NUREG-1556
Vol. 21

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

Draft Report for Comment

U.S. Nuclear Regulatory Commission
Office of Federal and State Materials and Environmental Management Programs
Washington, DC 20555-0001

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Draft Report for Comment

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ABSTRACT

On August 8, 2005, the Energy Policy Act of 2005 (EPAct) gave NRC new regulatory authority over additional byproduct material. This new byproduct material now also includes naturally occurring materials, such as discrete sources of radium-226 (Ra-226), and accelerator-produced radioactive materials (NARM). This guidance document provides assistance to applicants in preparing a license application for a specific possession license for the production of radioactive material using an accelerator. This guidance document should be used for activities that take place once radioactive materials are produced by the accelerator, which include material in the target and associated activation products, to the transfer or distribution of material to another license for preparation of the final product (e.g., radioactive drugs). This document does not include information for the operation of the accelerator, as NRC does not regulate the accelerator or its operation. Also, neutron accelerators and other types of accelerators (e.g., linear accelerators) that are used to produce particle beams and not radioactive materials will not be covered in this document.

This report also provides guidance to applicants in applying for authorization for the production and noncommercial distribution of Positron Emission Tomography (PET) radioactive drugs to medical use licensees in a consortium.

This document describes both the methods acceptable to NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

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FOREWORD

The United States Nuclear Regulatory Commission (NRC) is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is the consolidation and updating of numerous guidance documents into a NUREG-series of reports. Below is a list of volumes currently included in the NUREG-1556 series, "Consolidated Guidance About Materials Licenses."

Vol. No.	Volume Title	Status
1, Rev. 1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Industrial Radiography Licenses	Final Report
3, Rev. 1	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Final Report
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses	Final Report
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses	Final Report
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers	Final Report
8	Program-Specific Guidance About Exempt Distribution Licenses	Final Report
9, Rev. 2	Program-Specific Guidance About Medical Use Licenses	Draft Report
10	Program-Specific Guidance About Master Materials Licenses	Final Report
11	Program-Specific Guidance About Licenses of Broad Scope	Final Report
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution	Final Report
13, Rev. 1	Program-Specific Guidance About Commercial Radiopharmacy Licenses	Draft Report
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses	Final Report
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses	Final Report
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees	Final Report
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses	Final Report
18	Program-Specific Guidance About Service Provider Licenses	Final Report

Vol. No.	Volume Title	Status
19	Guidance For Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)	Final Report
20	Guidance About Administrative Licensing Procedures	Final Report
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator	Draft Report

The current document, NUREG-1556, Vol. 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator," dated May 2007, is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel.

A team composed of NRC staff from headquarters and regional offices prepared this document, drawing on their collective experience in radiation safety in general and as specifically applied to accelerator-produced radioactive materials.

This report represents a step in the transition from the current paper-based process to the new electronic process. This document is available on the Internet at the following address: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v21/.

NUREG-1556, Vol. 21 is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report will be acceptable if they provide a basis for the staff to make the determination needed to issue or continue a license.

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ABBREVIATIONS

AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANP	authorized nuclear pharmacist
ANSI	American National Standards Institute
bkg	background
BPR	Business Process Redesign
Bq	becquerel
CFR	Code of Federal Regulations
Ci	curie
cm	centimeter
cpm	counts per minute
DAC	derived air concentration
DFP	decommissioning funding plan
DIS	decay in storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
dpm/cm^2	disintegrations per minute per square centimeter
EPA	United States Environmental Protection Agency
EPAct	Energy Policy Act of 2005
FA	financial assurance
FDA	United States Food and Drug Administration
FSME	Office of Federal and State Management and Environmental Management Programs
GM	Geiger-Mueller
GPO	Government Printing Office
IN	Information Notice
IP	inspection procedure
LLW	low-level radioactive waste

LSC	liquid scintillation counter
LSA	low specific activity
MCA	multichannel analyzer
mCi	millicurie
mGy	milliGray
MDA	minimum detectable activity
MOU	Memorandum of Understanding
mR	milliroentgen
mrem	millirem
mrem/hr	millirem per hour
mSv	millisievert
mSv/hr	millisievert per hour
NARM	Naturally Occurring and Accelerator-Produced Radioactive Material
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OMB	Office of Management and Budget
P&GD	Policy and Guidance Directive
PET	Positron Emission Tomography
QA	quality assurance
R	roentgen
Ra-226	radium-226
RG	Regulatory Guide
RQ	reportable quantity
RSO	radiation safety officer
SI	International System of Units (abbreviated SI from the French, Le Système Internationale d'Unités)
SSDR	sealed source and device registry
std	standard

Sv	sievert
TAR	technical assistance request
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
USDA	United States Department of Agriculture
μCi	microcurie

1 PURPOSE OF REPORT

This report provides guidance to applicants that produce radioactive materials using an accelerator(s). It provides guidance to an applicant in preparing a license application as well as NRC criteria for evaluating the license application. The body of this document contains the standard requirements and guidance for the possession and distribution of radioactive material (e.g., radiochemicals) that is produced by an accelerator(s), which is located at the applicant's facility. This report also provides guidance to applicants in applying for authorization for the production and noncommercial distribution of PET radioactive drugs to medical use licensees in a consortium.

This report was developed in accordance with the EPAct, which expanded the definition of byproduct material as defined in Section 11(e) of the Atomic Energy Act of 1954 (AEA), placing additional material under NRC regulatory authority to include accelerator-produced radioactive materials and naturally occurring radioactive material such as discrete sources of radium-226 (Ra-226). This report does not provide guidance on the operation of an accelerator because NRC does not regulate the operation of the accelerator. Also, this report is not to be used by materials manufacturers that process raw material and/or sources without the use of an accelerator and distribute the processed materials to users as finished products. For manufacturing and distribution of byproduct material, see NUREG-1556, Vol. 12, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," dated December 2000.

This report identifies the information needed to complete NRC Form 313, "Application for Material License," (Appendix B) for the possession and use of byproduct material. If the applicant requires another type of license(s) for its activities such as a commercial radiopharmacy license or a broad-scope license, also refer to the other guidance documents in this NUREG-1556 series, which are available at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. The information collection requirements in 10 CFR Part 30 and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Numbers 3150-0017, 3150-0001, 3150-0020, 3150-0009, and 3150-0120, respectively.

As a guidance document intended to assist a wide variety of applicants, this report contains a considerable amount of information about how licensees may choose to implement their programs to meet NRC regulatory requirements. The information in this document is not intended to impose any conditions beyond those required by the regulations in 10 CFR. This report provides specific guidance on what information should be submitted in an application to satisfy NRC requirements.

Guidance and model procedures provided in this NUREG that are not required to be submitted are for illustrative purposes to guide licensees in developing their programs. Use of the word "should" implies "may" and is not intended to mean "must" or "shall"; the procedures provided in this guidance are intended to serve only as examples.

Sections 1 through 7 of this document provide background information. Section 8 describes, item-by-item, the information that should be provided in Items 1 through 11 of NRC Form 313, in completing a license application. The format within this document for each item of technical information is:

- **Regulations** - references the regulations applicable to the item;
- **Criteria** - outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** - provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** - provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and References are self-explanatory and may not be found for each item on NRC Form 313.

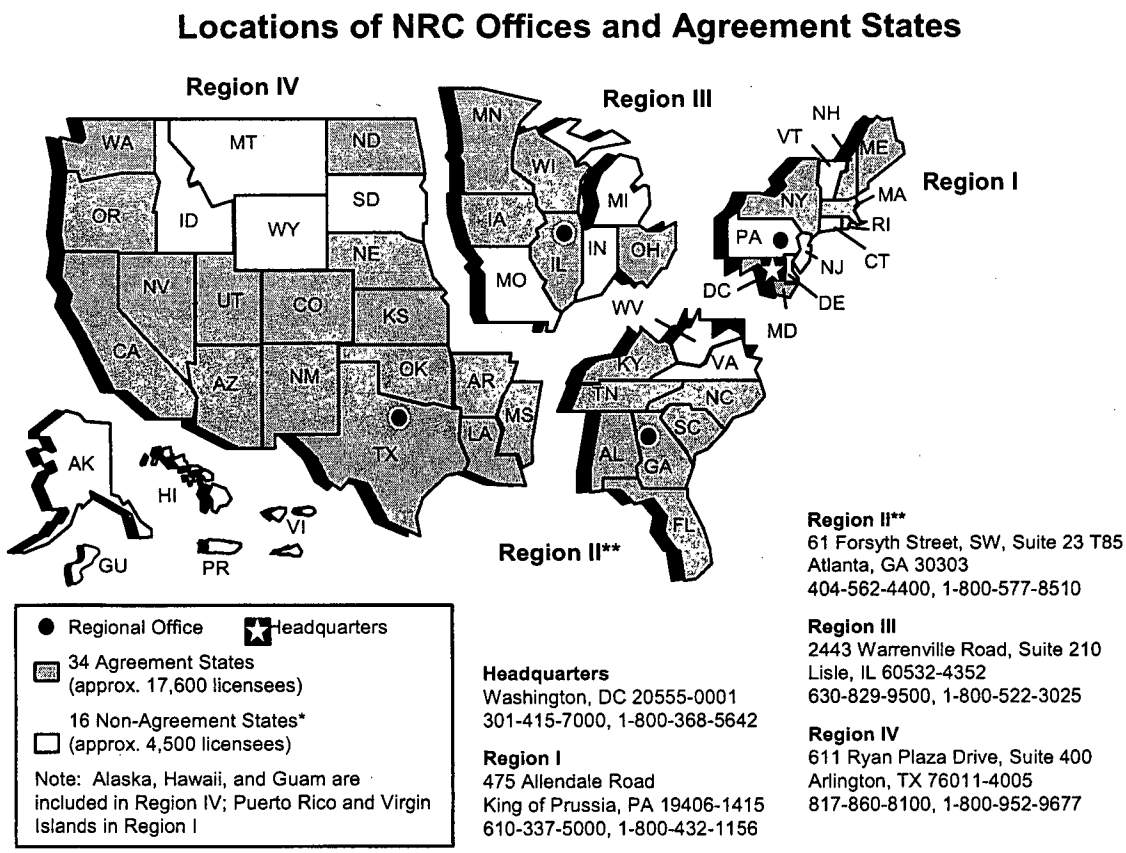
NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11; the answers to those items are to be provided on separate sheets of paper and submitted with the completed NRC Form 313. For convenience and for streamlined handling of possession for production and distribution applications, applicants may use the format in Appendix C, "Suggested Format For Providing Information Requested in Items 5 through 11 of NRC Form 313 for a Possession License," to provide supporting information to NRC.

Appendices E through O contain additional information on various radiation safety topics. Appendix D contains a sample possession license for production and distribution activities; it contains the conditions most often found on this type of license, although not all licenses will have all conditions. Appendix P provides guidance on preparing information for an authorization to produce and noncommercially distribute PET radioactive drugs to medical use licensees in a consortium.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in 10 CFR Part 20. Rem, and its SI equivalent Sievert (1 rem = 0.01 Sievert (Sv)), is used to describe units of radiation exposure or dose. This is done because 10 CFR Part 20 sets dose limits in terms of rem, not rad or roentgen (R). When the radioactive material emits beta and gamma rays, for practical reasons, we assume that 1 R = 1 rad = 1 rem. For alpha-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from an absorbed dose (rad) from alpha particles requires the use of an appropriate quality factor (Q) value. Q values are used to convert absorbed doses (rad) to dose equivalent (rem). Q values for alpha particles are addressed in Tables 1004(b)(1) and (2) in 10 CFR 20.1004.

2 AGREEMENT STATES

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant, other than a Federal agency, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with NRC.



* The 16 Non-Agreement States include three States that have filed letters of intent: Pennsylvania, New Jersey, and Virginia.
** All applicants for materials licenses located in Region II's geographical area must send their applications to Region I.

Figure 2.1 U.S. Map Location of NRC Offices and Agreement States. 1556-001m.ppt 090706

In the special situation of work at Federally controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that applicants ask their local contact for the Federal agency controlling the

site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, in order to comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996, which is available at http://nrc-stp.ornl.gov/asletters/other/sp96022.pdf.

Table 2.1 provides a quick way to check on which agency has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except the Department of Energy and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, District of Columbia, US territory, or possession, or in Offshore Federal Waters	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally controlled site *not* subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally controlled site subject to exclusive Federal jurisdiction	NRC

Reference: A current list of Agreement States is available at the Office of Federal and State Materials and Environmental Management Programs' (FSME) public website, which is located at http://nrc-stp.ornl.gov. As an alternative, request the list from an NRC Regional Office.

3 MANAGEMENT RESPONSIBILITY

NRC recognizes that effective Radiation Safety Program management is vital to achieving safe operations that are in compliance with the regulations.

> "Management" refers to the processes for conduct and control of a Radiation Safety Program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

To ensure adequate management involvement, a management representative must sign the submitted application, acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation safety records and all information provided to NRC (10 CFR 30.9);
- Knowledge about the contents of the license and application;
- Compliance with current NRC and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the Radiation Safety Program to ensure that the public and workers are protected from radiation hazards and that compliance with regulations is maintained;
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) for licensed activities;
- Prohibition against discrimination of employees engaged in protected activities (10 CFR 30.7);
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10, respectively;
- Commitment to obtain NRC's prior written consent before transferring control of the license; and
- Notification of the appropriate NRC Regional Administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of NRC's Enforcement Policy, which is included on NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement.html.

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain up-to-date copies of applicable regulations, read and understand the requirements of each of these regulations, and comply with each applicable regulation. The following Parts of the 10 Code of Federal Regulations (CFR) Chapter I contain regulations applicable to possession for production of radioactive materials using an accelerator:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders";
- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations";
- 10 CFR Part 20, "Standards for Protection Against Radiation";
- 10 CFR Part 21, "Reporting of Defects and Noncompliance";
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material";
- 10 CFR Part 31, "General Domestic Licenses for Byproduct Material";
- 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material";
- 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"; and
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

Part 71 requires that licensees or applicants who transport licensed material or who may offer such material to a carrier for transport comply with the applicable requirements of the DOT that are found in 49 CFR Parts 107, 171 through 180, and 390 through 397. Copies of DOT regulations can be found at http://hazmat.dot.gov/.

- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"; and
- 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC."

Copies of the above documents, may be obtained by calling the Government Printing Office (GPO) order desk in Washington, DC at (202) 512-1800, or online at http://www.bookstore.gpo.gov. A single copy of the above documents may be requested from NRC's Regional Offices (see Figure 2.1 for addresses and telephone numbers). In addition, 10 CFR Parts 1-199 can be found on NRC's website at http://www.nrc.gov/reading-rm/doc-collections/cfr/. Note that NRC and all other Federal agencies publish amendments to their regulations in the Federal Register.

5 HOW TO FILE

5.1 PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application;
- Complete NRC Form 313 (Appendix B) Items 1 through 4, 12, and 13 on the form itself;
- Complete NRC Form 313 Items 5 through 11 on supplementary pages or use the format provided in Appendix C;
- For each separate sheet, other than Appendix C, that is 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 8-1/2 x 11-inch paper;
- Avoid submitting proprietary information unless it is absolutely necessary;
- If submitted, proprietary information and other sensitive information must be clearly identified (see Section 5.2 below);
- Submit an original, signed application and one copy; and
- Retain one copy of the license application for future reference.

As required by 10 CFR 30.32(c), applications must be signed by duly authorized representative; see Section on "Certification."

Using the suggested wording of responses and committing to using the model procedures in this report will expedite NRC's review.

5.2 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

All licensing applications, except for portions containing sensitive information, will be made available for review in NRC's Public Document Room and electronically at the Public Electronic Reading Room. For more information on the Public Electronic Reading Room, visit www.nrc.gov/reading-rm.html.

There are several types of sensitive information which must be identified, marked, and protected against unauthorized disclosure to the public. Key examples are as follows:

- Proprietary Information/Trade Secrets: If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application.
- Private information: Personal information about employees or other individuals should not be submitted unless specifically requested by NRC. Examples of private information are:

social security number, home address, home telephone number, date of birth, and radiation dose information. If private information is submitted, it should be separated from the public portion of the application and clearly marked: "Privacy Act Information - Withhold Under 10 CFR 2.390."

- Security-Related Information: Following the events of September 11, 2001, NRC changed its procedures to avoid release of information that terrorists could use to plan or execute an attack against facilities or citizens in the United States. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, is no longer released to the public. Therefore, sensitive security-related information in an application should be marked as specified in Regulatory Issue Summary 2005-31, available at http:\\www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf. Additional information on procedures and any updates are available at http://www.nrc.gov/reading-rm/sensitive-info.html.

5.3 PAPER FORMAT AND ELECTRONIC FORMAT

NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications in the future. NRC will continue to accept paper applications. However, these will be scanned through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition to electronic applications, applicants should:

- Submit printed or typewritten – not handwritten – text on smooth, crisp paper that will feed easily into the scanner;
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Universe; the text of this document is in a serif font called Times New Roman;
- Use 12-point or larger font;
- Avoid stylized characters such as script, italic, etc.;
- Ensure that the print is clear and sharp; and
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via CD-ROM and through the Internet. Additional filing instructions will be provided as NRC implements these new mechanisms.

When the electronic process becomes available, applicants may file electronically instead of on paper.

6 WHERE TO FILE

Applicants wishing to possess or use licensed material in any State or U.S. territory or possession subject to NRC jurisdiction must file an application with the NRC Regional Office for the locale in which the material will be possessed and/or used. Figure 2.1 shows NRC's four Regional Offices and their respective areas for licensing purposes and identifies Agreement States. Note that all materials license applications are submitted to Regions I, III, or IV. All materials license applicants located in Region II's geographical area should send their applications to Region I.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State, not NRC. However, if work will be conducted at federally controlled sites in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. See the section on "Agreement States" for additional information.

7 LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the licensing action prior to fee receipt. Consult 10 CFR 170.11 for information on exemptions from these fees. Once technical review has begun, no fees will be refunded; application fees will be charged regardless of NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

Direct all questions about NRC's fees or completion of Item 12 of NRC Form 313 to the Office of the Chief Financial Officer (OCFO) at NRC Headquarters in Rockville, Maryland, (301) 415-7554. Information about fees may also be obtained by calling NRC's toll free number (800) 368-5642, extension 415-7554. The e-mail address is fees@nrc.gov.

8 CONTENTS OF AN APPLICATION

The following comments apply to the indicated items on NRC Form 313 (Appendix B).

All items in the application should be completed in enough detail for NRC to determine that the proposed equipment, facilities, training and experience, and Radiation Safety Program satisfies regulatory requirements and are adequate to protect health and minimize danger to life and property. Consideration will be given, when developing the application, to the concepts of keeping exposure as low as is reasonably achievable (ALARA) and the minimization of contamination.

Regarding ALARA, 10 CFR 20.1101(b) states that "The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." ALARA concepts and philosophy are discussed in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable." Applicants for production licenses must address ALARA considerations in all aspects of their programs; e.g., monitoring and controlling external and internal personnel exposure and monitoring and controlling air and liquid effluents. ALARA considerations, including establishing administrative action levels and monitoring programs, need to be documented in the application.

Under 10 CFR 20.1406 license applicants are required to 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. Like ALARA, the applicant must address these concerns in all aspects of its programs.

All information submitted to NRC during the licensing process will be incorporated as part of the license and will be subject to review during inspection.

8.1 ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR (Check appropriate item)

Type of Action	License No.
[ ] A. New License	Not Applicable
[ ] B. Amendment	XX-XXXXX-XX
[ ] C. Renewal	XX-XXXXX-XX

Check A for a new license request.
Check B for an amendment[1] to an existing license, and provide license number.
Check C for renewal[1] of an existing license, and provide license number.

[1] See "Amendments and Renewals to a License" later in this document.

8.2 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 possession and use of the radioactive material. A division or department within a legal entity may not be a licensee; however, a subsidiary of a larger entity may be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the possession and use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address.

Notify NRC of any changes in the mailing address; these changes do not require a fee.

Note: NRC must be notified before control of the license is transferred or when bankruptcy proceedings have been initiated. See below for more details. NUREG-1556, Vol. 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b).

Criteria: Licensees must provide full information and obtain NRC's prior written consent before transferring control of the license, also commonly referred to as "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior NRC written consent. This ensures that:

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

Response from Applicant: None required from an applicant for a new license. For additional information, refer to NUREG-1556, Vol. 15, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated November 2000.

Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h).

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

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. NRC must know when licensees are in bankruptcy proceedings in order to determine whether there are any public health and safety concerns (e.g., contaminated facility). NRC shares the results of its determinations with other involved entities (e.g., trustee) so that health and safety issues can be resolved before bankruptcy actions are completed.

Response from Applicant: None required at the time of application for a new license. Licensees must immediately (within 24 hours) notify NRC following the filing of a voluntary or involuntary petition for bankruptcy for or against the licensee.

Reference: See NUREG-1556, Vol. 15, "Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated November 2000.

8.3 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

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, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. Sketches or street maps indicating the nearest intersection and the location of the proposed facility would be helpful but are not required. A Post Office Box address is not acceptable, as illustrated in Figure 8.1. If licensed material is to be possessed or possessed and used at more than one location, give the specific address of each location. Applicants for a broad-scope license need not identify each facility at a particular address where licensed material will be possessed or possessed and used. For example, broad-scope applicants can specify that licensed material will be possessed or possessed and used on the manufacturing campus of ABC Corporation located on Presidential Avenue in Anytown, State.

Applicants should identify all facilities designed or established for special uses; e.g., interim or long-term waste storage facilities, high-activity laboratories, iodination facilities, alpha laboratories, and incinerators.

A NRC-approved license amendment identifying a new location of possession or possession and use, which is not encompassed by a location described on the existing license, is required before receiving, using, and storing licensed material at that location.

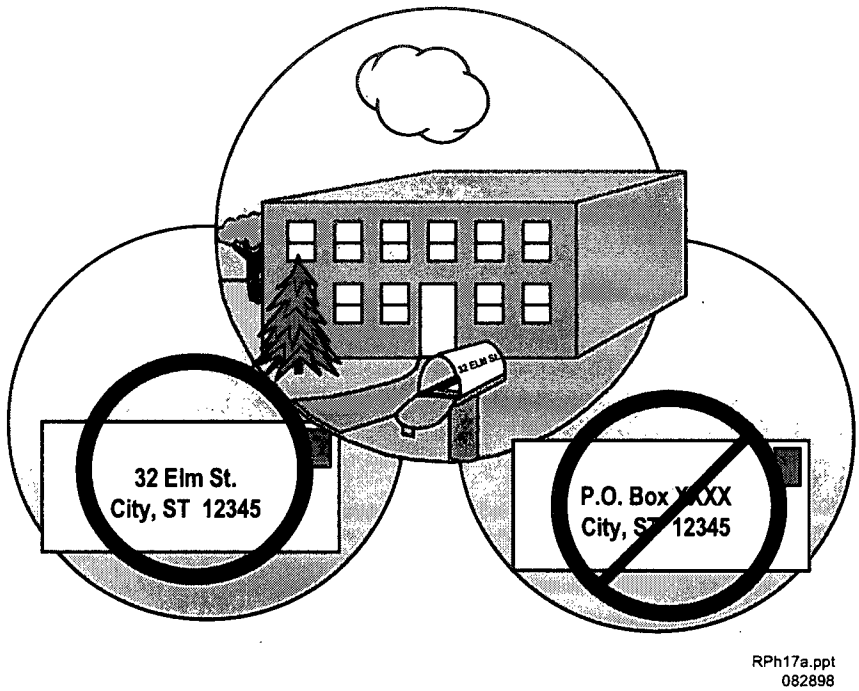


Figure 8.1 Location of Possession and/or Use. *An acceptable location of possession and/or use specifies street address, city, state, and zip code and does not include a Post Office box number.*

A NRC-approved license amendment is required before receiving, using, and storing licensed material at an address or location not listed on the license.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements).

Note: As discussed later under "Financial Assurance and Recordkeeping for Decommissioning," licensees must maintain permanent records of where licensed material was possessed or possessed and 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 licensed material is possessed and used or stored, and any records of spills or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

8.4 ITEM 4: 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 individual, usually the Radiation Safety Officer (RSO), will serve as the point of contact during the review of the application and during the period of the license. If this individual is not a full-time employee of the licensed entity, his or her position and relationship should be specified. No individual other than the duly authorized applicant may, for any licensing matter, act on behalf of the applicant or provide information without the

applicant's written authorization. The NRC should be notified if the person assigned to this function changes or if his or her telephone number changes. Notification of a contact change is for information only and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

8.5 ITEM 5: RADIOACTIVE MATERIAL

8.5.1 UNSEALED AND/OR SEALED BYPRODUCT MATERIAL

Regulations: 10 CFR 30.4, 10 CFR 30.6, 10 CFR 30.11, 10 CFR 30.32, 10 CFR 30.33, 10 CFR 30.34, 10 CFR 30.36, 10 CFR 30.37, 10 CFR 30.38, 10 CFR 32.19, 10 CFR 32.210, 10 CFR Part 51.

Criteria: A specific license is required, describing and authorizing the production and distribution of radioactive materials to persons specifically licensed. Applicants must submit information specifying each radionuclide that will be produced, the form of the radionuclide, and the maximum activity to be possessed at any one time. The list of radionuclides should also include activation radionuclides that are produced during production of the primary radionuclide(s).

For activation radionuclides, the applicant could request authorization to possess and use byproduct material with atomic numbers from 1 through 83. The applicant should indicate the maximum quantity of each radionuclide to be possessed at any one time, and the total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and demonstrated experience. If certain activation radionuclides will be produced in much larger quantities than described in the atomic number 1-83 request, the applicant should list these separately rather than increase the possession limit for all radionuclides. Similarly, if it is known that certain relatively more hazardous activation radionuclides are produced in smaller quantities, they should also be listed separately.

Discussion: Each authorized radioisotope is listed on an NRC license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit), as shown in items 6, 7, and 8 of the sample licenses in Appendix D.

On August 8, 2005, the EPAct gave NRC regulatory authority over additional byproduct material. This new byproduct material includes naturally occurring radionuclides, such as radium-226, and accelerator-produced radionuclides (see 10 CFR 30.4 for a complete definition of byproduct material under the EPAct).

Applicants and licensees should also determine whether they possess or will possess sealed sources or devices, which would include check, calibration, transmission, and reference sources, or unsealed radioactive materials containing this new byproduct material. Applicants must request authorization for possession of these sealed source(s) or device(s).

It should also be noted that NRC's regulatory authority includes the new byproduct material produced prior to August 8, 2005. As a result, neither NRC, nor a Non-Agreement state may have performed a safety evaluation of the sealed sources or devices for this newly defined

material. Therefore, the sealed source or device may not have a Sealed Source and Device Registry (SSDR) certificate. The requirements regarding the application of a specific license for the use of sealed sources or devices containing naturally occurring or accelerator-produced radioactive material are provided in 10 CFR 30.32(g).

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 SSDR Certificate. Information on SSDR certificates is available on NRC's web site at http://www.nrc.gov/materials/miau/ssd/obtain-reports.html 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 NUREG-1556, Vol. 3., Rev. 1, "Applications for Sealed Source and Device Evaluation and Registration."

The applicant should list each requested radioisotope by its element name and its mass number in Item 5 on NRC Form 313. 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 listing activation radioisotopes, the location (e.g., target body or building materials) of the activated material should be indicated under the chemical and/or physical form column.

For unsealed radioactive material, applicants should specify whether radioisotopes that are produced will be in volatile or nonvolatile form, since additional safety precautions are required when handling material in a volatile form. Also, if the facility possesses discrete sources of radium-226, the discrete source should be described, since additional precautions may need to be taken if the source is compromised. Applicants requesting discrete sources of radium-226 and authorization to manipulate volatile radioactive material must describe appropriate facilities and engineering controls as described in Section 8.9, "Facilities and Equipment," and radiation safety procedures for handling of such material in specific responses to Section 8.10.4, "Occupational Dose"; Section 8.10.5, "Public Dose"; Section 8.10.6, "Safe Handling of Radionuclides and Emergency Procedures"; and Section 8.10.7, "Surveys and Leak Tests."

The applicant should also request authorization to possess depleted uranium if it will be used for shielding purposes. Depleted uranium is frequently used as shielding for molybdenum-99/technetium-99m generators when the molybdenum-99 activity is greater than 148 gigabecquerels (4 curies). 10 CFR 40.13(c)(6) 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 NRC is needed to possess and use the depleted uranium as a shield during the time that the applicant may use or store the generator at its facility. The applicant should specify the total amount of depleted uranium, in kilograms, that will be needed.

The anticipated possession limit in becquerel (Bq) or curie (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 the Section on Financial Assurance and Decommissioning.

Response from Applicant:

For unsealed materials:

- Provide an element name with mass number, chemical and/or physical form, and a maximum requested possession limit for each radionuclide produced. For listing activation radioisotopes, the location (e.g., target body or target foil) of the activated material should be indicated under the chemical and/or physical form column.
- Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored, and waste materials.

Note: For activation radionuclides, the applicant may request authorization to possess and use any form of byproduct material with atomic numbers 1 through 83. However, the applicant should indicate the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.

For potentially volatile materials (e.g., I-123):

- Specify whether the material will be free (volatile) or bound (nonvolatile) and the requested possession limit for each form.

For sealed radioactive materials and discrete sources of radium-226:

- Identify each radionuclide (element name and mass number) that will be used in each source;
- Provide the manufacturer's (distributor's) name and model number for each sealed source and device and discrete source of radium-226 requested;
- Confirm that each sealed source, device, source/device combination, and discrete source of radium-226 is registered as an approved sealed source, device or discrete source by NRC or an Agreement State;
- Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State; and
- If the above information cannot be provided for the discrete source of radium-226, describe the discrete source.

Note:

- Licensees who request a possession limit in excess of the quantities specified in 10 CFR 30.72, must submit an emergency plan, as specified in 10 CFR 30.32(I).

- For depleted uranium, specify the total amount (in kilograms).
- When responding to this section, licensees should follow the guidance in Section 5.2 to determine if their response includes sensitive security-related information and needs to be marked accordingly.

8.5.2 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Regulations: 10 CFR 30.35, 10 CFR 30.34(b).

Criteria: A licensee authorized to possess radioactive material in excess of the limits specified in 10 CFR 30.35 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 10 CFR 30.35(g), licensees must transfer records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned according to 10 CFR 30.34(b); or
- The appropriate NRC regional office before the license is terminated.

Discussion: NRC wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment (53 FR 24018). Most accelerator production facilities will be required to comply with the financial assurance requirements because of the activation materials that are produced during operation.

NRC regulations requiring a DFP or FA are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee, through a third party, that funds will be available. Applicants are required to submit a DFP or FA when the possession of radioactive material of half-life ($T_{1/2}$) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a DFP or has an option of submitting either a DFP or FA (or neither) are stated in 10 CFR 30.35. A DFP contains a site-specific cost estimate and a certification of financial assurance. A Certification of Financial Assurance includes a certification that the licensee has provided the required financial assurance and an acceptable financial assurance instrument.

NUREG-1757, Vol. 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," dated September 2003, provides guidance acceptable to NRC staff on the information (see Figure 8.2) to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information.

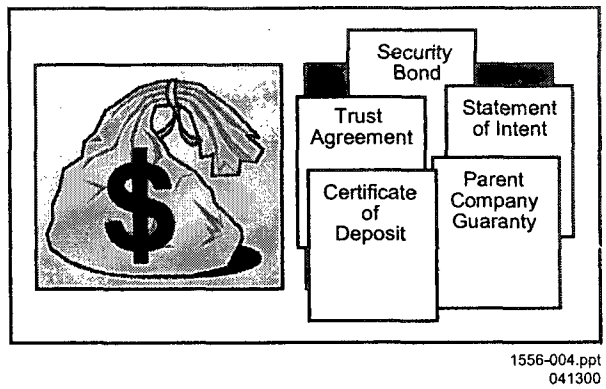


Figure 8.2 Financial Assurance for Decommissioning. *Most licensees that possess and operate an accelerator will need to provide financial assurance for decommissioning. Large manufacturers may need one of several approved financial mechanisms.*

The requirements for maintaining records important to decommissioning, including the type of information required, (see Figure 8.3) are stated in 10 CFR 30.35(g). All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee prior to transfer of the licensed activities. The new licensee is responsible for maintaining these records until the license is terminated. Careful recordkeeping of radionuclides possessed and used, including form, amount, and area used, will facilitate area release and license termination.

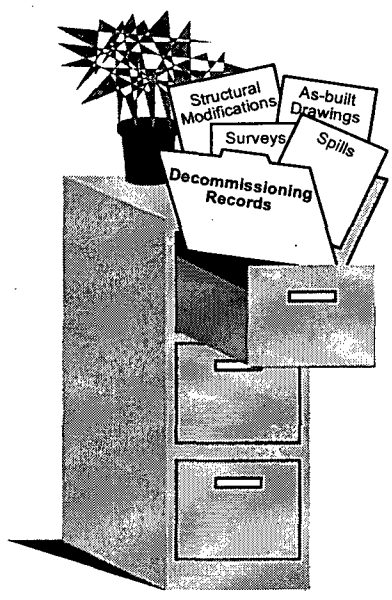


Figure 8.3 Records Important to Decommissioning. *All possession for production and distribution licensees must maintain records important to decommissioning, regardless of whether they need financial assurance for decommissioning.*

Response from Applicants: If a DFP or FA is required, submit the required documents as described in NUREG-1757, Vol. 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," dated September 2003.

8.6 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Regulations: 10 CFR 30.33(a)(1), 10 CFR 30.4.

Criteria: For this license, the materials will be produced by an accelerator and transferred or distributed to another license for use. The radioactive material produced will be possessed and possibly stored. Also, the activated products will be handled during maintenance, repair and disposal activities.

Discussion: Applicants should specify that the radioactive material requested in Item 5 will be possessed and/or stored incident to production by an accelerator in accordance with the regulations. Applicants may use the format given in Table 8.1 to provide the requested information. Once material is produced, it will be transferred internally to another license or it will be distributed to another licensee that will use the produced material to manufacture the final product. The produced radioactive material can be transferred or distributed to the following types of licenses:

- Manufacturing and distribution license;
- Commercial radiopharmacy license;
- Broad-scope license;
- Limited-scope license; and
- Medical use license (e.g., noncommercial radiopharmacy).

For more information on applying for these types of licenses, refer to the following NUREG-1556 guidance reports:

- For a manufacturing and distribution license, refer to NUREG-1556 Vol. 12, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution";
- For a commercial radiopharmacy license, refer to NUREG-1556 Vol. 13 Rev.1, "Program-Specific Guidance About Commercial Radiopharmacy Licenses";
- For a broad-scope license, refer to NUREG-1556 Vol. 11, "Program-Specific Guidance About Licenses of Broad Scope";
- For a limited-scope license, refer to NUREG-1556 Vol. 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers"; and
- For a Medical Use License, refer to NUREG-1556 Vol. 9, Rev. 2, "Program-Specific Guidance About Medical Use Licenses."

As defined in 10 CFR 30.4, a consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own and share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distribution among its associated members for medical use. Furthermore, the PET radionuclide production facility within the consortium must be located at an educational institution, Federal facility, or a medical facility. If the applicant is a member of a consortium, and plans to produce and noncommercially distribute PET radioactive drugs to medical use licensees within the consortium, the applicant will also need to request an authorization to perform these activities as part of the possession license application. Specific guidance for applicants requesting authorization for the production and noncommercial distribution of PET radioactive drugs to medical use licensees in a consortium can be found in Appendix P of this document.

Table 8.1 Sample Format for Providing Information About Requested Radioisotopes.

Radioisotope	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
Fluorine-18	Any	20 Curies	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Indium-111	Any	1 Curie	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Thallium-201	Any	1 Curie	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Iodine-123	Unbound/volatile	100 millicuries	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Pd-103	Any	50 Curies	Production and possession of a sealed source for transfer or distribution to authorized licensees.
Germanium-68	Sealed source, Mfg. name & model number	10 microcuries per source and 50 millicuries total	Calibration and check of instruments
Cobalt-60	Target Foils	50 millicuries	Possession and storage incident to production activities
Maganese-54	Target Body	100 millicuries	Possession and storage incident to production activities
Cadmium-109	Target Body	100 millicuries	Possession and storage incident to production activities
Any byproduct material with atomic numbers 1 through 83	Activated Components associated with equipment and/or shielding/building	Not to exceed 20 millicuries per radionuclide and 1 curie total, except as noted	Possession and storage incident to production activities

Response from Applicant: For accelerator-produced radionuclides, applicants should state that radioactive materials will be possessed and stored incident to their production by an accelerator in accordance with the regulations. For sealed sources that are not produced, specify their proposed use (e.g., calibration of instruments). Use of the format in Table 8.1 will facilitate the review of the application.

8.7 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

Regulation: 10 CFR 30.33(a)(3).

Criteria: Executive management, the RSO (and his/her staff, as necessary), and users work as a team to implement the Radiation Safety Program. Each individual plays a critical role within his or her area of responsibility. The roles and responsibilities of executive management, the RSO, the RSO's staff, users, and others in restricted areas are discussed in the sections that follow. Refer to the subsequent sections specific to the RSO and individuals authorized to handle licensed material described below.

Discussion: Individuals must be qualified by training and experience to possess and use the material for the purpose(s) requested in a manner that will protect health and minimize danger to life or property before an application for a license is approved.

Each program in which radioactive materials are possessed and used under a Commission license will have someone responsible for radiation safety and compliance with the Commission's regulations. The individual's training and experience must be commensurate with his or her duties and responsibilities. Supporting staff should be provided, as appropriate, for the size and scope of the program. A Radiation Safety Program for a production facility may consist of some or all of the following characteristics:

- The need for accurate detection, identification, and measurement of radioactivity in various types of effluents (gas, liquid, solid) containing varying amounts of different radionuclides and for evaluation of these effluents against NRC regulatory requirements and limitations;
- The need for radioactive effluent treatment by filtration, absorption, adsorption, holdup;
- The need for the selection, evaluation, design, maintenance, and use of radioactive effluent treatment systems;
- The need for the selection, evaluation, and maintenance of radiation measurement and analysis equipment; and/or
- A potential for the contamination of facilities, equipment, and personnel, accompanied by the need to control such contamination (including airborne contamination), decontaminate personnel and equipment, and evaluate possible internal dose (including determination of the need for bioassays and interpretation of bioassay results).

NRC holds the licensee responsible for the Radiation Safety Program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted safely. Management responsibility and liability are sometimes under-emphasized or

not addressed in applications and are often poorly understood by licensee employees and managers. As discussed later in this guide, senior management will delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions and to terminate unsafe activities involving byproduct material. Other responsibilities will be delegated to other individuals. Such delegations should be clearly communicated to all parties. While these delegations are important to the operation of the program, the licensee senior management maintains the ultimate responsibility for the safety 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.

8.7.1 RADIATION SAFETY OFFICER

Regulation: 10 CFR 30.33(a)(3).

Criteria: RSOs must have training and specific experience with the types and quantities of licensed material to be authorized on the license.

Discussion: The person responsible for implementing the Radiation Safety Program is the RSO. This individual may also be called the Radiation Protection Officer. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are possessed and used in a safe manner. Typical RSO duties are illustrated in Figure 8.4 and described in Appendix E. NRC requires the name of the RSO to be listed on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

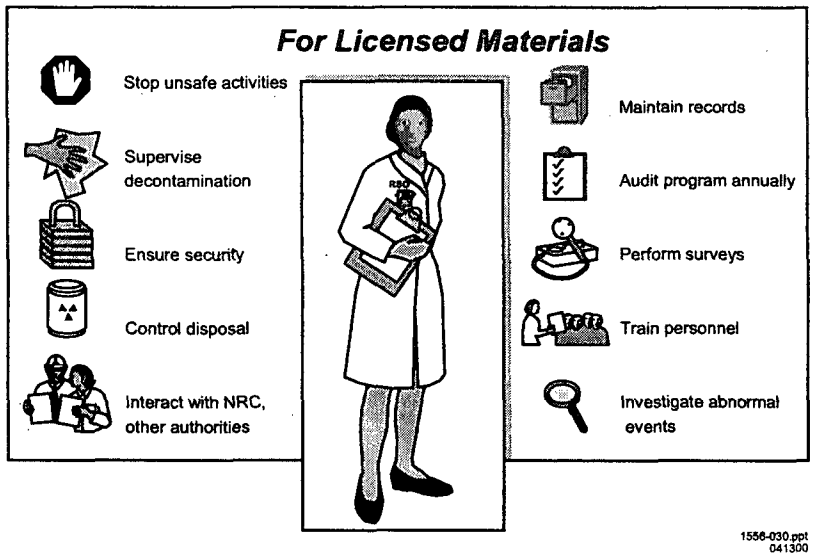


Figure 8.4 RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

To demonstrate adequate training and experience at a production facility, it is recommended that the RSO have: (1) at 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 Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of licensed material to be possessed and used);
- NRC Regulatory Requirements and Standards; and
- Handling of Radioactive Materials in Relation to Production Activities (e.g., maintenance and repair of the accelerator).

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree, RSOs at accelerator facilities where workers may handle curie quantities of radioactive material should be specialists in the field of radiation protection and may need at least 40 hours of radiation safety training specific to their job duties as well as a year of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be RSO. The proposed RSO's training and experience must be sufficient to identify and control the anticipated radiation hazards. For example, the RSO should have experience planning and

conducting evaluations, surveys, and measurements similar to those required by the licensee's Radiation Safety Program. In addition, the RSO designee should have obtained the above training in a formal course designed for RSOs, presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts.

Response from Applicant: Provide the following:

- Name of the proposed RSO; and
- Information demonstrating that the proposed RSO is qualified by training and experience.

Applicants should provide information about the proposed RSO's training and experience relative to the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, social security number, date of birth, and radiation dose information). Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, and personal private information. Submittal of unrelated material may delay the review process.

Note: It is important to notify NRC, as soon as possible, of changes in the designation of the RSO. The name and qualifications of the replacement RSO should be submitted to NRC as part of an amendment request.

8.7.2 INDIVIDUALS AUTHORIZED TO HANDLE LICENSED MATERIAL

Regulations: 10 CFR 19.12, 10 CFR 20.1101(b), 10 CFR 30.33(a)(3).

Criteria: Individuals authorized to handle licensed material must have adequate training and experience with the types and quantities of licensed material that they propose to possess and handle.

Discussion: Applicants must name at least one individual who is qualified to handle the requested licensed materials. For a production license, handling of licensed materials includes, for example, the processing of radiochemicals and the handling or manipulation of activated targets and/or components. An individual who is authorized to handle licensed material is a person whose training and experience have been reviewed and approved by NRC, who is named on the license, and who uses or directly supervises the use of licensed material. This individual's primary responsibility is to ensure that radioactive materials are handled safely and according to regulatory requirements. The individual is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

Individuals authorized to handle licensed material must have adequate and appropriate training to provide reasonable assurance that they will handle licensed material safely, including

maintaining security of, and access to, licensed material, and respond appropriately to events or accidents involving licensed material to prevent the spread of contamination.

To demonstrate adequate training and experience at an accelerator facility, the authorized individual should have: (1) a college degree at the bachelor level, or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities such as handling of activated targets and activated products associated with accelerator activities. Training should include the following subjects:

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Unites of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of byproduct material to be used); and
- Handling of Radioactive Materials Relevant to Accelerator Activities.

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree or equivalent experience, an authorized individual at a production facility who may handle Curie quantities of radioactive material should have at least 40 hours of radiation safety training specific to his or her job duties as well as a minimum of 6 months of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be authorized to handle licensed material. In general, authorized individuals should demonstrate training and experience with the type and quantity of material they propose to handle. For example, an individual with training and experience only with sealed radioactive sources might not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities of radioactive materials may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with low-energy beta emitters may not have appropriate experience for high-energy gamma emitters.

An individual who is authorized to handle licensed material is considered to be supervising the handling of radioactive materials when he or she directs personnel in activities involving licensed material. Although the authorized individual may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), the authorized individual is responsible for the safe handling of radioactive material to assure that areas are not contaminated.

Note that accelerator manufacturers or companies that provide repair and/or maintenance service to licensed accelerator facilities may need to possess an NRC service provider license or equivalent Agreement State license. In particular, this would be required when individuals (e.g., service engineers) perform certain maintenance and repair activities that involve the handling of radioactive materials (e.g., activated targets or components) during the accelerator maintenance

and repair activities. For guidance on how to apply for an NRC service provider license see NUREG-1556, Vol. 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses." For guidance on how to work under an Agreement State license while in NRC jurisdiction, refer to NUREG-1556, Vol. 19, "Guidance for Agreement State Licensees About NRC Form 241 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters' and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)."

Response from Applicant: Provide the following:

- Name of each proposed individual with the types and quantities of licensed material to be possessed and handled; and
- Information demonstrating that each proposed individual is qualified by training and experience to possess and handle the requested licensed materials.

Applicants should provide information about the proposed authorized individual's training and experience relative to the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, social security number, date of birth, and radiation dose information). Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, and personal privacy information. Submittal of unrelated material may delay the review process.

Note: Applicants for broad-scope programs should refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope." Broad-scope programs may be permitted to name authorized individuals without amending the license.

8.8 ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Regulations: 10 CFR 19.12, 10 CFR 30.33(a)(3).

Criteria: Individuals whose assigned duties involve exposure to radiation and/or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), whether from all external sources, all internal sources, or any combination, must receive instruction commensurate with potential radiological health protection problems present in the work place, as required by 10 CFR 19.12.

Discussion: Before beginning work with licensed material, individuals should receive radiation safety training commensurate with their assigned duties and specific to the licensee's Radiation Safety Program. Each individual should also receive periodic refresher training at no more than 12-month intervals. Training should also be performed whenever there is a significant change in hazards, duties, procedures, regulations, or terms of the license.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and it should emphasize practical subjects important to the safe possession and use of licensed material. If training is not conducted by an instructor, a method should be adopted whereby a trainee can ask questions and discuss topics relating to occupational radiation exposure. The guidance in Appendix F, "Radiation Safety Training Topics," may be used to develop a training program. The program should consider all topics pertinent for each group of workers as well as the method and frequency of training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program).

Response from Applicant: Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.

8.9 ITEM 9: FACILITIES AND EQUIPMENT

Regulations: 10 CFR 20.1101(b), 10 CFR 20.1406, 10 CFR 30.3, 10 CFR 30.33(a)(2), 10 CFR 30.35(g).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. Licensee must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

Discussion: Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the uses of the types and quantities of radioactive materials to be used.

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 may not 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 include the following:

- As-built drawings and modifications of structures and equipment in restricted areas;
- As-built drawings and modifications of locations of possible inaccessible contamination such as buried pipes or transfer lines that may be subject to contamination; and
- Records of spills and unusual occurrences that may result in contamination of the facility or site.

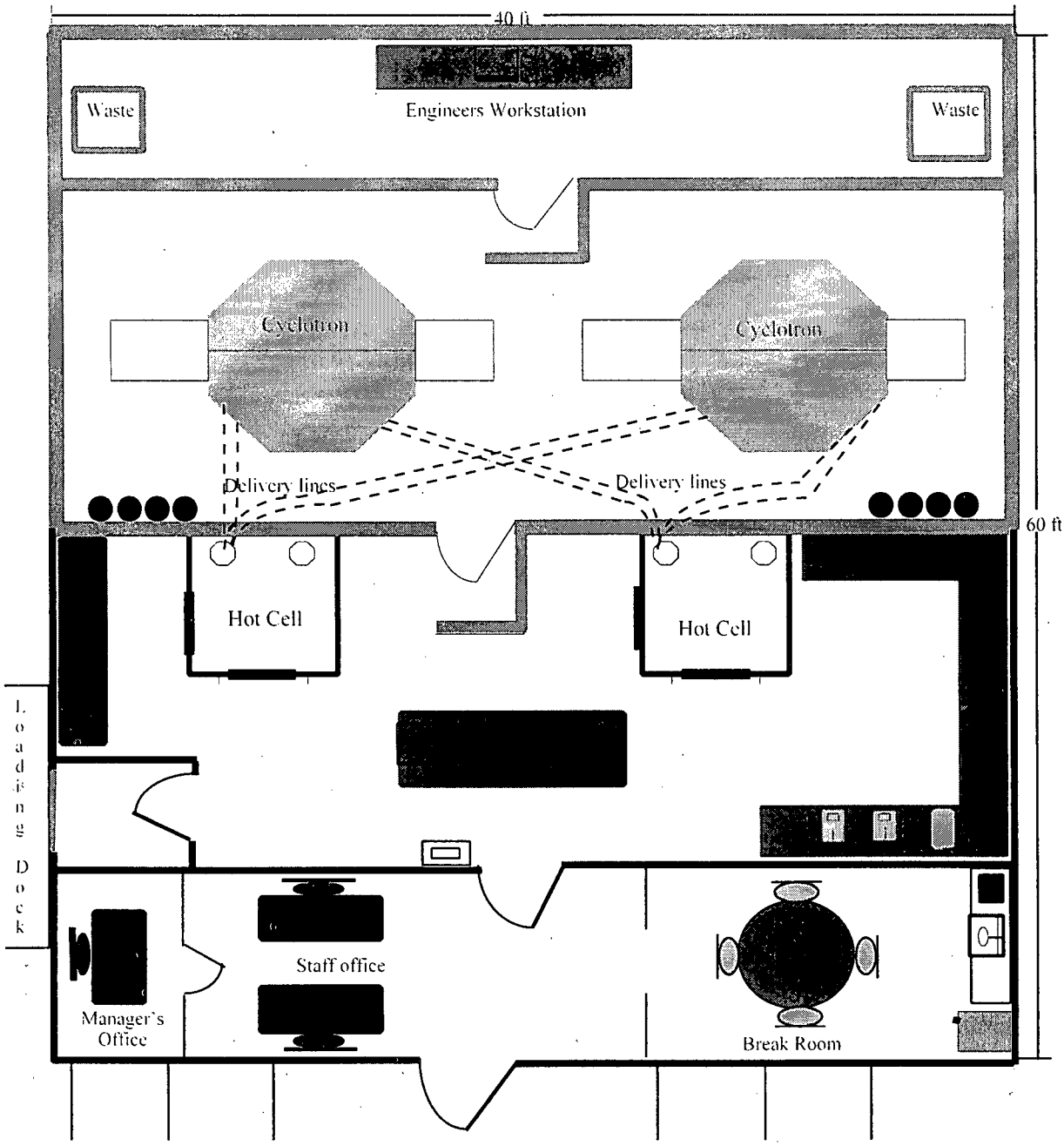
These records are required to be maintained in an identifiable location. Facilities are required to meet NRC criteria prior to release. Therefore, careful facility design is important to prevent contamination, or facilitate decontamination, reducing the costs needed for decommissioning. For further information, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

For additional guidance regarding facilities and equipment, refer to Appendix G, Facilities and Equipment.

Response from Applicant: Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, and/or used (see Appendix G for topics to consider). Include the following information:

- A description of the accelerator, which includes the name of the manufacturer, model accelerator energy, maximum current, type of targets, and type of shielding materials. Note that this information will assist the license reviewer in understanding the types of materials and activation products that could be produced and the maximum quantity of radioactive material that could be produced and will not be incorporated into the license as a license condition;
- A description of the areas assigned for the production, which includes transfer of produced material, storage, preparation, shipping, security, and measurement of radioactive materials;
- A description and diagrams that show the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety (see Figures 8.5 and 8.6);
- A diagram and a description of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne; and
- Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d).

SECURITY-RELATED INFORMATION - WITHHOLD UNDER 10CFR 2.390*



SECURITY-RELATED INFORMATION - WITHHOLD UNDER 10CFR 2.390*

* For the purposes of this NUREG, this diagram is marked appropriately for an application. This particular diagram does not contain real security-related information.

Figure 8.5 Facility Diagram for a Radioactive Materials Production Facility.

Note: When responding to this section, applicants should follow the guidance in Section 5.2 to determine if their response includes sensitive security-related information and needs to be marked accordingly.

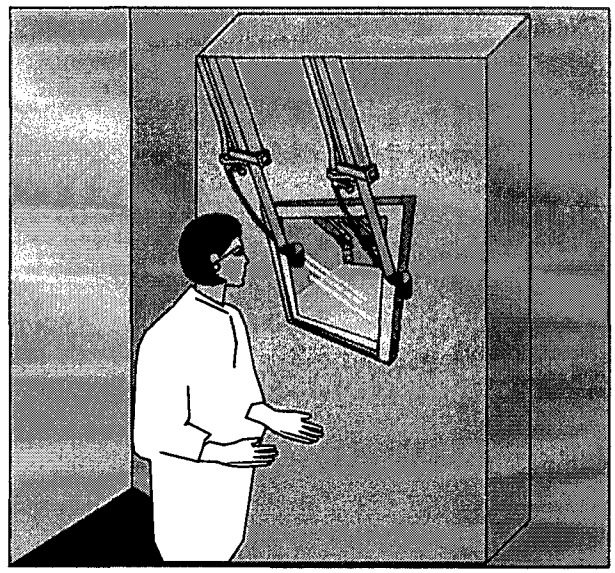


Figure 8.6 Shielded Protective Enclosure (Hot Cell) With Remote Manipulators.

8.10 ITEM 10: RADIATION SAFETY PROGRAM

8.10.1 AUDIT PROGRAM

Regulations: 10 CFR 19.11, 10 CFR 19.12, 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1501(c), 10 CFR 20.1902, 10 CFR 20.1904, 10 CFR 20.1906, 10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2108, 10 CFR 20.2101-2104, 10 CFR 20.2106, 10 CFR 21.6, 10 CFR 21.21(a), 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51.

Criteria: Licensees must review the content and implementation of their Radiation Safety Programs at least annually.

Discussion: It is in the best interest of licensees to have a strong audit program to ensure:

1. Compliance with NRC and DOT regulations and the terms and conditions of the license;

2. Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101) and dose reduction efforts have been considered; and

3. Operating procedures are in place for activities that could potentially affect radioactive material or occupational dose (10 CFR 20.1101(a)).

An audit program that promptly identifies potential violations of regulatory requirements and takes prompt, comprehensive steps to correct them, meets NRC's expectations. Elements of an effective audit program are described below.

Audit Objectives. NRC holds the licensee responsible for the Radiation Safety Program. It is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Audits may be used by licensees to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take early corrective actions (before an NRC inspection). The objectives of the audit should include an evaluation of the licensees': (1) efforts to maintain doses ALARA; (2) compliance with NRC requirements; (3) ability to identify and correct deficiencies in their Radiation Safety Program; (4) management of the Radiation Safety Program including the role of senior management and the RSO; and (5) implementation of the Radiation Survey Program.

Scope of Audit. Audits should cover both the management of the Radiation Safety Program and the details of its implementation in the areas chosen for review. Mechanisms used by senior management to ensure that adequate oversight of the program is exercised should be included in the scope of the audit.

Auditor Qualifications. Auditors should have training and experience similar to that of an individual authorized for the types, forms, uses, and quantities of radioactive material used in the areas audited. Auditors should not be selected from the staff of areas to be audited, nor their management. Ideally, auditors are third parties, from independent organizations.

Audit Frequency. Audits should be conducted at least once every 12 months. However, it is recommended that program audits be conducted more frequently than annually if the licensee's activities involve the use of high-activity materials or frequent handling of intermediate activity materials. Applicants should consider developing survey and audit schedules based on activity and use (e.g., high-use/activity areas may be audited monthly, moderate-use/activity areas may be audited quarterly). More frequent audits should be considered if the potential for overexposures exists.

Audit Techniques. While documentation should be reviewed during any audit of a Radiation Safety Program, emphasis should be placed on actual observations of work in progress. Applicants should consider performing unannounced audits of radioactive material users to observe work in progress and determine if, for example, operating and emergency procedures are available and are being followed. Radiation safety audits should include activities conducted during all shifts. Some details of typical audit techniques follow:

- **Audit History.** Note the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.
- **Organization and Scope of Program Area Audited.** Give a brief description of the organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the RSO is the person identified in the license and fulfills the duties specified in the license.

- **Training, Retraining, and Instructions to Workers.** Ensure that workers have received the training required by 10 CFR 19.12. Be sure that, before being permitted to use byproduct material, the user has received training and has a copy of the licensee's operating and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments and that all shift workers are included. By interview and/or observation of selected workers, ensure that each has a copy of the licensee's procedures and can implement them properly. Special attention should be directed to the adequacy of training and observation of new employees performing their radioactive material duties.
- **Facilities.** Verify that the facilities are as described in the license documents.
- **Materials.** Verify that the license authorizes the quantities and types of byproduct material that the licensee possesses.
- **Leak Tests.** Verify that all sealed sources are tested for leakage at the prescribed frequency and in accordance with licensee commitments. Records of results should be maintained.
- **Inventories.** Verify that inventories are conducted at least once every 6 months to account for all sources; inventory records should be maintained.
- **Radiation Surveys.** Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are calibrated (at the required frequency) in accordance with license conditions and survey records are in accordance with 10 CFR 20.2103. Calibration records must be retained for 3 years after the record is made. Check that radiation levels in areas adjacent to use areas are within regulatory limits. Verify compliance with 10 CFR 20.1301 for dose limits to the public. Records of surveys must be retained for 3 years after the record is made.
- **Production Activities.** Verify that used accelerator parts (e.g., targets, o-rings) and other activated products are properly stored and shielded. Also, verify that maintenance/repair logs are maintained and accurate.
- **Transfer of Radioactive Material (Includes Waste Disposal).** Ensure that transfers are performed in accordance with 10 CFR 30.41. Records of surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103, and 10 CFR 30.51.
- **Transportation.** Determine compliance with DOT requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with 49 CFR Parts 172 and 173 requirements. Verify that shipping papers are prepared, contain all needed information, and are readily accessible during transport (49 CFR 172.200-204 and 177.718).
- **Personnel Radiation Protection.** Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10% of the allowable limits. Alternatively, if personnel dosimetry is provided and required, verify that it complies with 10 CFR 20.1501(c) and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. The licensee is also responsible for ensuring that dosimetry results are assigned accurately and should consider that the assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. Therefore, if possible, whole body and extremity dosimeters should be placed in the areas that receive the highest exposure. An evaluation should be performed to determine if the maximum dose to a part of the whole body or an extremity may be substantially higher than

the dose measured by the dosimeter. If the evaluation indicates that the maximum dose to a part of the whole body or extremity is higher than that measured by the dosimeter, the higher dose will be used as the dose of record (see Section 8.10.4). If any worker declared her pregnancy in writing, evaluate compliance with 10 CFR 20.1208. Check whether records are maintained as required by 10 CFR 20.2101-2104 and 20.2106.

- **Auditor's Independent Measurements.** The auditor should make independent survey measurements and compare the results with those made or used by the licensee. Survey measurements should include engineer's workstation, waste/storage locations, and other shielded locations/equipment.
- **Notification and Reports.** Check for compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, 21, and 30. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center; (301) 816-5100.
- **Posting and Labeling.** Check for compliance with the posting and labeling requirements of 10 CFR 19.11, 10 CFR 20.1902, 10 CFR 20.1904, and 10 CFR 21.6.
- **Recordkeeping for Decommissioning.** Check to determine compliance with 10 CFR 30.35(g).
- **Bulletins and Information Notices.** Check to determine if such notifications as bulletins, information notices, and newsletters are received from NRC. Check whether appropriate actions were taken in response to NRC mailings.
- **Special License Conditions or Issues.** Verify compliance with any special conditions in the license. If there are any unusual aspects of work, review and evaluate compliance with regulatory requirements.
- **Recommendations.** List any recommendations to improve the overall efficiency and effectiveness of the audit and Radiation Safety Program.
- **Evaluation of Other Factors.** Evaluate management's involvement with the Radiation Safety Program, whether the RSO has sufficient time to perform his/her duties, and whether there is sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Problems or Deficiencies Noted. The licensee should have a process for correcting violations and deficiencies during and after the audit. The licensee should identify the safety significance of each violation to set priorities and identify resources to correct these violations. Results of the audit program reviews should be reported to senior management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with NRC regulations and licensee conditions. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to NRC. Licensees are encouraged to contact NRC for guidance if they are uncertain about a reporting requirement. All audit findings and corresponding corrective actions, whether from internal, state, or Federal audit findings, should be communicated to the staff for review and added to new and refresher radiation safety training sessions. If the findings represent a significant safety impact to the staff, special training sessions may be appropriate.

Records to be Maintained: Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. Audit records should contain the following information: 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. These records must be maintained for inspection by NRC.

Response from Applicant: No response is required. The licensee's program for auditing its Radiation Safety Program will be reviewed during inspection.

8.10.2 RADIATION MONITORING

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2).

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:

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

For the purposes of this document, radiation monitoring instruments are defined as any device used to measure the radiological conditions, which include licensed and non-licensed (e.g., accelerator operation) activities, 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;
- Area monitors;
- Single or multichannel analyzers (MCA);
- Liquid scintillation counters (LSC);
- Gamma counters;
- Proportional counters;

- Stack monitors;
- Solid state detectors;
- Neutron detectors; and
- Hand and foot contamination monitors.

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.). Figure 8.7 illustrates some common survey instruments used for contamination surveys. Applications should include descriptions of the instrumentation available for use and the instrumentation that applicants intend to purchase prior to starting licensed activities. The description should include type of instrument and probe, and the instrument's intended purpose.

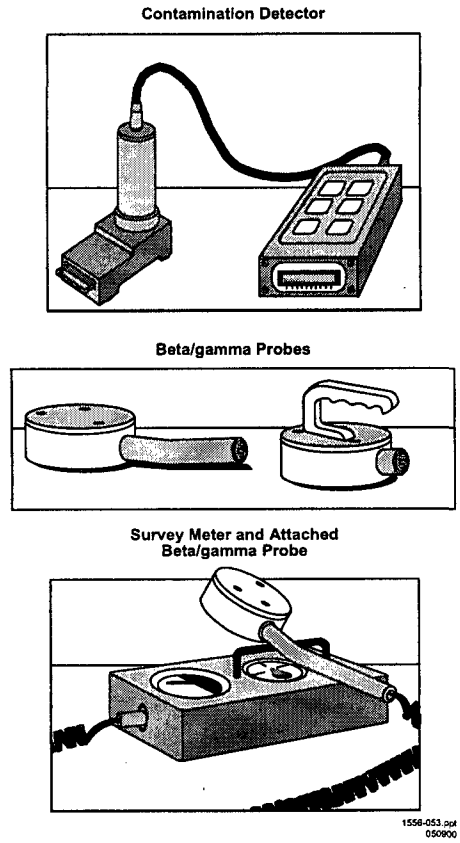


Figure 8.7 Examples of Portable Instruments Used in Laboratory Settings.

Instruments used for qualitative surveys are only intended to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without performing a calibration with appropriate radioactive sources, as described in Appendix H, "Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program."

Instrument calibrations should be performed by the instrument manufacturer or a person specifically authorized by NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations should submit procedures for review. Appendix H provides information about instrument specifications and model calibration procedures. Applicants should be aware that calibrations often require possession and use of a calibration source or device. Instruments for counting smear wipes to detect contamination and/or leakage need calibration sources that may be listed on the production license.

Response from Applicant: Provide one of the following:

A description of the instrumentation (as described above) that will be used to perform required surveys, and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H to NUREG-1556, Vol. 21, 'Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator', dated May 2007."

OR

A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer's license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others.

AND

A description of the instruments used to quantitatively measure the radioactivity in the products and process, and the procedures followed to ensure accuracy of those measurements.

Note: Alternative responses will be reviewed using the criteria listed above.

8.10.3 MATERIAL ACCOUNTABILITY

Regulations: 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2102, 10 CFR 20.2201, 10 CFR 30.41, 10 CFR 30.51.

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

Discussion: As illustrated in Figure 8.6, licensed materials must be tracked from production 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 may exercise control over licensed material accountability by including the following items:

- Physical inventories of sealed sources at intervals not to exceed 6 months;
- Maintaining material inventory within license possession limits;

- Maintaining records of transferred and distributed materials; and
- Maintaining records of disposed material (e.g., waste records).

Licensees must secure and control licensed material and should have a means of promptly detecting losses of licensed material. 10 CFR 20.1801 and 20.1802 require licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed 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 D). 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 licensed material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for production, use, transfer, disposal, and radioactive decay. These methods help to ensure that possession limits are not exceeded.

Table 8.2 list the types and retention times for the records the applicant must maintain of production, use, transfer, and disposal (as waste) of all licensed material. Other records such as transfer records could be linked to radioactive material inventory records.

Table 8.2 Record Maintenance

Type of Record	How Long Record Must be Maintained
Production	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until NRC 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 byproduct 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 licensed materials disposed of as waste, 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 10 CFR 30.35(g). See also the section on "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant: Provide the following statements:

"We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that:

- license possession limits are not exceeded;
- licensed material in storage is secured from unauthorized access or removal;
- licensed material not in storage is maintained under constant surveillance and control; and
- records of production, transfer, and disposal of licensed material are maintained";

AND

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

8.10.4 OCCUPATIONAL DOSE

Regulations: 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.2106, 10 CFR Part 20 Appendix B.

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, which may be received from licensed and non-licensed (e.g., accelerator operation) activities, 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 Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses, dated July 1992."

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:
  - 1.0 mSv (0.1 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 one year an intake in excess of 10% of the applicable annual limit on intake (ALI) for ingestion and inhalation; and
  - Minors and declared pregnant women likely to receive in one year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

If an individual is likely to receive in one year a dose greater than 10% of any applicable limit (see Figure 8.8 for annual dose limits for adults), monitoring for occupational exposure is required. When working at an NRC-licensed facility, in addition to exposure to material regulated by NRC, a worker may be exposed to radiation (e.g., radiation emitted by accelerators) that is regulated by the State in which the facility is located. With respect to NRC regulation of activities at the facility, State-regulated sources of radiation and radioactive material are considered to be "unlicensed." An occupational dose includes the dose received by individuals in the course of their employment (see 10 CFR 20.1003), including exposure to radiation and to radioactive material from licensed and "unlicensed" sources of radiation, whether in the possession of the licensee or other person. Therefore, authorized individuals and other radiation workers at a production facility are generally likely to receive 10% of the limits for an occupational dose.

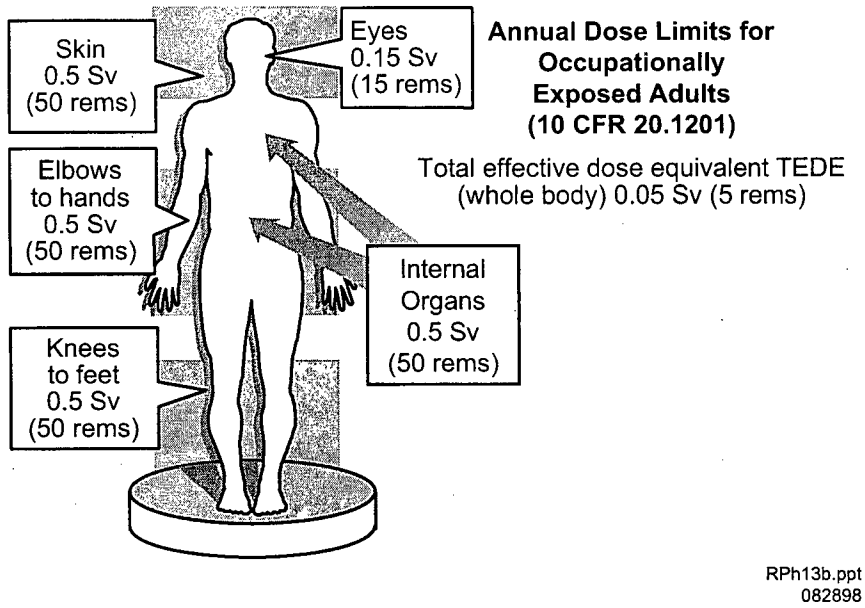


Figure 8.8 Annual Dose Limits for Occupationally Exposed Adults.

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

Most licensees use either film badges, thermoluminescent dosimeters (TLDs), or Optically-Stimulated Luminescence (OSL) dosimeters that are supplied by a processor approved by the National Voluntary Laboratory Accreditation Program (NVLAP) to monitor for external exposure. 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. For individuals that handle licensed material at production facilities, extremity and whole body dosimeters should be worn. It is recommended that extremity and whole body dosimeters be exchanged at least monthly. Also, for individuals that will handle PET radionuclides or other radionuclides that emit high energy gammas/photons, it is recommended that extremity dosimeters be exchanged at least bi-weekly and a pocket or alarming dosimeter, which provides a real-time dose estimate, be used in addition to the individual's personal whole body dosimeter.

Workers are typically monitored for a year or more to determine an actual annual dose. The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be reevaluated if there are changes to the licensee's program, such as procedures, frequency of use, quantity of licensed material used, or isotopes used. The licensee should also consider a more frequent exchange of dosimeters when employees start a new job function, so that their doses can be closely monitored when they are performing unfamiliar tasks. In addition, see Appendix L, "Radiation Safety Survey Topics" for information on bioassay monitoring for internal exposure assessment. Routine bioassays should be performed when volatile radioactive material (e.g., I-123) is produced and/or handled. Note that

Table 8.3 below provides a list of other guidance documents that provide information on personnel monitoring and bioassay procedures.

Table 8.3 Documents That Contain Guidance Relating to Personnel Monitoring and Bioassay That May Be Applicable.

Regulatory Guide 8.7, Revision 1	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20	Applications of Bioassay for I-125 and I-131
Regulatory Guide 8.21	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.23	Radiation Safety Surveys at Medical Institutions
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Doses
Regulatory Guide 8.35	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
Regulatory Guide 8.37	ALARA Levels for Effluents from Materials Licensees
NUREG-0938	Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure
NUREG-4884	Interpretation of Bioassay Measurements
ANSI N13.30-1996	"Performance Criteria for Radiobioassay," dated 1996
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain written procedures for monitoring occupational doses that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.2106, as applicable."

Note:

- Alternative responses will be evaluated using the criteria listed above;
- Some licensees choose to monitor their workers for reasons other than compliance with NRC requirements (e.g., in response to worker requests).

8.10.5 PUBLIC DOSE

Regulations: 10 CFR 20.1003, 10 CFR 20.1101(d), 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107, 10 CFR 20.2203.

Criteria: Licensees must do the following:

- Ensure that licensed 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; and
- Prevent unauthorized access, removal, or use of licensed material.

Discussion: "Member of the public" is defined in 10 CFR Part 20 as "any individual except when that individual is receiving an occupational dose." "Public dose" is defined in 10 CFR Part 20 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 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 the public, refer to Appendix I, "Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits."

Figure 8.9 shows the steps to calculate the annual dose to an individual member of the public.

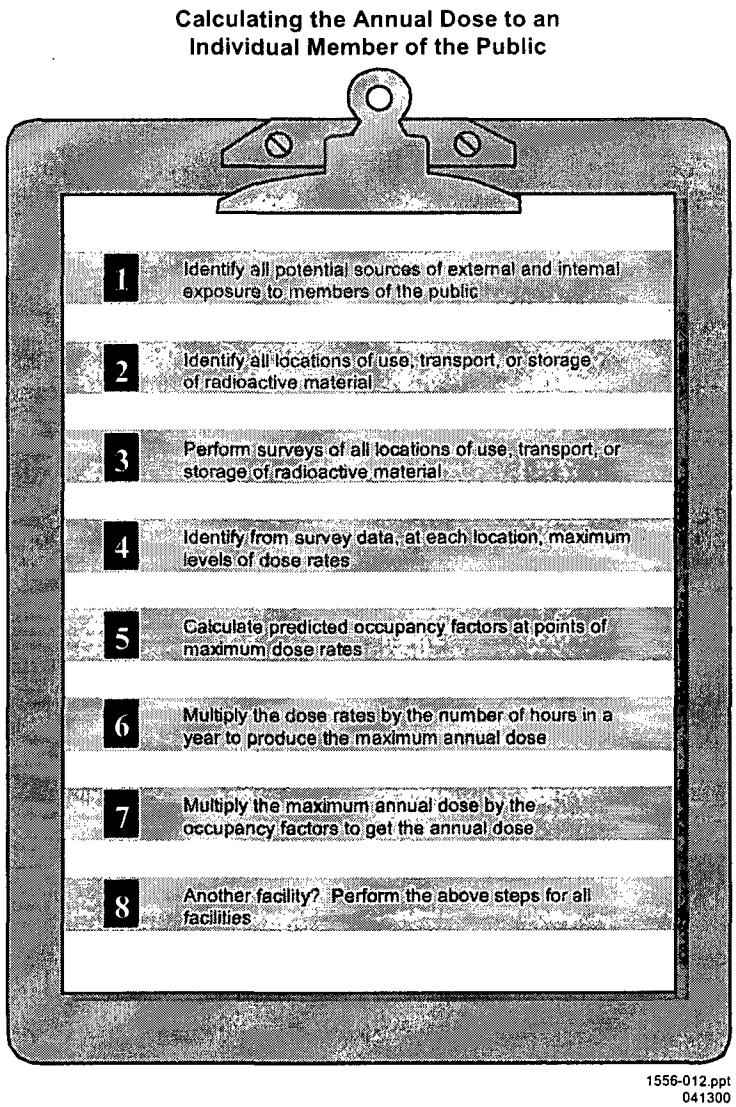


Figure 8.9 Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public (see Appendix I for more information about occupancy factors).*

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 TEDE 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 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 10 CFR 20.2203, and take prompt actions to ensure against recurrence.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1101(d) and 20.1302(b). The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to the section entitled, "Radiation Safety Program - Surveys."

During NRC 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.

Response from Applicant: Initially, the applicant need not provide a response. The application will be evaluated and the license reviewer will determine if enough information is present to assure compliance with the limiting exposure to a member of the public. A response may be required when there is insufficient information to assure that a member of the public will not receive a total exposure exceeding 0.1 mSv (100 mrem). When no response is required, compliance will be examined during inspection. During NRC inspections, licensees must be able to demonstrate, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix I for examples of methods to demonstrate compliance.

8.10.6 SAFE HANDLING OF RADIONUCLIDES AND EMERGENCY PROCEDURES

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1902, 10 CFR 20.1903, 10 CFR 20.1904, 10 CFR 20.1905, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 30.32(I), 10 CFR 30.50.

Criteria: Operating procedures for activities that can potentially impact radioactive material or occupational dose must be developed, documented, implemented and maintained to comply with 10 CFR 20.1101(a), Radiation Safety Programs.

Discussion: Licensees are responsible for the security and safe possession and use of all licensed material from the time it is produced at the facility until it is used, transferred/delivered, and/or disposed of. Licensees must develop written procedures to ensure safe possession and use of licensed 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;
- Recordkeeping Requirements;
- Reporting Requirements; and
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Use of appropriate shielding (see Figure 8.10); and
- Frequent change of gloves to minimize exposure to the individual and to avoid spread of contamination in the laboratory.

Applicants should also develop product- and radioisotope-specific procedures based on the respective hazards associated with the products and radioisotopes. General safety guidelines are described in Appendix J, "General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures" and Appendix L, "Radiation Safety Survey Topics." Applicants should use these guidelines to develop procedures for the safe use of radioisotopes.

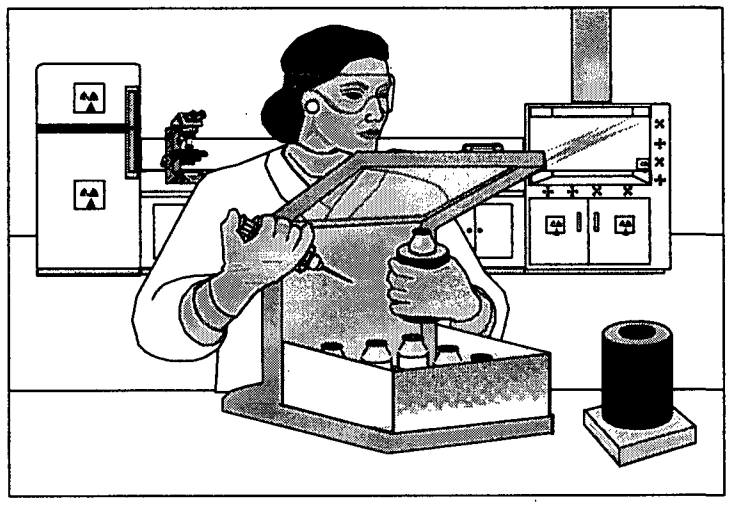


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Figure 8.10 Use of Appropriate Shielding.

Licensees should determine if they have areas that require posting in accordance with 10 CFR 20.1902, unless they meet the exemptions listed in 10 CFR 20.1903. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with 10 CFR 20.1904, unless they meet the exemptions in 10 CFR 20.1905.

Security Procedures

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who are not knowledgeable about radioactive materials cannot be exposed to or contaminated by the material and cannot take the material. When any licensed material is handled in controlled or unrestricted areas, it must be under constant surveillance to prevent others from becoming contaminated by or exposed to the material, or to prevent persons from removing the material from the area. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include: storage and use of licensed materials only in restricted areas; limiting access to an entire facility or building or portion of the building only to radiation workers; providing storage areas that can be locked to prevent access to the material; and implementing procedures that require a radiation worker to be within "line of sight" of the materials whenever licensed materials are in use. Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may need to be paid to security procedures at facilities that may have unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their transportation, use, production processes, 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, such incidents as loss or theft of licensed material, sabotage, fires, and floods can jeopardize the safety of personnel and members of the public. It may therefore be necessary to develop written procedures to minimize, as much as possible, the impact of these incidents on personnel, members of the public, and the environment. Applicants who plan to possess quantities of material in excess of the applicable amounts listed in 10 CFR 30.72, Schedule C may also be required to submit an "Emergency Response Plan for Responding to a Release."

Applicants should establish written procedures to handle events ranging from a minor spill (see Figure 8.11) to a major accident that may require intervention by outside emergency response personnel. For accelerator facilities, written procedures should be included for specific accident scenarios such as target failures, spills or releases outside a containment enclosure, delivery line failures, malfunction of air supply or exhaust systems, and high radiation levels in exhaust monitors or systems. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should have a clear understanding of

their limitations in an emergency, along with step-by-step instructions and clear guidelines for whom to contact.

Licensees should have a sufficient number of appropriate and calibrated survey instruments readily available. Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Appendix J includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

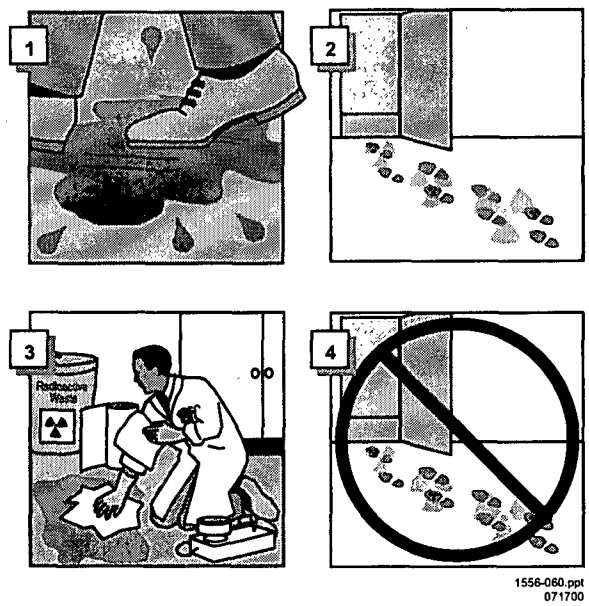

Figure 8.11 Proper Handling of Incident. *Panels 1 and 2 indicate how contamination can be spread if the incident is not handled properly as in panels 3 and 4.*

Response from Applicant: The applicant should state that procedures for safe handling of radionuclides and emergencies will be developed and documented before production of licensed material. In addition, the applicant should state that operating and emergency procedures will be implemented and maintained. The applicant should submit a statement that "Procedures will be revised only if: (1) the changes are reviewed and approved by the licensee management and the RSO in writing; (2) the licensee staff is provided training in the revised procedures prior to implementation; (3) the changes are in compliance with NRC regulations and the license; and (4) the changes do not degrade the effectiveness of the program."

If an "Emergency Response Plan" is required for a license pursuant to 10 CFR 30.32(I), the applicant should submit it as a separate part of the application.

8.10.7 SURVEYS AND LEAK TESTS

Regulations: 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 30.53, 10 CFR 32.59, 10 CFR 32.102.

Criteria: Licensees are required by 10 CFR 20.1501 to make surveys of potential radiological hazards in their workplace. NRC requires testing to determine whether there is any radioactive leakage from sealed sources. Records of surveys and leak tests results must be maintained.

Discussion: Surveys are evaluations of radiological conditions and potential hazards (see Figure 8.12). These evaluations may be measurements (e.g., radiation levels measured with survey instruments or results of wipe tests for contamination), calculation, 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 for both licensed and non-licensed (e.g., accelerator operation) activities and the licensed facility. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

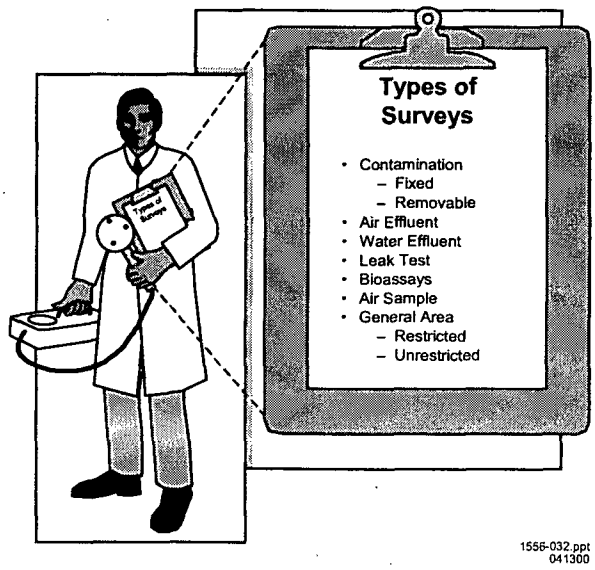

Figure 8.12 Types of Surveys. *There are many different types of surveys performed by manufacturer and distribution licensees.*

Radiation surveys are used to detect and evaluate contamination of:

- Facilities;
- Equipment;
- Personnel (during production, use, possession, transfer, or disposal of licensed material, see Figure 8.13);
- Restricted and unrestricted areas;
- Packages; and
- Products produced.

Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

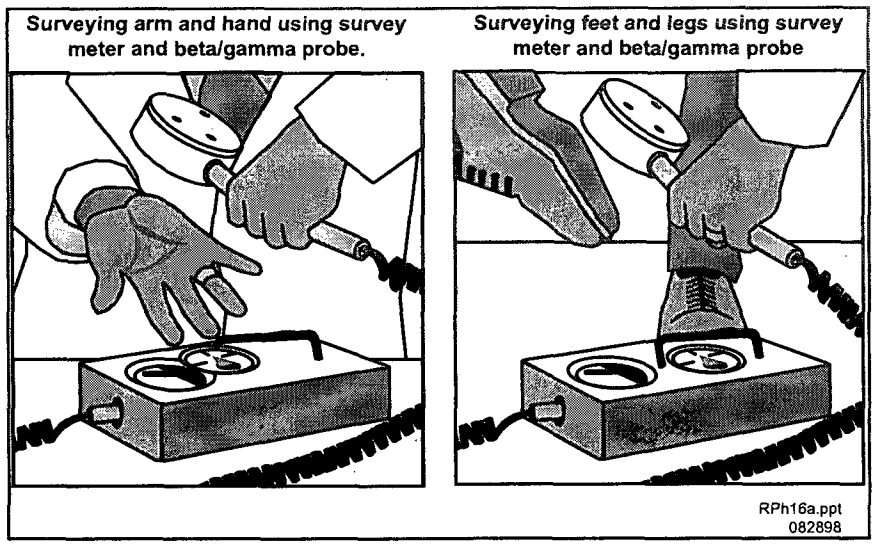

Figure 8.13 Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the restricted area(s) of the facility.*

10 CFR 20.1501 states that 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 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, workstations, and equipment;
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form, and where operations could expose workers to the inhalation of radioactive material, or where licensed material is, or could be, released to unrestricted areas;
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer;
- Bioassays to determine the kinds, quantities, or concentration, and in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement *(in vivo* counting), or by analysis and evaluation of material excreted or removed from the human body (*in vitro* counting); and
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

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 the worker from external and internal exposure. Also, the frequency of the

survey depends on the type of survey, such as those listed above (see Appendix L, "Radiation Safety Survey Topics").

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any Radiation Safety Program. Table H.1 in Appendix H contains radiation monitoring and survey instruments and calibration programs that are acceptable to NRC.

10 CFR Part 20 does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Contamination checks are required before distributing licensed material. Table L.5 in Appendix L contains contamination limits that are acceptable to NRC.

Sealed Source and Plated Foil Leak Tests

When issued, a license will require performance of leak tests of sealed/plated foil sources at intervals as approved by NRC or an Agreement State and specified by the SSDR 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.

Manufacturers, consultants, and other organizations may be authorized by NRC or an Agreement State either to perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee should take the leak test sample according to the sealed source or plated foil manufacturer's (distributor's) and the kit supplier's instructions and return it to the kit supplier 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. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Leak tests are not required if:

- Sources contain only licensed material with a half-life of less than 30 days;
- Sources contain only a radioactive gas;
- Sources contain 3.7 MBq (100 microcuries) or less of beta-emitting or gamma-emitting material or 370 kBq (10 microcuries) or less of alpha-emitting material; or
- Sources are stored and are not being used (must be leak tested before use or transfer).

For more information regarding leak tests, see Appendix M, Model Leak Test Program.

Response from Applicant: Do one of the following:

- State: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix L to NUREG-1556, Vol. 21." If applicable, state: "We will perform contamination checks on all manufactured

sealed sources prior to distribution. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSDR certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix M to NUREG-1556, Vol. 21";

OR

- Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foils.

Note:

- Alternative responses will be reviewed using the criteria listed above;
- If a sealed source or plated foil is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the sealed source or plated foil according to the procedures previously approved on its license.

8.10.8 MAINTENANCE

Regulation: 10 CFR 20.1101.

Criteria: Maintenance of equipment and facilities for the production and use of radioactive materials (e.g., accelerators and chemistry synthesis units) is necessary. Maintenance should be planned and carried out as frequently as needed, using ALARA principles. Individuals performing maintenance should be trained in the procedures they implement. Procedures should be written to account for the skills of the implementing personnel. Ordinarily, individuals handling unshielded materials should have up to forty hours of classroom and on-the-job training in radiation safety. Instructors should be more extensively qualified than the staff they teach.

Discussion: Maintenance of equipment and facilities is necessary in order to produce a quality product safely and efficiently and to ensure a safe environment for staff and the public. Producing radioactive materials is an additional hazard, requiring attention to detail when incorporating maintenance information into procedures. Licensee staff should ensure that materials in the process stream are properly shielded/located/protected to minimize the hazard to maintenance staff. Maintenance staff should be aware of the hazards and the procedures to minimize their exposure to radioactive materials that are possessed and used to control the production process. As examples: (1) the staff should survey the accelerator working area prior to entry into the accelerator vault or opening of accelerator self-shields; and (2) a maintenance procedure should direct the shutdown and lockout of the accelerator before beginning work in the area. Maintenance procedures should be prepared with the use of engineering controls first, using ALARA principles and administrative controls, as needed.

Response from Applicant: No response is required in the application process. The results of actions taken in the maintenance and repair of facilities and equipment process will be reviewed during inspection.

8.10.9 TRANSPORTATION

Regulations: 10 CFR 30.41, 10 CFR 30.51, 10 CFR 71.5, 10 CFR 71.14, 10 CFR 71.17, 10 CFR 71.19, 10 CFR 71.20, 10 CFR 71.47, 10 CFR 71.87, 49 CFR 107, 49 CFR 171-180, 49 CFR 390-397.

Criteria: A licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport. Therefore, applicants who will package, transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: In accordance with a Memorandum of Understanding between the DOT and NRC, NRC inspects and enforces DOT's regulations governing the transport of radioactive materials by NRC's licensees.

Licensees should consider the safety of all individuals who may handle or come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that package integrity is not compromised during transport and that radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of 10 CFR 71.47, but are ALARA. DOT regulations 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, safety training, and security awareness training. DOT also specifies the frequency of the training and a record retention requirement for training.

The types and quantities of radioactive materials shipped by production licensees generally meet the criteria for shipment in a "Type A" package, as defined by 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 licensees who transport their own packages, the packages must be blocked and braced, and shipping papers must be stored in the driver's compartment as described in 49 CFR 177.817.

All domestic shipping paper and label information must be stated in the International System of Units (SI) only **OR** must be in SI units first, with English units in parenthesis.

The general license in 10 CFR 71.17 provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Transporting licensed materials originating at some facilities involves quantities of radioactive material that require a Type B package. The manufacturer (or service licensee) who is subject to

the provisions of 10 CFR 71.17 or 10 CFR 71.19, as appropriate, is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the 10 CFR 71.17 general license. For information about QA plans, see Revision 2 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated March 2005.

Licensees should also develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own using Type B packages, a licensee needs to have registered with NRC as a user of the package and obtained NRC's approval of its QA program. Transportation activities will be reviewed during inspection.

8.10.10 MINIMIZATION OF CONTAMINATION

Regulation: 10 CFR 20.1406.

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 fullest extent practicable, the generation of radioactive waste.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination/decontamination during operation and during decommissioning efforts, and how to minimize radioactive waste generation during all phases of facility life cycle.

For accelerator production facilities, it is important to consider the types of materials used for the construction of the facility and for the shielding of the accelerator. Due to the neutron activation that generally takes place during the operation of the accelerator, it is important to carefully characterize all of the materials used in the accelerator (e.g., target material), the shielding of the accelerator, and the accelerator facility to minimize the amount of activated products that are produced.

Customers may also request the licensee of the production facility to provide recovery and shipping services for unwanted, damaged, and replacement materials/sources. As such, the licensee should consider the designs of shipping and recovery containers to meet transportation requirements. Procedures should be developed to enable these activities to be carried out with small impact on the radiological condition of the facility, decommissioning in the future, and employee external and internal radiation exposure.

When submitting new applications, applicants should also consider the following:

- Implementation of, and adherence to, good health physics practices in operations;
- Minimization of areas, to the extent practicable, where licensed materials are used and stored;
- Maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill;
- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition;
- Appropriate filtration of effluent streams;
- Use of nonporous materials for such areas as laboratory bench tops and flooring;
- Ventilation stacks and duct-work with minimal lengths and minimal abrupt changes in direction;
- Air flows appropriate to the work being conducted;
- Use of appropriate plumbing materials with minimal pipe lengths and traps; and
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed if there is a sanitary sewer system.

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

Response from Applicant: The applicant does not need to provide a response to this item under the following condition: NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: Section 8.5.1, "Radioactive Material – Unsealed and/or Sealed Byproduct Material," Section 8.9, "Facilities and Equipment," Section 8.10.6, "Radiation Safety Program – Safe Handling of Radionuclides and Emergency Procedures," Section 8.10.7, "Radiation Safety Program – Surveys and Leak Tests," and Section 8.11, "Waste Management."

8.11 ITEM 11: WASTE MANAGEMENT

Regulations: 10 CFR 20.1101, 10 CFR 20.1302, 10 CFR 20.1904, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2108, 10 CFR 20.1101, 10 CFR 20.1302, 10 CFR 30.51, 10 CFR 61.52.

Criteria: Radioactive waste generated as part of the production and distribution process must be disposed of in accordance with regulatory requirements and license conditions. Appropriate

records of waste disposal must be maintained. Waste materials (such as glove, rags, tools) may not be received from others unless recipients are specifically licensed to receive such waste. Licensed materials which were distributed (such as decayed sources or devices at end of useful life) may be received from others and sent for proper disposal.

Discussion: The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Environmental Protection Agency (EPA) guidance for developing a comprehensive program to reduce hazardous waste was transmitted to licensees by NRC in IN-94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994. The application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (e.g., radioactive from nonradioactive, short from long half-life, liquid from solid waste).

The following methods of waste disposal may be considered and should be addressed in the application, as appropriate.

Transfer to an Authorized Recipient

Waste may be transferred to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in accordance with 10 CFR 20.2001(a). Each shipment must comply with all applicable NRC and DOT requirements.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented.

Decay-in-Storage

Storage of radioactive materials with half-lives of greater than 120 days should be characterized regarding volume and anticipated time in residence at the licensee's facility prior to disposal. NRC permits licensed materials with half-lives of less than or equal to 120 days to be disposed of by decay-in-storage (DIS). Waste should be held in storage until the radiation exposure rate cannot be distinguished from background radiation levels. Applicants should assure that adequate space and facilities are available for the storage of such waste and care should be taken to ensure that the waste form does not degrade or adversely interact with the waste container. 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.

NRC does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, LLW should be stored only when disposal capacity is unavailable, and for no longer than is necessary. NRC Information Notice No. 90-09, "Extended-Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Material Licensees," dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

A model procedure for DIS is contained in Appendix O, "Waste Disposal."

Release into Air and Water

Release of radioactive material into air and water must conform to the requirements described in 10 CFR 20.1302(b)(2) (See Figure 8.14). The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the "constraint" on air emissions of radioactive material required by 10 CFR 20.1101(d) which effectively reduces the limits specified in 10 CFR 20.1302(b)(2) for release of gaseous effluents by a factor of ten. Applicants considering release of radioactive material into air and water should review Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993, which deals with the application of ALARA in controlling gaseous and liquid effluents and references documents with acceptable methods of effluent monitoring.

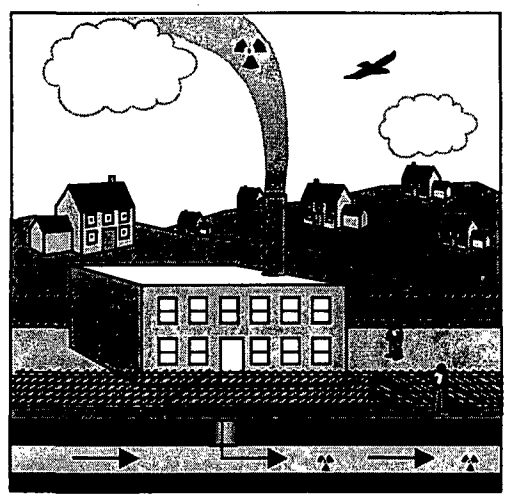

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Figure 8.14 Air and Water Effluents from a Production Facility. *Also note the fence, creating a "controlled area."*

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of 10 CFR 20.2003. Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are readily soluble or biologically readily

dispersible in water. NRC IN-94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994, provides the criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be readily dispersible. Licensees should carefully consider the possibility of reconcentration of radioisotopes that are released into the sewerage system. NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewerage systems in IN-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.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage system meet the criteria stated in 10 CFR 20.2003 and do not exceed the monthly and annual limits specified in the regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage system. A model procedure for disposal of radioactive waste via a sanitary sewer is described in Appendix O.

If liquid releases are made to a private sewerage treatment system, septic system, or leach field, the sludges or other solids from these systems may become contaminated with radioactive material. Applicants should describe the monitoring planned for these systems in Item 8.10.7 of the application. Contaminated sludges should be disposed of as radioactive waste using one of the methods described in this section. Applicants may obtain approval of alternative disposal methods through application to the NRC as described in 10 CFR 20.2002.

Incineration

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of 10 CFR 20.2004. A model procedure for incineration of waste is described in Appendix O. Applicants who are considering disposal of radioactive material by incineration should review Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Waste Volume Reduction

Waste volume reduction operations (e.g., compaction) that could create a radiological hazard to licensee employees or the general public should be described in detail in the application. A model procedure for waste compaction is described in Appendix O.

Other Methods Specifically Approved by NRC Pursuant to 10 CFR 20.2002

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste-containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant

must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

Some licensees do not have an LLW disposal facility available to them and therefore may wish to use on-site interim storage until such time that a facility becomes available. Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site extended interim storage of radioactive waste only as a last resort, since protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it on-site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC Information Notice (IN) 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

Additional Considerations

The application should describe the ALARA considerations taken before disposal of radioactive materials. Discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points (i.e., hoods and incinerator stacks). To be in compliance with the ALARA philosophy stated in 10 CFR 20.1101, radioactive material waste stream concentrations should be a fraction (generally 10% to 20%) of the limits specified in 10 CFR Part 20, Appendix B, Table II. Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of licensed material possessed or possessed and in use, a program for physically measuring releases should be in place whenever releases exceed the specified ALARA action point.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should pre-plan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. Sealed source manufacturers and suppliers that accept return of sealed sources should consider this when developing their waste management programs.

Response from Applicant: Provide procedures for waste collection, storage, and disposal by any of the authorized methods described in this section. Applicants should contact the appropriate NRC Regional Office for guidance and obtain advance approval of any method(s) of waste disposal other than those discussed in this section.

Note: Alternative responses will be reviewed using the criteria listed above.

8.12 ITEM 12: FEES

The next two items on NRC Form 313 are to be completed on the form itself.

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application. Refer to Section 7, License Fees.

8.13 ITEM 13: CERTIFICATION

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. ***Representatives signing an application should be authorized to make binding commitments and to sign official documents on behalf of the applicant.*** As discussed previously in Section 3, Management Responsibility, signing the application acknowledges management's commitment and responsibilities for the Radiation Safety Program. ***NRC will return all unsigned applications for proper signature.***

Note:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

9 AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: 10 CFR 2.109, 10 CFR 30.36(a), 10 CFR 30.37, 10 CFR 30.38.

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee should submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109 and 10 CFR 30.36(a)).

Applicants for license renewal and amendment should do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request;
- Submit, in duplicate, NRC Form 313;
- Provide the license number;
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or if there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or its Radiation Safety Program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions; and
- If a renewal is requested, provide the appropriate fee.

Using the suggested wording of responses and committing to use the model procedures in this report will expedite NRC's review.

10 APPLICATIONS FOR EXEMPTIONS

Regulations: 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11(a).

Criteria: Licensees who request exemptions to regulations must demonstrate that the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest.

Discussion: Various sections of NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, 10 CFR 20.2301 and 10 CFR 30.11(a)). These regulations state that NRC may grant an exemption, either acting on its own initiative or on an application from an interested person.

Until NRC has granted an exemption in writing, strict compliance with all applicable regulations and license conditions is required. An exemption will be included in the license as a license condition.

Exemptions are not intended to revise regulations, are not intended for large classes of licenses, and are generally limited to unique situations. Exemption requests should be accompanied by descriptions of the following:

- Exemption and why it is needed;
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested; and
- Alternative methods for complying with the regulation and why they are not feasible.

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 20.1401, 10 CFR 20.1402, 10 CFR 20.1403, 10 CFR 20.1404, 10 CFR 20.1405, 10 CFR 20.1406, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36(d), 10 CFR 30.36(g), 10 CFR 30.36(h), 10 CFR 30.36(j).

Criteria: The licensee must do the following:

- Notify NRC, in writing, within 60 days of:
  - — the expiration of its license;
  - — a decision to permanently cease licensed activities at the entire site (regardless of contamination levels);
  - — a decision to permanently cease licensed activities in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to NRC requirements;
  - — no principal activities having been conducted at the entire site under the license for a period of 24 months; and
  - — no principal activities having been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to NRC requirements.
- Submit decommissioning plan, if required by 10 CFR 30.36(g);
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j);
- Submit, to the appropriate NRC Regional Office, completed NRC Form 314, "Certificate of Disposition of Materials," (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey); and
- Before a license is terminated, send the records important to decommissioning to the appropriate NRC Regional Office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

Discussion: As discussed above in "Criteria," before a licensee can decide whether it must notify NRC, the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release according to NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

NUREG-1727, "NMSS Decommissioning Standard Review Plan," dated September 2000, and NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," dated March 1997, contain the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of NUREG/BR-0241 contains a comprehensive list of NRC's decommissioning regulations and guidance. NUREG-1727 contains a list of superceded guidance; however, due to ongoing revisions,

applicants are encouraged to consult with NRC staff regarding updates of decommissioning guidance. NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," dated December 1997, should be reviewed by licensees who have large facilities to decommission.

An acceptable computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is DandD. NUREG-1727 includes a table (Table C2.2) of acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination. NUREG-1727 also contains methods for conducting site-specific dose assessments for facilities with contamination levels above those in the table.

Response from Applicant: The applicant is not required to submit a response to NRC during the initial application. The applicant's obligations in this matter begin when the license expires or at the time the licensee ceases operations, whichever is earlier. These obligations are to undertake the necessary decommissioning activities, to submit NRC Form 314 or equivalent information, and to perform any other actions as summarized in the "Criteria."

References: Copies of NRC Form 314, "Certificate of Disposition of Materials," are available upon request from NRC's Regional Offices. (See Figure 2.1 for addresses and telephone numbers).

APPENDIX A

List of Documents Considered in Development of this NUREG

This report incorporates and updates the guidance previously found in the NUREG reports, Regulatory Guides (RGs), Policy and Guidance Directives (P&GDs or PGs), and Information Notices (INs). Other NRC documents such as Manual Chapters (MCs), Inspection Procedures (IPs), Memoranda of Understanding (MOU), and Technical Assistance Requests (TARs) were also consulted during the preparation of this report. See Tables A.1 and A.2 for a list of the documents considered in the development of this NUREG.

Table A.1 List of NUREG Reports, Regulatory Guides, and Policy and Guidance Directives

Document Identification	Title	Date
NUREG-1556 Vol. 12	Program-Specific Guidance About Possession Licenses For Manufacturing and Distribution	12/2000
NUREG-1556 Vol. 13, Rev. 1	Program-Specific Guidance About Commercial Radiopharmacy Licenses	3/2007
NUREG-1556 Vol. 11	Program-Specific Guidance About Licenses of Broad Scope	4/1999
NUREG-1556 Vol. 7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope	12/1999
NUREG-1556 Vol. 3	Applications for Sealed Source and Device Evaluation and Registration	4/2004
NUREG-1556 Vol. 20	Guidance About Administrative Licensing Procedures	12/2000
NUREG-1727	NMSS Decommissioning Standard Review Plan	9/2000
NUREG-1556 Vol. 15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, Special Nuclear Materials Licenses	11/2000
NUREG-1757, Vol-3	Consolidated NMSS Decommissioning Guidance - Financial Assurance, Recordkeeping, and Timeliness	9/2003
NUREG-1556 Vol. 16	Program-Specific Guidance About Licenses Authorizing Distribution To General Licenses	12/2000
NUREG-1556 Vol. 18	Program-Specific Guidance About Special Service Provider Licenses	11/2000
RG 4.13 Rev. 1	Performance Testing, and Procedural Specifications for Thermoluminescence Dosimetry: Environmental Applications	07/77
RG 4.20	Constraint on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors	12/96
RG 8.28	Audible-Alarm Dosimeters	08/81
RG 8.29 Rev. 1	Instruction Concerning Risks from Occupational Radiation Exposure	02/96

Table A.1 List of NUREG Reports, Regulatory Guides, and Policy and Guidance Directives (Cont.)

Document Identification	Title	Date
RG 8.32	Criteria for Establishing a Tritium Bioassay Program	07/88
RG 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses	07/92
RG 8.35	Planned Special Exposures	06/92
RG 8.36	Radiation Dose to the Embryo/Fetus	07/92
RG 8.37	ALARA Levels for Effluents from Materials Facilities	07/93

Table A.2 List of Generic Communications

Document Identification	Title	Date
IN-01-001	The Importance of Accurate Inventory Controls to Prevent the Unauthorized Possession of Radioactive Material	03/01
RIS 04-017	NRC Regulatory Issue Summary 2004-17: Revised Decay-in-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material	11/04
RIS 04-001	NRC Regulatory Issue Summary 2004-01: Method for Estimating Effective Dose Equivalent from External Radiation Sources Using Two Dosimeters	02/04
IN 90-09	Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees	02/05/90
IN 98-06	Unauthorized Use of License to Obtain Radioactive Materials, and its Implication under the Expanded Title 18 of the *U.S. Code*	02/19/98
IN 98-12	Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Power Pacemakers	04/03/98
IN 98-16	Inadequate Operational Checks of Alarm Ratemeters	04/30/98
IN 98-08	Information Likely to be Requested if an Emergency is Declared	03/02/98
IN 98-17	Federal Bureau of Investigations's (FBI) Awareness of National Security Issues and Responses (ANSIR) Program	05/07/98
IN 98-18	Recent Contamination Incidences Resulting from Failure to Perform Adequate Surveys	05/13/98
IN 98-20	Problems with Emergency Preparedness Respiratory Protection Programs	06/13/98
IN 2000-10	Recent Events Resulting In Extremity Exposures Exceeding Regulatory Limits	07/18/00

APPENDIX B

United States Nuclear Regulatory Commission Form 313

NRC FORM 313 (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 10/31/2008**

Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*:
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER _____
   - ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY	AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (10-2005) PRINTED ON RECYCLED PAPER

APPENDIX C

Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313 for a Possession License

The table below is designed to help applicants develop their applications. It may also be used as a License Reviewer Checklist for applications for a production and distribution license. A box (in a column ❒) indicates that the licensee may agree to use a model procedure, or if not using a model procedure, the licensee should describe its program or submit its procedures for the particular item.

Item No.	Suggested Response	Agree to Use	Description Attached
5.	**RADIOACTIVE MATERIAL**		
	Unsealed and/or Sealed Sources		
	• For unsealed materials:	N/A	❒
	– Provide radionuclide (element name and mass number), chemical and/or physical form, and maximum requested possession limit for each radionuclide produced. For listing activation radionuclides, the location (e.g., target body or concrete) of the activated material should be indicated under the chemical and/or physical form column (Item 5.b); and		
	– Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored, and waste materials.		
	Note: For activation radionuclides, the applicant could request authorization to possess and use any form of byproduct material with atomic numbers 1through 83. However, the applicant should indicate the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.		
	• For potentially volatile materials (e.g., I-123):	N/A	❒
	– Specify whether the material will be free (volatile) or bound (nonvolatile) and the requested possession limit for each form.		
	• For sealed radioactive materials and discrete sources of radium-226:	N/A	❒
	– Identify each radionuclide (element name and mass number) that will be used in each source;		
	– Provide the manufacturer's (distributor's) name and model number for each sealed source and device and discrete source of radium-226 requested;		
	– Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State;		
	– Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State; and		
	– If the above information cannot be provided for the discrete source of radium-226, describe the discrete source.		

Item No.	Suggested Response	Agree to Use	Description Attached
5.	**RADIOACTIVE MATERIAL (*Cont.*)**		
	Financial Assurance and Recordkeeping for Decommissioning		
	If a DFP or FA is required, submit the required documents as described in NUREG-1757, Vol. 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," dated September 2003.	N/A	❒
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED**		
	List the specific use or purpose of each radioisotope that will be possessed and used.	N/A	❒
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**		
	Applicants should submit an organizational chart describing the management structure, reporting paths, and flow of authority between executive management and the RSO.	N/A	❒
	RSO		
	Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.	N/A	❒
	Individuals Authorized to Handle Licensed Material		
	Provide the name of each proposed individual, with the types and quantities of licensed material to be possessed and/or handled. Also provide information demonstrating that each proposed individual is qualified by training and experience to possess and handle the requested licensed materials.	N/A	❒
8.	**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally Exposed Individuals and Ancillary Personnel)**		
	Submit a description of the Radiation Safety Training Program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.	N/A	❒
9.	**FACILITIES AND EQUIPMENT**		
	Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, and/or used. Include the following information:	N/A	❒
	• Provide a description of the accelerator, which includes the name of the manufacturer, model, accelerator energy, maximum current, type of targets, and type of shielding materials;		❒

Item No.	Suggested Response	Agree to Use	Description Attached
9.	**FACILITIES AND EQUIPMENT (*Cont.*)**		
	Note: This information about the accelerator will assist the license reviewer in understanding the types of materials and activation products that could be produced and the maximum quantity of radioactive material that could be produced and will not be incorporated into the license as a license condition;		
	• Provide a description of the areas assigned for the production, which includes transfer of produced material, storage, preparation, shipping, security, and measurement of radioactive materials;		❒
	• Provide a description and diagrams showing the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety (see Figures 8.6 and 8.7);		❒
	• Provide a diagram and a description of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne; and		❒
	• Provide verification that ventilation systems ensure that effluents are within the dose limits of 10 CFR 20.1301, and the ALARA constraints for air emissions established under 10 CFR 20.1101(d) are ALARA.		❒
10.	**RADIATION SAFETY PROGRAM**		
	Audit Program		
	No response is required. The licensee's program for auditing its Radiation Safety Program will be reviewed during inspection.	N/A	N/A
	Radiation Monitoring Instruments		
	Describe the instrumentation that will be used to perform required surveys, and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H to NUREG-1556, Vol. 21, 'Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator', dated May 2007."	❒	❒
	OR		

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM** ***(Cont.)***		
	Describe the alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer's license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others.	N/A	❒
	AND		
	Describe the instruments used to quantitatively measure the radioactivity in the products and process, and the procedures followed to ensure accuracy of those measurements.	N/A	❒
	Material Accountability		
	• "We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that: – license possession limits are not exceeded; – licensed material in storage is secured from unauthorized access or removal; – licensed material not in storage is maintained under constant surveillance and control; and – records of production, transfer, and disposal of licensed material are maintained."	❒	N/A
	AND		
	• "We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months."	❒	N/A
	Occupational Dose		
	"We have developed and will implement and maintain written procedures for monitoring occupational dose that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.2106, as applicable."	❒	N/A
	Public Dose		
	Initially, a response is not required from the applicant.	N/A	N/A

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM** ***(Cont.)***		
	Safe Handling of Radionuclides and Emergency Procedures		
	Develop and maintain procedures for safe handling of radionuclides and emergencies. State that such procedures will be developed and documented before production of licensed material.	☐	N/A
	The applicant should state that procedures will be revised only if:		
	• The changes are reviewed and approved by licensee management and the RSO;	☐	N/A
	• Licensee staff is trained in the revised procedures before they are implemented;		
	• The changes are in compliance with NRC regulations and the license; and		
	• The changes do not degrade the effectiveness of the program.		
	If an emergency response plan is needed, submit it as a separate part of the application.	N/A	☐
	Surveys		
	"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix L to NUREG-1556, Vol. 21. Leak tests of sealed sources will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix M to NUREG-1556, Vol. 21."	☐	N/A
	OR		
	Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foils.	N/A	☐
	Maintenance		
	No response is required in the application process.	N/A	N/A

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM** ***(Cont.)***		
	Transportation		
	No response is needed from applicants during the licensing phase.	N/A	N/A
	Minimization of Contamination		
	The applicant does not need to provide a response to this item under the following condition:	N/A	N/A
	NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: Section 8.5.1, "Radioactive Material – Sealed Sources and Devices or Unsealed Radioactive Material," Section 8.9, "Facilities and Equipment," Section 8.10.6, "Radiation Safety Program – Safe Handling of Radionuclides and Emergency Procedures," Section 8.10.7, "Radiation Safety Program – Surveys and Leak Tests," and Section 8.11, "Waste Management."		
11.	**WASTE MANAGEMENT**		
	Provide procedures for waste collection, storage, and disposal by any of the authorized methods described in this section. Applicants should contact the appropriate NRC Regional Office for guidance and obtain advance approval of any method(s) of waste disposal other than those discussed in this section.	N/A	❒

APPENDIX D

Sample License

SAMPLE PRODUCTION MATERIALS LICENSE

1. Production, Inc.
2. 1234 RAM Street
   Anytown, GA 20001
3. License number
4. Expiration date
5. Docket No.
   Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Fluorine-18	A. Any	A. 20 curies
B. Gallium-67	B. Any	B. 20 curies
C. Palladium-103	E. Any	E. 50 curies
D. Indium-111	C. Any	C. 50 curies
E. Iodine-123	D. Any	D. 5 curies
F. Thallium-201	F. Any	F. 50 curies
G. Germanium-68	G. Sealed Source (ILL Model SS-068)	G. 10 millicuries per source, 50 millicuries total possession
H. Cesium-137	H. Sealed Source (NEN Model NSS-137)	H. 20 millicuries per source, 50 millicuries total possession
I. Cobalt-56	I. Activated Foil	I. 100 millicuries
J. Cobalt-60	J. Activated Building Materials	J. 100 millicuries
K. Zinc-65	K. Activated Foil	K. 250 millicuries
L. Any byproduct material with atomic numbers 1 through 83	L. Activated Components, Associated Equipment, and/or Building Materials	L. 50 millicuries per nuclide, 1 curie total possession, except as noted

9. Authorized use:

A. through F. (1) For production, possession, or handling of radiochemicals and sealed sources for transfer to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

(2) Research and development as defined in 10 CFR 30.4.

(3) For packaging and distribution of produced radiochemicals and sealed sources to persons authorized to receive licensed materials pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement States. This should not be distributed as a radiopharmaceutical or radioactive drug.

G. and H. Calibration and checking of the licensee's instruments.

SAMPLE PRODUCTION MATERIALS LICENSE *(Cont.)*

I. through L. For storage and disposal of byproduct materials incidental to the production of radionuclides.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at [fill in the street address of the facility].

11. The Radiation Safety Officer for this license is [insert name of RSO].

12. Licensed material shall be used by, or under the supervision of: [insert name(s)].

13. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.21, inclusive, or equivalent regulations of any Agreement State.

14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

    B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested and the test results received.

    C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

    D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

    E. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license.

SAMPLE PRODUCTION MATERIALS LICENSE *(Cont.)*

17. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.

18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee;

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated [insert date]

    B. Letter dated [insert date]

Date: [insert license issue date] By: [Signature]

APPENDIX E

Radiation Safety Officer Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license (see Figure 8.5). Typically, these duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of licensed material listed on the license;
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301;
- Ensure security of radioactive material;
- Post documents as required by 10 CFR Parts 19.11 and 21.6;
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements;
- Ensure that radiation exposures are ALARA;
- Oversee all activities(licensed and non-licensed) involving radioactive material, including monitoring and surveys of all areas in which radioactive material is possessed or possessed and used;
- Act as liaison with NRC and other regulatory authorities;
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations;
- Oversee proper transfer and delivery of radioactive material, and conduct radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution;
- Distribute and process personnel radiation monitoring equipment, determine the need for and evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching established limits, and recommend appropriate remedial action;
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to possession or possession and use, both at periodic intervals (refresher training), and as required by changes in procedures, equipment, or regulations;
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records;
- Oversee the storage of radioactive material not in current use, including waste;
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments;
- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license;

- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property;
- Supervise decontamination and recovery operations;
- Maintain other records not specifically designated above (e.g., records of production, transfers, and surveys as required by 10 CFR 30.51 and 10 CFR 20, Subpart L, "Records");
- Hold periodic meetings with, and provide reports to, licensee management;
- Ensure that all users are properly trained;
- Perform periodic audits of the Radiation Safety Program to ensure that the licensee is complying with: all applicable NRC regulations, the terms and conditions of the license (e.g., leak tests, inventories, possession or possession and use limited to trained, approved users), the content and implementation of the Radiation Safety Program to achieve occupational doses and doses to members of the public that are ALARA in accordance with 10 CFR 20.1101, and the requirement that all records be properly maintained;
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review and ensure that prompt action is taken to correct deficiencies;
- Ensure that the audit results and corrective actions are communicated to all personnel who possess or possess and use licensed material;
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or Part 20 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits; and
- Maintain an understanding of, and up-to-date copies of, NRC regulations, the license, and revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.

APPENDIX F

Radiation Safety Training

This appendix is intended only as a guide for developing a training program. Individuals working with radioisotopes may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be accomplished by providing a simple hand-out, whereas others may require extensive training, including a written exam to assess retention of the topics presented.

The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

Frequency of Training

A. Before assuming duties with, or in the vicinity of, radioactive materials;

B. Whenever there is a significant change in duties, regulations, or the terms of the license; and

C. Annually (refresher training).

General Information

A. Radiation safety:

1. radiation vs. contamination;
2. internal vs. external exposure;
3. biological effects of radiation;
4. ALARA concept;
5. use of time, distance, and shielding to minimize exposure;
6. contact dose rates and dose rates at a distance from high-activity sources;
7. dose reduction responsibilities.

B. Regulatory requirements:

1. RSO;
2. material control and accountability;
3. personnel dosimetry;
4. Radiation Safety Program audits;
5. transfer and disposal;
6. recordkeeping;
7. surveys;

8. postings;
9. labeling of containers;
10. handling and reporting of incidents or events;
11. licensing and inspection by NRC;
12. need for complete and accurate information;
13. employee protection;
14. deliberate misconduct.

Licensee-Specific Program Elements

A. Authorized individuals and supervised individuals.

B. Worker-specific production activities (e.g., maintenance of the accelerator).

C. Shipping.

D. Moving/transferring radioisotopes to different areas or licensees.

E. Applicable regulations and license conditions.

F. Areas where radioactive material is used or stored.

G. Potential hazards associated with radioactive material in each area where the individuals will work.

H. Appropriate radiation safety procedures.

I. Licensee's in-house work rules (for instructions on laboratory safety and uses of radioisotopes, see Appendix J).

J. Each individual's obligation to report unsafe conditions to the RSO.

K. Appropriate response to spills, emergencies, or other unsafe conditions.

L. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable.

M. Locations where the licensee has posted or made available: notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

N. Emergency procedures:

1. RSO name and telephone number;
2. immediate steps to prevent or control spread of contamination;
3. clean-up instructions, decontamination.

O. Survey program:

1. survey instrument accessibility;
2. who is responsible;

3. types, contamination, and areas;
4. frequency;
5. levels of contamination;
6. personnel, hands, shoes;
7. records.

P. Waste:

1. liquid;
2. solids;
3. sanitary sewer;
4. burial (transfer to low-level waste repository);
5. storage;
6. decay-in-storage;
7. waste storage surveys;
8. incineration;
9. records.

Q. Dosimetry:

1. whole body;
2. extremities;
3. lost or replacement badges and dose assessment;
4. bioassay procedures;
5. records.

R. Instrumentation:

1. survey meters – use, calibration frequency, use of check sources;
2. analytical instruments – gas flow counters, liquid scintillation counters;

S. Procedures for receiving packages containing radioactive materials (if applicable):

1. normal;
2. off-duty;
3. notification of user and RSO;
4. security;
5. exposure levels;
6. possession limit;
7. receipt of damaged packages.

T. Sealed sources:

   1. leak-test requirements;
   2. inventory requirements;
   3. exempt quantities;
   4. records.

U. NRC/State/Licensee audit findings.

V. Other topics.

W. Question and answer period.

For Laboratory Safety and Use of Radioisotopes

A. Control procedures for obtaining permission to possess or possess and use radioactive materials at the facility; give limitations on quantity to be handled per user, or allowed per experiment.

B. Protective clothing and what laboratory apparel to wear and what equipment to use.

C. Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. For example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or glove boxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma-emitting licensed materials are handled.

D. Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.

E. Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel.

F. Decontamination procedures to use and whom to contact in case of an emergency.

G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.

H. Requirements for storage, labeling of containers, and identification of areas where licensed materials are possessed or possessed and used.

I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.

J. Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If the program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.

K. Records to be maintained on possession, use, and disposal of licensed materials.

L. Prohibitions of pipetting by mouth, eating, smoking, and drinking in areas where licensed materials are possessed or possessed and used.

APPENDIX G

Facilities and Equipment

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use or otherwise have available. Not every applicant will need to address each of these topics in its application.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. Restricted areas do not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area. Refer to 10 CFR Part 20 for more information regarding restricted area controls. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment. Drawings should show the uses of adjacent areas, including those beside, above, and below, and a recitation of the various shielding materials in the separating surfaces.
- A site diagram should indicate buildings and areas and their uses such as research, production, or waste storage.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside the closed systems discussed below. Surfaces should be smooth and nonporous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods, glove boxes, or hot cells with controlled, and possibly filtered, exhaust systems.
- Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be necessary for the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 10 CFR 20, Appendix B.
- Glove boxes are sealed boxes with transparent viewing windows, sealable ports and/or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- Hot cells are generally sealed shielded compartments with transparent viewing windows, sealable ports and/or doors for handling high gamma/photon emitting radioactive materials. Generally, remote manipulator arms are used within the hot cell to manipulate/handle license materials. Also, hot cells can be used for gases, for unsealed volatile licensed

materials, and for processes such as evaporation that may release gases, fine particulates, and vapors. Hot cells can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and duct work should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods, or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Shielded shipping containers are frequently used for continued storage after receipt of materials. Other shielding used may consist of high-density plastic for beta-emitting radioactive materials.
- Optimal shielding requirements will depend on the intensity and energy of the radiation; the type, quality and configuration of the local shielding in place; and the duration of personnel exposure in conducting the operation.
- The proper ventilation system is very important at production facilities. Systems should be designed to ensure adequate performance for each area in terms of flow rates and directions. When describing ventilation systems, applicants should provide a detailed description of the ventilation system, which includes location of air intakes for the building and any surrounding buildings, airflow rates, pressures, and any filtration equipment that is used within the system.
- Particular sinks should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on the number of users and the distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas, placed away from areas frequently occupied by personnel, and secured from unauthorized removal. Additionally, these containers should be effectively enclosed to prevent airborne contamination from deposited radioactive materials.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down and isolated to contain radioactivity. For an accelerator facility, generally the ventilation system should be designed so that the accelerator(s) has the most negative pressure and a higher air flow within the restricted areas of the facility. This is done to help avoid airborne contamination from possible high activity releases such as target ruptures or other failures within the accelerator during operation.

- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with low background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of the operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H.
- If compaction of waste is performed, ensure that the facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per 10 CFR 20.1204.

APPENDIX H

Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program

The specifications in Table H.1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies).

Table H.1 Typical Survey Instruments[1] (Instruments used to measure radiological conditions at licensed facilities).

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range/Range**	**Efficiency**
REM Meter	Neutron	mrem – rem	Low
Exposure Rate Meters (e.g., ion chambers)	Gamma, X-ray	μR-R	N/A
Count Rate Meters			
Zinc Sulfide*	Alpha	All energies	Moderate
GM	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Gas Flow Proportional	Alpha	All energies	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma	Low energy	Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

[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 should 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 should 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 should consist 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 should 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 should:

- 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 ± 5% accuracy by the National Institute 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 x 10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8 x 10^{2} megabecquerels (21 mCi) of cobalt-60].

ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration" provides the following:

- 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 ± 15% of the conventionally true values for the lower point and ± 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; and
  - Meters with a digital display device shall be calibrated the same as meters with a linear scale.

Note:

- Readings above 2.58 X 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[2]

- The efficiency of survey meters must be determined by using radiation sources with energies and types of radiation that are similar to those the survey instrument will 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.

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[2]ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration."

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

A radioactive sealed source used for calibrating instruments should 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 ± 5% accuracy by NIST; and
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration should produce readings within ± 20% of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters should include quench correction.

Calibration Records

Calibration reports, for all survey instruments, should 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 the 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 should 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 should 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 9th Edition, American Conference of Governmental Industrial Hygienists, 2001, provides guidance on total air sample volume calibration methods acceptable to NRC staff, 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 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 for 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 ± 1% and secondary standards to within ± 2%.

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

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).[3]

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.

E_V: 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:

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

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:

$$Vs = V1 * (P1/760) * (273/T1)$$

where: Vs = volume at standard conditions (760 mm & 0C)

V1 = volume measured at conditions P1 and T1

T1 = temperature of V1 in K

P1 = pressure of V1 in mm Hg

[3]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.

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: See the Notice of Availability on the inside front cover of this report to obtain a copy of:

- NUREG-1556 Vol. 18, "Program-Specific Guidance About Service Provider Licenses," dated November 2000;
- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992; and
- NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Additional References:

- The Health Physics & Radiological Health Handbook, Third Edition, Edited by Bernard Shleien, dated 1998;
- 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
- "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th Edition, dated 2001.

APPENDIX I

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

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

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 mrem] in one calendar year resulting from the licensee's possession and/or use of licensed materials;
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour; and
- Air emissions of radioactive material to the environment will not result in a TEDE in excess of 10 mrem (0.1 mSv) per year.

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

Doses to Members of the Public	
INCLUDES doses from:	DOES NOT INCLUDE doses from:
• Radiation and/or radioactive material released by a licensee • Sources of radiation under the control of a licensee • Air effluents from sources of licensed radioactive materials	• Sanitary sewerage discharges from licensees • Natural background radiation • Medical administration of radioactive material • Participation in medical research

Typical unrestricted areas may include offices, shops, areas outside building's property, and storage areas (where access is neither limited nor controlled by the licensee).

The licensee may show compliance with the annual dose limit 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);
- 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 10 CFR Part 20, Appendix B, Table 2; 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; and
- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1 mSv (10 mrem) TEDE.

In order to perform a dose assessment, licensees 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 facilities. Licensees must then take radiation measurements or perform calculations to demonstrate compliance with public dose limits.

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as 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). 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. Airborne effluents may be discharged when accelerator targets rupture during accelerator operation. Due to the uncertainty of this type of discharge, it is important to perform effluent monitoring continuously or at least during the operation of the accelerator. 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 should 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. A conservative 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 I.1). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further

evaluation. Figure I.1 provides the steps on how to calculate the annual dose to an individual member of the public.

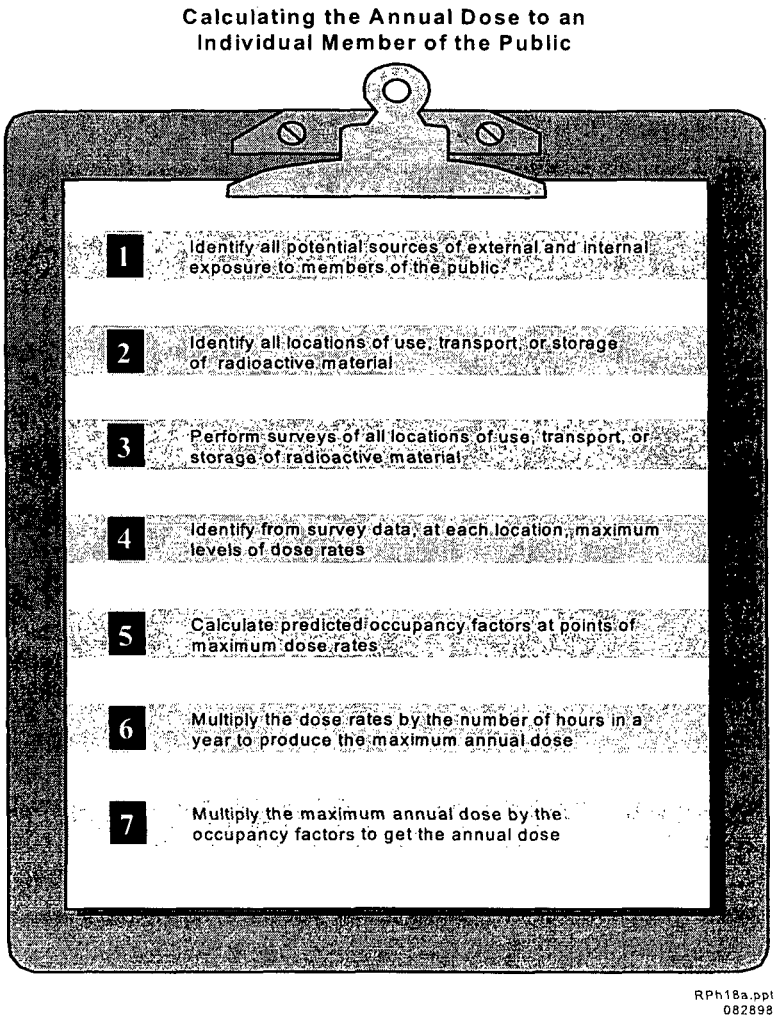

Figure I.1 Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public.*

If the calculation demonstrates that the public dose 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 may be made. The licensee may use the occupancy factors in Table I.1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table I.1 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.

Records

The licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public until the Commission 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 J

General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures

This appendix describes general topics for safe possession and use of radioactive materials, and procedures for handling and reporting emergencies.

General Topics for Safe Possession and Use of Radioactive Materials

Each area where radioactive material is produced, handled, or stored should have general rules, so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are handled;
- Wear disposable gloves at all times when handling licensed materials;
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area;
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used;
- Do not store food, drink, or personal effects in areas where licensed material is stored or used (see Figure J.1);
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are handled 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 licensed material when it is not under the constant surveillance and immediate control of the user(s).

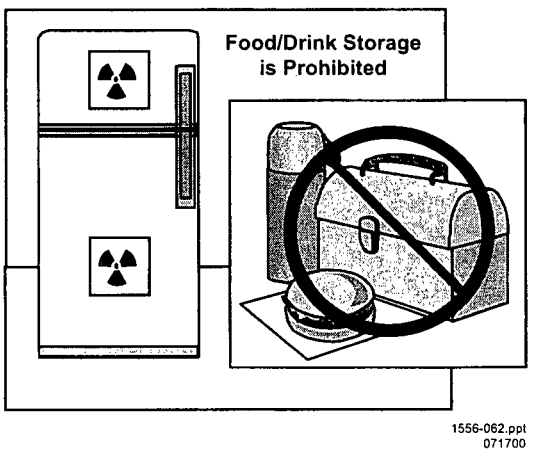

Figure J.1 Storage of Food and Drink. *Food or drink shall not be stored in refrigerators with radioisotopes.*

Radionuclide-Specific Procedures

Licensees should develop written procedures for use of different radionuclides so that users know the types of shielding, protective clothing, survey instruments, surveys, and decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq (1 mCi) of iodine-123 or iodine-131, special safety instructions should be provided to users, including provisions for the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- Bioassay procedures for individuals working with millicurie quantities of radioiodine;
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine;
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures; and
- Procedures for measuring the concentration of radioiodine effluents from the hoods.

Example 2:

If requesting more than 37 MBq (1 mCi) of fluorine-18, special safety instructions should be provided to users, including provisions for the following:

- The use of high-density materials (e.g., lead, tungsten), layered properly, in order to keep radiation exposure to a minimum;
- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- The use of extremity monitors for procedures that involve one millicurie or more; and
- A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures.

Model Procedures for Handling Emergencies

The following are acceptable procedures for responding to emergencies:

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

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 they are readily available to workers in case of emergencies. The licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
  - Disposable gloves;
  - Housekeeping gloves;
  - Disposable lab coats;
  - Disposable head coverings;
  - Disposable shoe covers;
  - Roll of absorbent paper with plastic backing;
  - Masking tape;
  - Plastic trash bags with twist ties;
  - "Radioactive Material" labeling tape;
  - Marking pen;
  - Pre-strung "Radioactive Material" labeling tags;
  - Box of wipes;
  - Instructions for "Emergency Procedures";
  - Clipboard with a copy of the Radioactive Spill Report Form for the facility;
  - Pen or Pencil; and
  - Appropriate calibrated survey instruments including batteries (for survey meters).

Minor Spills of Liquids and Solids

- Instructions to Workers:
  - 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 any other contaminated disposable material in the bag;
  - Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination;

- — Report the incident to the RSO promptly;
- — Allow no one to return to work in the area unless approved by the RSO;
- — Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
- — Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO:
  - — Follow up on the decontamination activities and document the results;
  - — As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
  - — If necessary, notify NRC.

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 lock or otherwise 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;
  - — Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
  - — Follow the instructions of the RSO/RSO staff (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;
  - Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results;
  - Determine cause and needed corrective actions; consider the need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
  - If necessary, notify NRC.

Note: For production facilities, the criteria for minor or major spills are generally determined based on exposure rate (e.g., minor spills < 50 mR/hr, major spills ≥ 50 mR/hr).

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

- Instructions to Workers:
  - Notify all personnel to vacate the room immediately;
  - Shut down the ventilation system, if appropriate, to prevent the spread of contamination throughout the system and other parts of the facility;
  - Vacate the room. Seal the area, if possible;
  - Notify the RSO immediately;
  - Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area;
  - Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO;
  - Promptly report suspected inhalation and ingestion of licensed material to the RSO;
  - Decontaminate the area only when advised and/or supervised by the RSO;
  - Allow no one to return to work in the area unless approved by the RSO;
  - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
  - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

- Reminders to RSO:
  - Supervise decontamination activities;
  - Perform air sample surveys in the area before permitting resumption of work with licensed materials;
  - Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc;
  - Consider the need for a medical exam and/or whole body count before permitting involved individuals to return to work with licensed material;
  - Determine cause and corrective actions needed; consider the need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident; and
  - If necessary, notify NRC.

Minor Fires

- Instructions to Workers:
  - If possible, immediately attempt to put out the fire by approved methods (e.g., 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 RSO and fire department or 911 (as instructed by RSO);
  - Once the fire is out, isolate the area to prevent the spread of possible contamination;
  - Ensure that injured personnel receive 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 any contamination that was released by the perspiration;
- Consult with fire safety officials to ensure that there is no likelihood of fire restarting and that it is safe to re-enter the building;
- Determine cause and needed corrective actions; consider the need for bioassays if licensed material may have been ingested or inhaled. Document incident; and
- If necessary, notify NRC.

Fires, Explosions, or Major Emergencies

- Instructions to Workers:
  - Notify all persons in the area to leave immediately;
  - Notify the fire department or 911;
  - Notify the RSO and other facility safety personnel;
  - Ensure that injured personnel receive medical attention;
  - Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed 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;
  - 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 or other emergency personnel;
  - Consult with the firefighting personnel or other emergency personnel and set up a controlled area where personnel can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished;
  - Once the fire is extinguished, provide assistance to firefighters or other emergency personnel who may need to re-enter restricted areas to determine the extent of the damage to the licensed material use and storage areas. To the extent practical, assist firefighters and emergency personnel in maintaining their exposures ALARA if the fire resulted in a significant release of radioactive material or loss of shielding capability, such that excessive radiation levels (greater than 100 mrems per hour) are created;

- Perform thorough contamination surveys of firefighters and emergency personnel and their equipment before they leave the controlled area, and decontaminate if necessary;
- Supervise decontamination activities;
- Consider bioassays if licensed material may have been ingested or inhaled. Document incident; and
- If necessary, notify NRC.

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

APPENDIX K

Typical Notification and Reporting Requirements

This appendix lists some typical notification and reporting requirements found in Title 10 of the Code of Federal Regulations. It is not meant to be all inclusive.

Table K.1 Typical NRC Notifications and/or Reports.

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material (for certain quantities)	immediate	30 days	10 CFR 20.2201
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(I)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(I)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems)	none	30 days	10 CFR 20.2203(a)(2)(I)
Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(I)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a) and (c)(2)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2) and (c)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material (for certain conditions)	24 hours	30 days	10 CFR 30.50(b)(4) and (c)(2)

Note: Telephone notifications shall be made to NRC Operations Center at 301-816-5100 or (301) 951-0550, except as noted.

APPENDIX L

Radiation Safety Survey Topics

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

Training

Before allowing an individual to perform surveys, the RSO should ensure that he or she has sufficient training and experience to perform surveys independently.

Academic 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;
- Using and measuring radioactivity; and
- Biological effects of radiation.

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

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples; and
- Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples should be analyzed in a low-background area.
- A gamma counter system with a single or multichannel analyzer can be used to count samples containing gamma-emitters (e.g., cesium-137, cobalt-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

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. It is also recommended that area monitors be used in areas where high-energy gamma/photon-emitting radioactive materials or radiation are produced and handled.

- 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour.

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses 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 a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, work benches, and equipment;
- After any spill or contamination event;
- When procedures or processes have changed;
- To evaluate contamination of users and the immediate work area, at the end of the day, or when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than quarterly; and
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material in an amount greater than or equal to 10% of the smallest ALI (either the inhalation or ingestion ALI) listed for that radionuclide in 10 CFR Part 20 Appendix B. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use, but at a minimum, quarterly. If amounts are used that are greater than or equal to the smallest ALI listed for that radionuclide in 10 CFR Part 20, detailed, documented surveys should be performed at least monthly.

Table L.1 contains the suggested contamination survey frequency from Regulatory Guide 8.23. (See Tables L.2, L.3, and L.4 for alternate survey frequencies).

Table L.1 Suggested Frequency of Contamination Surveys from Regulatory Guide 8.23.

Areas Where RAM Has Been Used	Frequency
Areas where > 7.4 MBq (200 ↦Ci) is used at any one time	Weekly
Areas where < 7.4 MBq (200 ↦Ci) is used at any one time	Monthly

Alternate Survey Frequency

Classification of Laboratories or Areas of Use

Table L.2 Survey Frequency Category.

Group	Low	Medium	High
1	< 370 kBq (10 ↦Ci)	370 kBq (10 ↦Ci) to 37 ↦MBq (1 mCi)	> 37 MBq (1 mCi)
2	< 37 MBq (1 mCi)	37 MBq (1 mCi) to 3.7 GBq (100 mCi)	> 3.7 GBq (100 mCi)
3	< 3.7 GBq (100 mCi)	3.7 GBq (100 mCi) to 370 GBq (10 Ci)	>370 GBq (10 Ci)
4	< 370 GBq (10 Ci)	370 GBq (10 Ci) to 37 TBq (1000 Ci)	> 37 TBq (1000 Ci)

Proportional fractions should be used for more than one isotope.

Table L.3 Survey Frequency Category Modifiers.

Modifying Factors	Factors
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of nonoccupational persons	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

The object is to determine how often to survey the laboratory or area of use. To do this, multiply the activity range under the LOW, MEDIUM, and HIGH survey frequency in Table L.2 by the appropriate Modifying Factor to construct a new set of FCi ranges for LOW, MEDIUM, and HIGH survey frequency.

Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week; and
- High – Not less than once per normal working day.

Table L.4 Isotope Groups.

Group 1	Pb-210 Po-210 Ra-223 Ra-226 Ra-228 Ac-227 Th-227 Th-228 Th-230 Pa-231 U-230 U-232 U-233 U-234 Np-237 Pu-238 Pu-239 Pu-240 Pu-241 Pu-242 Am-241 Am-243 Cm-242 Cm-243 Cm-244 Cm-245 Cm-246 Cf-249 Cf-250 Cf-252
Group 2	Na-22 Cl-36 Ca-45 Sc-46 Mn-54 Co-56 Co-60 Sr-89 Sr-90 Y-91 Zr-95 Ru-106 Ag-110m Cd-115m In-114m Sb-124 Sb-125 Te-127m Te-129m I-124 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Ba-140 Ce-144 Eu-152 (13 y) Eu-154 Tb-160 Tm-170 Hf-181 Ta-182 Ir-192 Tl-204 Bi-207 Bi-210 At-211 Pb-212 Ra-224 Ac-228 Pa-230 Th-234 U-236 Bk-249
Group 3	Be-7 C-14 F-18 Na-24 Cl-38 Si-31 P-32 S-35 Ar-41 K-42 K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77 Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-31m Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-31 La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr) Tm-171 Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-191 Pt-193 Pt-197 Au-196 Au-198 Au-199 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203 Bi-206 Bi-212 Rn-220 Rn-222 Th-231 Pa-233 Np-239
Group 4	H-3 O-15 Ar-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87 Y-9lm Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m Th-232 Th-Nat U-235 U-238 U-Nat

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 should ensure that the amounts do not exceed the contamination levels listed in Table L.5.

Table L.5 Acceptable Surface Contamination Levels.

Nuclide[1]	Average[2,3]	Maximum[2,4]	Removable[2,5]
I-123, I-125, I-129	1.7 Bq/100 cm^2 (100 dpm/100 cm^2)	5.0 Bq/100 cm^2 (300 dpm/100 cm^2)	0.3 Bq/100 cm^2 (20 dpm/100 cm^2)
I-126, I-131, I-133, Sr-90	16.7 Bq/100cm^2 (1,000 dpm/ 100 cm^2)	50.0 Bq/100 cm^2 (3,000 dpm/ 100 cm^2)	3.3 Bq/100 cm^2 (200 dpm/100 cm^2)
Alpha emitters	8.33 Bq/100 cm^2 (500 dpm/100 cm^2)	25 Bq/100 cm^2 (1500 dpm/100 cm^2)	1.67 Bq/100 cm^2 (100 dpm/100 cm^2)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq/100 cm^2 (5,000 dpm/100 cm^2)	250 Bq/100 cm^2 (15,000 dpm/ 100 cm^2)	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)

1 Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

2 As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

3 Measurements of average contaminant should not be averaged over more than 100 square centimeters. For objects of less surface area, the average should be derived for each such object.

4 The maximum contamination level applies to an area of not more than 100 cm^2.

5 The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

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 to 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 smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm^2 is acceptable to indicate levels of removable contamination.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed (See Figure L.1);
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where the wipe test was taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make, model, and serial number of the instruments used;
- Background levels; and
- Name of the person making the evaluation and recording the results and date.

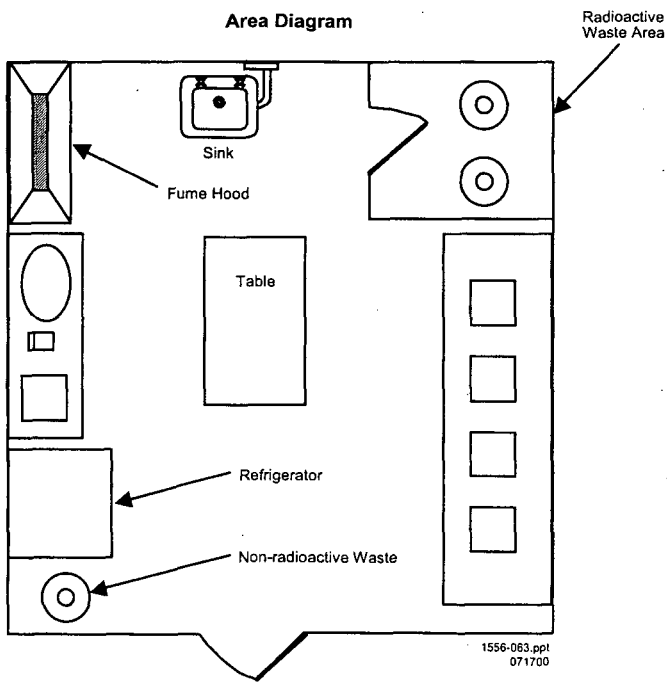

Figure L.1 Area Diagram. *This is an example of a laboratory survey map.*

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 future incidents of contamination, times and dates, and the surveyor's signature.

Air Monitoring in the Workplace

Air monitoring 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.

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program can eliminate the need for bioassays.

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

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

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

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

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur any time unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent concentrations found in Column 1 of Table 2 in 10 CFR Part 20, Appendix B, whichever is greater.

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."

Liquid Effluent 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 10 CFR 20.1301 and 20.2003, respectively.

The topic of sanitary sewer releases is more fully discussed in Appendix O.

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 10 CFR 20.1502(b), 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. The method of bioassay selected (for example, whole body counting and urinalysis) and the samples collected will vary according to the radionuclides and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

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 is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

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

Collection of Emergency Bioassay Samples

In the event of an emergency where an individual becomes contaminated and radioactive material has been taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body should be performed. Frequently, this estimate is made by performing a bioassay of the individual. Bioassays may be performed through direct methods such as whole body counting or thyroid counting, where the radioactive material in the body can be directly measured using appropriate instruments. Bioassays may also be performed through indirect means such as sampling urine or other excreta from the body and calculating the intake from the amount of material detected in the samples, the time between suspected intake and sample collection, and knowledge of the rate of excretion of the compound and/or radionuclide from the body. While there are many ways to perform the calculations, including using computer models, the method of calculation is only as good as the quality of the samples and analyses performed. Because a dose estimate may be required, bioassay procedures for a suspected intake may differ from those in a routine bioassay screening program, and the licensee's Radiation Safety Program should include procedures and equipment for appropriate sample collection in an emergency. The following items should be considered in developing your procedures:

- Type of bioassay that must be performed (direct or indirect);
- Number of samples or data points to be collected;
- Frequency of sampling (hourly, daily, weekly, once, etc.);
- Size of the sample to be collected (e.g., 24-hour urine collection);

- Ease/difficulty of sample collection; and
- Need for written instructions to be provided to the sample collector, who may be the contaminated individual.

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 a failed respiratory protective device, 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:

- The presence of unusually high levels of facial and/or nasal contamination;
- Entry into airborne radioactivity areas without appropriate exposure controls;
- 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;
- Incidents that result in contamination of wounds or other skin absorption; and
- Evidence of damage to or failure of a respiratory protective device.

References:

- Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996.
- Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993.
- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992.
- Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993.
- NUREG-1400, "Air Sampling in the Workplace," dated September 1993 or current revision.
- NUREG/CR- 4884, "Interpretation of Bioassay Measurements," dated July 1987 or current revision.
- ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," dated 1991.
- ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents," 1991.

APPENDIX M

Model Leak Test Program

Model Leak Test Program

Training

Before allowing an individual to perform leak testing, the licensee should 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 should cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations used for measuring radioactivity; 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 should 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 (e.g., NaI (Tl) well counter system for gamma-emitters, liquid scintillation for beta-emitters, gas-flow proportional counters for alpha-emitters).
- If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) should be determined. The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65\sqrt{(B_R \times t)}}{t \times E} = \text{Minimum Detectable Activity}$$

where:

MDA	=	minimum detectable activity in disintegrations per minute (dpm)
bkg	=	background count rate in counts per minute (cpm)
t	=	background counting time in minutes
E	=	detector efficiency in counts per disintegration

For example:

where: bkg = 200 counts per minute (cpm)
E = 0.1 counts per disintegration (10% efficient)
t = 2 minutes

$$MDA = \frac{2.71 + 4.65\sqrt{(200\text{ cpm} \times 2\text{ minutes})}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{(400)}}{0.2}$$

$$= \frac{2.71 + 4.65\,(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

$$= \frac{478.55\text{ disintegrations}}{\text{minute}}$$

$$\text{becquerels (Bq)} = \frac{1\text{ disintegration}}{\text{second}}$$

$$Bq = \frac{478.55\text{ disintegration}}{\text{minutes}} \times \frac{\text{minute}}{60\text{ seconds}} = 7.976\text{ Bq}$$

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests must be conducted at the frequency specified in the respective SSDR 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 the 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 ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency.

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

- Sign and date the list of sources, data and calculations. In accordance with 10 CFR 20.2103(a), records must be retained for three years. 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, and also notify NRC.

Reference: See NUREG-1556 Vol. 18, "Program-Specific Guidance About Service Provider Licenses," dated November 2000.

APPENDIX N

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Licensed Material

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Licensed Material

The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101: Purpose and use of hazardous materials table;
- Shipping Papers 49 CFR 172.200-204: Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper's certification;
- Package Marking 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: Applicability, general marking requirements for nonbulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in nonbulk packaging;
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;
- Emergency Response Information 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;
- Shippers – General Requirements for Shipments and Packaging 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limitations, requirements for NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and
- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping papers, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

For additional transportation information, licensees may consult DOT's "A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials" or contact the DOT at http://www.dot.gov.

APPENDIX O

Waste Disposal

General Discussion

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal into nonradioactive waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.
5. The waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
6. Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or radiation.

Model Procedure for Decay-In-Storage (DIS)

Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

1. Only waste with a physical half-life of less than or equal to 120 days may be disposed of by DIS.
2. Waste with a half-life of greater than 65 days but less than or equal to 120 days should be segregated at the source of generation from waste which has a half-life of less than or equal to 65 days.
3. Waste should be stored in suitable well-marked containers, the containers should provide adequate shielding, and the waste's physical form should be compatible with the waste container.
4. Liquid and solid wastes should be stored separately.
5. Filled containers should be sealed. Sealed containers should be identified with labels affixed or attached to them.
6. The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, and the initials of the individual who sealed the container. The container may then be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives so that persons performing surveys should be aware of the potential for measurable radiation.

7. Prior to disposal as ordinary trash, each container should be monitored as follows:
   a. Check the radiation detection survey meter for proper operation with a radiation source;
   b. Survey the contents of each container in a low background area;
   c. Remove any shielding from around the container;
   d. Monitor all surfaces of the container;
   e. Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity (i.e., surface readings are indistinguishable from background readings); and
   f. If the surveys indicate residual radioactivity, return the container to the DIS area and contact the RSO for further instructions.
8. If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

Note: All radiation labels should be defaced or removed from containers and packages prior to disposal as ordinary trash.

Model Procedure for Disposal of Liquids Into Sanitary Sewerage

1. Confirm that the sewer system is a public system, not a private sanitary sewer, septic system, or leach field.
2. Confirm that the liquid waste being discharged is readily soluble (or is easily dispersible biological material) in water.
3. Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in 10 CFR 20, Appendix B.
4. Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B, Table 3 (records for individual users/laboratories).
5. 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 10 CFR Part 20, Appendix B, Table 3 should not exceed unity.
6. Make sure the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 Gbq (1 Ci) of all other radioisotopes combined.
7. Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.
8. Liquid waste should be discharged only via designated sinks or toilets.

9. Discharge liquid waste slowly to minimize splashing, with water running to dilute it and to ensure that the material moves out of the sink into the sewer system.

10. Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remains in the sink or on work surfaces. Decontaminate as appropriate.

11. Prior to leaving the area, decontaminate all areas or surfaces if found to be contaminated.

12. For all releases to the sanitary sewer from the licensed facility, maintain records of each radioisotope and the quantity and concentration that is released into the sewer system in order to demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Model Procedure for Incineration

These guidelines apply to noncommercial waste disposal (e.g., incineration of a licensee's own waste). Specific NRC approval is not necessary in order to incinerate certain categories of radioactive waste. For example, 10 CFR 20.2005 provides that tritium and carbon-14 in low level concentrations, in liquid scintillation media and animal tissue, may be disposed of without regard to radioactivity. After reviewing the disposal program and confirming the existence of waste that requires specific NRC approval for incineration, provide the following information in the license application [20.2108]:

1. Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.

2. Describe the waste that is proposed to be incinerated to include the chemical and/or physical form of the waste containing licensed material and a description of how the waste is segregated, packaged, and labeled for transfer from the generation site to the incinerator; the name of the radioisotope, concentration of radioactivity averaged over the weight of the material to be incinerated (microcurie per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.

3. Describe the procedures for the packaging, handling, securing, and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.

4. Describe the method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe the procedures for collection, handling, and disposal of the ash residue.

5. Describe the recordkeeping procedures for the waste incineration program. Records should be adequate to document all receipts, incineration, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records should be maintained in the same units as applicable regulations.

6. Describe the characteristics of the incinerator and site location including: height of the stack; rated air flow (cubic feet per hour or similar units); proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital); and distance to the nearest

air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that is present.

7. State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.

8. Provide a copy of the written safety analysis that demonstrates that the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in 10 CFR Part 20.

9. Provide a written commitment that the applicant has coordinated with appropriate state and local authorities and that such permits and other authorizations as may be necessary have been obtained.

10. Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations, and for monitoring all effluent generated by the incineration process. The procedures should ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant should describe disposal procedures for any ash generated exceeding regulatory limits.

Model Procedure for Compaction

The following information should be provided by licensees who propose to compact waste [20.2108]:

1. Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations (e.g., manufacturer's specifications, annotated sketches, photographs);

2. Describe the type, quantities, and concentrations of waste to be compacted;

3. Provide an analysis of the potential for airborne release of radioactive material during compaction activities;

4. State the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange;

5. Discuss the methods used to monitor worker breathing zones and/or exhaust systems;

6. Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area; and

7. Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examination of containers for defects.

APPENDIX P

Production and Noncommercial Distribution of PET Radioactive Drugs to Consortium Members

(Note: This guidance is only for educational institutions or Federal facilities. Guidance for medical facility PET radioactive drug production is found in Appendix AA of the current version of NUREG 1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.")

PURPOSE OF APPENDIX

The purpose of this appendix is to provide guidance to the educational institution or Federal facility applicant with a Positron Emission Tomography (PET) radionuclide production facility that is a member of a "consortium" as defined in 10 CFR 30.4 and that is requesting authorization under 10 CFR 30.32(j) for the production and noncommercial distribution of PET radioactive drugs to medical use licensees within the consortium. The information required in this appendix is specific to this authorization and supplements information required for other uses of byproduct material covered under the applicant's byproduct materials license application.

10 CFR 30.4 states: "consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility."

The regulatory requirements for educational institutions, Federal facilities, and medical facilities to receive authorization for producing PET radioactive drugs for noncommercial distribution to licensees in a consortium may be found in 10 CFR 30.32(j). Regulatory requirements for licensees with this specific authorization are found in 10 CFR 30.34(j). The noncommercial distribution of PET radioactive drugs can be requested as an additional authorization on a current byproduct material possession license (e.g., educational institution or Federal facility broad-scope or limited specific license). The information associated with the Radiation Safety Program specifically needed for producing PET radioactive drugs can be found in the current version of NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses." To avoid duplication, many sections in this appendix refer the applicant to the appropriate sections in NUREG 1556 Vol. 13.

It should be noted that, as stated in 10 CFR 30.34(j)(1), the authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial distribution to medical use licensees in a consortium does not relieve the applicant or licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

CONSORTIUM CRITERIA

The authorization in 10 CFR 30.32(j) only authorizes noncommercial transfer (distributions) of PET radioactive drugs to medical use licensees in the educational institution's or Federal facility's consortium. Therefore, the staff must have sufficient information to make the necessary determination that the licensee is a member of a consortium that meets the definition in 10 CFR 30.4, and that the applicant will distribute the PET radioactive drugs only to medical use licensees in its consortium. To assist the staff in making this determination, the applicant should describe this consortium. Since the medical use consortium members are authorized by 10 CFR 35.100(a), 35.200(a), or 35.300(a) to receive the PET radioactive drugs, the applicant does not have to specifically identify the medical use members of the consortium if the description of the criteria for consortium membership is provided. This description should focus

on the regulatory requirements. This includes a description of the geographical area in which the members are located. Even if the individual members of the consortium are provided, the applicant should provide documentation of the terms of the association demonstrating the joint ownership or sharing of the operation and maintenance cost of the PET radionuclide production facility. This documentation may include, but may not be limited to, signed agreements or contracts indicating roles and responsibilities of all of the individuals/entities involved.

The applicant for authorization under 10 CFR 30.32(j) for the production of PET radioactive drugs is required to be a consortium member but is not required to be the consortium member that has the PET radionuclide production facility. The applicant is required by 10 CFR 30.32(j)(1) to either request authorization for the production of PET radionuclides, if the applicant has the PET radionuclide production facility and does not have a license for it, or provide evidence of an existing license issued under 10 CFR Part 30 or the Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

Response from the Applicant:

- Identify the medical use members of the consortium or provide a description of the criteria for consortium membership.
- Describe the geographical area in which the members are located.
- Provide documentation of the terms of the association demonstrating the joint ownership or sharing of the operation and the maintenance cost of the PET radionuclide production facility.
- Request authorization for the production of PET radionuclides if the applicant has the PET radionuclide production facility but does not have a license for it.
- Provide evidence of an existing license issued under 10 CFR Part 30 or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides

QUALIFIED TO PRODUCE PET RADIOACTIVE DRUGS

10 CFR 30.32(j)(2) requires that the applicant be qualified to produce PET radioactive drugs for medical use by meeting one of the following criteria:

- Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
- Registered or licensed with a state agency as a drug manufacturer;
- Licensed as a pharmacy by a State Board of Pharmacy;
- Operating as a nuclear pharmacy within a Federal medical institution; or
- A PET drug production facility registered with a State agency.

Response from the Applicant:

- Provide documentation of registration with the FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a); or
- Provide a copy of State agency registration or license as a drug manufacturer; or
- Provide a copy the State Board of Pharmacy pharmacy license; or
- Provide evidence of operation as a nuclear pharmacy within a Federal medical institution; or
- Provide a copy of State agency registration as a PET drug production facility.

RADIOACTIVE MATERIALS AND USES

10 CFR 30.32(j)(4) requires the applicant to identify the PET radioactive drugs authorized under 10 CFR 30.32(j) for production and noncommercial distribution and requires the applicant to submit information on the radionuclide in the PET radioactive drug; the chemical and physical form; and the maximum activity per vial, syringe, generator, or other container of the radioactive drug. It is the responsibility of the medical use consortium licensees to dispose of unused dosages, empty syringes, and vials received from the licensee authorized to produce and transfer PET radioactive drugs to consortium members. Because applicants are only authorized for production and noncommercial distribution of these PET radioactive drugs, the applicant must request authorization to receive potentially contaminated "empty" radiation transport shields back from consortium members.

Response from the Applicant:

- Identify the radionuclide; the chemical and physical form; and the maximum activity per vial, syringe, generator, or other container for each PET radioactive drug produced under this authorization.
- Request authorization to receive potentially contaminated "empty" radiation transport shields back from consortium members.

INDIVIDUALS RESPONSIBLE FOR RADIOACTIVE SAFETY PROGRAMS AND THEIR TRAINING AND EXPERIENCE

Individuals responsible for the Radiation Safety Program for the production of PET radioactive drugs and their transfer are the applicant's (or licensee's) Radiation Safety Officer (RSO) and the authorized individual(s) responsible during the production processing of the PET radionuclides into radioactive drugs. The applicant's RSO and authorized individuals must meet the requirements in 10 CFR 30.33(a)(3). If these individuals are already identified for other materials and uses, they may already be authorized for the quantities, materials, and radiation safety considerations associated with the PET radioactive drug production process. In order to demonstrate that these individuals are qualified by their training and experience to use these materials for the purposes requested, as required by 10 CFR 30.33(a)(3), these individuals must

describe their additional training and experience for the quantities, materials, and radiation safety considerations that differ substantially from the current authorization(s).

If the applicant is producing the PET radioactive drugs in a pharmacy, the applicant must be an Authorized Nuclear Pharmacist (ANP). The applicant should refer to the current version of NUREG-1556, Vol. 13, "Commercial Radiopharmacy Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," for guidance on the minimum training and experience requirements for an ANP and optional use of NRC Form 313A (ANP) to document the individuals' training and experience.

A licensee that produces PET radioactive drugs under a 10 CFR 30.32(j) authorization in a pharmacy is permitted to let an individual begin work as an ANP if the individual meets the board certification requirements in 10 CFR 35.55, and is listed on an NRC or Agreement State license as an ANP or listed as an ANP on a permit issued by a master materials licensee. Note that the licensee is required to notify the NRC within 30 days from the date the individual began work and must provide the specified information in accordance with 10 CFR 35.14.

Response from the Applicant:

- Identify the individuals responsible for the Radiation Safety Program and describe their training and experience using similar quantities, materials, and uses of radioactive materials.
- Describe the RSO's additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.
- Describe the authorized individuals' additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.
- If producing the PET radioactive drugs in a pharmacy, identify at least one individual who meets the requirements of an ANP and document that his or her training and experience meets the requirements in 10 CFR 35.55 for a new ANP or 10 CFR 35.57 for an experienced ANP. NRC Form 313A (ANP) may be used to document this information for new ANPs.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Individuals working with licensed 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 10 CFR 19.12.

Applicants should have already provided the training information for individuals working in or frequenting restricted areas as part of their radionuclide possession license application. In addition to this training information, applicants must ensure that individuals that will be involved in the preparation and transportation of hazardous materials, such as PET radioactive drugs, meet the training requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704.

Section 8.8.2 and Section 8.8.3 of the current version of NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses" provide guidance on training requirements for individuals involved in the preparation and transport of hazardous materials packages and for supervised individuals who will prepare radioactive drugs.

Response from the Applicant:

For personnel involved in the preparation and transport of hazardous materials, the applicant should submit the following statement:

"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."

For supervised individuals preparing radioactive drugs, the applicant does not need to provide a response. Supervision will be reviewed during inspection.

FACILITIES AND EQUIPMENT

Applicants should have already provided information regarding the facilities and equipment used for the radionuclide facility. In addition to this information, in order to demonstrate that the facilities and equipment are adequate to protect public health and safety, as required by 10 CFR 30.33(a)(2), the applicant must provide a description of the facilities and equipment used for the production of PET radioactive drugs and the noncommercial distribution to consortium members. Section 8.9.2 (Facilities and Equipment for PET Radioapharmacies) of the current version of NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," provides guidance on the information that should be provided regarding the PET radioactive drug production and distribution facility/area.

Response from the Applicant:

- Describe the facilities and equipment to be made available at each location where radioactive materials will be used, which includes the method used to physically transfer licensed material to the different processes (e.g., chemical synthesis, dispensing). A diagram should be submitted showing the applicant's entire facility and identifying activities conducted in all contiguous areas surrounding the facility (see Figure 8.5). Diagrams should be drawn to a specified scale, or dimensions should be indicated.

Include the following information:

- Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive drugs and the location(s) for radioactive waste storage;
- Sufficient detail in the diagram to indicate locations of shielding and/or shielding equipment (e.g., hot cells for positron emitting radionuclides), the proximity of radiation sources to

unrestricted areas, and other items related to radiation safety, such as remote handling equipment and area monitors;

- A general description of the ventilation system, including representative equipment such as glove boxes or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the production, use or storage of radioactive drugs; and
- Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d).

RADIATION SAFETY PROGRAM

The majority of information regarding the Radiation Safety Program may have already been provided to NRC as part of a radionuclide production/possession license application. The applicant should review its authorization to determine whether supplementary information should be submitted about its Radiation Safety Program. Section 8.10 (Item 10: Radiation Safety Program) of this guidance document provides guidance regarding an acceptable Radiation Safety Program for a radionuclide production facility. This guidance also applies to the production of PET radioactive drugs. However, in addition to the radiation safety guidance mentioned in this document, applicants that will produce and noncommercially distribute PET radioactive drugs to their consortium members pursuant to 10 CFR 30.32 (j), must adhere to the following:

Dosage Measurement System

10 CFR 30.33(a)(2) requires, among other things, that the applicant's proposed equipment be adequate to protect public health. 10 CFR 30.34(j)(2)(ii), requires a licensee to possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and have procedures for use of the instrumentation. 10 CFR 30.34(j)(2)(ii) also requires licensees to measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. The licensee must also perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; make adjustments when necessary; and check each instrument for constancy and proper operation at the beginning of each day of use.

Therefore, the licensee shall have procedures for the use of instrumentation. In addition, the licensee shall measure, by direct measurement or a combination of direct measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to noncommercial distribution.

The licensee must also ensure that the dose calibrator, or other dose measurement systems, function 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. For photon-emitters such as PET radionuclides, activity measurement is a fairly straightforward determination. Generally, PET radionuclides can be measured using direct measurement only and do not require calculations to be performed, which is often required for beta-emitting radionuclides.

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). Licensees should assay patient dosages in the same type of vial or syringe and geometry as used to determine the correct dose calibrator settings. The use of vials or syringes other than those used for geometry dependence may result in measurement errors. Also, 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.

Response from the Applicant:

- Describe instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium.
- Describe the types of systems (measurement or combination of measurement and calculation) intended for the measurement of PET radioactive drugs.
- For each dose measurement system used to measure the amount of radioactivity in PET radioactive drugs, state: "We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meets the requirements in 10 CFR 30.34(j)(2)(ii)."

Radioactive Drug Labeling for Distribution

10 CFR 30.34(j)(2)(i) requires the licensee for the noncommercial transfer of PET radioactive drugs to label each transport radiation shield to show the radiation symbol (as described in 10 CFR 20.1901). 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 term transport radiation shield refers to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. In order to comply with 10 CFR 30.32(j)(4), the transport radiation shield should be constructed of material appropriate for the isotope to be transferred for noncommercial distribution.

The licensee must also label each syringe, vial, or other container (e.g., generator) used to hold PET radioactive drugs for noncommercial transfer to consortium members. The label must include the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL." The label must also include an identifier that ensures the syringe, vial, or other container can be correlated with the information on the transport radiation

shield label. Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

Response from the Applicant:

- 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).
- Confirm that the required labels will be affixed to all transport radiation shields and to each container used to hold the radioactive drugs.

Radioactive Drug Shielding for Noncommercial Transfer

10 CFR 30.33(a)(2) requires, among other things, that the applicant's proposed equipment be adequate to protect public health. 10 CFR 30.34(j)(4) requires that the shielding provided for each radioactive drug to be noncommercially distributed be appropriate for safe handling and storage by the consortium members. The applicant must provide appropriate transport radiation shields for the primary container of each PET radioactive drug that it intends to distribute. The shielding must be adequate for the types and quantities of radioactive materials that the applicant intends to transfer. Typically, transport radiation shields used to carry radioactive drugs include two-piece, shielded syringe and vial containers (or "pigs"). Facilities have used lead and tungsten shields for gamma/photon-emitting materials. 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.

Response from the Applicant: For each PET radioactive drug to be noncommercially distributed:

- 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: With respect to the transport radiation shield, 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.

Transportation

For the transportation of PET radioactive drugs to consortium members, refer to Section 8.10.9 (Transportation) of this document for guidance. The required transportation information should be consistent with the information provided for the production and distribution of accelerator-produced radionuclides.

WASTE MANAGEMENT

Radioactive waste generated as part of the production of PET radioactive drugs for noncommercial distribution to consortium members must be disposed of in accordance with regulatory requirements and license conditions. In order to comply with the regulations in 10 CFR Part 20 and 10 CFR 30.51, appropriate records of waste disposal must be maintained. Section 8.11 (Item 11: Waste Management) of this document provides guidance on the information required for handling waste.

Return Waste

It is the responsibility of the other medical use consortium licensees to dispose of unused dosages, empty syringes, and vials received from the licensee who is authorized to produce and transfer PET radioactive drugs to its consortium members. Under 10 CFR Part 20, these consortium members can only send radioactive waste to individuals authorized to receive it. The licensee authorized to produce and transfer PET radioactive drugs to consortium members will not be authorized to receive returned used or unused radioactive drugs from consortium members. Therefore, only "empty" radiation transport shield packages can be returned to the production facility.

APPENDIX Q

Addendum: Summary of Comments Received on Draft NUREG-1556, Vol. 21

[COMMENTS WILL BE ADDED AND ADDRESSED HERE]

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10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

On August 8, 2005, the Energy Policy Act of 2005 (EPAct) gave NRC new regulatory authority over additional byproduct material. This new byproduct material now also includes naturally occurring materials, such as discrete sources of radium-226, and accelerator produced radioactive materials (NARM). This guidance document provides assistance to applicants in preparing a license application for a specific possession license for the production of radioactive material using an accelerator. This guidance document should be used for activities that take place once radioactive materials are produced by the accelerator, which include material in the target and associated activation products, to the transfer or distribution of material to another license for preparation of the final product (e.g., radioactive drugs). This document does not include information for the operation of the accelerator as NRC does not regulate the accelerator or its operation. Also, neutron accelerators and other types of accelerators (e.g., linear accelerators) that are used to produce particle beams and not radioactive materials will not be covered in this document.

This report also provides guidance to applicants in applying for authorization for the production and noncommercial distribution of Positron Emission Tomography radioactive durgs to medical use licenees in a consortium.

This document describes both the methods acceptable to NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*

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