sheet Number			

Is Depleted Uranium used as a shielding material? Yes No
If yes, specify the total amount (in Kilograms) _____

Item 9.6 Maximum Possession Limit			
9.7 Proposed Use			

PURPOSE(S) FOR WHICH RADIOACTIVE MATERIAL WILL BE USED

ITEM 10 DISTRIBUTION AND REDISTRIBUTION OF RADIOACTIVE MATERIALS

Item 10.1 Radiopharmaceuticals (Check all that apply)

- We will confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to *s. HFS 157.13 (4) (I)*, or under equivalent NRC or Agreement State requirements;
- AND*
- We will describe all licensed material to be distributed or redistributed.

Item 10.2 Generators (Check all that apply)

- We confirm that the generators will be obtained from a manufacturer licensed pursuant to *s. HFS 157.13 (4) (j)*, or under equivalent NRC or Agreement State requirements;
- AND*
- We confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

Item 10.3 Redistribution of Generators (Check all that apply)

- We will submit a description of the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport;
- AND*
- We confirm that the manufacturer's packaging and labeling will not be altered;
- AND*
- We confirm that the generator will not be distributed beyond the expiration date shown on the generator label;
- AND*
- We confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator;
- AND*
- We confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

NOTE: ALTHOUGH REDISTRIBUTION OF USED GENERATORS MAY BE AUTHORIZED BY DHFS, DHFS APPROVAL DOES NOT RELIEVE THE LICENSEE FROM COMPLYING WITH APPLICABLE FDA OR OTHER FEDERAL OR STATE REQUIREMENTS.

Item 10.4 Redistribution of Sealed Sources – For Brachytherapy or Diagnosis (Check all that apply)

- We confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued in pursuant to *s. HFS 157.13 (4) (k)*, or under equivalent NRC or Agreement State requirements;
- AND*
- We confirm that the manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.5 Redistribution of Calibration and Reference Sealed Sources (Check all that apply)

- We confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to *s. HFS 157.13 (4) (k)*, or under equivalent NRC or Agreement State requirements, to initially distribute such sources;
- AND*
- We confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.6 Redistribution of Prepackaged Units for *In-Vitro* Tests (Check all that apply)

- We confirm that the prepackaged units for *in-vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in-vitro* tests in accordance with a specific license issued pursuant to *s. HFS 157.13 (4) (g)*, or under equivalent license of an NRC or Agreement State.

Item 10.7 Redistribution to General Licensee (Check all that apply)

We confirm that the manufacturer's packaging and labeling of the prepackaged units for *in-vitro* tests will not be altered in any way,

AND

We confirm that each redistributed prepackaged unit for *in-vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

Item 10.8 Redistribution to Specific License (Check all that apply)

We confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in-vitro* test will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license. *s. HFS 157.11 (2) (f)*

AND

We confirm that the labeling on redistributed prepackaged units for *in-vitro* tests will conform to the requirements of *s. HFS 157.29 (1) and s. HFS 157.29 (4)*

ITEM 11 PREPARATION OF RADIOPHARMACEUTICALS (Check one box)

We will attach a document that indicates the types of radiopharmaceuticals preparation activities we intend to perform (e.g. compounding of Iodine-131 capsules, radioiodination, and technetium-99m kit preparation).

ITEM 12 SERVICE ACTIVITIES (Check one box)

We will submit specific procedures for all radiation protection services that we intend to provide to other licensees (e.g. customers).

FACILITIES AND EQUIPMENT

ITEM 13 FACILITIES AND EQUIPMENT (Check boxes and attach diagram.)

We will provide copies of registration or a license from a State Board of Pharmacy as a pharmacy; or evidence that we are operating as a nuclear pharmacy within a state medical institution.

NOTE: THERE MAY BE A JURISDICTION THAT DOES NOT RECOGNIZE THE PRACTICE OF COMMERCIAL RADIOPHARMACY. IN THESE CASES, THE APPLICANT MUST SUBMIT EVIDENCE THAT IT IS REGISTERED OR LICENSED WITH THE FDA AS A DRUG MANUFACTURER.

AND

We will provide a description of the facilities and equipment to be made available where radioactive material will be used. A diagram should be submitted showing the entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to specified scale, or dimensions should be indicated. For additional information refer to WISREG "Guidance for Commercial Radiopharmacy Licenses." **(Description is Attached)**

RADIATION SAFETY PROGRAM

ITEM 14 RADIATION SAFETY PROGRAM

Item 14.1 RADIATION SAFETY PROGRAM -AUDIT

The applicant is not required to, and should not, submit its audit program to the Department for review during the licensing phase. This matter will be examined during an inspection.

Item 14.2 RADIATION MONITORING INSTRUMENTS (Check one box)

We will use equipment that meets the radiation monitoring instrument specifications and implement the model survey meter calibration program published in Appendix J of WISREG "Guidance for Commercial Radiopharmacy Licenses."

OR

We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J of WISREG "Guidance for Commercial Radiopharmacy Licenses", and instruments will be calibrated by other licensees authorized by **DHFS**, the NRC or an Agreement State, or a Licensing State to perform that service.

OR

We will provide a description of alternative equipment to be used for radiation monitoring and alternative procedures for the calibration of radiation monitoring equipment. **(Procedures are Attached)**

Item 14.3 MATERIAL RECEIPT AND ACCOUNTABILITY (Check all that apply)

- We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in s. *HFS 157.29 (6)*.

AND

- We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.

AND

- We have developed, and will implement and maintain written procedures for radioactive material accountability and control to ensure that: **(Procedures are attached)**

1. License possession limits are not exceeded;
2. Radioactive material in storage is secured from unauthorized access or removal;
3. Radioactive material not in storage is maintained under constant surveillance and control; and
4. Records of receipt, transfer, and disposal of licensed material are maintained.

ITEM 14.4 OCCUPATIONAL DOSIMETRY (Check one box)

- We will maintain for inspection by *DHFS*, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in s. *HFS 157.22*.

OR

- We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

ITEM 14.5 PUBLIC DOSE

No response is required, in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

ITEM 14.6 SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES (Check one box)

- We will develop, implement and maintain safe use of radionuclides and emergency procedures that will meet criteria in the section entitled 'Safe Use of Radionuclides and Emergency Procedures' in WISREG "Guidance for Commercial Radiopharmacy Licenses." **(Procedures are Attached)**

ITEM 14.7 SURVEYS (Check all that apply)

- We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R of WISREG "Guidance for Commercial Radiopharmacy Licenses."

Item 14.8 DOSE CALIBRATOR AND OTHER DOSAGE MEASURING EQUIPMENT (Check all that apply)

- We shall describe the types of systems (measurement or combination of measurement and calculation) that we intend to use for the measurement of alpha-beta, and photon-emitting radioactive drugs;

AND

- We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meet the requirements in s. *HFS 157.13 (4) (I)*. **(Procedures are Attached)**

AND

- We will provide, if applicable, a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers;

OR

- We will include, if applicable, a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer, or other entity.

Item 14.9 RADIOACTIVE DRUG LABELING FOR DISTRIBUTION (Check all that apply)

- We will describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g. on the "transport radiation shield" or the container used to hold the radioactive drug); **(Description is attached)**

AND

- We agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.

Item 14.10 RADIOACTIVE DRUG SHIELDING FOR DISTRIBUTION (Check all that apply)

- We will for each drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):
- Indicate the radionuclide and the maximum activity for each type of container (e.g. vial, syringe);
 - Describe the type and thickness of the "transport radiation shield" provided for each type of container; and
 - Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

NOTE: IT IS NOT ACCEPTABLE TO STATE THAT THE APPLICANT WILL COMPLY WITH DOT REGULATIONS. THE DOSE RATE LIMITS THAT DOT IMPOSES APPLY TO THE SURFACE OF THE PACKAGE, NOT THE SURFACE OF THE "TRANSPORT RADIATION SHIELD."

ITEM 14.11 LEAK TEST (Check one box)

- Leak tests will be performed by an organization authorized by *DHFS*, 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 *DHFS*, the *NRC* or an Agreement State to provide leak test kits to other licensees according to kit suppliers instructions.

License number of organization authorized to perform or analyze leak test (Specify whether Department, *NRC*, or other Agreement State): _____

Or

- We will perform our own leak testing and sample analysis. We will follow the model procedures in Appendix L of WISREG "Guidance for Commercial Radiopharmacy Licenses."

Or

- We will submit alternative procedures. (**Procedures are attached**)

WASTE DISPOSAL AND TRANSFER

ITEM 15 WASTE DISPOSAL AND TRANSFER

ITEM 15.1 WASTE MANAGEMENT (Check all that apply)

- We will use the model waste procedures published in Appendix Z of WISREG "Guidance for Commercial Radiopharmacy Licenses."
- OR*
- We will use: Decay-In-Storage, or Disposal of Liquids Into Sanitary Sewerage model waste procedures that are published in Appendix Z of WISREG "Guidance for Commercial Radiopharmacy Licenses."
- OR*
- We will provide procedures for waste collection, storage and disposal by any of the authorized methods described in Item 11 Waste Management of WISREG "Guidance for Commercial Radiopharmacy Licenses." We will contact *DHFS* for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 11 Waste Management of WISREG "Guidance for Commercial Radiopharmacy Licenses."
- OR*
- If access to a radioactive waste burial site is unavailable, we will request authorization for extended interim storage of waste. We will refer to *NRC IN 90-09 "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses,"* dated February 1990, for guidance and submit the required information with this application.

NOTE: APPLICANTS DO NOT NEED TO PROVIDE INFORMATION TO DHFS IF THEY PLAN TO DISPOSE OF LLW VIA TRANSFER TO ANOTHER AUTHORIZED RECIPIENT OR TO DISPOSE OF LIQUID SCINTILLATION MEDIA OR ANIMALS CONTAINING LOW LEVELS OF H-3 OR C-14 AS AUTHORIZED BY s. HFS 157.30 (5).

Item 15.2 RETURNED WASTE FROM CUSTOMERS (Check one)

We will develop, implement and maintain procedures for returned waste from customers, that will meet the criteria in the section entitled 'Returned Waste from Customers' in WISREG "Guidance for Commercial Radiopharmacy Licenses."
(Procedures are attached)

OR

We will develop, implement and maintain procedures for returned waste from customers in accordance with Appendix S of WISREG "Guidance for Commercial Radiopharmacy Licenses."

SPECIFIC LICENSE FEE

ITEM 16 LICENSE FEES (REFER TO s. HFS 157.10)

CATEGORY:

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)

ITEM 17

I HEREBY CERTIFY THAT THIS APPLICATION WAS PREPARED IN CONFORMANCE WITH CHAPTER HFS 157 "RADIATION PROTECTION" AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF.

SIGNATURE:

DATE:

NAME (Print or Type):

TITLE:

Appendix B:

Reserved

Appendix C:

Reserved

Appendix D:

Reserved

Appendix E:
Sample License

Appendix F:

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain *DHFS's prior written consent* before transferring control of the license; some licensees refer to this as "transferring 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. The new name of the licensed organization. If there is no change, the licensee should so state.
2. The new licensee's contact and telephone number(s) to facilitate communications.
3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of radioactive material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.
4. An indication of whether the transferor will remain in non-licensed business without the license.
5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.
6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).
7. A detailed description of any changes in the use, possession, location, or storage of the radioactive material.
8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.
9. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.
10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to *HFS 157.15*; public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the department for license terminations.
11. A description of the status of the facility, specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in *HFS 157.15*. Include information about how the transferee and transferor propose to divide the transferor's assets, and responsibility for any cleanup needed at the time of transfer.
13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to *DHFS* by the transferor. These include, but are not limited to; maintaining decommissioning records required by *HFS 157.15*; implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

With regard to open inspection items, the transferee should confirm, in writing, that it accepts full responsibility for open inspections and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with the department before license transfer.

14. Documentation that the transferor and transferee agree to transferring control of the radioactive material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.
15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and rule.

Appendix G:

Model Formats for Documenting Training and Experience for Individuals Responsible for Radiation Protection Program

Authorized User or Radiation Safety Officer Training in Basic Radioisotope Handling Techniques

Name (Last, First, Initial) _____

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
Totals								

RPP **Radiation Protection Principles**

BH **Biological Hazards**

IR **Ionizing Radiation Units & Characteristics**

INST **Radiation Detection Instrumentation**

REG **DHFS Rule**

Authorized User and Radiation Safety Officer Experiences in Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)

Name (Last, First, Initial)

Isotope(s) Used	Maximum amount Used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience

*** Purpose of Use**

1. Shipping, receiving, and performing related radiation surveys
2. Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides
3. Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides
4. Calculating, assaying, and safely preparing radioactive materials
5. Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures

Authorized Nuclear Pharmacist Training in Basic Radioisotope Handling Techniques

Name (Last, First, Initial) _____

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
			Totals					

Signature of Preceptor Authorized Nuclear Pharmacist: "I certify that the above described training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy."	Signature: _____	Date: _____
---	-------------------------	--------------------

- | | |
|---|---|
| RPP Radiation Protection Principles
IR Ionizing Radiation Units & Characteristics
REG <i>DHFS</i> Rule | BH Biological Hazards
INST Radiation Detection Instrumentation |
|---|---|

Authorized Nuclear Pharmacist Experiences in Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)

Name (Last, First, Initial)

Isotope(s) Used	Maximum amount Used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience
Signature of Preceptor Authorized Nuclear Pharmacist: "I certify that the above training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a Nuclear Pharmacy."			Signature:	Date:

*** Purpose of Use**

1. Shipping, receiving, and performing related radiation surveys
2. Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides
3. Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides
4. Calculating, assaying, and safely preparing radioactive materials
5. Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures

Appendix H:

Duties and Responsibilities of the RSO

Duties and Responsibilities of the RSO

The RSO's duties and responsibilities include ensuring radiological safety and compliance with the department and DOT regulations, and with the conditions of the license (See **Figure 9**). Typically, these duties and responsibilities include ensuring that:

- General surveillance is provided over all activities involving radioactive material; including routine monitoring, special surveys, and responding to events;
- Incidents are responded to, investigated and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Proper authorities are notified of incidents such as damage, fire or theft;
- Corrective actions are developed, implemented, and documented when violations of the rule or license conditions or program weaknesses are identified;
- Immediate termination of all activities following any unsafe condition or activity that is found to be a threat to public health and safety;
- He or she is the primary source of radiation protection information for personnel at all levels of responsibility;
- All radiation workers are properly trained;
- Procedures for the safe use of radioactive materials are developed and implemented;
- The licensee's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit;
- Prospective evaluations are performed of occupational exposures, and those individuals likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits are provided personnel monitoring devices;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- The performance of fume hoods and gloveboxes used for volatile radioactive work are monitored for proper operation;
- The receipt, opening, and delivery of all packages of radioactive material arriving at the nuclear pharmacy are overseen and coordinated;
- An inventory of all radioactive materials is maintained and the types and quantities of radionuclides at the facility are limited to the forms and amounts authorized by the license;

- Sealed sources are leak-tested at required intervals;
- There is effective management of the radioactive waste program, including effluent monitoring;
- Packaging and transport of radioactive material is in accordance with all applicable DOT requirements;
- An up-to-date license is maintained and amendment and renewal requests and notifications of new ANP's are submitted in a timely manner;
- Radiation safety program audits are performed at least annually and documented;
- He or she acts as liaison to the department; and
- All required records are properly maintained.

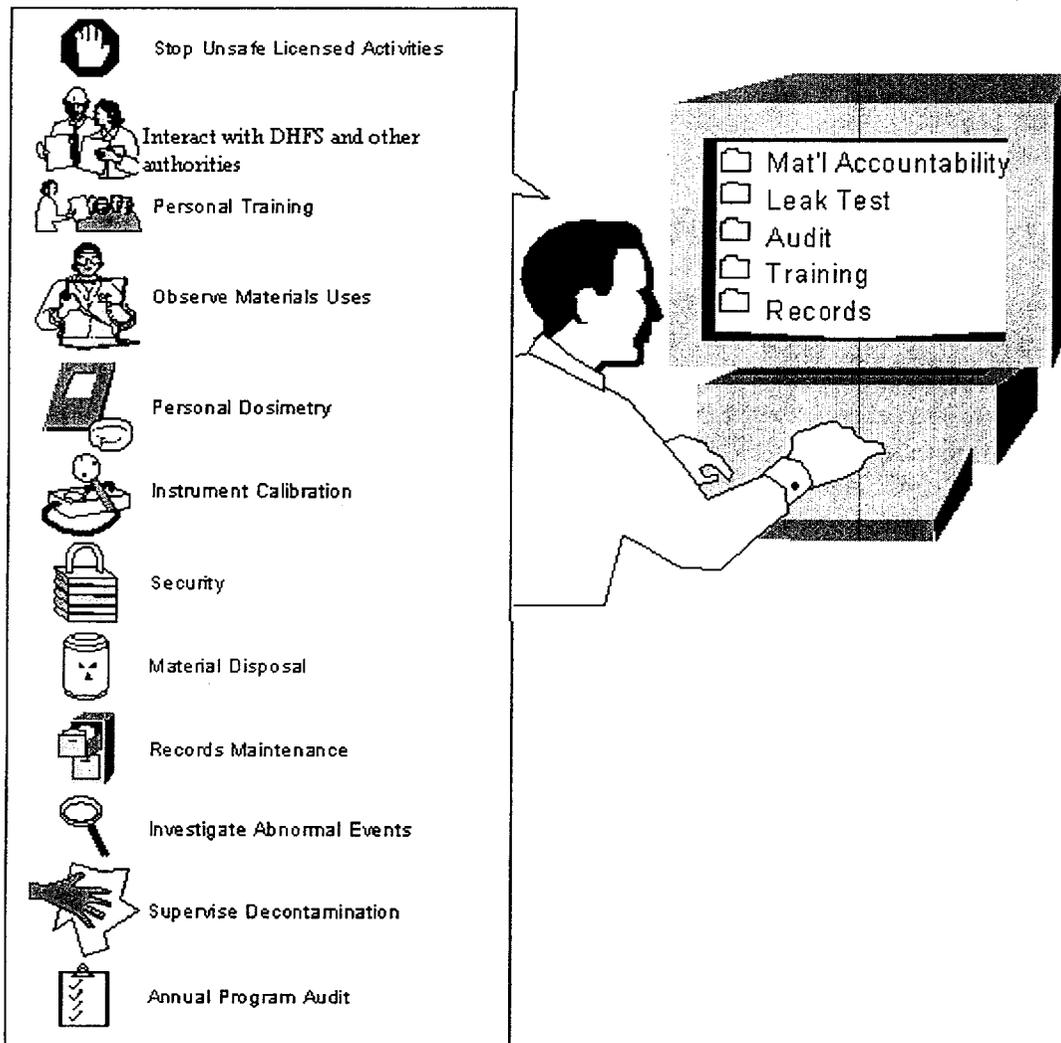


Figure 9. Typical Duties and Responsibilities of the RSO.

Appendix I:

Suggested Commercial Radiopharmacy Audit Checklist

Suggested Commercial Radiopharmacy Audit Checklist

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 which do not apply to the licensee's activities and activities which 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)

Audit History

- A. Last audit of this location conducted on (date) _____
- B. Were previous audits conducted at intervals not to exceed 12 months? *HFS 157.21*
- C. Were records of previous audits maintained? *HFS 157.31*
- D. Were any deficiencies identified during last two audits or two years, whichever is longer?
- E. Were corrective actions taken? (Look for repeated deficiencies.)

Organization and Scope of Program

- A. If the mailing address or places of use changed, was the license amended? *HFS 157.13*
- B. If ownership changed or bankruptcy filed, was the department's prior consent obtained or was the department notified? *HFS 157.13*
- C. Authorized Nuclear Pharmacists
 - 1. New ANP since last audit? If so, does new ANP meet the department's requirements? *HFS 157.13; and HFS 157.03*
 - 2. If an individual began work as an ANP, was the department notified within 30 days or was the license amended? *HFS 157.13*
- D. Radiation Safety Officer
 - 1. New RSO since last audit? If so, does new RSO meet the department's training requirement?
 - 2. If the RSO was changed, was license amended?
 - 3. Is RSO fulfilling his/her duties?
 - 4. To whom does RSO report to?
- E. Authorized Users
 - 1. New AU since last audit? If so, does new AU meet the department's requirements?
 - 2. If an AU was added, was the license amended?

- F. If the designated contact person for the department changed, was the department notified?
- G. Type and quantity of radioactive material
 - 1. Does the license authorize all of the regulated radionuclides possessed?
 - 2. Is actual possession of those radionuclides within the limits on the license?

Facilities

- A. Are facilities as described in the department's license application?
- B. If facilities have changed, has the license been amended?

Equipment and Instrumentation

- A. Sufficient numbers of portable and fixed radiation monitors (i.e., points of entry and exit into hotlab, package shipping area)?
- B. Do survey meters meet the department's criteria? *HFS 157.25*
- C. Are calibration records maintained? *HFS 157.31*
- D. Are there sufficient lead shields (L-block, etc.) for work with radionuclides?
- E. Are generators housed in separate room and/or properly shielded to keep doses ALARA?
- F. Are procedures established for identifying, evaluating and reporting safety component defects?
- G. Dose calibrators for Photon-emitters *HFS 157.13*
 - 1. Constancy, at least once a day prior to assay of patient dosages (+/- 10%)?
 - 2. Linearity, at installation and at required frequency (+/- 10%)?
 - 3. Geometry dependence, at installation (+/- 10%)?
 - 4. Accuracy, at installation and at required frequency (+/- 10%)?
 - 5. After repair, adjustment, or relocation of the dose calibrator, were appropriate tests listed above repeated?
- H. Dose Measurement Systems for Beta- and Alpha-emitters *HFS 157.13*
 - 1. Calibrated for each isotope used, with that isotope?
 - 2. Constancy, at least once each day, prior to assay of patient dosages (+/- 10%)?
 - 3. Geometry dependence, at installation (+/- 10%)?
 - 4. Accuracy, at installation and annually (+/- 10%)?
 - 5. Linearity, at installation and quarterly (+/- 10%)?
 - 6. After repair, adjustment, or relocation of the dose calibrator, were appropriate test above repeated?

Area Surveys and Contamination Control *HFS 157.25*

- A. Are area surveys being performed at applicable locations (i.e., hotlab and radioactive material storage locations) and required frequencies? Records maintained? *HFS 157.31*
- B. Are removable contamination surveys being performed at applicable locations and required frequencies? Records maintained? *HFS 157.31*

- C. Is appropriate corrective actions taken and documented when excess radiation or contamination levels are detected?

Leak Tests

- A. Was each sealed source leak tested every six months or at other prescribed intervals?
B. Was the leak test performed according to the license?
C. Are records of results retained with the appropriate information included?
D. Were any sources found leaking if yes, was the department notified?

Sealed Source Inventory

- A. Is a record kept showing the receipt of each sealed source? *HFS 157.06; and HFS 157.06*
B. Are all sealed sources physically inventoried every six months?
C. Are records of inventory results with appropriate information maintained?

Training and Instructions to Workers

- A. Were all workers who are likely to exceed 1mSv (100 mrem) in a year instructed annually per *HFS 157.88*? Records maintained?
B. Were other workers trained as needed (e.g., radiopharmacy technicians, authorized users, couriers/drivers, ancillary personnel)? *HFS 157.13* Records maintained?
C. Are workers knowledgeable of applicable *HFS 157 'Radiation Protection' Subchapter III 'Standards for Protection'*, radiation protection procedures, emergency response procedures and license conditions?
D. HAZMAT training provided, if required? *49 CFR 172.700-704*

Material Use Control and Transfer

- A. Are restricted and unrestricted areas delineated?
B. Are radioactive materials that are stored in a controlled or unrestricted area secured from unauthorized access or removal? *HFS 157.28*
C. Are radioactive materials that are in a controlled or unrestricted area and not in storage controlled and maintained under constant surveillance? *HFS 157.28*
D. Procedures for receiving and opening packages? *HFS 157.29*
E. Transfer of radioactive material only to authorized recipients? *HFS 157.13*
F. Records of receipt and transfer? *HFS 157.13; and HFS 157.06*

Personnel Radiation Protection

- A. Are ALARA considerations incorporated into the radiation protection program? *HFS 157.21*
B. Were prospective evaluations performed showing that unmonitored individuals receive less than 10% of the limit? *HFS 157.25*

- C. Did unmonitored individuals' activities change during the year which could put them over 10% of the limit?
- D. If yes to C. above, was a new evaluation performed?
- E. Is external dosimetry required (individuals likely to receive >10% of the limit)? And is dosimetry provided to these individuals?
 - 1. Is the dosimetry supplier NVLAP approved? *HFS 157.25*
- 2. Are the dosimeters exchanged at appropriate frequency?
- 3. Are dosimetry reports reviewed by the RSO when they are received?
- 4. Are the records on department forms or equivalent? *HFS 157.22; and HFS 157.31*
 - a. *DHFS* Form ##### "Cumulative Occupational Exposure History" completed?
 - b. *DHFS* Form ##### "Occupational Exposure Record for a Monitoring Period" completed?
- 5. Declared pregnant worker/embryo/fetus
 - a. If a worker declared her pregnancy, did the licensee ensure that the dose to the embryo or fetus during the entire pregnancy was less than 5 mSv (500 mR)? *HFS 157.22 (8)*
 - b. Were records kept of embryo/fetus dose per *HFS 157.31*?
- F. Monitoring for internal dose if individuals likely to receive >10% of ALI?
- G. Are workers notified manually of their exposures?
- H. Are records of exposures, surveys, monitoring, and evaluations maintained *HFS 157.31; and HFS 157.31*?

Waste Management

- A. Waste storage areas
 - 1. Is storage area properly posted? *HFS 157.29*
 - 2. Are containers properly labeled? *HFS 157.29*
- B. Decay-in-Storage
 - 1. Do radionuclides being stored all have half-lives less than 120 days (or 300 days if permitted by license condition)?
 - 2. Are radionuclides being segregated for storage according to half-life?
 - 3. Each radionuclide in radioactive waste stored for a minimum of 10 half-lives?
 - 4. Before waste is disposed of:
 - a. Survey performed at the container surface with an appropriate survey instrument set on its most sensitive scale with no interposed shielding to determine that its radioactivity cannot be distinguished from background?
 - b. All radiation labels removed or obliterated, as appropriate?
 - 5. Record Keeping?
- C. Disposal by release into sanitary sewerage.
 - 1. Is radioactive material readily soluble (or readily dispersible biologically material) in water? *HFS 157.30*

2. Quantity of radioactive material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in *HFS 157, Appendix E, Table III*?
 3. If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in *HFS 157, Appendix E, Table III* does not exceed unity?
 4. Total quantity of radioactive material released into the sanitary sewerage system in a year does not exceed the limits specified in *HFS 157.30(3)*.
- D. Transfer to Authorized Recipient
1. Is waste transferred to a person specifically authorized to receive it? *HFS 157.30*
 2. Is waste properly manifested? *HFS 157.30*

Receipt of Radioactive Waste from Customers

- A. Waste returned consists only of items that contained radioactive materials that the radiopharmacy supplied (e.g., pharmacy supplied syringes, vials)?
- B. Waste package checked for removable contamination upon receipt?

Effluents

- A. Effluents from materials being maintained As Low As Reasonably Achievable (ALARA)?
- B. Fume hoods checked to confirm an adequate airflow?
- C. Effluent monitored to determine activity being released?
- D. Filters being maintained according to the manufacturer's instructions and pharmacy procedures?

Public Dose

- A. Public access to radioactive materials and exposure to effluents controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? *HFS 157.23*
- B. Air emissions maintained below constraint limit of 0.1 mSv (10 mrem) in a year? *HFS 157.21*
- C. Survey or prospective evaluation performed per *HFS 157.25*? 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. Unrestricted area radiation levels exceed 0.02 mSv (2mrem) in any one hour? *HFS 157.23*
- E. Records maintained? *HFS 157.31*

Use and Emergency Procedures

- A. Procedures for safe use of radioactive materials and emergency procedures developed and implemented?
- B. Do the procedures contain the required elements?
- C. Radioactive materials being handled safely?
- D. Staff wearing protective clothing and personnel monitors as appropriate?

- E. Assistance coordinated with outside agencies for emergency response (e.g., fire department, *DHFS*)?
- F. Did any emergencies occur?
 1. If so, were they handled properly?
 2. Were appropriate corrective actions taken?
 3. Was department notification or reporting required? *HFS 157.32*

Transportation

- A. DOT-7A or other authorized packages used? *49 CFR 173.415; and 49 CFR 173.416(b)*
- B. Package performance test records on file?
- C. Package has two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? *49 CFR 172.403; and 49 CFR 173.441*
- D. Package properly marked? *49 CFR 172.301; 49 CFR 172.304; 49 CFR 172.310; and 49 CFR 172.324*
- E. Package closed and sealed during transport? *49 CFR 173.475(f)*
- F. Shipping papers prepared and used? *49 CFR 172.200(a)*
- G. Shipping papers contain proper entries? (Shipping name, Hazard Class, Identification Number {UN Number}, Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity {SI units required}, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Emergency Response Information, and Cargo Aircraft Only {If applicable}) *49 CFR 172.204; and 49 CFR 172.604*
- H. Shipping papers within drivers reach and readily accessible during transport? *49 CFR 177.817(e)*
- I. Package secured against movement? *49 CFR 177.834*
- J. Any incidents reported to DOT? *49 CFR 171.15; and 49 CFR 171.16*

Auditor's Independent Survey Measurements (if Made)

- A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits? *HFS 157.25*

Notification and Reports

- A. Was any radioactive material lost or stolen? Were reports made? *HFS 157.13; and HFS 157.32*
- B. Did any reportable incidents occur? Were reports made? *HFS 157.13; and HFS 157.32*
- C. Did any overexposures and high radiation levels occur? Reported? *HFS 157.13; and HFS 157.32*
- D. Were any contaminated packages or packages with surface radiation levels exceeding 200mrem received? Reported to *DHFS*?
- E. If any events (as described in items A. through D. above) did occur, what was the root cause? Were appropriate notifications made and corrective actions taken?

- F. Is the management/RSO aware of the emergency phone number for the department (608-258-0099)?

Posting and Labeling

- A. *DHFS Form #####* "Notice to Workers" posted? *HFS 157.88*
B. *DHFS* rules, license documents posted or a notice posted? *HFS 157.88*
C. Other postings and labeling? *HFS 157.29*

Record Keeping for Decommissioning

- A. Records kept of information important to decommissioning? *HFS 157.15*
B. Records include all information outlined in *HFS 157.15*?

Bulletins and Information Notices

- A. Department Bulletins and department Information Notices received?
B. Appropriate training and action taken in response?

Special License Conditions or Issues

- A. Did auditor review special license conditions or other issues?

Deficiencies Identified in Audit; Corrective Actions

- A. Summarize problems/deficiencies identified during audit.
B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken by the facility. Include date(s) when corrective actions are implemented.
C. Provide any other recommendations for improvement.

Evaluation of Other Factors

- A. Senior licensee management is appropriately involved with the radiation protection program and/or RSO oversight?
B. RSO has sufficient time to perform his/her radiation safety duties?
C. Licensee has sufficient staff to support the radiation protection program?

Appendix J:

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

The specifications in **Table 3** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility.

Table 3. Typical Survey Instruments

Instruments used to measure radiological conditions at licensed facility.

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-Ray	millirem through Rem	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, Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Flow Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	<1%

*Table from The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, 1992 (except for * items)*

Model Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

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

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel performing survey instrument calibration; and
- Conducting 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 Rate or Exposure Rate Instruments

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present;
- Individuals conducting calibrations will wear assigned dosimetry; and
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by National Institutes of Standards and Technology (NIST);
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed; and
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8×10^2 megabecquerels (21 mCi) of cobalt-60].

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall 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 shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within $\pm 15\%$ of the conventionally true values for the lower point and $\pm 10\%$ for the upper point;
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10% of the full decade value;
- Meters with a digital display device shall be calibrated the same as meters with a linear scale;
- Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation; and
- The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.

If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20% of the conventionally true value.

Model Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by National Institutes of Standards and Technology (NIST); and
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration must produce readings within $\pm 20\%$ of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration reports, for all survey instruments, will indicate the procedure used and the data obtained. The description of the calibration will include:

- The owner or user of the instrument;
- A description of the instrument, including 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 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 radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
- The exposure rate or count rate from a check source, if used; and
- 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:

- For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale;
- The efficiency, of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use);
- 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; and
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

In order to assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample must be determined. Accurate determination of the volume of air sampled requires standard, reproducible, and periodic calibration of the air metering devices that are used with air sampling instruments.

The publication entitled "Air Sampling Instruments" found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 1989, provides guidance on total air sample volume calibration methods acceptable to the department, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (see NRC Regulatory Guide 8.25).
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.
- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument, to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard. Primary standards are usually accurate to within $\pm 1\%$ and secondary standards to within $\pm 2\%$.

The following are significant errors associated with determining the total air volume sampled:

$$E_v = [E_s^2 + E_c^2 + E_t^2]^{1/2}$$

E_c : The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)

Note: The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factors to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20%, an additional error term should be included in the calculation above.

E_s : Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)

E_t : The percentage error in measurement of sampling time that should be kept within 1%.

E_v : The most probable value of the cumulative percentage error in the determination of the total air volume sampled can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_v = [E_s^2 + E_c^2 + E_t^2]^{1/2}$$

The most probable value of the cumulative error E_v , in the determination of total volume, should be less than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows: If accuracies of the scale reading, the calibration factor, and sample time are ± 4 , 2, and 1%, respectively, and there are no other significant sources of error, the cumulative error would be:

$$E_v = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\% \text{ or approx. } 5\%$$

The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factor to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20%, an additional error term should be included in the calculation above.

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

$$V_s = V_1 * (P_1/760) * (273/T_1)$$

Where:
 V_s = volume at standard conditions (760 mm & 0 degree C)
 V_1 = volume measured at conditions P_1 and T_1
 T_1 = temperature of V_1 in K
 P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References: Contact the department to obtain a copy of:

1. Draft Regulatory Guide FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985:
2. Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992; and
3. NUREG – 1400, "Air Sampling in the Workplace," dated September 1993.

Additional References:

4. The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, dated 1992.
5. ANSI N323A- 1997, "Radiation Protection Instrumentation Test and Calibration." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: www.ansi.org; and
6. "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 7th Edition, dated 1989.

Appendix K:

Public Dose

Public Dose

This Appendix describes different methods for determining radiation doses to members of the public.

Licensees must ensure that:

- The radiation doses received by individual members of the public do not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials. *HFS 157.23*;
- Air emissions of radioactive material 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 those emissions. *HFS 157.21*; and
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour. *HFS 157.23*

Members of the public include persons who live, work, or may be near locations where radioactive material is used or stored and employees whose assigned duties do not include the use of radioactive material but may who work in the vicinity where such materials are used or stored.

Doses to Members of the Public

INCLUDES doses from:

- Radiation and/or radioactive material released by a licensee;
- Sources of radiation under the control of a licensee; and
- Air effluents from sources of radioactive materials.

DOES NOT INCLUDE doses from:

- Sanitary sewerage discharges from licensees;
- Natural background radiation;
- Medical administration of radioactive material; or
- Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, areas outside buildings, property, and 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.

The licensee may show compliance with the annual dose and constraint limits for individual members of the public by:

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem) from all exposure pathways, and does not exceed 0.1 mSv (10 mrem) from air emissions.; and
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in *Table 2 of Appendix E, ch. HFS 157* (20% of the values for gaseous effluents); and if an individual were continuously present in an unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year.

In order to perform a dose assessment, the licensee should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport and storage of radioactive material at their facility. The licensee must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

The licensee may use measurements to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem) and does not exceed 0.1 mSv (10 mrem) from air emissions. These measurements may include:

- Dose rate surveys for radiation exposures from external radiation sources; and
- Measurements of radionuclides in air and water effluent.

The method used to measure dose will depend upon the nature of the radiation source. If the source of radiation is constant, it may be adequate to measure the dose rate and integrate it over time. If the source of radiation differs or changes over time, it may be necessary to perform continuous measurements.

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. At radiopharmacies, airborne effluents are discharged when potentially volatile materials are used, such as during iodine capsule preparation, but the discharge itself is usually not continuous since volatile materials are used periodically rather than continuously. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

Using a calculation method, the licensee must determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations, therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. This calculation should assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 4**). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose and constraint limits are not exceeded, then there is no need for further evaluation.

If the calculation demonstrates that either the public dose or constraint limit is exceeded with an occupancy factor of 1, then more realistic assumptions of the individual's occupancy at the points of highest internal and external exposures must be made. The licensee may use the occupancy factors in **Table 4** or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 4 Standard Occupancy Factors

Occupancy Factor	Description
1	Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas
1/4	Corridors, lounges, elevators using operators, unattended parking lots
1/16	Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic

Calculating the Annual Dose to an Individual Member of the Public

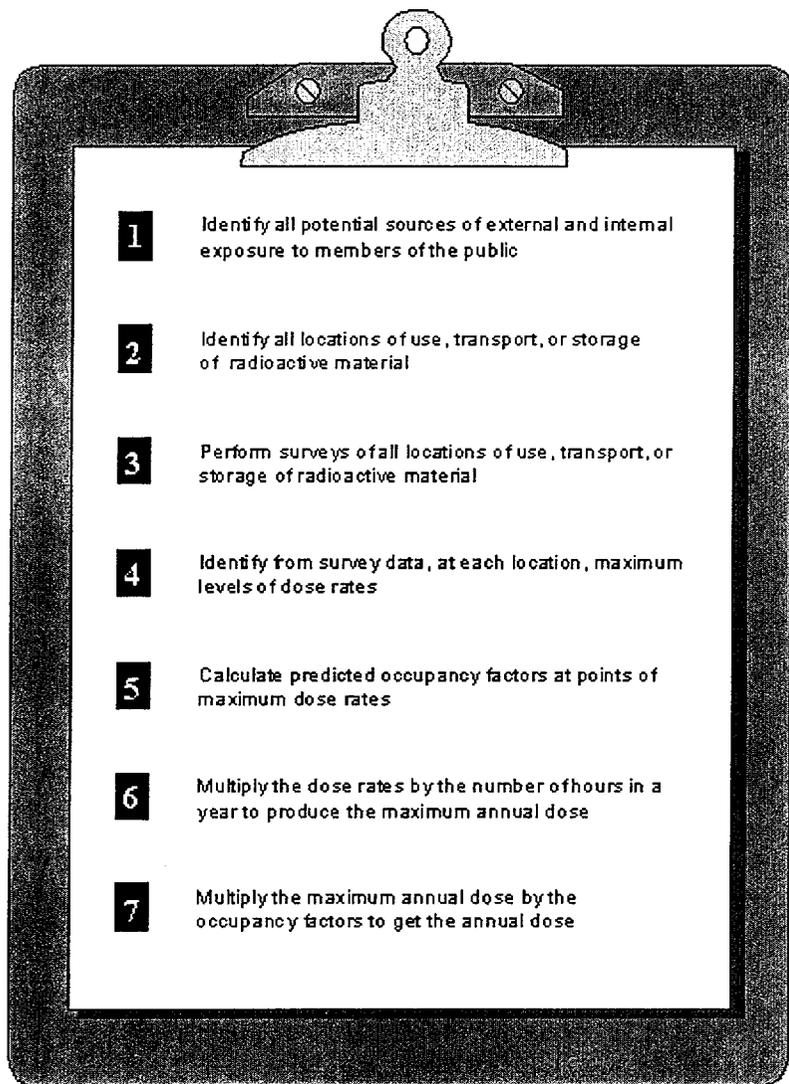


Figure 10. Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public.*

Records

The licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public, until the department terminates the license. In general, survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey, the name of the surveyor, the date of the survey, the location of the survey(s), including a description or drawing of the area surveyed, survey results, and, if applicable, the occupancy factors used and justification for their use. In addition, records demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, minimum detectable activity of the system and the estimated uncertainty of measurements.

Appendix L:
Model Leak Test Program

Model Leak Test Program:

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 tests independently.

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

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples; and
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured (NaI(Tl) well counter system, liquid scintillation, gas flow proportional counter).
- If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$\text{MDA} = \frac{3 + 4.65(\text{bkg}/t)^{1/2}}{E}$$

Where: MDA = minimum detectable activity in disintegration's 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 = 10%, or 0.1
 t = 2 minutes

$$\text{MDA} = \frac{3 + 4.65(200 \text{ cpm}/2 \text{ minutes})^{1/2}}{(0.1)}$$

= 495 dpm

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcuries) of the radionuclide.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

For example: $\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$

Where: cpm = counts per minute
 std = standard
 bkg = background
 Bq = becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in Bq (or mCi).

For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$

- Sign and date the list of sources, data and calculations. Retain records for 3 years (*HFS 157.31*). If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify the department.

Reference: Contact the department obtain a copy of Draft RG FC 412-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

Appendix M:

Transportation: DOT Regulations Applicable to Radiopharmacy Shipments

Transportation: DOT Regulations Applicable to Radiopharmacy Shipments

The major areas in the DOT regulations most relevant to commercial radiopharmacies for the transportation of radioactive material are:

- Hazardous Materials Table, 49 CFR 172.101, App. A, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides.

For the majority of packages shipped by radiopharmacies to their customers, the proper shipping name to use will be "Radioactive Material, N.O.S." Other shipments, involving primarily small quantities of radioactive material, and especially return shipments by customers, will likely be excepted packages of limited quantity. The DOT requirements for those shipments can be found in 49 CFR 173.421 and 173.422.

Likewise, for the majority of packages shipped by radiopharmacies, it will not be necessary to identify the radioactive material as a Hazardous Substance in accordance with Table 2 of 49 CFR 172.101. For the majority of radionuclides contained in packages from radiopharmacies (i.e., technetium-99m and thallium-201) the threshold for identification as a Hazardous Substance is on the order of 100 to 1000 curies, which is significantly more than is contained in the typical shipment. However, for shipments containing more than 10 millicuries of iodine-131, the packages and shipping papers must include the "RQ" designation of the shipment as containing a reportable quantity. The "RQ" must appear either before or after the basic description of the shipment on the shipping papers (i.e., "RQ Radioactive Material, N.O.S., UN 2982") and must be included in the package markings (Ref. 49 CFR 172.203(c) and 49 CFR 172.324).

- Shipping Papers 49 CFR 172.200-204: General entries, description, additional description requirements, shipper's certification.

For most packages likely to be shipped by commercial radiopharmacies shipping papers are required. These must include:

- proper shipping name (as described above);
- hazard class of the material; for radioactive materials, the hazard class is 7;
- identification number; for the proper shipping name, "Radioactive Material, N.O.S.," the identification number is UN 2982;
- package type, which will usually be Type A;
- name and quantity of each radionuclide in the shipment; the radionuclide may be abbreviated (i.e., Tc-99m);
- physical and chemical form of the radioactive material;
- category of label applied to each package in the shipment (i.e., "Radioactive White-I");
- transport index (TI) of each package bearing Radioactive Yellow-II or Radioactive Yellow-III labels;
- emergency response telephone number; and
- shipper's certification and signature.

Shipping papers may include additional information; however, the additional information must not detract from the required entries.

For most, if not all, return shipments of wastes from radiopharmacy customers, the packages can be shipped as excepted packages (limited quantity of radioactive material) and will not require shipping papers; however, such shipments must include a statement on, in, or transported with, the package. The statement is contained in 49 CFR 173.422(a)(1), and must be verbatim. Although the proper preparation of the package of returned waste is the responsibility of the shipper (i.e., the customer), radiopharmacies should be aware of the specific requirements if they intend to provide guidance to their customers regarding these types of shipments.

- Package Markings 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: General marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging

All certification packages shipped by commercial radiopharmacies (i.e., Type A packages) must be properly marked, as follows:

- proper shipping name and identification number (i.e., "Radioactive Material, N.O.S., UN 2982");
- the letters RQ if the packages contain a hazardous substance, which will only likely occur when the packages contain more than 10 millicuries of iodine-131; and
- the designation Type A, if the package conforms to the Type A requirements.

DOT also specifies the size and appearance of the markings and markings that are prohibited.

- 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, radioactive materials, placement of labels, specifications for radioactive labels.

All packages routinely prepared and shipped by commercial radiopharmacies are required to be labeled in accordance with DOT regulations. The labels will usually be either "Radioactive White-I," or "Radioactive Yellow-II." Radiopharmacies have rarely offered a package labeled as "Radioactive Yellow-III" for shipment. Packages exhibiting surface radiation levels equal to or less than 0.5 millirem per hour will be labeled as "Radioactive White-I." There is no TI, defined as a unitless number equivalent to the radiation level, in millirems per hour, at one meter from the surface of the package, for a White-I label. Packages with surface radiation levels greater than 0.5 millirem per hour, but less than or equal to 50 millirems per hour, will be labeled with a Yellow-II label. The TI for a Yellow-II label must be less than or equal to "1." The lowest TI is "0.1," and all TIs are rounded to the nearest tenth.

Packages required to be labeled must have two labels affixed, on opposite sides, but not on the top or bottom. The labels must include the identity and quantity of the radionuclides in the package. Yellow-II and Yellow-III labels must also include the TI. A label may not be affixed to a package that does not meet the applicable labeling requirements.

- 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, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards.

DOT regulations specify when vehicles carrying hazardous materials must be placarded. For radiopharmacy shipments, this is usually applicable only when packages with Yellow-III labels affixed are offered or transported. Since commercial radiopharmacies rarely, if ever, offer Yellow-III packages for transport, placarding of the vehicles is not of concern and will not be discussed in detail.

- Emergency Response Information, Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number.

Persons who offer hazardous materials for transport, including radioactive materials, must provide or make available emergency response information, including:

- An emergency response telephone number must be included on the shipping papers and the number must be monitored at all times that the material is being transported. The person monitoring the telephone number must be either knowledgeable of the hazardous material being shipped or have comprehensive emergency response and incident mitigation information for that material, or have immediate access to a person who has such knowledge and information; and
- Emergency response information for the shipment that will aid emergency responders in mitigating the consequences of an accident, including the health hazards of the material, handling fires and spills involving the material, and first aid measures must be included on, or with, the shipping papers.

Applicants and licensees should review the specific DOT requirements applicable to emergency response information in the development of their programs and procedures.

- Training, Subpart H, 49 CFR 172.700, 49 CFR 172.702; and 49 CFR 172.704; Purpose and Scope, applicability and responsibility for training and testing, training requirements.

Licensees who prepare packages of radioactive materials and who transport their own packages must provide training to their employees who perform those functions. The training must include:

- General awareness and familiarization training designed to provide familiarity with DOT requirements, and enable the employee to recognize and identify hazardous materials;
- Function-specific training concerning the DOT requirements which are specifically applicable to the functions the employee performs (i.e., if the employee's duties require him/her to affix DOT Radioactive labels to packages, he or she must receive training in DOT's regulations governing package labeling); and
- Safety training concerning emergency response information, discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

The training must be provided initially, and then every three years. Records of training must be maintained.

- Shippers - General Requirements for Shipments and Packaging, Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A_1 and A_2 , table of A_1 and A_2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment.

Package Activity Limits

Before offering a radioactive materials package for transport, the shipper must determine the category of the shipment. Licensees will likely prepare or transport two categories of packages containing radioactive material. The categories are based, in part, on the activity of the radioactive material contained in the package. The categories, activity ranges, packaging requirements, and examples are provided in **Table 5**. All quantities referenced here are multiples of the A_2 (normal form) values specified for radionuclides in 49 CFR 173.435, and the physical form is assumed to always be liquid.

Table 5 Package Activity Limits

Category	Activity Range	Packaging Requirements	Example
Excepted packages, limited quantity of radioactive material	Less than $10^{-4} A_2$	49 CFR 173.421 and 173.422	Less than 21.6 millicuries of technetium-99m (usually for returned waste shipments)
Radioactive Material, N.O.S.	Greater than $10^{-4} A_2$ but less than A_2	Type A packaging (49 CFR 173.410; 49 CFR 173.412; 49 CFR 173.415; 49 CFR 173.431; 49 CFR 173.433)	More than 21.6 millicuries, but less than 216 curies of technetium-99m

Once the quantity of material in the package has been determined, the appropriate packaging must be selected.

Packaging Design

Packages of radioactive material offered as excepted packages, limited quantity of radioactive material, in accordance with 49 CFR 173.421, are required to meet the minimum packaging requirements of 49 CFR 173.410. Those requirements primarily address, but are not limited to, maintaining package integrity and contents during conditions normally expected to occur during transport. This does not include survival during accidents. Packaging normally used by commercial radiopharmacies (i.e., military ammunition boxes, "briefcases," and cardboard/fiberboard boxes, typically meet and exceed those minimal requirements).

Packages containing "Type A" quantities must meet more stringent criteria, including testing to demonstrate that the packages will maintain their integrity of containment and shielding during normal conditions of transport. The testing criteria for Type A packages are listed in 49 CFR 173.465. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and maintaining a certificate of testing. Shippers are not required to personally test the packages, only to ensure that the testing was performed before use.

Quality Control

Prior to each shipment, the shipper is required to determine that the package is in condition for shipment. The determinations must include, but are not limited to verification of the following:

- Package is proper for the contents to be shipped;
- Packaging is in unimpaired physical condition; and
- External radiation and contamination levels are within the allowable limits.

The quality control requirements for radioactive material packages are located in 49 CFR 173.475. The external radiation and contamination level limits are located in 49 CFR 173.441 and 173.443. The applicant should ensure that its procedures for preparing radioactive material packages include provisions to survey the handle on ammunition boxes and briefcases used as packaging, in addition to the closure clasp on ammunition boxes. Excessive contamination has been identified in those locations in several package contamination events reported in the past.

Carriage by Public Highway - General Information and Regulations, Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834, 49 CFR 177.842: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Licensees who intend to transport their own packages must ensure that their drivers receive training in the safe operation of the vehicle transporting the hazardous material packages. The training requirements include, but are not limited to:

- Pre-trip safety inspection of the vehicle;
- Requirements pertaining to vehicle attendance and incident reporting; and
- Loading and unloading of the materials, including blocking and bracing the packages and separation from occupied compartments.

The specific training requirements are located in 49 CFR 177.816.

The licensee must also ensure that its drivers maintain the shipping papers accessible during transport and when the driver is not at the vehicle controls. During transport, the shipping papers must be located within the driver's reach while restrained by the lap belt -- either in a pocket in the driver's door of the vehicle or readily visible to someone entering the driver's compartment. In an accident, emergency responders are instructed to look in those locations for the shipping papers to aid in handling the hazardous material aspects, if any. Failure to properly locate shipping papers could adversely impact the response to an accident, result in actions that spread radioactive contamination, and result in unnecessary radiation exposures to the responders. When the driver is not at the vehicle controls, such as during deliveries to customers, the shipping papers for the packages remaining in the vehicle must be either in the pocket in the driver's side door or on the driver's seat in the vehicle.

49 CFR 177.834(a) and 177.842 require that packages of radioactive materials be blocked and braced so that they cannot change position during conditions normally incident to transportation. The method used must prevent lateral movement of the packages during normal transport conditions (turns, curves, potholes, dips, stopping and acceleration, etc.). This does not include accident situations. The key test for evaluating the effectiveness of blocking and bracing is to attempt to move the package by hand after it is loaded. If the package can be moved through normal (non-Herculean) effort, then it is not properly blocked and braced. The use of a non-skid material on the vehicle surface where the package is loaded is not sufficient by itself. Additional means are necessary to block the package within the vehicle.

Appendix N:
Model Personnel Training Program

Model Personnel Training Program

Training Program

1. General Instructions

1.1. Training will be provided:

- Before an employee assumes duties with, or in the immediate vicinity of, radioactive materials;
- At least annually, as refresher training for all employees; and
- Whenever a significant change occurs in duties, regulations, or the terms of a department license.

1.2 Subjects covered for individuals working with, or in the vicinity of, radioactive materials or radiation:

- Safe radiation practices associated with the job (examples of topics that may be covered are found in Section 3 of this Appendix);
- Site-specific radiation safety practices; and
- Applicable department rule.

1.3 Subjects covered for ancillary personnel:

- Significance of the radiation symbol and its use on signs and labels;
- Location of unrestricted areas; and
- Whether the individual is authorized access to the restricted areas of the pharmacy.

1.4. Type of instruction:

- Instruction in the licensee's site-specific radiation safety program and *DHFS* regulatory requirements may be in the form of lecture, demonstrations, videotape, or self study, and should emphasize practical subjects important to the safe use of radioactive material; and
- Individuals receiving instructions should be provided an opportunity to ask questions.

2. Instruction for individuals likely to receive an occupational dose in excess of 100 mSv (100 mrem)

2.1 Instruction will be provided:

- Before an employee assumes duties with or in the immediate vicinity of radioactive materials;
- At least annually, as refresher training; and
- Whenever a significant change occurs in duties, regulations, or terms of the department license.

2.2 Licensee must provide instruction in subjects covered in *HFS 157.88*

2.3 Records of initial and refresher training should be maintained and should include:

- Name of the individual who provided the instruction;
- Names of the individuals who received the instruction; and
- Date of instruction List of Topics covered.

3. Suggested radiation safety training topics for individuals working with, or in the vicinity of, radioactive material (this section is intended as a guide to topics covered in a typical radiation safety training program; topics selected should be commensurate with the individuals' duties).

3.1 Basic radiation safety information:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues);
- Radiation safety
 - ✓ Radiation vs. contamination
 - ✓ Internal vs. external exposure;
 - ✓ Biological effects of radiation;
 - ✓ ALARA concept; and
 - ✓ Use of time, distance, and shielding to minimize exposure;
- Risk estimates, including comparison with other health risks *HFS 157.88*;
- Regulatory requirements;
 - ✓ RSO;
 - ✓ Material control and accountability;
 - ✓ Dose to individual members of the public;
 - ✓ Personnel dosimetry;
 - ✓ Occupational dose limits and their significance;
 - ✓ Dose limits to the embryo/fetus, including instruction on declaration of pregnancy;
 - ✓ Workers' right to be informed of occupational radiation exposure;
 - ✓ Radiation safety program audits;
 - ✓ Ordering and receipt of packages;
 - ✓ Transfer;
 - ✓ Waste disposal;
 - ✓ Recordkeeping;
 - ✓ Surveys;
 - ✓ Postings;
 - ✓ Labeling of containers;
 - ✓ Handling and reporting of incidents or events;
 - ✓ Licensing and inspection by the department;
 - ✓ Need for complete and accurate information;
 - ✓ Employee protection; and
 - ✓ Deliberate misconduct

3.2. General topics for safe use of radioisotopes:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials;

- Use syringe shields and vial shields when preparing and handling radioactive drugs;
- Measure all radiopharmaceuticals prior to transfer;
- Measure the molybdenum-99 content of each generator elution and do not transfer those radiopharmaceuticals for human medical use that will contain more than 0.15 microcuries of molybdenum-99 per mCi of technetium-99m at the time of administration;
- Wear disposable gloves at all times when handling radioactive materials and change gloves frequently to minimize the spread of contamination;
- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response;
- Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used;
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used (see **Figure 11**). Personnel items brought into the restricted area (i.e., radios, compact discs, notepads, books, etc.) should be surveyed for contamination before removal from the area;
- Food and beverages used in the preparation of radiopharmaceuticals should be clearly labeled "Not for personal consumption" if stored with radioactive materials;
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive material is used or stored;
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all radioactive material when it is not under the constant surveillance and immediate control of the user(s).

3.3. Instruction on radiopharmacy-specific program elements:

- Applicable regulations and license conditions;
- Areas where radioactive material is used or stored;
- Potential hazards associated with radioactive material in each area where the individuals will work;
- Special procedures for handling volatile materials;
- Proper use of radiation shielding;
- Proper use of survey and analytical instruments;
- Appropriate response to spills, emergencies or other unsafe conditions;
- Emergency procedures;
- Previous incidents, events and/or accidents;
- Survey program;
- Effluent monitoring and control;
- Customer-returned waste pickup, receipt, and handling;
- Waste management and minimization;

- Personnel monitoring;
- Procedures for receiving packages containing radioactive materials;
- Procedures for opening packages;
- Sealed sources and leak tests; and
- Other topics, as applicable.

Appendix O:

Model Dose Calibrator Testing Program

Model Dose Calibrator Testing Program

Model Procedures for Testing Dose Calibrators Used to Measure Photon-emitting Radionuclides

This model procedure can be used by applicants and licensees for checking and testing done calibrators.

Model Procedure

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances.
 - 1.1. Constancy, at least once each day prior to assay of patient dosages (a safe margin is considered to be below $\pm 10\%$).
 - 1.2. Linearity at installation and at least quarterly thereafter (a safe margin is considered to be below $\pm 10\%$).
 - 1.3. Geometry dependence at installation (a safe margin is considered to be below $\pm 10\%$).
 - 1.4. Accuracy, at installation and at least annually thereafter (a safe margin is considered to be below $\pm 10\%$).
2. After repair, adjustment, or relocation of the dose calibrator, such that proper function of the ionization chamber or electronics would likely be in doubt, repeat the above tests as appropriate.
3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as cesium-137, cobalt-60, cobalt-57, or radium-226 using a reproducible geometry each day before using the calibrator; Consider using two or more sources with different photon energies and activities.

Use the following procedure:

- 3.1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the cesium 137 setting to assay cesium-137).
 - 3.2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background circuit if it is used.
 - 3.3. For each source used either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.
 - 3.4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
 - 3.5. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the authorized nuclear pharmacist or the radiation safety officer of a suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The dose calibrator should be repaired or replaced if the error exceeds 10%.
4. The linearity of a dose calibrator should be ascertained over the range of its use between the maximum activity in a vial and 30 microcuries. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This example uses a vial of technetium-99m that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator) and assumes your predetermined safety margin is $\pm 5\%$.

4.1. Time Decay Method

- 4.1.1. Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).
- 4.1.2. Assay the technetium-99m vial in the dose calibrator and subtract background to obtain net activity in millicuries.
- 4.1.3. Repeat step 4.1.2. at time intervals of 6, 24, 30, and 48 hours after the initial assay.
- 4.1.4. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

<u>Assay Time⁴ (hours)</u>	<u>Correction Factor</u>
0	31.6
6	15.8
24	2.00
30	1.00
48	0.126

Note: ⁴ Assay times should be measured in whole hours and correction factors should be used to three significant figures as indicated. The half-life of $T_{1/2} = 6.02$ hours has been used in calculating these correction factors.

Example: If the net activity measured at 30 hours was 15.6 mCi, the calculated activities for 6 and 48 hours would be $15.6 \times 15.9 = 248$ mCi and $15.6 \text{ mCi} \times 0.126 = 1.97$ mCi, respectively.

- 4.1.5. Plot both the measured net activity and the calculated activity versus time.
- 4.1.6. On the graph, the measured net activity plotted should be within $\pm 5\%$ of the calculated activity if the instrument is linear and functioning properly. If variations greater than 5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

4.2. Shield Method:

If a set of "sleeves" of various thicknesses are used to test for linearity, it will first be necessary to calibrate them.

- 4.2.1. Begin the linearity test by assaying the technetium-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time. After making the first assay, the sleeves can be calibrated as follows (Steps 4.2.2. through 4.2.4 must be completed within 6 minutes).
- 4.2.2. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- 4.2.3. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- 4.2.4. Continue for all sleeves.
- 4.2.5. Complete the following decay method linearity test steps:
 - 4.2.5.1. Repeat the assay at about noon, and again at about 4:00 p.m. Continue on subsequent days until the assayed activity is less than 30 millicuries. For dose calibrators on which the range is selected with a switch, select the range normally used for the measurement.
 - 4.2.5.2. Convert the time and date information recorded to hours elapsed since the first assay.

- 4.2.5.3. On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.
- 4.2.5.4. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$(A\text{-observed}) - (A\text{-line}) / (A\text{-line}) = \text{deviation.}$$
- 4.2.5.5. If the worst deviation is more than ± 0.05 , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph.
- 4.2.6. From the graph made in step 4.2.5.3, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data received in step 4.2.2.
- 4.2.7. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data received in step 4.2.3.
- 4.2.8. Continue for all sleeves.
- 4.2.9. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

- 4.2.10. Assay the technetium-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.
 - 4.2.11. Steps 4.2.12 through 4.2.14 below must be completed within 6 minutes.
 - 4.2.12. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
 - 4.2.13. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
 - 4.2.14. Continue for all sleeves.
 - 4.2.15. On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
 - 4.2.16. Plot the data using the equivalent decay time associated with each sleeve.
 - 4.2.17. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$(A\text{-observed}) - (A\text{-line}) / (A\text{-line}) = \text{deviation.}$$
 - 4.2.18. If the worst deviation is more than ± 0.05 , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to "true activity."
5. Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence should be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following examples assumes that injections are done with 3-cc plastic syringes, that radiopharmaceutical kits are made in 30-cc glass vials, and that the predetermined safety margin is $\pm 5\%$.

- 5.1. In a small beaker or vial, mix 2 cc of a solution of technetium-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second beaker or vial with nonradioactive saline. Tap water may be used.
 - 5.2. Draw 0.5 cc of the technetium-99m solution into the syringe and assay it. Record the volume and millicuries.
 - 5.3. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
 - 5.4. Repeat the process until a volume of 2.0 cc has been assayed. The entire process must be completed within 10 minutes.
 - 5.5. Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal error lines above and below the chosen "standard volume."
 - 5.6. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the error lines, it will be necessary to make a correction table or graph that will allow a conversion from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and model and serial number of the calibrator.
 - 5.7. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the technetium-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
 - 5.8. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
 - 5.9. Repeat the process until a volume of 19.0-cc has been assayed. The entire process must be completed within 10 minutes.
 - 5.10. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 5% error lines drawn above and below the chosen "standard volume."
 - 5.11. If any correction factors are greater than 1.05, or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated value" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
6. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as cobalt-57, cobalt-60, cesium-137) should be used. One source should have a principal photon energy between 100keV and 500keV. If a radium-226 source is used it should be at least 10 microcuries, other sources should be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.
 - 6.1. Assay a calibrated reference source at the appropriate setting (i.e., use the cobalt-57 setting to assay cobalt-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.

- 6.2. Average the three determinations. The average value should be within the predetermined safety margin, which in this example is 5% of the certified activity of the reference source, mathematically corrected for decay.
- 6.3. Repeat the procedure for other calibrated reference sources.
- 6.4. If the average value does not agree, within 5%, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The dose calibrator should be repaired or replaced if the error exceeds 10%.
- 6.5. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.
- 6.6. Put a sticker on the dose calibrator noting when the next accuracy test is due.
- 6.7. The individual performing the tests will sign or initial the records of geometry, linearity, and accuracy tests.

Appendix P:
Material Receipt and Accountability

Material Receipt and Accountability

Sample Model Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- Carriers should be instructed to deliver radioactive packages directly to the designated receiving area.

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, within 3 hours of receipt of any package of radioactive material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any suspected damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package, if still on site, to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries may be made to a designated, secured storage area. These packages must be checked for contamination and external radiation levels within 3 hours after personnel arrive at the facility. They should not be allowed to remain in the designated storage area any longer than necessary, as they may be a source of exposure for pharmacy personnel.

Sample Model Procedure for Safely Opening Packages Containing Radioactive Materials

For packages received under the specific license, authorized individuals should implement procedures for opening each package, as follows:

- Wear gloves to prevent hand contamination;
- Visually inspect the package for any sign of damage (e.g., crushed, punctured). If damage is noted, stop and notify the RSO;
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, to ensure that the shipment does not exceed license possession limits;
- Monitor the external surfaces of a labeled package according to specifications in **Table 1** in Item 14.3;
- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents, comparing requisition, packing slip and label on the container. Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Again check that the shipment does not exceed license possession limits. If anything other than the expected observation is identified, stop and notify the RSO;

- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash;
- Maintain records of receipt, package survey, and wipe test results; and
- Notify the final carrier and the department when removable radioactive surface contamination exceeds the limits of 22 disintegrations per minute per square centimeter (dpm/cm²) averaged over 300 cm² (6600 dpm / 300 square centimeters); or external radiation levels exceed 2.0 mSv/hr (200 mrem/hr) at the surface.

Appendix Q:

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

General Topics for Safe Use of Radioisotopes

Each licensee using radioactive material should establish general rules for the safe use of the material so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials;
- Use syringe shields and vial shields when preparing and handling radioactive drugs;
- Measure all radiopharmaceuticals prior to transfer;
- Measure the molybdenum-99 content of each generator elution and do not transfer those radiopharmaceuticals for human medical use that will contain more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m at the time of administration;
- Wear disposable gloves at all times when handling radioactive materials and change gloves frequently to minimize the spread of contamination;
- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response;
- Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used;
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used (see **Figure 11**). Personal items brought into the restricted area (i.e., radios, compact discs, notepads, books, etc.) should be surveyed for contamination before removal from the area;
- Food and beverages used in the preparation of radiopharmaceuticals should be clearly labeled "Not for personal consumption" if stored with radioactive materials;
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored;
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all radioactive material when it is not under the constant surveillance and immediate control of the user(s).

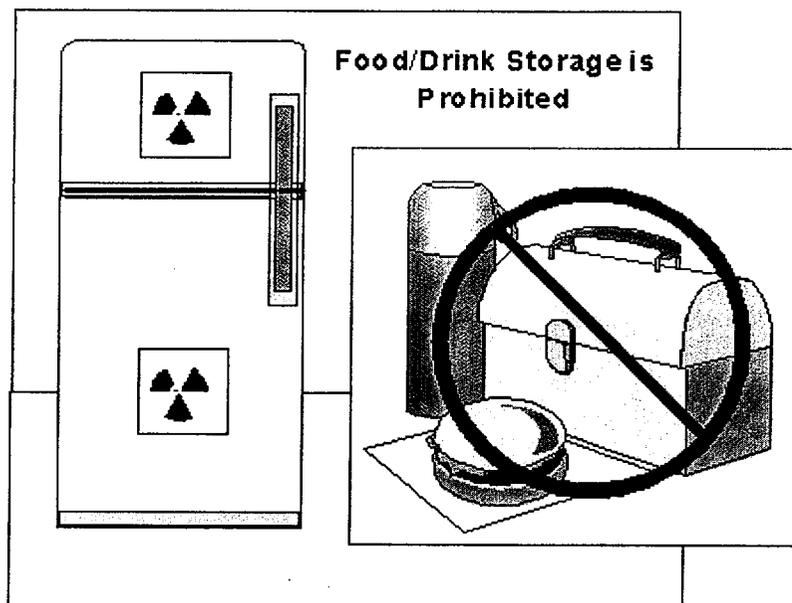


Figure 11. Storage of Food and Drink. *Food or drink for personal consumption should not be stored in refrigerators with radioisotopes.*

Model Procedures for Handling Millicurie Quantities of Radioiodine

Due to the potential for significant intakes, due to volatility and accidental ingestion, and skin exposures (SDE) from contamination, licensees should establish specific procedures for the containment and handling of millicurie quantities of radioiodine, most commonly iodine-131. The following guidance is the minimum that should be considered if the applicant intends to manipulate radioiodine:

- Manipulation of radioiodine (e.g., handling or compounding capsules, performing radioiodination, dispensing from bulk solution) should be conducted in an isolated area within the main hot lab of the pharmacy. This will aid in maintaining exposures ALARA and provide a means to isolate the area in the event of a spill;
- Radioiodine handling should only be performed inside a glovebox or fume hood. The ventilation for gloveboxes and fume hoods should be checked at least once every six months to ensure adequate airflow and confirm negative pressure with respect to the area around the glovebox or fume hood. Exhaust stacks for gloveboxes and fume hoods used for handling radioiodine should not be located near ventilation intakes to minimize the likelihood of recirculation to the pharmacy or to other tenants in a shared building;
- Gloveboxes and fume hoods must include appropriate filters (activated charcoal) to minimize effluents from radioiodine handling;
- Filters must be installed and used in accordance with the manufacturer's specifications (e.g., adequate air flow to ensure adequate residence time);
- Filters should be checked at installation and periodically, based on use, but not less than once per calendar quarter, to ensure continued efficiency;
- Air flow through fume hoods and gloveboxes should be confirmed before each use;
- Magna-helic sensors, if used, should be checked before each use of the glovebox or fume hood, to ensure minimum flow across the filter;
- Absorbent materials and dry chemical buffers, for use in the event of a spill, should be located near the area where millicurie quantities of radioiodine are handled;

- Additional protective clothing should be used when handling millicurie quantities of radioiodine. Personnel should be double gloved and use shoulder-length sleeve guards. The gloves and glove seals on gloveboxes should be checked periodically and replaced when needed; and
- All personnel handling greater than 500 millicuries of iodine-131 in a year should be considered for bioassay. This is the threshold below which intakes over 1% of the annual limit on intake (ALI) are not likely, and assumes no containment. When used in a properly operating fume hood, the threshold for consideration of the need for bioassay rises to 5 curies of iodine-131. If used in a properly operating glovebox, with properly sealed glove ports and well maintained gloves, the threshold rises to 50 curies of iodine-131 handled by one person per year. Pharmacies using gloveboxes that do not have sealed glove ports may not use the threshold indicated for that equipment, but may use the threshold for properly maintained fume hoods.

Model Procedures for Handling Events

Suggested Thresholds for Defining Minor Contamination Events, Minor Spills, and Major Spills

Licensees should establish clearly delineated thresholds for describing these types of events. Licensees should establish a graded response to emergencies, incorporating increasing formality of a response based on the potential risks posed by the events. No emergency procedure can anticipate every likely event; therefore, flexibility and judgment must be incorporated into such procedures. Most importantly, if licensee staff are not sure of the proper or expected response to any event, no matter how minor, they should be instructed to immediately cease further action, control access to the area, contact the RSO and wait for instructions.

Although the following is only suggested guidance for establishing response thresholds, *significant* deviations in actual licensee emergency procedures should be clearly justified.

Minor Contamination Events

Those events typically identified through routine surveys that involve removable contamination levels greater than the licensee's action limit, but less than ten times the licensee's action limit. Minor contamination events can be easily decontaminated without the need for strict adherence to a step-by-step procedure. Such events require judgment on the part of the individual responding to determine the scope and extent of the contamination and to assess their ability to respond effectively. In order to prevent the spread of contamination, coworkers should be notified if decontamination of the area will be delayed. The RSO should be notified promptly of such events, either before, or immediately after, cleanup of the area. Isolated minor contamination events may not require a formal root cause evaluation or extensive corrective action determinations; however, several events in the same location, involving the same individual, or during similar processes may warrant such in-depth evaluations and determinations.

Minor Spills

Those events typically identified at the time they occur (i.e., a dropped syringe or vial containing radioactive material) involving the release (spill) of radioactive material requiring a more formal adherence to a step-by-step procedure. Such events will usually involve millicurie quantities of material and have a potential for exposures to personnel or the public if not properly controlled and decontaminated. The upper limit for defining minor spills should not be more than five times the lowest annual limit on intake (ALI) of the material involved in the spill. Such a limit would include the following quantities of radioactive material:

1. Up to 400 millicuries of technetium-99m;
2. Up to 150 microcuries of iodine-131;
3. Up to 100 millicuries of thallium-201; and
4. Up to 10 millicuries of samarium-153.

Minor spills may warrant root cause evaluations and corrective action determinations, depending on the circumstances. The RSO should be notified immediately of such events so that decontamination procedures can be monitored. Minor spills involving quantities of radioactive material near the upper threshold may require more than one person to respond to assist in the cleanup, perform confirmation surveys, or monitor materials and personnel exiting the area.

Major Spills

Any spill involving a quantity of radioactive material in excess of the quantity defined for a minor spill is considered a major spill. Such spills have a greater potential for exposures to workers and the public, including the possibility of overexposure, if not properly contained. Individuals should never attempt to clean a major spill by themselves, or without the personal supervision and direction of the RSO. Major spills should generally be reported to the department in accordance with the requirements of *HFS 157.13*. Major spills may also require evaluations of intakes and skin doses, if personnel contamination is identified, as well as root cause evaluations and corrective action determinations. Qualified assistance should be sought immediately for those major spills that are beyond the licensee's capability to address.

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensees should have emergency equipment readily available for handling spills. Spill response materials should include the following:
 - ✓ Disposable gloves;
 - ✓ Housekeeping gloves;
 - ✓ Disposable lab coats;
 - ✓ 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;
 - ✓ Box of wipes;
 - ✓ Instructions for "Emergency Procedures";
 - ✓ Clipboard with a copy of the Radioactive Spill Report Form for the facility; and
 - ✓ Pencil

Minor Contaminations and Spills of Liquids and Solids

- Instructions to Workers
 - ✓ These instructions apply to minor contamination events (less than 10 times the licensee's action limit) and minor spills of radioactive material. The response to each is similar; however, the response to minor contamination events need not be as formal as the response to spills involving millicurie quantities of radioactive material.
 - ✓ Notify persons in the area that a spill has occurred;
 - ✓ Prevent the spread of contamination by covering the spill with absorbent paper. Paper should be dampened if solids are spilled;
 - ✓ Clean up the spill, wearing disposable gloves and using absorbent paper;
 - ✓ Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and other contaminated disposable material in the bag;
 - ✓ Resurvey the area. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination; and
 - ✓ Report the incident to the Radiation Safety Officer (RSO) promptly.
- Reminders to RSO
 - ✓ Follow up on the decontamination activities and document the results;
 - ✓ As appropriate, determine cause and corrective actions needed; consider bioassays if radioactive material may have been ingested or inhaled; and
 - ✓ If necessary, notify the department.

Major Spills of Liquids and Solids

- Instructions to Workers
 - ✓ Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room;
 - ✓ Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated;
 - ✓ Shield the source only if it can be done without further contamination or significant increase in radiation exposure;
 - ✓ Close the room and secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred;
 - ✓ Notify the RSO immediately;
 - ✓ Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap;
 - ✓ Allow no one to return to work in the area unless approved by the RSO; and
 - ✓ Follow the instructions of the RSO (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
 - ✓ Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
 - ✓ Skin contamination must be evaluated to determine potential exposures. Beta-emitting radionuclides have a high potential for resulting in shallow-dose exposures in excess of regulatory limits from small (microcurie) quantities of contamination;
 - ✓ Supervise decontamination activities and document the results. Documentation should include location and results of surveys and decontamination results;
 - ✓ Determine root cause and needed corrective actions; consider need for bioassays if radioactive material may have been ingested, inhaled, or absorbed; and
 - ✓ If necessary, notify the department.

Minor Fires

- Instructions to Workers
 - ✓ If possible, immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if other fire hazards or radiation hazards are not present;
 - ✓ Notify all persons present to vacate the area and have one individual immediately call the fire department and RSO (as instructed by RSO);
 - ✓ Once the fire is out, isolate the area to prevent the spread of possible contamination;
 - ✓ Ensure injured personnel received medical attention;
 - ✓ Survey all persons involved in combating the fire for possible contamination;
 - ✓ Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap;
 - ✓ In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area;
 - ✓ Allow no one to return to work in the area unless approved by the RSO; and
 - ✓ Follow the instructions of the RSO (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - ✓ Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested.
 - ✓ Supervise decontamination activities at the facility;
 - ✓ If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove contamination that was released by the perspiration;
 - ✓ Consult with fire safety officials to ensure that there is no likelihood of fire restarting;
 - ✓ Determine cause and needed corrective actions; consider need for bioassays if radioactive material may have been ingested or inhaled. Document incident; and
 - ✓ If necessary, notify the department.

Fires, Explosions, or Major Emergencies

- Instructions to Workers
 - ✓ Notify all persons in the area to leave immediately;
 - ✓ Notify the fire department;
 - ✓ Notify the RSO and other facility safety personnel;
 - ✓ Ensure injured personnel receive medical attention;
 - ✓ Upon arrival of firefighters, inform them where radioactive material are stored and where radioisotopes were being used; inform them of the present location of the radioactive material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc;
 - ✓ Allow no one to return to work in the area unless approved by the RSO; and
 - ✓ Follow the instructions of the RSO (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
 - ✓ Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested;
 - ✓ Coordinate activities with local fire department;
 - ✓ Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after fire is extinguished;
 - ✓ Once the fire is extinguished, provide assistance to firefighters who may need to re-enter restricted areas to determine the extent of the damage to the radioactive material use or storage areas. To the extent practical, assist firefighters in maintaining their exposures ALARA if the fire resulted in a significant release of radioactive material or lost of shielding capability, such that excessive radiation levels (greater than 100 millirems per hour) are created;
 - ✓ Perform thorough contamination surveys of firefighters and their equipment before they leave the controlled area, and decontaminate if necessary;
 - ✓ Supervise decontamination activities;
 - ✓ Consider bioassays if radioactive material may have been ingested or inhaled. Document incident; and
 - ✓ If necessary, notify the department

Copies of emergency procedures should be provided to all users. A current copy of the emergency procedure should be posted in each area where radioactive material is used.

Appendix R:
Model Radiation Survey Procedures

Model Radiation Survey Procedures

This Appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits.
- Dose-rate surveys, at a minimum, should be performed in locations where members of the public could receive a total effective dose equivalent of 1 mSv (100 mrem) in a year, or the dose in any unrestricted area from external sources could exceed 0.02 mSv (2 mrem) in any one hour.
- Dose-rate surveys should be performed in a manner and frequency that is representative of the use of radioactive materials. At a minimum, these surveys should be conducted daily in areas of radioactive material use, where exposures to workers could reasonably occur, e.g. generator storage/elution and dose preparation stations. Other areas, where radiological conditions are not expected to change appreciably from day-to-day, should be surveyed weekly, e.g. radioactive waste storage areas.

Contamination Surveys

Licensee's contamination surveys should be sufficient to identify areas of contamination that might result in unacceptable levels of exposure to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through wipe tests, which should be analyzed using an appropriate counting instrument. Fixed contamination may be measured directly at the surface of the contamination with the appropriate instrument detector held at close proximity to the surface without direct contact. See **Table 3** in Appendix J for examples of appropriate instruments.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, or equipment;
- After any spill or contamination event;
- To evaluate contamination of users and the immediate work area at the end of each day when radioactive material is used;

In unrestricted areas at frequencies consistent with the types and quantities of materials in use; and in areas adjacent to restricted areas and in all areas through which radioactive materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily. All other areas where radioactive materials are used or stored should be surveyed weekly.

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. 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 6**.

Table 6. Recommended Action Levels in dpm/100 cm² for Removable Surface Contamination by Radiopharmaceuticals

	P-32, Se-75, Sr-85, Sr-89, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Re-186, Au-198	Cr-51, Ga-67, Tc-99m, Tl-201
1. Unrestricted areas, personal clothing	200	2000
2. Restricted areas, protective clothing used only in restricted areas, skin	2000	20000

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, the above table provides the maximum acceptable residual levels. To the extent practicable, it is appropriate to decontaminate below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use to ensure that they meet these limits.

A standardized method for wipe testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A wipe taken from an area of approximately 100 cm² is acceptable to indicate levels of removable contamination.

Survey Record Requirements

Each survey report should include the following:

- Diagram of the area identifying specific locations surveyed (See **Figure 2** in Item 13);
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background levels;
- Name of the person making the evaluation and recording the results and date; and
- Corrective actions taken for elevated levels identified and results of resurveys.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce recurrence of contamination, times and dates, and surveyor's signature.

Air Sampling

Air sampling can be used to do the following:

- Determine whether the confinement of radioactive materials is effective;
- Measure airborne radioactive material concentrations in the workplace;
- Estimate worker intakes of radioactive material;
- Determine posting requirements;
- Determine what protective equipment and measures are appropriate; and
- Warn of significantly elevated levels of airborne radioactive materials.

Refer to NRC Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992 and NRC NUREG - 1400, "Air Sampling in the Workplace," dated September 1993 for further guidance on air sampling, available from the department.

Air Stack Release Monitoring

Airborne radioactive effluents should be monitored at the release points (e.g., stack) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration of equipment and checks of filtration to ensure their reliability.

NRC Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996 (available from the department upon request), provides guidance on methods acceptable (calculation or COMPLY code) to the department for compliance with the constraint on air emissions to the environment.

NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993, (available from the department upon request) provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," and ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents (available from the department, upon request)."

Radioiodine Monitoring

The handling of radioiodine requires additional surveys and monitoring. Such surveys and monitoring include:

- Routine surveys should be performed of air filters incorporated in fume hoods and gloveboxes to identify when filters should be exchanged prior to saturation;
- Routine surveys should be performed in the area where radioiodine is handled immediately following each use to identify elevated radiation and contamination levels; and
- Continuous monitoring of the air effluent should be performed during radioiodine use. In-line filters should be monitored periodically to determine actual effluents.

Sanitary Sewerage Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in *HFS 157.23*; and *HFS 157.30* respectively.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual;
- Retention and excretion characteristics of the radionuclide;
- Sensitivity of the measurement technique; and
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with *HFS 157.25*, which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements, and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity (since the most recent bioassay measurement) is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than two hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

When an individual is no longer subject to the bioassay program because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- Presence of unusually high levels of facial and/or nasal contamination;
 - Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity);
 - Known or suspected incidents of a worker ingesting radioactive material; and
 - Incidents that result in contamination of wounds or other skin absorption.
1. NRC Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996.
 2. NRC Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993.
 3. NRC Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992.
 4. NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993.
 5. NRC NUREG-1400, "Air Sampling in the Workplace," dated September 1993.
 6. NRC NUREG/CR-4884, "Interpretation of Bioassay Measurements," dated July 1987.
 7. ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," dated 1991.
 8. ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents," 1991.

Appendix S:

Model Procedure for Return of Radioactive Wastes from Customers

Model Procedure for Return of Radioactive Wastes from Customers

Procedures for Customers to Return Radioactive Waste to The Radiopharmacy

Return only items that contained or contain radioactive materials supplied by the radiopharmacy (e.g., pharmacy-supplied syringes and vials and their contents). Most return shipments to radiopharmacies will qualify as excepted packages of limited quantity, in accordance with DOT requirements (49 CFR 173.421). For those packages containing radioactive material in excess of the limited quantity, customers should ensure that all applicable DOT requirements are met for the packages. This includes, but is not limited to, certification packaging (Type A), package marking and labeling, and shipping papers. For specific guidance on preparing these types of packages, please follow your in-house procedures for shipping radioactive material packages or contact the pharmacy for guidance.

Preparation of radioactive materials for return as excepted package of limited quantity:

- Ensure that the activities of material being returned are limited quantities as defined by DOT (see table below). Special attention should be given for the return of unused doses that may still contain significant activities of radionuclides. The amount of radioactivity in unused doses may necessitate that a syringe or vial be held for decay to reduce the activity to that permitted for shipment of limited quantities.
- Place the syringe or vial in the original, labeled, lead shield in which it was delivered; and
- Place shielded waste into the shipping package (e.g., padded briefcase or ammo box) in which it was delivered.

Note: Packages used to ship radioactive material to customers must meet the DOT package requirements for transport of limited quantities.

Preparation of package:

- Using a calibrated survey meter, measure the radiation levels at all points on the surface of the package to ensure that levels are less than or equal to 0.5 mrem/hr;
- Use contamination wipes on the surface of the package to ensure that the removable contamination does not exceed the limit specified in 49 CFR 173.443(a), 22 dpm/cm² over a 300 cm² area;
- Label the package as a "Excepted Package - Limited Quantity of Material"; and
- Seal the package so that it will be evident upon receipt whether the package accidentally opened during shipment.

Note: Shipping papers are not required when shipping limited quantities however, the statement specified in 49 CFR 173.422 ("This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN2910.") must be included in, on, or otherwise provided with the shipment.

Limited Quantities (49 CFR 173.421) For Typical Radionuclides as Liquid Used by Radiopharmacies (49 CFR 173.425 - Table 7)

Table 7. Limited Quantity Values for Liquid Radioactive Material Packages

Radionuclide – Liquids	A2 Value	Limited Quantity Shipment (mCi) A2 X 10⁻⁴
Co-57	216	21.6
Co-58	27	2.7
Cr-51	811	81.1
Ga-67	162	16.2
I-123	162	16.2
I-125	54.1	5.41
I-131	13.5	1.35
In-111	54.1	5.41
Mo-99	20 (for domestic use)	2
P-32	8.11	0.81
Se-75	81.1	8.1
Sr-89	13.5	1.35
Tc-99m	216	21.6
Tl-201	270	27

Table 8. Limited Quantity Values for Gaseous Radioactive Material Packages

Radionuclide Uncompressed Gas	A2 Value (Ci)	Limited Quantity Shipment (mCi) A2 X 10⁻³
Xe-133 (uncompressed)	541	541

Table 9. Limited Quantity Values for Special Form Radioactive Material Packages

Radionuclide Solid – Special Form	A1 Value (Ci)	Limited Quantity Shipment (mCi) A1 X 10⁻³
Ir-192	27	27
Cs-137	54.1	54.1

The values above are derived from 49 CFR 173.423, Table 7, and the Table of A1 and A2 values for radionuclides in 49 CFR 173.435. If shipping more than one radionuclide in the same package, the limits in 173.433(d) apply as follows: The sum of the ratios of the activity of each radionuclide divided by its respective A2 value must be less than, or equal to, one. For special form material, the sum of the ratios of the activities of each radionuclide divided by its respective A1 value must be less than, or equal to, one.

Procedure for Driver or Courier for Pick-up of Radioactive Waste from Customers

- Ensure that the shipping package is properly labeled "Excepted Package - Limited Quantity of Material";
- Ensure that the shipping package has been sealed; and
- Do not accept any package that is not properly labeled and sealed.

Procedure for Receipt and Opening of Packages from Customers Containing Radioactive Waste

- Place all returned packages in an identifiable location within the radiopharmacy;
- Put on disposable gloves;
- Monitor the package for removable contamination. If wipe tests indicate contamination levels greater than 22 dpm/cm² over a 300 cm² area, take the following actions:
 - ✓ Notify the customer and the department; and
- Survey the driver/courier who retrieved the waste and the vehicle used to transport the waste to the radiopharmacy.
 - ✓ Decontaminate the package or remove it from service for decay.

Open the package and identify each nuclide in the shielded containers.

Dispose of radioactive waste into the appropriate container for the half-life of the nuclide being disposed, in accordance with the radiopharmacy's procedures for disposal of waste by decay-in-storage.

Survey the dose shields for contamination with a low-level survey meter. Any dose shield that indicate activity exceeding background should be decontaminated or removed from service.

Appendix T:
DHFS Incident Notifications

DHFS Incident Notifications

Table 10. Typical Notifications Required for Radiopharmacy Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	Immediate	30 days	<i>HFS 157.32(1)</i>
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	<i>HFS 157.32(2)</i>
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	<i>HFS 157.32(2)</i>
Intake of five times the annual limit on intake	Immediate	30 days	<i>HFS 157.32(2)</i>
Removable contamination exceeding the limits of <i>HFS 157.94(1)</i> – [beta/gamma/low toxicity alpha – 22 dpm/cm ² ; all other alpha – 2.2 dpm/cm ²]	Immediate	30 days	<i>HFS 157.29(6)</i>
External radiation levels exceeding the limits of <i>10 CFR 71.47</i> – [any point on the surface – 2 mSv/hr (200 mrem/hr)]	Immediate	None	<i>HFS 157.29(6)</i>
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	<i>HFS 157.32(2)</i>
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	<i>HFS 157.32(2)</i>
Intake one annual limit on intake	24 hours	30 days	<i>HFS 157.32(2)</i>
Occupational dose greater than the applicable limit in <i>HFS 157.22(1)</i>	None	30 days	<i>HFS 157.32(3)</i>
Dose to individual member of public greater than 1 mSv (100 mrems)	None	30 days	<i>HFS 157.32(3)</i>
Filing petition for bankruptcy under 11 U.S.C.	None	Immediately after filing petition	<i>HFS 157.13 (9)(b) and (10)</i>

Event	Telephone Notification	Written Report	Regulatory Requirement
Expiration of license	None	60 days	<i>HFS 157.13(11)</i>
Decision to permanently cease licensed activities at <i>entire site</i>	None	60 days	<i>HFS 157.13(11)</i>
Decision to permanently cease licensed activities in any <i>separate building or outdoor area</i> that is unsuitable for release for unrestricted use	None	60 days	<i>HFS 157.13(11)</i>
No principal activities conducted for 24 months <i>at the entire site</i>	None	60 days	<i>HFS 157.13(11)</i>
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	<i>HFS 157.13(17)</i>
An unplanned contamination event involving greater than 5 times the ALI, and half-life greater than 24 hours requiring access to be restricted for more than 24 hours	24 hours	30 days	<i>HFS 157.13(17)</i>
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	<i>HFS 157.13(17)</i>
Unplanned fire or explosion that affects the integrity of any radioactive material or device, container, or equipment with radioactive material	24 hours	30 days	<i>HFS 157.13(17)</i>

Note: Telephone notifications shall be made to **DHFS** at **(608) 267-4797** (office hours) and in an emergency to **(608) 258-0099** (after hours).

Appendix U:

Reserved

Authorized User and Radiation Safety Officer Experiences in Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)

Name (Last, First, Initial)

Isotope(s) Used	Maximum amount Used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience

*** Purpose of Use**

1. Shipping, receiving, and performing related radiation surveys
2. Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides
3. Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides
4. Calculating, assaying, and safely preparing radioactive materials
5. Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures

Authorized Nuclear Pharmacist Experiences in Handling Radioisotopes

(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)

Name (Last, First, Initial)

Isotope(s) Used	Maximum amount Used at any one time	Location of Use	Purpose of Use*	Total Hours of Experience
Signature of Preceptor Authorized Nuclear Pharmacist: "I certify that the above training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a Nuclear Pharmacy."			Signature:	Date:

*** Purpose of Use**

1. Shipping, receiving, and performing related radiation surveys
2. Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides
3. Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides
4. Calculating, assaying, and safely preparing radioactive materials
5. Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures

Authorized Nuclear Pharmacist Training in Basic Radioisotope Handling Techniques

Name (Last, First, Initial) _____

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
Totals								

Signature of Preceptor Authorized Nuclear Pharmacist: "I certify that the above described training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy."	Signature: _____	Date: _____
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- | | |
|---|---|
| RPP Radiation Protection Principles
IR Ionizing Radiation Units & Characteristics
REG <i>DHFS</i> Rule and Standards | BH Biological Hazards
INST Radiation Detection Instrumentation |
|---|---|

Authorized User or Radiation Safety Officer Training in Basic Radioisotope Handling Techniques

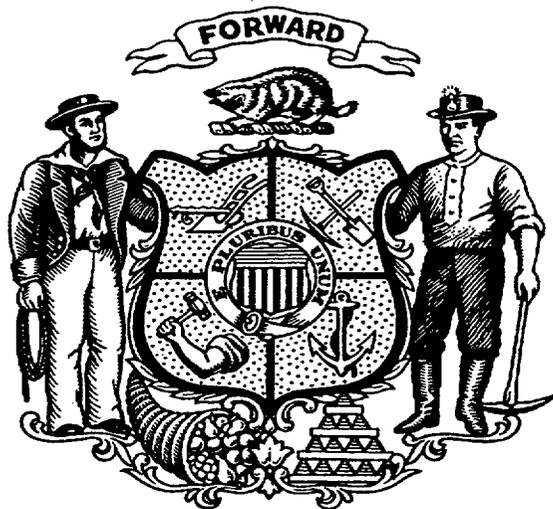
Name (Last, First, Initial) _____

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
Totals								

RPP Radiation Protection Principles
IR Ionizing Radiation Units & Characteristics
REG *DHFS* Rule and Standards

BH Biological Hazards
INST Radiation Detection Instrumentation

Wisconsin
Chapter HFS 157 -Radiation Protection
Regulatory Guide
WISREG 8.29



**Instructions Concerning Risks from Occupational
Radiation Exposure**

**Department of Health and Family Services
Radiation Protection Section
1 West Wilson Street
P.O. Box 2659
Madison, WI 53701-2659
Phone: (608) 267-4797
Fax: (608) 267-3695**

INTRODUCTION

HFS 157.88(2) requires that *all individuals who in the course of employment are likely to receive an occupational dose in excess of one mSv (100 millirem) in a year shall be given the following annually; (2.) Health risk to the individual and potential offspring associated with exposure to radiation and radioactive material.* HFS 157.22(6) also requires that *before a planned special exposure, a licensee or registrant ensures that each individual involved has been informed and instructed in all the following: (1) The purpose of the planned operation. (2) The estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task. (3) The measures to be taken to keep the dose ALARA considering other risk that may be present.* “

This Wisconsin Regulatory Guide (WISREG 8.29) describes the information that should be provided to workers by licensees or registrants about health risks from occupational exposure.

Any information collection activities mentioned in this regulatory guide are contained as requirements in Chapter HFS 157 “Radiation Protection”. These rules provide the regulatory bases for this guide.

DISCUSSION

It is important to qualify the material presented in this guide with the following considerations.

The coefficient used in this guide for occupational radiation risk estimates, 4×10^4 health effects per rem, is based on data obtained at much higher doses and dose rates than those encountered by workers. The risk coefficient obtained at high doses and dose rates was reduced to account for the reduced effectiveness of lower doses and dose rates in producing the stochastic effects observed in studies of exposed humans. The assumption of a linear extrapolation from the lowest doses at which effects are observable down to the occupational range has considerable uncertainty. The report of the Committee on the Biological Effects of Ionizing Radiation (Ref. 1) states that

“departure from linearity cannot be excluded at low doses below the range of observation. Such departures could be in the direction of either an increased or decreased risk. Moreover, epidemiologic data cannot rigorously exclude the existence of a threshold in the 100 mrem dose range. Thus, the possibility that there may be no risk from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero.”

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (Ref. 2) addresses the issue of beneficial effects from low doses, or hormesis, in cellular systems. UNSCEAR states that *“it would be premature to conclude that cellular adaptive responses could convey possible beneficial effects to the organism that would outweigh the detrimental effects of exposures to low doses of low-LET radiation.”*

In the absence of scientific certainty regarding the relationship between low doses and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation can cause biological effects that may be harmful to the exposed person and that the magnitude or probability of these effects is directly proportional to the dose. These effects may be classified into three categories:

Somatic Effects: Physical effects occurring in the exposed person. These effects may be observable after a large or acute dose (e. g., 100 rem) (**Note:** *In the International System of*

Units (S1), the rem is replaced by the sievert; 100 rem is equal to 1 sievert (1 Sv) or more to the whole body in a few hours); or there may be effects such as cancer that may occur years after exposure to radiation.

Genetic Effects: Abnormalities that may occur in the future children of exposed individuals and in subsequent generations (genetic effects exceeding normal incidence have not been observed in any of the studies of human populations).

Teratogenic Effects: Effects such as cancer or congenital malformation that may be observed in children who were exposed during the fetal and embryonic stages of development (these effects have been observed from high, i.e., above 0.2 Sv (20 rem) acute exposures).

The normal incidence of effects from natural and manmade causes is significant. For example, approximately 20% of people die from various forms of cancer whether or not they ever receive occupational exposure to radiation. To avoid increasing the incidence of such biological effects, regulatory controls are imposed on occupational doses to adults and minors and on doses to the embryo/fetus from occupational exposures of declared pregnant women.

Radiation protection training for workers who are occupationally exposed to ionizing radiation is an essential component of any program designed to ensure compliance with The State of Wisconsin, Department of Health and Family Services (DHFS 157) rule. A clear understanding of what is presently known about the biological risks associated with exposure to radiation will result in more effective radiation protection training and should generate more interest on the part of the workers in complying with radiation protection standards. In addition, pregnant women and other occupationally exposed workers should have available to them relevant information on radiation risks to enable them to make informed decisions regarding the acceptance of these risks. It is intended that workers who receive this instruction will develop respect for the risks involved, rather than excessive fear or indifference.

REGULATORY POSITION

Instruction to workers performed in compliance with HFS 157.88(2) should be given prior to occupational exposure and annually thereafter. If a worker is to participate in a planned special exposure, the worker should be informed of the associated risks in compliance with HFS 157.22(6).

In providing instruction concerning health protection problems associated with exposure to radiation, all occupationally exposed workers and their supervisors should be given specific instruction on the risk of biological effects resulting from exposure to radiation. The extent of these instructions should be commensurate with the radiological risks present in the workplace. The instruction should be presented orally, in printed form, or in any other effective communication media to workers and supervisors. The appendix to this guide provides useful information for demonstrating compliance with the training requirements in Chapter HFS 157 "Radiation Protection". Individuals should be given an opportunity to discuss the information and to ask questions. Testing is recommended, and each trainee should be asked to acknowledge in writing that the instruction has been received and understood.

IMPLEMENTATION

The purpose of this section is to provide information to applicants, licensees and registrants regarding DHFS's plans for using this regulatory guide. Except in those cases in which an applicant, licensee, or registrant proposes acceptable alternative methods for complying with specified portions of the DHFS rule, the guidance

and instructional materials in this guide will be used in the evaluation of applications for new licenses, registrations, license renewals, and license amendments and for evaluating compliance with HFS 157.88(2) and HFS 157.22.

REFERENCES

1. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation*, Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.
2. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.

APPENDIX

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

This instructional material is intended to provide the user with the best available information about the health risks from occupational exposure to ionizing radiation. Ionizing radiation consists of energy or small particles, such as gamma rays and beta and alpha particles, emitted from radioactive materials, which can cause chemical or physical damage when they deposit energy in living tissue. A question and answer format is used. The Nuclear Regulatory Commission (NRC) developed many of the questions or subjects.

The information in this appendix is intended to help develop respect by workers for the risks associated with radiation, rather than unjustified fear or lack of concern. Additional guidance concerning other topics in radiation protection training is provided in other DHFS regulatory guides and NRC regulatory guides.

1. What is meant by health risk?

A health risk is generally thought of as something that may endanger health. Scientists consider health risk to be the statistical probability or mathematical chance that personal injury, illness, or death may result from some action. Most people do not think about health risks in terms of mathematics. Instead, most of us consider the health risk of a particular action in terms of whether we believe that particular action will, or will not, cause us some harm. The intent of this appendix is to provide estimates of, and explain the bases for, the risk of injury, illness, or death from occupational radiation exposure. Risk can be quantified in terms of the probability of a health effect per unit of dose received.

When x-rays, gamma rays, and ionizing particles interact with living materials such as our bodies, they may deposit enough energy to cause biological damage. Radiation can cause several different types of events such as the very small physical displacement of molecules, changing a molecule to a different form, or ionization, which is the removal of electrons from atoms and molecules. When the quantity of radiation energy deposited in living tissue is high enough, biological damage can occur as a result of chemical bonds being broken and cells being damaged or killed. These effects can result in observable clinical symptoms.

The basic unit for measuring absorbed radiation is the rad. 0.01 Gy (One rad) equals the absorption of 100 ergs (a small but measurable amount of energy) in a gram of material such as tissue exposed to radiation. To reflect biological risk, rads must be converted to rem. The new international unit is the sievert (100 rem = 1 Sv). This conversion accounts for the differences in the effectiveness of different types of radiation in causing damage. The rem is used to estimate biological risk. For beta and gamma radiation, a rem is considered equal to a rad.

2. What are the possible health effects of exposure to radiation?

Health effects from exposure to radiation range from no effect at all to death, including diseases such as leukemia or bone, breast, and lung cancer. Very high (10's of Gy or 100s of rads), short-term doses of radiation have been known to cause prompt (or early) effects, such as vomiting and diarrhea, (**Note:** These symptoms are early indicators of what is referred to as the acute radiation syndrome, caused by high doses delivered over a short time period, which includes damage to the blood-forming organs such as bone marrow, damage to the gastrointestinal system, and, at very high doses, can include damage to the central nervous system) skin burns, cataract and even death. It is suspected that radiation exposure may be linked to the potential for genetic effects in the children of exposed parents. Also, children who were exposed to high doses (20 mGy or 20 or more rads) of radiation prior to birth (as an embryo/fetus) have shown an increased risk of mental retardation and other congenital malformations. These effects (with the exception of genetic effects) have been observed in various studies of medical radiologists, uranium miners, radium workers, radiotherapy

patients, and the people exposed to radiation from atomic bombs dropped on Japan. In addition, radiation effects studies with laboratory animals, in which the animals were given relatively high doses, have provided extensive data on radiation-induced health effects, including genetic effects.

It is important to note that these kinds of health effects result from high doses, compared to occupational levels, delivered over a relatively short period of time.

Although studies have not shown a consistent cause-and-effect relationship between current levels of occupational radiation exposure and biological effects, it is prudent from a worker protection perspective to assume that some effects may occur.

3. What is meant by early effects and delayed or late effects?

EARLY EFFECTS

Early effects, which are also called immediate or prompt effects, are those that occur shortly after a large exposure that is delivered within hours to a few days. They are observable after receiving a very large dose in a short period of time, for example, 3 Gy (300 rads) received within a few minutes to a few days. Early effects are not caused at the levels of radiation exposure allowed under DHFS's occupational limits.

Early effects occur when the radiation dose is large enough to cause extensive biological damage to cells so that large numbers of cells are killed. For early effects to occur, this radiation dose must be received within a short time period. This type of dose is called an acute dose or acute exposure. The same dose received over a long time period would not cause the same effect. Our body's natural biological processes are constantly repairing damaged cells and replacing dead cells; if the cell damage is spread over time, our body is capable of repairing or replacing some of the damaged cells, reducing the observable adverse conditions.

For example, a dose to the whole body of about 3-5 Gy (300-500 rads), more than 60 times the annual occupational dose limit, if received within a short time period (e.g., a few hours) will cause vomiting and diarrhea within a few hours; loss of hair, fever, and weight loss within a few weeks; and about a 50 percent chance of death if medical treatment is not provided. These effects would not occur if the same dose were accumulated gradually over many weeks or months (Refs. 1 and 2). Thus, one of the justifications for establishing annual dose limits is to ensure that occupational dose is spread out over time.

It is important to distinguish between whole body and partial body exposure. A localized dose to a small volume of the body would not produce the same effect as a whole body dose of the same magnitude. For example, if only the hand were exposed, the effect would mainly be limited to the skin and underlying tissue of the hand. An acute dose of 4-6 Gy (400 to 600 rads) to the hand would cause skin reddening; recovery would occur over the following months and no long-term damage would be expected. An acute dose of this magnitude to the whole body could cause death within a short time without medical treatment. Medical treatment would lessen the magnitude of the effects and the chance of death; however, it would not totally eliminate the effects or the chance of death.

DELAYED EFFECTS

Delayed effects may occur years after exposure. These effects are caused indirectly when the radiation changes parts of the cells in the body, which causes the normal function of the cell to change, for example, normal healthy cells turn into cancer cells. The potential for these delayed health effects is one of the main concerns addressed when setting limits on occupational doses.

A delayed effect of special interest is genetic effects. Genetic effects may occur if there is radiation damage to the cells of the gonads (sperm or eggs). These effects may show up as genetic defects in the children of the exposed individual and succeeding generations. However, if any genetic effects (i.e., effects in addition to the normal expected number) have been caused by radiation, the numbers are too small to have been observed in human populations exposed to radiation. For example, the atomic bomb survivors (from Hiroshima and Nagasaki) have not shown any significant radiation-related increases in genetic defects (Ref. 3). Effects have been observed in animal studies conducted at very high levels of exposure and it is known that radiation can cause changes in the genes in cells of the human body. However, it is believed that by maintaining worker exposures below the DHFS limits and consistent with ALARA, a margin of safety is provided such that the risk of genetic effects is almost eliminated.

4. What is the difference between acute and chronic radiation dose?

Acute radiation dose usually refers to a large dose of radiation received in a short period of time. Chronic dose refers to the sum of small doses received repeatedly over long time periods, for example, 0.2 mSv (20 mrem) per week every week for several years. It is assumed for radiation protection purposes that any radiation dose, either acute or chronic, may cause delayed effects. However, only large acute doses cause early effects; chronic doses within the occupational dose limits do not cause early effects. Since the DHFS limits do not permit large acute doses, concern with occupational radiation risk is primarily focused on controlling chronic exposure for which possible delayed effects, such as cancer, are of concern.

The difference between acute and chronic radiation exposure can be shown by using exposure to the sun's rays as an example. An intense exposure to the sun can result in painful burning, peeling, and growing of new skin. However, repeated short exposures provide time for the skin to be repaired between exposures. Whether exposure to the sun's rays is long term or spread over short periods, some of the injury may not be repaired and may eventually result in skin cancer,

Cataracts are an interesting case because they can be caused by both acute and chronic radiation. A certain threshold level of dose to the lens of the eye is required before there is any observable visual impairment, and the impairment remains after the exposure is stopped. The threshold for cataract development from acute exposure is an acute dose on the order of 1 Gy (100 rads). Further, a cumulative dose of 8 Gy (800 rads) from protracted exposures over many years to the lens of the eye has been linked to some level of visual impairment (Refs. 1 and 4). These doses exceed the amount that may be accumulated by the lens from normal occupational exposure under the current regulations.

5. What is meant by external and internal exposure?

A worker's occupational dose may be caused by exposure to radiation that originates outside the body, called "external exposure," or by exposure to radiation from radioactive material that has been taken into the body, called "internal exposure." Most DHFS licensed or registered activities involve little, if any, internal exposure. It is the current scientific consensus that a rem of radiation dose has the same biological risk regardless of whether it is from an external or an internal source. DHFS requires that dose from external exposure and dose from internal exposure be added together, if each exceeds 10% of the annual limit, and that the total be within occupational limits. The sum of external and internal dose is called the total effective dose equivalent (TEDE) and is expressed in units of Sv (rem).

Although unlikely, radioactive materials may enter the body through breathing, eating, drinking, or open wounds, or they may be absorbed through the skin. The intake of radioactive materials by workers is generally due to breathing contaminated air. Radioactive materials may be present as fine dust or gases in the workplace atmosphere. The surfaces of equipment and workbenches may be contaminated, and these materials can be resuspended in air during work activities.

If any radioactive material enters the body, the material goes to various organs or is excreted, depending on the biochemistry of the material. Most radioisotopes are excreted from the body in a few days. For example, a fraction of any uranium taken into the body will deposit in the bones, where it remains for a longer time. Uranium is slowly eliminated from the body, mostly by way of the kidneys. Most workers are not exposed to uranium. Radioactive iodine is preferentially deposited in the thyroid gland, which is located in the neck.

To limit risk to specific organs and the total body, an annual limit on intake (ALI) has been established for each radionuclide. When more than one radionuclide is involved, the intake amount of each radionuclide is reduced proportionally. DHFS's rules specify the concentrations of radioactive material in the air to which a worker may be exposed for 2,000 working hours in a year. These concentrations are termed the derived air concentrations (DACs). These limits are the total amounts allowed if no external radiation is received. The resulting dose from the internal radiation sources (from breathing air at 1 DAC) is the maximum allowed to an organ or to the worker's whole body.

6. How does radiation cause cancer?

The mechanisms of radiation-induced cancer are not completely understood. When radiation interacts with the cells of our bodies, a number of events can occur. The damaged cells can repair themselves and permanent damage is not caused. The cells can die, much like the large numbers of cells that die every day in our bodies, and be replaced through the normal biological processes. Or a change can occur in the cell's reproductive structure, the cells can mutate and subsequently be repaired without effect, or they can form pre-cancerous cells, which may become cancerous. Radiation is only one of many agents with the potential for causing cancer, and cancer caused by radiation cannot be distinguished from cancer attributable to any other cause.

Radiobiologists have studied the relationship between large doses of radiation and cancer (Refs. 5 and 6). These studies indicate that damage or change to genes in the cell nucleus is the main cause of radiation-induced cancer. This damage may occur directly through the interaction of the ionizing radiation in the cell or indirectly through the actions of chemical products produced by radiation interactions within cells. Cells are able to repair most damage within hours; however, some cells may not be repaired properly. Such misrepaired damage is thought to be the origin of cancer, but misrepair does not always cause cancer. Some cell changes are benign or the cell may die; these changes do not lead to cancer.

Many factors such as age, general health, inherited traits, sex, as well as exposure to other cancer-causing agents such as cigarette smoke can affect susceptibility to the cancer-causing effects of radiation. Many diseases are caused by the interaction of several factors, and these interactions appear to increase the susceptibility to cancer.

7. Who developed radiation risk estimates?

Radiation risk estimates were developed by several national and international scientific organizations over the last 45 years. These organizations include the National Academy of Sciences (which has issued several reports from the Committee on the Biological Effects of Ionizing Radiation, BEIR), the National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). Each of these organizations continues to review new research findings on radiation health risks.

Several reports from these organizations present new findings on radiation risks based upon revised estimates of radiation dose to survivors of the atomic bombing at Hiroshima and Nagasaki. For example, UNSCEAR published risk estimates in 1988 and 1993 (Refs. 5 and 6). The NCRP also published a report in 1988, "New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates" (Ref. 7). In January 1990, the

National Academy of Sciences released the fifth report of the BEIR Committee, "Health Effects of Exposure to Low Levels of Ionizing Radiation" (Ref. 4). Each of these publications also provides extensive bibliographies (other published studies concerning radiation health effects for those who may wish to read further on this subject).

8. What are the estimates of the risk of fatal cancer from radiation exposure?

We don't know exactly what the chances are of getting cancer from a low-level radiation dose, primarily because the few effects that may occur cannot be distinguished from normally occurring cancers. However, we can make estimates based on extrapolation from extensive knowledge from scientific research on high dose effects. The estimates of radiation effects at high doses are better known than are those of most chemical carcinogens (Ref. 8).

From currently available data, DHFS has adopted a risk value for an occupational dose of 1 rem (0.01 Sv) Total Effective Dose Equivalent (TEDE) of 4 in 10,000 of developing a fatal cancer, or approximately 1 chance in 2,500 of fatal cancer per rem of TEDE received. The uncertainty associated with this risk estimate does not rule out the possibility of higher risk, or the possibility that the risk may even be zero at low occupational doses and dose rates.

The radiation risk incurred by a worker depends on the amount of dose received. Under the linear model explained above, a worker who receives 0.05 Sv (5 rem) in a year incurs 10 times as much risk as another worker who receives only 0.5 rem (0.005 Sv). Only a very few workers receive doses near 0.05 Sv (5 rem) per year (Ref. 9).

According to the BEIR V report (Ref. 4), approximately one in five adults normally will die from cancer from all possible causes such as smoking, food, alcohol, drugs, air pollutants, natural background radiation, and inherited traits. Thus, in any group of 10,000 workers, we can estimate that about 2,000 (20%) will die from cancer without any occupational radiation exposure.

To explain the significance of these estimates, we will use as an example a group of 10,000 people, each exposed to 0.01 Sv (1 rem) of ionizing radiation. Using the risk factor of 4 effects per 100 Sv (10,000 rem) of dose, we estimate that 4 of the 10,000 people might die from delayed cancer because of that 0.01 Sv (1-rem) dose (although the actual number could be more or less than 4) in addition to the 2,000 normal cancer fatalities expected to occur in that group from all other causes. This means that a 0.01 Sv (1-rem) dose may increase an individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 0.1 Sv (10 rem), we could raise the estimate to 20.4 percent. A lifetime dose of 1 Sv (100 rem) may increase chances of dying from cancer from 20 to 24 percent. The average measurable dose for radiation workers reported to the NRC was 31. mSv (0.31 rem) for 1993 (Ref. 9). Today, very few workers ever accumulate 1 Sv (100 rem) in a working lifetime, and the average career dose of workers at NRC licensed facilities is 0.015 Sv (1.5 rem), which represents an estimated increase from 20 to about 20.06 percent in the risk of dying from cancer.

It is important to understand the probability factors here. A similar question would be, "If you select one card from a full deck of cards, will you get the ace of spades?" This question cannot be answered with a simple yes or no. The best answer is that your chance is 1 in 52. However, if 1000 people each select one card from full decks, we can predict that about 20 of them will get an ace of spades. Each person will have 1 chance in 52 of drawing the ace of spades, but there is no way we can predict which persons will get that card. The issue is further complicated by the fact that in a drawing by 1000 people, we might get only 15 successes, and in another, perhaps 25 correct cards in 1000 draws. We can say that if you receive a radiation dose, you will have increased your chances of eventually developing cancer. It is assumed that the more radiation exposure you get, the more you increase your chances of cancer.

The normal chance of dying from cancer is about one in five for persons who have not received any occupational radiation dose. The additional chance of developing fatal cancer from an occupational exposure of 0.01 Sv (1 rem) is about the same as the chance of drawing any ace from a full deck of cards three times in a row. The additional chance of dying from cancer from an occupational exposure of 0.1 Sv (10 rem) is about equal to your chance of drawing two aces successively on the first two draws from a full deck of cards.

It is important to realize that these risk numbers are only estimates based on data for people and research animals exposed to high levels of radiation in short periods of time. There is still uncertainty with regard to estimates of radiation risk from low levels of exposure. Many difficulties are involved in designing research studies that can accurately measure the projected small increases in cancer cases that might be caused by low exposures to radiation as compared to the normal rate of cancer.

These estimates are considered by the DHFS to be the best available for the worker to use to make an informed decision concerning acceptance of the risks associated with exposure to radiation. A worker who decides to accept this risk should try to keep exposure to radiation as low as is reasonably achievable (ALARA) to avoid unnecessary risk.

9. If I receive a radiation dose that is within occupational limits, will it cause me to get cancer?

Probably not, based on the risk estimates previously discussed, the risk of cancer from doses below the occupational limits is believed to be small. Assessment of the cancer risks that may be associated with low doses of radiation are projected from data available at doses larger than 0.1 Sv (10 rem) (Ref. 3). For radiation protection purposes, these estimates are made using the straight-line portion of the linear quadratic model (Curve 2 in Figure 1). We have data on cancer probabilities only for high doses, as shown by the solid line in Figure 1. Only in studies involving radiation doses above occupational limits are there dependable determinations of the risk of cancer, primarily because below the limits the effect is small compared to differences in the normal cancer incidence from year to year and place to place. The ICRP, NCRP, and other standards-setting organizations assume for radiation protection purposes that there is some risk, no matter how small the dose (Curves 1 and 2). Some scientists believe that the risk drops off to zero at some low dose (Curve 3), the threshold effect. The ICRP and NCRP endorse the linear quadratic model as a conservative means of assuring safety (Curve 2); For regulatory purposes, DHFS uses the straight line portion of Curve 2, which shows the number of effects decreasing linearly as the dose decreases. Because the scientific evidence does not conclusively demonstrate whether there is or is not an effect at low doses, DHFS assumes for radiation protection purposes, that even small doses have some chance of causing cancer. Thus, a principle of radiation protection is to do more than merely meet the allowed regulatory limits; doses should be kept as low as is reasonably achievable (ALARA). This is as true for natural carcinogens such as sunlight and natural radiation as it is for those that are manmade, such as cigarette smoke, smog, and x-rays.

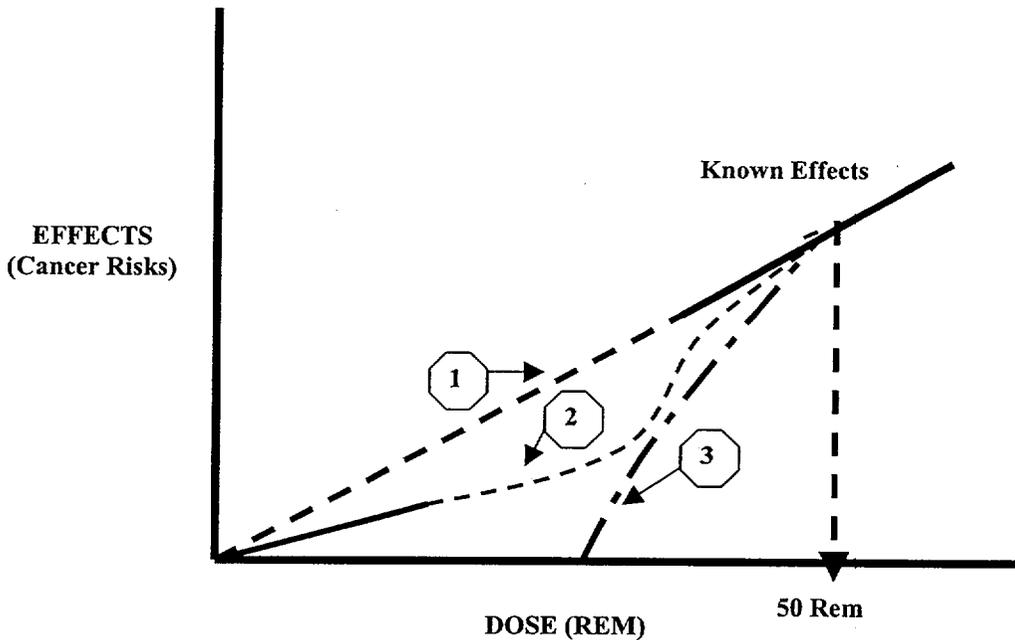


Figure 1. *Some Proposed Models for How the Effects of Radiation Vary With Doses at Low Levels*

10. How can we compare the risk of cancer from radiation to other kinds of health risks?

One way to make these comparisons is to compare the average number of days of life expectancy lost because of the effects associated with each particular health risk. Estimates are calculated by looking at a large number of persons, recording the age when death occurs from specific causes, and estimating the average number of days of life lost as a result of these early deaths. The total number of days of life lost is then averaged over the total observed group.

Several studies have compared the average days of life lost from exposure to radiation with the number of days lost as a result of being exposed to other health risks. The word "average" is important because an individual who gets cancer loses about 15 years of life expectancy, while his or her coworkers do not suffer any loss.

Some representative numbers are presented in Table 1. For categories of NRC-regulated industries with larger doses, the average measurable occupational dose in 1993 was 3.1 mSv (0.31 rem). A simple calculation based on the article by Cohen and Lee (Ref. 10) shows that 3 mSv (0.3 rem) per year from age 18 to 65 results in an average loss of 15 days. These estimates indicate that the health risks from occupational radiation exposure are smaller than the risks associated with many other events or activities we encounter and accept in normal day-to-day activities.

It is also useful to compare the estimated average number of days of life lost from occupational exposure to radiation with the number of days lost as a result of working in several types of industries. Table 2 shows average days of life expectancy lost as a result of fatal work-related accidents. Table 2 does not include non-accident types of occupational risks such as occupational disease and stress because the data is not available.

These comparisons are not ideal because we are comparing the possible effects of chronic exposure to radiation to different kinds of risk such as accidental death, in which death is inevitable, if the event occurs. This is the best we can do because good data is not available on chronic exposure to other workplace

carcinogens. Also, the estimates of loss of life expectancy for workers from radiation-induced cancer do not take into consideration the competing effect on the life expectancy of the workers from industrial accidents.

Table 1
Estimated Loss of Life Expectancy from Health Risks^a

Health Risk	Estimate of Life Expectancy Lost (Average)
Smoking – 20 cigarettes a day	6 years
Overweight (by 15%)	2 years
Alcohol consumption (U.S. average)	1 year
All accidents combined	1 year
Motor vehicle accidents	207 days
Home accidents	74 days
Drowning	24 days
All natural hazards (earthquake, lightning, flood, etc.)	7 days
Medical radiation	6 days
Occupational Exposure	
0.3 rem/y from age 18 to 65	15 days
1 rem/y from age 18 to 65	51 days

^a *Adapted from Reference 10*

Table 2
Estimated Loss of Life Expectancy from Industrial Accidents^a

Industry Type	Estimated Days of Life Expectancy Lost (Average)
All Industries	60

Agriculture	320
Construction	227
Mining and Quarrying	167
Transportation and Public Utilities	160
Government	60
Manufacturing	40
Trade	27
Services	27

^a Adapted from Reference 10

11. What are the health risks from radiation exposure to the embryo/fetus?

During certain stages of development, the embryo/fetus is believed to be more sensitive to radiation damage than adults. Studies of atomic bomb survivors exposed to acute radiation doses exceeding 0.2 Gy (20 rads) during pregnancy show that children born after receiving these doses have a higher risk of mental retardation. Other studies suggest that an association exists between exposure to diagnostic x-rays before birth and carcinogenic effects in childhood and in adult life. Scientists are uncertain about the magnitude of the risk. Some studies show the embryo/fetus to be more sensitive to radiation-induced cancer than adults, but other studies do not. In recognition of the possibility of increased radiation sensitivity, and because dose to the embryo/fetus is involuntary on the part of the embryo/fetus, a more restrictive dose limit has been established for the embryo/fetus of a declared pregnant radiation worker, see WISREG *"Instruction Concerning Prenatal Radiation Exposure."*

If an occupationally exposed woman declares her pregnancy in writing, she is subject to the more restrictive dose limits for the embryo/fetus during the remainder of the pregnancy. The dose limit of 5 mSv (500 mrem) for the total gestation period applies to the embryo/ fetus and is controlled by restricting the exposure to the declared pregnant woman. Restricting the woman's occupational exposure, if she declares her pregnancy, raises questions about individual privacy rights, equal employment opportunities, and the possible loss of income. Because of these concerns, the declaration of pregnancy by a female radiation worker is voluntary. Also, the declaration of pregnancy can be withdrawn for any reason, for example, if the woman believes that her benefits from receiving the occupational exposure would outweigh the risk to her embryo/fetus from the radiation exposure.

12. Can a worker become sterile or impotent from normal occupational radiation exposure?

No. Temporary or permanent sterility cannot be caused by radiation at the levels allowed under DHFS's occupational limits. There is a threshold below which these effects do not occur. Acute doses on the order of 0.1 Sv (10 rem) to the testes can result in a measurable but temporary reduction in sperm count. Temporary sterility (suppression of ovulation) has been observed in women who have received acute doses of 1.5 Gy (15

rads) . The estimated threshold (acute) radiation dose for induction of permanent sterility is about 2 Gy (200 rads) for men and about 3.5 Gy (350 rads) for women (Refs. 1 and 4). These doses are far greater than the DHFS's occupational dose limits for workers.

Although acute doses can affect fertility by reducing sperm count or suppressing ovulation, they do not have any direct effect on one's ability to function sexually. No evidence exists to suggest that exposures within the **DHFS's** occupational limits have any effect on the ability to function sexually.

13. What are DHFS's occupational dose limits?

For adults, an annual limit not to exceed:

- 0.05 Sv (5 rem)) for the total effective dose equivalent (TEDE), which is the sum of the deep dose equivalent (DDE) from external exposure to the whole body and the committed effective dose equivalent (CEDE) from intakes of radioactive material.
- 0.5 Sv (50 rem) for the total organ dose equivalent (TODE), which is the sum of the DDE from external exposure to the whole body and the committed dose equivalent (CDE) from intakes of radioactive material to any individual organ or tissue, other than the lens of the eye.
- 0.15 Sv (15 rem) for the lens dose equivalent (LDE), which is the external dose to the lens of the eye.
- 0.5 Sv (50 rem) for the shallow dose equivalent (SDE), which is the external dose to the skin or to any extremity.

For minor workers, the annual occupational dose limits are 10 percent of the dose limits for adult workers.

For protection of the embryo/fetus of a declared pregnant woman, the dose limit is 5 mSv (0.5 rem) during the entire pregnancy.

The occupational dose limit for adult workers of 0.05 Sv (5 rem) TEDE is based on consideration of the potential for delayed biological effects. The 0.05 Sv (5-rem) limit, together with application of the concept of keeping occupational doses ALARA, provides a level of risk of delayed effects considered acceptable by **DHFS**. The limits for individual organs are below the dose levels at which early biological effects are observed in the individual organs.

The dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of the possibility of greater sensitivity to radiation of the embryo/ fetus and the involuntary nature of the exposure.

14. What is meant by ALARA?

ALARA means "as low as is reasonably achievable." In addition to providing an upper limit on an individual's permissible radiation dose, DHFS requires that its licensees and registrants establish radiation protection programs and use procedures and engineering controls to achieve occupational doses, and doses to the public, as far below the limits as is reasonably achievable. "Reasonably achievable" also means "to the extent practicable". What is practicable depends on the purpose of the job, the state of technology, the costs for averting doses, and the benefits. Although implementation of the ALARA principle is a required integral part of

each licensee's or registrant's radiation protection program, it does not mean that each radiation exposure must be kept to an absolute minimum, but rather that "reasonable" efforts must be made to avert dose; In practice, ALARA includes planning tasks involving radiation exposure so as to reduce dose to individual workers and the work group.

There are several ways to control radiation doses, e.g.; limiting the time in radiation areas, maintaining distance from sources of radiation, and providing shielding of radiation sources to reduce dose. The use of engineering controls, from the design of facilities and equipment to the actual set-up and conduct of work activities is also an important element of the ALARA concept.

An ALARA analysis should be used in determining whether the use of respiratory protection is advisable. In evaluating whether or not to use respirators, the goal should be to achieve the optimal sum of external and internal doses. For example, the use of respirators can lead to increased work time within radiation areas, which increases external dose. The advantage of using respirators to reduce internal exposure must be evaluated against the increased external exposure and related stresses caused by the use of respirators. Heat stress, reduced visibility, and reduced communication associated with the use of respirators could expose a worker to far greater risks than are associated with the internal dose avoided by use of the respirator. To the extent practical, engineering controls, such as containment and ventilation systems, should be used to reduce workplace airborne radioactive materials.

15. What are background radiation exposures?

The average person is constantly exposed to ionizing radiation from several sources. Our environment and even the human body contain naturally occurring radioactive materials (e.g., potassium-40) that contribute to the radiation dose that we receive. The largest source of natural background radiation exposure is terrestrial radon, a colorless, odorless, chemically inert gas, which causes about 55 percent of our average, non-occupational exposure. Cosmic radiation originating in space contributes additional exposure. The use of x-rays and radioactive materials in medicine and dentistry adds to our population exposure. As shown below in Table 3, the average person receives an annual radiation dose of about 3.6 mSv (0.36 rem). By age 20, the average person will have accumulated over 70 mSv (7 rem) of dose. By age 50, the total dose is up to 180 mSv (18 rem). After 70 years of exposure this dose is up to 250 mSv (25 rem).

Table 3
Average Annual Effective Dose Equivalent to Individuals in the U.S.^A

Source	Effective Dose Equivalent (mrems)(uSv)
Natural	
Radon	200
Other than Radon	100
Total	300
Nuclear Fuel Cycle	0.05
Consumer Products ^B	9
Medical	
Diagnostic X-rays	39
Nuclear Medicine	14
Total	53
Total	About 360 mrems/yr

^A Adapted from Table 8.1, NCRP 93 (Ref. 11).

^B Includes building material, television receivers, luminous watches, smoke detectors, etc. (from Table 5.1, NCRP 93, Ref. 11).

16. What are the typical radiation doses received by workers?

In 1993 the Nuclear Regulatory Commission (NRC) received reports on about a quarter of a million people who were monitored for occupational exposure to radiation. Almost half of those monitored had no measurable doses. The other half had an average dose of about 3.1 mSv (310 mrem) for the year. Of these, 93 percent received an annual dose of less than 10 mSv (1 rem) 98.7 percent received less than 20 mSv (2 rem) ; and the highest reported dose was for two individuals who each received between 50 and 60 mSv (5 and 6 rem) .

Table 4 lists average occupational doses for workers (persons who had measurable doses) in various occupations based on 1993 data. It is important to note licensees and registrants are required to sum external and internal doses and certain licensees are required to submit annual reports.

Table 4
NRC's Licensees Reported Occupational Doses for 1994^a

Occupational Subgroup	Average Measurable Dose per Worker (millirems)(uSv)
Industrial Radiography	540
Commercial Nuclear Power Reactors	310
Manufacturing and Distribution of Radioactive Materials	300
Low-Level Radioactive Waste Disposal	270
Independent Spent Nuclear Fuel Storage	260
Nuclear Fuel Fabrication	130

^aFrom Table 3.1 in NUREG-0713 (Ref. 9).

17. How do I know how much my occupational dose (exposure) is?

If you are likely to receive more than 10 percent of the annual dose limits, DHFS requires your employer, the DHFS licensee or registrant, to monitor your dose, to maintain records of your dose, and, to notify you in writing of your annual occupational dose. The purpose of this monitoring and reporting is so that DHFS can be sure that licensees and registrants are complying with the occupational dose limits and the ALARA principle.

Using individual monitoring devices monitors external exposures. These devices are required to be used if it appears likely that external exposure will exceed 10 percent of the allowed annual dose, i.e., 5 mSv (0.5 rem). The most commonly used monitoring devices are film badges, thermoluminescence dosimeters (TLDs), and optically stimulated luminescent dosimeter (OSL).

With respect to internal exposure, your employer is required to monitor your occupational intake of radioactive material and assess the resulting dose if it appears likely that you will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in 1 year. Internal exposure can be estimated by measuring the radiation emitted from the body (for example, with a "whole body counter") or by measuring the radioactive materials contained in biological samples such as urine or feces. Dose estimates can also be made if one knows how much radioactive material was in the air and the length of time during which the air was breathed.

18. What happens if a worker exceeds the annual dose limit?

If a worker receives a dose in excess of any of the annual dose limits, the regulations prohibit any occupational exposure during the remainder of the year in which the limit is exceeded. The licensee or registrant is also required to file an overexposure report with DHFS and provide a copy to the individual who received the dose. The licensee or registrant may be subject to DHFS enforcement action such as a fine (civil penalty), just as

Individuals are subject to a traffic fine for exceeding a speed limit. Fines and, in instances of serious or repetitive exposures, suspension of a license or registration is possible.

Radiation protection limits do not define safe or unsafe levels of radiation exposure. Exceeding a limit does not mean that you will get cancer. For radiation protection purposes, it is assumed that risks are related to the size of the radiation dose. Therefore, when your dose is higher your risk is also considered to be higher. These limits are similar to highway speed limits. If you drive at 70 mph, your risk is higher than at 55 mph, even though you may not actually have an accident. Those who set speed limits have determined that the risks of driving in excess of the speed limit are not acceptable. In the same way, Chapter HFS 157 "Radiation Protection" establishes a limit for normal occupational exposure of 0.05 Sv (5 rem) a year. Although you will not necessarily get cancer or some other radiation effect at doses above the limit, it does mean that the licensee's or registrant's safety program has failed in some way; investigation is warranted to determine the cause and correct the conditions leading to the dose in excess of the limit.

19. What is meant by a "planned special exposure"?

A "planned special exposure" (PSE) is an infrequent exposure to radiation, separate from and in addition to the radiation received under the annual occupational limits. The licensee or registrant can authorize additional dose in any one year that is equal to the annual occupational dose limit as long as the individual's total dose from PSEs does not exceed five times the annual dose limit during the individual's lifetime. For example, licensees or registrants may authorize PSEs for an adult radiation worker to receive doses up to an additional 0.05 Sv (5 rem) in a year above the 0.05 Sv (5 rem) annual TEDE occupational dose limit. Each worker is limited to no more than 25 rem (0.25 Sv) from planned special exposures in his or her lifetime. Such exposures are only allowed in exceptional situations when alternatives for avoiding the additional exposure are not available or are impractical.

Before the licensee or registrant authorizes a PSE, the licensee or registrant must ensure that the worker is informed of the purpose and circumstances of the planned operation, the estimated doses expected, and the procedures to keep the doses ALARA while considering other risks that may be present.

The licensee or registrant must also inform the department of the "planned special exposure" (including the date the planned special exposure occurred and the information required by HFS 157.31(6)) within 30 days following any "planned special exposure." (See the Nuclear Regulatory Commission's Regulatory Guide 8.35, "Planned Special Exposure, which is available from DHFS.)

20. Why do some facilities establish administrative control levels that are below DHFS limits?

There are two reasons. First, DHFS's rules state that licensees and registrants must take steps to keep exposures to radiation ALARA. Specific approval from the licensee or registrant for workers to receive doses in excess of administrative limits usually results in more critical risk-benefit analyses as each additional increment of dose is approved for a worker. Secondly, an administrative control level that is set lower than DHFS limit provides a safety margin designed to help the licensee or registrant avoid doses to workers in excess of the limit.

21. Why aren't medical exposures considered as part of a worker's allowed dose?

DHFS rules exempt medical exposure, but equal doses of medical and occupational radiation have equal risks. Medical exposure to radiation is justified for reasons that are quite different from the reasons for occupational exposure. A physician prescribing an x-ray, for example, makes a medical judgment that the benefit to the patient from the resulting medical information justifies the risk associated with the radiation. This judgment

may or may not be accepted by the patient. Similarly, each worker must decide on the benefits and acceptability of occupational radiation risk, just as each worker must decide on the acceptability of any other occupational hazard.

Consider a worker who receives a dose of 0.03 Sv (3 rem) from a series of x-rays in connection with an injury or illness. This dose and any associated risk must be justified on medical grounds. If the worker had also received 0.02 Sv (2 rem) on the job, the combined dose of 0.05 Sv (5 rem) would in no way incapacitate the worker. Restricting the worker from additional job exposure during the remainder of the year would not have any effect on the risk from the 0.03 Sv (3 rem) already received from the medical exposure. If the individual worker accepts the risks associated with the x-rays on the basis of the medical benefits and accepts the risks associated with job-related exposure on the basis of employment benefits, it would be unreasonable to restrict the worker from employment involving exposure to radiation for the remainder of the year.

22. How should radiation risks be considered in an emergency?

Emergencies are “unplanned” events in which actions to save lives or property may warrant additional doses for which no particular limit applies. Chapter HFS 157 “Radiation Protection” does not set any dose limits for emergency or lifesaving activities and states that nothing in Chapter HFS 157 “Radiation Protection”, “*shall be construed as limiting actions that may be necessary to protect health and safety.*”

Rare situations may occur in which a dose in excess of occupational limits would be unavoidable in order to carry out a lifesaving operation or to avoid a large dose to large populations. However, persons called upon to undertake any emergency operation should do so only on a voluntary basis and with full awareness of the risks involved.

For perspective, the Environmental Protection Agency (EPA) has published emergency dose guidelines (Ref. 2). These guidelines state that doses to all workers during emergencies should, to the extent practicable, be limited to 0.05 Sv (5 rem). The EPA further states that there are some emergency situations for which higher limits may be justified. The dose resulting from such emergency exposures should be limited to 0.1 Sv (10 rem) for protecting valuable property, and to 0.25 Sv (25 rem) for lifesaving activities and the protection of large populations. In the context of this guidance, the dose to workers that is incurred for the protection of large populations might be considered justified for situations in which the collective dose to others that is avoided as a result of the emergency operation is significantly larger than that incurred by the workers involved, Table 5 presents the estimates of the fatal cancer risk for a group of 1,000 workers of various ages, assuming that each worker received an acute dose of 0.25 Sv (25 rem) in the course of assisting in an emergency. The estimates show that a .25 Sv (25 -rem) emergency dose might increase an individual’s chances of developing fatal cancer from about 20% to about 21%.

Table 5
Risk of Premature Death from Exposure to 25 Rem (0.25 Sv)
Acute Dose

Age of Exposure (years)	Estimated Risk of Premature Death (Deaths per 1,000 Persons Exposed)
20-30	9.1
30-40	7.2
40-50	5.3
50-60	3.5

Source: EPA-400-R-91-001 (Ref. 2).

23. How were radiation dose limits established?

The DHFS radiation dose limits in Chapter HFS 157 "Radiation Protection" were established by the State of Wisconsin and are compatible with the Nuclear Regulatory Commission regulations, which are based on the recommendations of the ICRP and NCRP as endorsed in federal radiation protection guidance developed by the EPA 8.29-13.(Ref. 12). The limits were recommended by the ICRP and NCRP with the objective of ensuring that working in a radiation-related industry was as safe as working in other comparable industries. The dose limits and the principle of ALARA should ensure that risks to workers are maintained indistinguishable from risks from background radiation.

24. Several scientific reports have recommended that lower dose limits be established.

Since the State of Wisconsin is an Agreement State, all dose limits are compatible with the Nuclear Regulatory Commission dose limits. Any recommendation to establish lower dose limits would be recommended by the Nuclear Regulatory Commission to all Agreement States including the State of Wisconsin.

Since publication of the Nuclear Regulatory Commission's proposed rule in 1986, the ICRP in 1990 revised its recommendations for radiation protection based on newer studies of radiation risks (Ref. 13), and the NCRP followed with a revision to its recommendations in 1993. The ICRP recommended a limit of 0.1 Sv (10 rem) effective dose equivalent (from internal and external sources), over a 5-year period with no more than 0.05 Sv (5 rem) in 1 year (Ref. 13). The NCRP recommended a cumulative limit in rem, not to exceed the individual's age in years, with no more than 0.05 Sv (5 rem) in any year (Ref. 14).

The Nuclear Regulatory Commission does not believe that additional reductions in the dose limits are required at this time. Because of the practice of maintaining radiation exposures ALARA (as low as is reasonably achievable), the average radiation dose to occupationally exposed persons is well below the limits in the current Title 10 Code of Federal Regulation Part 20 and the average doses to radiation workers are below the new limits recommended by the ICRP and the NCRP.

25. What are the options if a worker decides that the risks associated with occupational radiation exposure are too high?

If the risks from exposure to occupational radiation are unacceptable to a worker, he or she can request a transfer to a job that does not involve exposure to radiation. However, the risks associated with the exposure to radiation that workers, on the average, actually receive are comparable to risks in other industries and are considered acceptable by the scientific groups that have studied them. An employer is not obligated to guarantee a transfer if a worker decides not to accept an assignment that requires exposure to radiation.

Any worker has the option of seeking other employment in a non-radiation occupation. However, the studies that have compared occupational risks in the nuclear industry to those in other job areas indicate that nuclear work is relatively safe. Thus, a worker may find different kinds of risk but will not necessarily find significantly lower risks in another job.

26. Where can one get additional information on radiation risk?

The following list suggests sources of useful information on radiation risk:

- The employer—the radiation protection or health physics office where a worker is employed.
- The State of Wisconsin
Department of Health and Family Services
Radiation Protection Section
1 West Wilson Street
P.O. Box 2659
Madison, WI 53701-2659
Telephone: (608) 267-47-97
- U.S. Nuclear Regulatory Commission Headquarters
Radiation Protection & Health Effects Branch
Office of Nuclear Regulatory Research
Washington, DC 20555
Telephone: (301) 415-6187
- Department of Health and Human Services
Center for Devices and Radiological Health
1390 Piccard Drive, MS HFZ-1
Rockville, MD 20850
Telephone: (301) 443-4690
- U. S. Environmental Protection Agency
Office of Radiation and Indoor Air
Criteria and Standards Division
401 M Street NW.
Washington, DC 20460
Telephone: (202) 233-9290

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4. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation*, Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.
5. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR); *Sources, Effects and Risks of Ionizing Radiation*, Report E.88.IX.7, United Nations, New York, 1988.
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10. B.L. Cohen and L.S. Lee, "Catalog of Risks Extended and Updated," *Health Physics*, Vol. 61, September 1991.
11. National Council on Radiation Protection and Measurements, *Ionizing Radiation Exposure of the Population of the United States*, NCRP Report No. 93, September 1987.
12. U.S. Environmental Protection Agency, "Radiation Protection Guidance to Federal Agencies for Occupational Exposure," *Federal Register*, Vol. 52, No. 17, January 27, 1987.
13. International Commission on Radiological Protection, *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, Pergamon Press, Oxford, UK, 1991.
14. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, March 1993.

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Abrahamson, S., *et al.*, "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis, Modifications of Models Resulting From Recent Reports on Health Effects of Ionizing Radiation, Low LET Radiation," Part II: *Scientific Basis for Health Effects Models*, U.S. Nuclear Regulatory Commission, NUREG/CR-4214, Rev. 1, Part II, Addendum 1, August 1991.

Abrahamson, S., *et al.*, "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis, Modifications of Models Resulting From Addition of Effects of Exposure to Alpha-Emitting Radionuclides," Part II: *Scientific Bases for Health Effects Models*, U.S. Nuclear Regulatory Commission, NUREG/CR-4214, Rev. 1, Part II, Addendum 2, May 1993.

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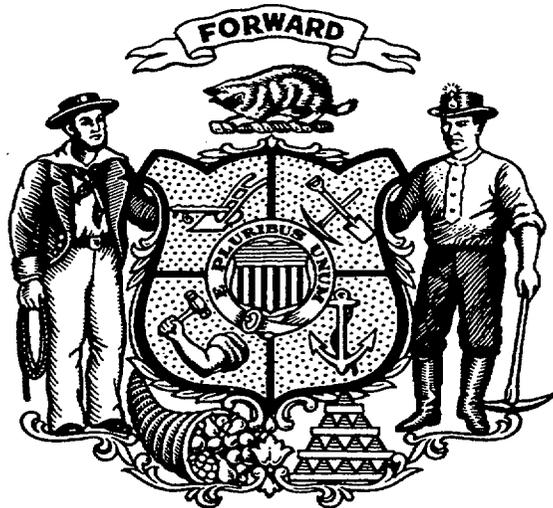
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Wisconsin
Chapter HFS 157 -Radiation Protection
Regulatory Guide
WISREG 8.13
Revision 1 – January 2002



**Instruction Concerning Prenatal Radiation
Exposure**

Department of Health and Family Services
Radiation Protection Section
1 West Wilson Street
P.O. Box 2659
Madison, WI 53701-2659
Phone: (608) 267-4797
Fax: (608) 267-3695

INTRODUCTION

HFS 157.88(2) requires that Instruction to Workers; *shall be commensurate with potential radiological health protection problems present in the workplace and shall take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material that can be reasonably be expected to occur during the life of licensee's or registrant's activities.*

The Department of Health and Family Services regulations specified in HFS 157.22(8) 'Dose to an Embryo or Fetus' requires licensees or registrants to *"ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (500 mrem)." HFS 157.22(8) also requires that "a licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman." A declared pregnant woman is defined in HFS 157.03(89), as a women who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception.*

This Wisconsin Regulatory Guide (WISREG) is intended to provide information to pregnant women, and other personnel, to help them make decisions regarding radiation exposure during pregnancy.

Other sections of the Department of Health and Family Services' (DHFS) regulations also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. In HFS 157.25(2), "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," *"licensees or registrants are required to monitor the occupational exposure to radiation sources under their control and supply and require the use of individual monitoring devices by a declared pregnant woman likely to receive, in one year from sources of external to the body, a dose in excess of one mSv (0.1 rem)." According to HFS 157.31(7), "Records of Individual Monitoring Results," "the licensee or registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records."*

DISCUSSION

Exposure to any level of radiation is assumed to carry with it a certain amount of risk. In the absence of scientific certainty regarding the relationship between low dose exposure and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects and that the likelihood of these effects increases as the dose increases. At the occupational dose limit for the whole body of 50 mSv (5 rem) per year, the risk is believed to be very low.

The magnitude of risk of childhood cancer following in utero exposure is uncertain in that both negative and positive studies have been reported. The data from these studies "are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult" (NCRP Report No. 116, Ref. 2). DHFS has reviewed the available scientific literature and has concluded that the 5 mSv (500 mrem) limit specified in HFS 157.22(8) provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions specified in Chapter HFS 157 "Radiation Protection", the woman must declare her pregnancy in writing to the licensee or registrant. A form letter for declaring pregnancy is provided in this guide or the licensee or

registrant may use its own form letter for declaring pregnancy. A separate written declaration should be submitted for each pregnancy.

REGULATORY POSITION

1. Who Should Receive Instruction.

Female workers who require training under HFS 157.88(2) should be provided with the information contained in this guide.

2. Providing Instruction

The occupational worker may be given a copy of this guide with its Appendix, an explanation of the contents of the guide, and an opportunity to ask questions and request additional information. The information in this WISREG and Appendix should also be provided to any worker or supervisor who may be affected by a declaration of pregnancy or who may have to take some action in response to such a declaration.

Classroom instruction may supplement the written information. If the licensee or registrant provides classroom instruction, the instructor should have some knowledge of the biological effects of radiation to be able to answer questions that may go beyond the information provided in this WISREG. Videotaped presentations may be used for classroom instruction. Regardless of whether the licensee or registrant provides classroom training, the licensee or registrant should give workers the opportunity to ask questions about information contained in this WISREG. The licensee or registrant may take credit for instruction that the worker has received within the past year at other licensed or registered facilities or in other courses or training.

3. Licensee's or Registrant's Policy on Declared Pregnant Women

The instruction provided should describe the licensee's or registrant's specific policy on declared pregnant women, including how those policies may affect a woman's work situation. In particular, the instruction should include a description of the licensee's or registrant's policies if any, which may affect the declared pregnant woman's work situation after she has filed a written declaration of pregnancy consistent with HFS 157.22(8).

The instruction should also identify whom to contact for additional information as well as identify who should receive the written declaration of pregnancy. The recipient of the woman's declaration may be identified by name (e.g., John Smith), position (e.g., immediate supervisor, the radiation safety officer), or department (e.g., the personnel department).

4. Duration of Lower Dose Limits for the Embryo/Fetus

The lower dose limit for the embryo/fetus should remain in effect until the woman withdraws the declaration in writing. If a declaration of pregnancy is withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time the declaration is withdrawn. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

5. Substantial Variations Above a Uniform Monthly Dose Rate

According to HFS 157.22(8), "A licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman." The National Council on Radiation Protection and Measurements (NCRP) recommends a monthly equivalent dose limit of 0.5 mSv (50 mrem) to the embryo/fetus once the pregnancy is known (Ref. 2). In view of the NCRP recommendation, any monthly dose of less than 1 mSv (100 mrem) may be considered as not a substantial variation above a uniform monthly dose rate and as such will not require licensee or registrants justification. However, the licensee or registrant should justify a monthly dose greater than 0.1 rem (1 mSv).

IMPLEMENTATION

The purpose of this section is to provide information to licensees, registrants and applicants regarding DHFS's plans for using this WISREG. Unless a licensee, registrant or an applicant proposes an acceptable alternative method for complying with the specified portions of Chapter HFS 157 "Radiation Protection", the methods described in this WISREG will be used by DHFS in the evaluation of instructions to workers on the radiation exposure of pregnant women.

REFERENCES

1. WISREG "Instructions Concerning Occupational Risk from Radiation Exposure", Rev. 0 June 2002
2. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.

APPENDIX

QUESTIONS AND ANSWERS CONCERNING PRENATAL RADIATION EXPOSURE

1. Why am I receiving this information?

Chapter HFS 157 'Radiation Protection' (in **HFS 157.88 (2)**, "Instructions to Workers") requires that licensees or registrants instruct individuals working with licensed or registered radioactive materials in radiation protection, as appropriate for the situation. The instruction below describes information that occupational workers and their supervisors should know about the radiation exposure of the embryo/fetus of pregnant women.

Chapter HFS 157 "Radiation Protection" allows a pregnant woman to decide whether she wants to formally declare her pregnancy. This instruction provides information to help women make an informed decision whether to declare a pregnancy.

2. If I become pregnant, am I required to declare my pregnancy?

No. The choice whether to declare your pregnancy is completely voluntary. If you choose to declare your pregnancy, you must do so in writing and a lower radiation dose limit will apply to your embryo/fetus. If you choose not to declare your pregnancy, you and your embryo/fetus will continue to be subject to the same radiation dose limits that apply to other occupational workers.

3. If I declare my pregnancy in writing, what happens?

If you choose to declare your pregnancy in writing, the licensee or registrant must take measures to limit the dose to your embryo/fetus to 5 millisievert (500 mrem) during the entire pregnancy. This is one-tenth of the dose that an occupational worker may receive in a year. If you have already received a dose exceeding 5 mSv (500 mrem) in the period between conception and the declaration of your pregnancy, an additional dose of 0.5 mSv (50 mrem) is allowed during the remainder of the pregnancy. In addition, HFS 157.22(8), "Dose to an Embryo/Fetus," requires licensees or registrants to make efforts to avoid substantial variation above a uniform monthly dose rate so that all the 5 mSv (500 mrem) allowed dose does not occur in a short period during the pregnancy.

This may mean that, if you declare your pregnancy, the licensee or registrant may not permit you to do some of your normal job functions if those functions would have allowed you to receive more than 5 mSv (500 mrem) and you may not be able to have some emergency response responsibilities.

4. Why do the regulations have a lower dose limit for the embryo/fetus of a declared pregnant woman than for a pregnant worker who has not declared?

A lower dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure. Several scientific advisory groups have recommended (References 1 and 2) that the dose to the embryo/fetus be limited to a fraction of the occupational dose limit.

5. What are the potentially harmful effects of radiation exposure to my embryo/fetus?

The occurrence and severity of health effects caused by ionizing radiation are dependent upon the type and total dose of radiation received, as well as the time period over which the exposure was received. The main concern is embryo/fetal susceptibility to the harmful effects of radiation such as cancer.

3. Are there any risks of genetic defects?

Although radiation injury has been induced experimentally in rodents and insects, and in the experiments was transmitted and became manifest as hereditary disorders in their offspring, radiation has not been identified as a cause of such effect in humans. Therefore, the risk of genetic effects attributable to radiation exposure is speculative. For example, no genetic effects have been documented in any of the Japanese atomic bomb survivors, their children, or their grandchildren.

7. What if I decide that I do not want any radiation exposure at all during my pregnancy?

You may ask your employer for a job that does not involve any exposure at all to occupational radiation dose, but your employer is not obligated to provide you with a job involving no radiation exposure. Even if you receive no occupational exposure at all, your embryo/fetus will receive some radiation dose ((on average (0.75 mSv (75 mrem))) during your pregnancy from natural background radiation.

DHFS has reviewed the available scientific literature and concluded that the 5 mSv (500 mrem limit provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers. If this dose limit is exceeded, the total lifetime risk of cancer to the embryo/fetus may increase incrementally. However, the decision on what level of risk to accept is yours. More detailed information on potential risk to the embryo/fetus from radiation exposure can be found in References 2-10.

8. What effect will formally declaring my pregnancy have on my job status?

Only the licensee or registrant can tell you what effect a written declaration of pregnancy will have on your job status. As part of your radiation safety training, the licensee or registrant should tell you the company's policies with respect to the job status of declared pregnant women. In addition, before you declare your pregnancy, you may want to talk to your supervisor or your radiation safety officer and ask what a declaration of pregnancy would mean specifically for you and your job status.

In many cases you can continue in your present job with no change and still meet the dose limit for the embryo/fetus. For example, most commercial power reactor workers (approximately 93%) receive, in 12 months, occupational radiation doses that are less than 5 mSv (500 mrem) (Ref. 11). The licensee or registrant may also consider the likelihood of increased radiation exposures from accidents and abnormal events before making a decision to allow you to continue in your present job.

If your current work might cause the dose to your embryo/fetus to exceed 5 mSv (500 mrem), the licensee or registrant has various options. It is possible that the licensee or registrant can and will make a reasonable accommodation that will allow you to continue performing your current job, for example, by having another qualified employee do a small part of the job that accounts for some of your radiation exposure.

9. What information must I provide in my written declaration of pregnancy?

You should provide, in writing, your name, a declaration that you are pregnant, the estimated date of conception (only the month and year need be given), and the date that you give the letter to the licensee or registrant. A form letter that you can use is included at the end of these questions and answers. You may use that letter, use a form letter the licensee or registrant has provided to you, or write your own letter.

10. To declare my pregnancy, do I have to have documented medical proof that I am pregnant?

DHFS's rule does not require that you provide medical proof of your pregnancy. However, DHFS does not preclude the licensee or registrant from requesting medical documentation of your pregnancy, especially if a change in your duties is necessary in order to comply with the 5 mSv (500 mrem) dose limit.

11. Can I tell the licensee or registrant orally rather than in writing that I am pregnant?

No. The regulations require that the declaration must be in writing.

12. If I have not declared my pregnancy in writing, but the licensee or registrant suspects that I am pregnant, do the lower dose limits apply?

No. The lower dose limits for pregnant women apply only if you have declared your pregnancy in writing. The United States Supreme Court has ruled (in *United Automobile Workers International Union v. Johnson Controls, Inc.*, 1991) that "Decisions about the welfare of future children must be left to the parents who conceive, bear, support, and raise them rather than to the employers who hire those parents" (Reference 7). The Supreme Court also ruled that your employer may not restrict you from a specific job "because of concerns about the next generation." Thus, the lower limits apply only if you choose to declare your pregnancy in writing.

13. If I am planning to become pregnant but am not yet pregnant and I inform the licensee or registrant of that in writing, do the lower dose limits apply?

No. The requirement for lower limits applies only if you declare in writing that you are already pregnant.

14. What if I have a miscarriage or find out that I am not pregnant?

If you have declared your pregnancy in writing, you should promptly inform the licensee or registrant in writing that you are no longer pregnant. However, if you have not formally declared your pregnancy in writing, you need not inform the licensee or registrant of your non-pregnant status.

15. How long is the lower dose limit in effect?

The dose to the embryo/fetus must be limited until you withdraw your declaration in writing or you inform the licensee or registrant in writing that you are no longer pregnant. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

16. If I have declared my pregnancy in writing, can I revoke my declaration of pregnancy even if I am still pregnant?

Yes, you may. The choice is entirely yours. If you revoke your declaration of pregnancy, the lower dose limit for the embryo/fetus no longer applies.

17. What if I work under contract at a licensed facility?

The regulations state that you should formally declare your pregnancy to the licensee or registrant in writing. The licensee or registrant has the responsibility to limit the dose to the embryo/fetus.

18. Where can I get additional information?

The references to this Appendix contain helpful information, especially Reference 3, *WISREG "Instructions Concerning Occupational Risk from Radiation Exposure"* for general information on radiation risks. The

licensee or registrant should be able to give this document to you or contact the Department of Health and Family Services at (608) 267-4797.

For information on legal aspects, see Reference 7, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children—What Can the Employer Do?" which is an article in the journal *Radiation Protection Management*.

You may also telephone the State of Wisconsin, Department of Health and Family Services, Radiation Protection Section at (608) 267-4797 for further information.

Note: Single copies of regulatory guides may be attained by contacting the State of Wisconsin, Department of Health and Family Services, Radiation Protection Section at (608) 267-4797 or by mail at 1 West Wilson Street, P.O. Box 2659, Madison, WI 53703-2659.

REFERENCES FOR APPENDIX

1. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.
2. International Commission on Radiological Protection, *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, Ann. ICRP 21: No. 1-3, Pergamon Press, Oxford, UK, 1991.
3. WISREG "Instructions Concerning Occupational Risk from Radiation Exposure", Rev. 0 June 2002
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5. United Nations Scientific Committee on the Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.
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7. David Wiedis, Donald E. Jose, and Timm O. Phoebe, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children—What Can the Employer Do?" *Radiation Protection Management*, 11, 41-49, January/February 1994.
8. National Council on Radiation Protection and Measurements, *Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child*, NCRP Commentary No. 9, Bethesda, MD, 1994.
9. National Council on Radiation Protection and Measurements, *Risk Estimates for Radiation Protection*, NCRP Report No. 115, Bethesda, MD, 1993.
10. National Radiological Protection Board, *Advice on Exposure to Ionising Radiation During Pregnancy*, National Radiological Protection Board, Chilton, Didcot, UK, 1998.
11. M.L. Thomas and D. Hagemeyer, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1996," Twenty-Ninth Annual Report, NUREG-0713, Vol. 18, USNRC, 1998.

FORM LETTER FOR DECLARING PREGNANCY

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter, you may use a form letter the licensee or registrant has provided to you, or you may write your own letter.

DECLARATION OF PREGNANCY

To: _____

In accordance with the State of Wisconsin, Department of Health and Family Services rules located at HFS 157.22(8) "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in (*only the month and year need be provided*).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 5 mSv (500 mrem) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

(Your signature)

(Your name printed)

(Date)