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Vol. 12

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution

Final Report

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ABSTRACT

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol. 12, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution," dated December 2000, is the twelfth program-specific guidance developed for the new process and is intended for use by applicants, licensees, and NRC staff, and will also be available to Agreement States. This document combines and updates the guidance found in: (1) Regulatory Guide 10.7, "Guide for the Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material," dated August 1979; (2) NMSS Policy and Guidance Directive FC 84-1, "Review Responsibility – Manufacturing and Distribution of Products to Persons Exempt Pursuant to 10 CFR 32.11 through 32.26," dated April 1984; (3) NMSS Policy and Guidance Directive FC 85-6, "Standard Review Plan for Applications for Licenses and Approvals to Authorize Distribution of Various Items to Group Medical Licensees," dated February 1985; and (4) Draft Regulatory Guide DG-0007, "Guide for the Preparation of Applications for Licenses to Authorize Distribution of Various Items to Commercial Nuclear Pharmacies and Medical Use Licensees," dated March 1997. This report takes a more risk-informed, performance-based approach to licensing possession and reduces the amount of detailed information needed to support an application. If a license of broad scope is being sought (under 10 CFR 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"), also refer to another document in this series, NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope." When published, this final report should be used in preparing manufacturing and distribution license applications. NRC staff will use this final report in reviewing these applications.

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FOREWORD

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	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Radiography Licenses	Final Report
3	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 Irradiators	Final Report
6	Program-Specific Guidance about 10 CFR Part 36 Irradiators	Final Report
7	Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope	Final Report
8	Program-Specific Guidance about Exempt Distribution Licenses	Final Report
9	Program-Specific Guidance about Medical Use Licenses	Draft
10	Program-Specific Guidance about Master Material 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	Program-Specific Guidance about Commercial Radiopharmacy Licenses	Final 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

Vol. No.	Volume Title	Status
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
19	Guidance For Agreement State Licensees Proposing to Work in NRC Jurisdiction (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

The current document, NUREG-1556, Vol. 12, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution," dated December 2000, is the twelfth program-specific guidance developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It combines and updates the guidance for applicants and licensees previously found in Regulatory Guide 10.7, "Guide for the Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material," dated August 1979; NMSS Policy and Guidance Directive FC 84-1, "Review Responsibility – Manufacturing and Distribution of Products to Persons Exempt Pursuant to 10 CFR 32.11 through 32.26," dated April 1984; NMSS Policy and Guidance Directive FC 85-6, "Standard Review Plan for Applications for Licenses and Approvals to Authorize Distribution of Various Items to Group Medical Licensees," dated February 1985; and Draft Regulatory Guide DG-0007, "Guide for the Preparation of Applications for Licenses to Authorize Distribution of Various Items to Commercial Nuclear Pharmacies and Medical Use Licensees," dated March 1997. This report also contains pertinent information found in Information Notices and other documents, as listed in Appendix A.

This report takes a risk-informed, performance-based approach to licensing possession for manufacturing and distribution. It reduces the amount of information needed from an applicant seeking to possess and use byproduct, source, and/or special nuclear materials for activities associated with possession for manufacturing, and/or distribution to specific licensees and distribution to medical use licensees. A team composed of NRC staff from Headquarters and Regional Offices drafted this document, drawing on their collective experience in radiation safety in general, and as specifically applied to licensing of possession for manufacturing and distribution. A representative of NRC's Office of the General Counsel provided a legal perspective.

NUREG-1556, Vol. 12, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution," dated December 2000, 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/NRC/NUREGS/SR1556/V12/index.html>.

NUREG-1556, Vol. 12, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution," dated December 2000, is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this report are provided for information. 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. If a license of broad scope is being sought (under 10 CFR 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"), also refer to another document in this series, NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANSI	American National Standards Institute
AU	authorized user
bkg	background
BPR	Business Process Redesign
Bq	becquerel = 1 disintegration (transformation) per second
CD-ROM	compact disc with read-only memory
Ci	curie = 3.7 x 1010 disintegrations per second
CFR	Code of Federal Regulations
CoC	certificate of compliance (shipping packages)
cpm	counts per minute
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
DAC	derived air concentration
DDE	deep dose equivalent
DFP	Decommissioning Funding Plan
DIS	decay in storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
EA	environmental assessment
EDE	effective dose equivalent
EPA	United States Environmental Protection Agency
F/A	financial assurance
FDA	United States Food and Drug Administration
GBq	gigabecquerel
GC	gas chromatograph
G-M	Geiger-Mueller
GPO	Government Printing Office
IAEA	International Atomic Energy Agency
IN	information notice
IMC	inspection manual chapter
L/C	license condition
LDE	lens (eye) dose equivalent
LLW	low level radioactive waste
LSC	liquid scintillation counter
LSA	low specific activity
mBq	millibecquerel
MCA	multichannel analyzer
MDA	minimum detectable activity
my	milligram
mR	milliroentgen

mrem	millirem
mSv	millisievert
NaI(Tl)	sodium iodide crystal doped with thallium
NCRP	National Council on Radiation Protection and Measurements
ND	not detectable
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Materials Safety and Safeguards
NORM	naturally occurring radioactive materials
NR	not required
NRC	Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
QC	quality control
QA	quality assurance
R	roentgen
rem	roentgen equivalent man
RG	regulatory guide
RQ	reportable quantities
RSO/RPO	Radiation Safety Officer/Radiation Protection Officer
SDE	shallow dose equivalent
SI	International System of Units (abbreviated SI from the French, “Systeme Internationale d’Unites”)
SPO	NRC Spent Fuel Project Office
SSD	sealed source and device
Std	standard
STP	Office of State and Tribal Programs
Sv	sievert
T1/2	half-life
TAR	technical assistance request
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
USDA	United States Department of Agriculture
kilo (k)	1,000
micro (F)	1 x 10-6
milli (m)	1 x 10-3
mega (M)	1 x 106
giga (G)	1 x 109
tera (T)	1 x 1012

1 PURPOSE OF REPORT

This report provides guidance on three types of licenses associated with the manufacturing and distribution of radioactive materials and products containing radioactive materials. It provides guidance to an applicant in preparing a license application for one of these license types: possession for manufacturing and distribution; possession for distribution only and for distribution (only) for medical use, as well as NRC criteria for evaluating the license application.

The body of this document contains the standard requirements and guidance for the first two types of licenses: (1) possession and use for manufacturing, including distribution of products to other specific licensees authorized to receive the products; and (2) possession for distribution only (which requires a separate distribution license). Appendix U of this document contains the standard requirements and guidance for the third type of materials licenses for the distribution (only) and transfer of radioactive drugs, sealed sources, and devices directly to medical use licensees. Note that this guidance does not apply to those quantities of special nuclear material exceeding those listed in 10 CFR 70.22 (h)(2)(i)(1).

For the purpose of this NUREG, materials manufacturers are those licensees that process raw material and/or sources and distribute those processed materials or manufactured products to users as finished products. Examples are: major radiopharmaceutical processor/manufacturers (not radiopharmacies); sealed source fabricators; device manufacturers; and other manufacturing licensees that possess and use irradiated bulk quantities of raw materials or sources.

As noted above, this NUREG also applies to licensing for distribution to specific licensees and to medical use licensees. Guidance for obtaining licenses for distribution to general licensees and for distribution of items to persons exempt from license requirements is supplied in other NUREGs in this series. Distribution-only licensees are not involved in the processing of raw materials or sources, nor in the manufacturing of devices. Distributors also include importers for purposes of distribution.

Quality control for finished products is part of the manufacturer licensee's responsibilities. These obligations are described in the regulations of 10 CFR Part 32. Quality control of finished products to be distributed to general licensees or individuals exempt from licenses are listed in NUREG-1556, Vol. 16 and NUREG-1556, Vol. 8, respectively.

This report identifies the information needed to complete NRC Form 313 (Appendix B), "Application for Material License," for the possession and use of byproduct, source, and/or special nuclear materials for manufacturing and distribution, and for distribution (only) for medical use. If a license of broad scope is being sought (under 10 CFR 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"), also refer to another document in this series, NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope." The information collection requirements in 10 CFR Part 30, Part 32, Part 40, Part 70, and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0017, 3150-0001, 3150-0020, 3150-0009, and 3150-0120, respectively.

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 manufacturing and distribution applications, applicants may use Appendix C, "Suggested Format For Providing Information Requested In Items 5 through 11 of NRC Form 313," to provide supporting information to NRC.

Appendices D through U contain additional information on various radiation safety topics. Appendix D has sample possession for manufacturing and distribution licenses; it contains the conditions most often found on these licenses, although not all licenses will have all conditions. Appendix F provides information on the types of licenses. Appendix U provides guidance in applying for distribution (only) to medical use licensees.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent (EDE), committed dose equivalent (CDE), committed effective dose equivalent (CEDE), or total effective dose equivalent (TEDE). These terms are defined in 10 CFR Part 20. Roentgen equivalent man (rem), and its SI (Systeme International) equivalent, sievert (Sv) (0.01 Sv = 1 rem), is used to describe units of radiation exposure or dose. This is because 10 CFR Part 20 sets dose limits in terms of rem, not rads or roentgens (R).

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, needs to contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with NRC.

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 non-exclusive Federal jurisdiction land. Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that licensees 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, so that licensees can 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 from NRC upon request. All Agreement States Letter, SP-96-022, dated February 16, 1996, is available by calling the Office of State and Tribal Programs (STP). Call NRC's toll free number (800) 368-5642, for extension 415-3340, or visit NRC's Office of State and Tribal Programs' (STP's) home page at <http://www.hsrd.ornl.gov/nrc>. Choose "NRC-State Communications," then choose "Other"; scroll down to find "1996" then "SP-96-022."

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 that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 70.11])	NRC
Non-Federal entity in non-Agreement State, U.S. territory, or possession	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

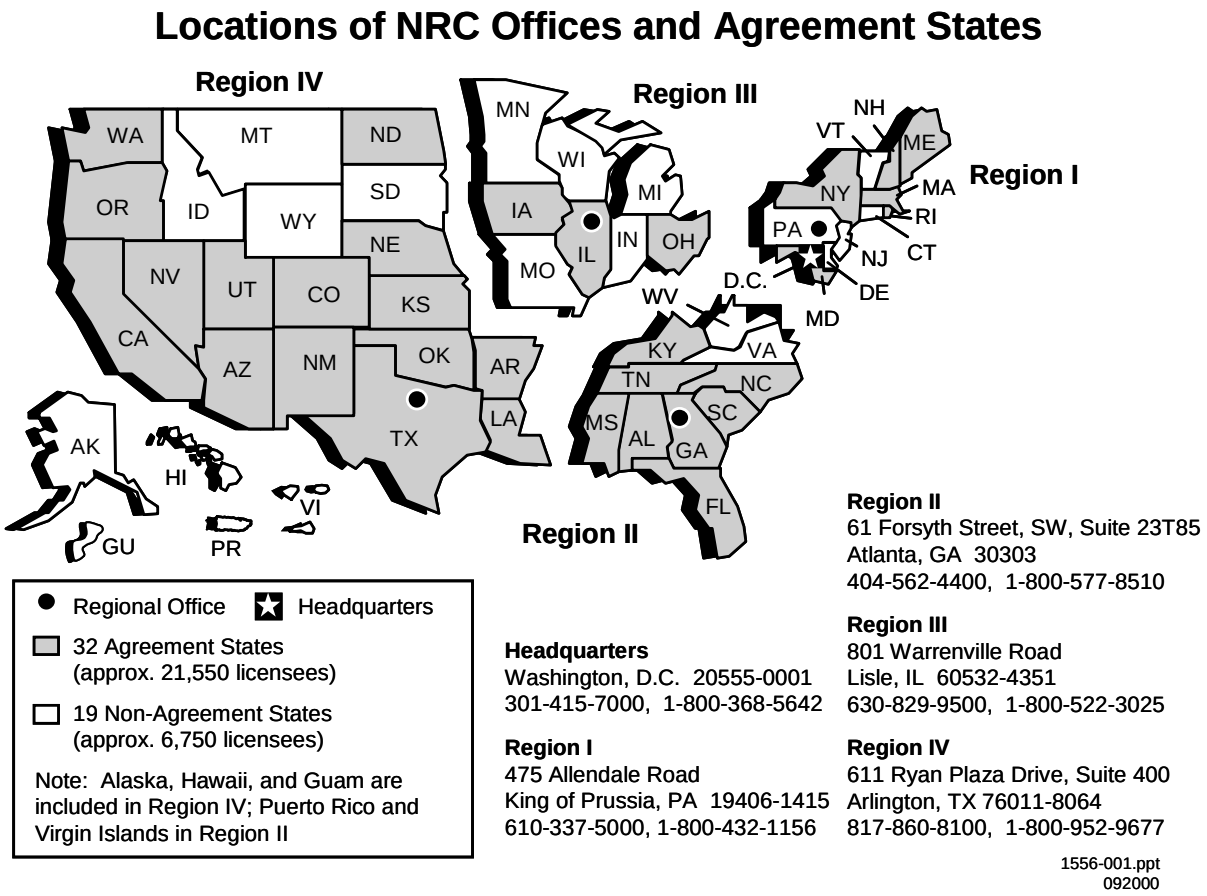

Figure 2.1 U.S. Map. *Location of NRC Offices and Agreement States.*

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices. You can also visit NRC's Office of State and Tribal Programs' (STP's) home page at <http://www.hsrd.ornl.gov/nrc> and choose "Directories," then "State Program Directors."

3 MANAGEMENT RESPONSIBILITY

NRC recognizes that effective Radiation Safety Program management is vital to achieving safe and compliant operations. NRC believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. NRC also believes that effective management will result in increased safety and compliance.

"Management" refers to the processes for conducting and controlling the licensee's 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 Protection Program to ensure that the public and workers are protected from radiation hazards and 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, 40.7 and 70.7).
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7, 40.7, and 70.7 and 10 CFR 30.10, 40.10, and 70.10, respectively.
- Obtaining NRC's prior written consent before transferring control of the license.
- Notifying the appropriate NRC Regional Administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current versions of "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, and Inspection Procedure 87110, Appendix A, "Industrial/Academic/ Research Inspection Record." The current version of NUREG-1600 is available electronically at <http://www.nrc.gov/OE>. To obtain hard copies of the current versions of NUREG-1600 and

Inspection Procedure 87110, Appendix A, see the Notice of Availability (on the inside front cover of this report). In addition, Inspection Procedure 87110 can be found at <http://www.nrc.gov>.

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation.

The following Parts of Title 10, Code of Federal Regulations (CFR), contain regulations applicable to possession for manufacturing and distribution:

- 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"
- 10 CFR Part 40, "Domestic Licensing of Source Material"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- 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 must comply with the applicable requirements of the U.S. DOT that are found in 49 CFR Parts 170 through 189. A summary of DOT and NRC requirements for transportation of radioactive materials may be found in NUREG-1660/ RAMREG-002, "U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments." Copies of DOT regulations can be ordered from the Government Printing Office (GPO), whose address and telephone number are listed below.

- 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material"
- 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"
- 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."

To obtain copies of the above documents, contact the GPO electronically at <http://www.gpo.gov> or call GPO's order desk in Washington, DC at (202) 512-1800. Applicants should contact the Customer Service desk of the GPO at (202) 512-1803 for inquiries about costs of these documents and methods of payment. To obtain the two-volume bound version of Title 10, Code of Federal Regulations (10 CFR), Parts 0-50 and 51-199, contact the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. Single copies of the above documents may also be obtained from NRC's Regional or Field Office (see Figure 2.1 for addresses and telephone numbers). Note that amendments to NRC regulations are published frequently (monthly) in the *Federal Register*. In addition, the *Federal Register* is available at <http://www.gpo.gov>. Title 10 is also available at <http://www.nrc.gov>.

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 Appendix C. If a license of broad scope is being sought (under 10 CFR 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"), also refer to another document in this series, NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."
- 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, including drawings, if practicable, printed on 8-1/2 x 11 inch paper. If submission of larger documents is necessary, fold them to 8-1/2 x 11 inches.
- Identify each drawing with drawing number, revision number, title, date, scale, and applicant's name. Clearly indicate if drawings have been reduced or enlarged.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original application with original attachments (if any) and one copy of the entire document.
- Retain one copy of the license application and attachments for future reference.

As required by 10 CFR 30.32 (c), applications must be signed by an authorized representative; see Section 8.13, Certification.

Use of the suggested wording of responses and a commitment to use the model procedures in this report will expedite NRC's review. Applicants need not adopt the model procedures; however, if they choose not to do so, they must submit procedures that, if followed, will ensure compliance with radiation protection requirements.

All license applications will be available for review by the general public in NRC's On-line Public Document Room. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information (i.e., home address, home telephone number, social security number, date of birth, and radiation dose information) should not be submitted unless specifically requested by NRC.

As explained in the Foreword to this document, NRC's new licensing process will eventually become faster and more efficient, in part, through accepting and processing electronic applications. In the meantime, NRC will continue to accept paper applications, which will be scanned and converted to electronic format. To ensure a smooth conversion, applicants are requested to follow these suggestions:

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

5.2 ELECTRONIC APPLICATION

In the future, as the electronic licensing process develops, it is anticipated that NRC will provide mechanisms for filing electronic applications on diskette, compact disc with read-only memory (CD-ROM), or via the Internet. NRC will provide additional filing instructions as these new mechanisms become available. The existing paper process will continue to be used until the electronic process is available.

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 identifies Agreement States and shows NRC's four Regional Offices and their respective areas for licensing purposes.

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 licensed materials will be possessed or used 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 Section 2, Agreement States, for additional information.

7 LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. If applying for both a possession and use license and a Medical Distribution license, fees should be included for both licensing actions. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the new license 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 should an application be withdrawn.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for additional 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 (Appendix B) to the Office of the Chief Financial Officer (OCFO) at NRC Headquarters in Rockville, Maryland, (301) 415-7554. You may also call 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).

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 box A for a new license request.

Check box B for an amendment[1] to an existing license, and provide license number.

Check box C for renewal[1] of an existing license, and provide license number.

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.

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

Timely Notification of Transfer of Control

Regulations: 10 CFR 30.34(b); 10 CFR 40.41(b); 10 CFR 70.32(a)(3).

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.
- 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."

Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h); 10 CFR 40.41(f)(1); 10 CFR 70.32(a)(9)(i).

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 needs to 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.

References: Information Notices are available in the "Reference Library" on NRC's home page at <http://www.nrc.gov>. See the Notice of Availability (on the inside front cover of this report) to obtain copies of Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," dated August 8, 1996; and NRC Inspection Manual, Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing." 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."

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

Regulations: 10 CFR 30.34(c); 10 CFR 40.41(c); 10 CFR 70.41(a).

Specify each proposed location of possession or possession and use by street address, city, state, and zip code, or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State). The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A Post Office box address is not acceptable, as illustrated in Fig. 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., panoramic irradiators, interim or long-term waste storage facilities, high activity laboratories, iodination facilities, alpha laboratories, and incinerators.

An 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.

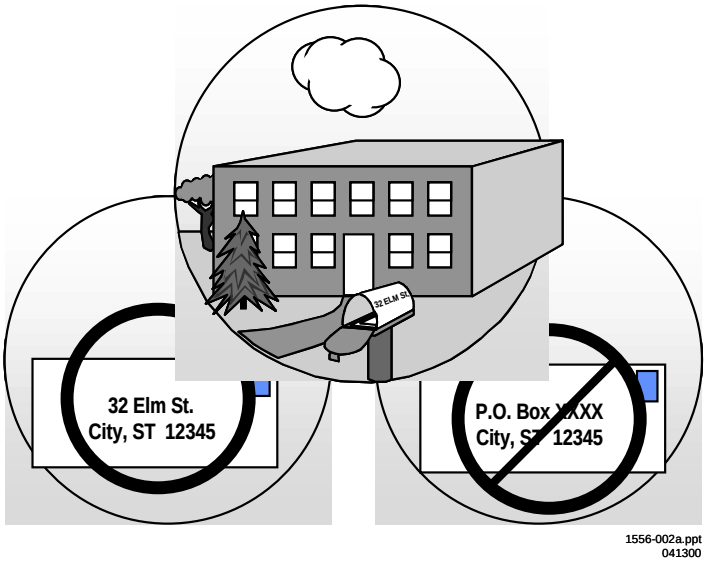

Figure 8.1 Location of Possession or Possession and Use. *An acceptable location of possession or possession and use specifies street address, city, state, and zip code and does not include a Post Office box number.*

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 or a local ordinance requiring registration of radioactive material).

Note: As discussed later in Section 8.5.2, 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 is typically the proposed RSO, unless the applicant has named a different person as the contact. NRC will contact this individual if there are questions about the application.

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

8.5 ITEMS 5: RADIOACTIVE MATERIAL

As indicated on NRC Form 313 (Appendix B), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C for this purpose and should note that use of the suggested wording of responses and a commitment to use the model procedures in this report will expedite NRC's review. Applicants need not adopt the model procedures; however, if they choose not to do so, they must submit procedures that if followed, will ensure compliance with radiation protection requirements.

Regulations: 10 CFR 30.6; 10 CFR 30.11; 10 CFR 30.32; 10 CFR 30.33; 10 CFR 30.36; 10 CFR 30.37; 10 CFR 30.38; 10 CFR Part 32; 10 CFR Part 40; 10 CFR Part 51; 10 CFR Part 70; 10 CFR 110.9; 10 CFR 110.9a; 10 CFR 110.31; 10 CFR 110.32.

Criteria: A specific license is required, describing and authorizing the manufacture or distribution of materials and devices to persons generally licensed, specifically licensed, or specifically licensed to distribute materials and devices to medical use licensees. Licenses authorizing distribution only to specifically licensed or generally licensed persons do not generally allow possession and processing of licensed materials. Licenses authorizing the distribution of materials to persons exempt from licensing are not described in this document. See NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses." Licenses authorizing the distribution of materials to generally licensed persons are not described in this document. See NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees." If a license of broad scope is being sought (under 10 CFR 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"), also refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

Discussion: Licensees are required to have a specific license authorizing manufacturing or incorporating licensed materials into devices or materials. Licensees or applicants desiring to incorporate a material into a sealed source or incorporate a sealed source into a device shall have the combination approved by NRC according to 10 CFR 32.51 or an Agreement State regulation, and listed in the Sealed Source & Device (SSD) Registry.

Licensees who possess and use licensed materials to support the process of manufacturing and/or distribution shall have the appropriate possession and uses described in their licenses. An example may be that a manufacturer of depleted uranium counterweights or shields possesses and uses a cesium-137 level gauge to detect blockage in the raw material hopper feed line. The manufacturer would need authorization not only to possess, use, and distribute the uranium for

the counterweights and the shields, but also a line authorization to possess and use the level gauging device. If the licensee wishes to calibrate its own survey meters and perform leakage/contamination tests, then separate line authorizations on the same license are needed for the survey instrument calibration source/device, and the calibration sources for the detection system for leakage/contamination testing. The licensee should have procedures for these uses.

Response from Applicant: No response is required.

8.5.1 SEALED SOURCES AND DEVICES OR UNSEALED RADIOACTIVE MATERIAL

Regulations: 10 CFR 30.6; 10 CFR 30.11; 10 CFR 30.32; 10 CFR 30.33; 10 CFR 30.36; 10 CFR 30.37; 10 CFR 30.38; 10 CFR 32.11; 10 CFR 32.14; 10 CFR 32.17; 10 CFR 32.18; 10 CFR 32.21; 10 CFR 32.22; 10 CFR 32.26; 10 CFR 32.51; 10 CFR 32.53; 10 CFR 32.57; 10 CFR 32.61; 10 CFR 32.71; 10 CFR 32.72; 10 CFR 32.74; 10 CFR 32.210; 10 CFR 40.13; 10 CFR 40.31; 10 CFR 40.32; 10 CFR 40.34; 10 CFR 40.35; 10 CFR 40.36; 10 CFR 40.38; 10 CFR 40.41; 10 CFR 40.44; 10 CFR 51.20; 10 CFR 51.21; 10 CFR 51.22; 10 CFR 70.39; 10 CFR 70.40; 10 CFR 70.41; 10 CFR 110.9; 10 CFR 110.9a; 10 CFR 110.31; 10 CFR 110.32; 10 CFR 150.7.

Criteria: An application for a license will be approved if the requirements of 10 CFR 30.33, 10 CFR 40.32, 10 CFR 51.20, 10 CFR 70.39, 10 CFR 110.31 and/or 10 CFR 110.32 are met. In addition, licensees will be authorized to possess and use only those sealed sources and devices that are specifically approved or registered by NRC or an Agreement State pursuant to 10 CFR 32.210 or equivalent Agreement State regulations.

Discussion:

Materials That Must Be Listed in the Application

Each authorized radioisotope is listed on the NRC license by its element name, chemical and/or physical form, and the maximum possession limit, as shown in the sample licenses in Appendix D. Table 8.1 shows the type of radioactive material covered by this report. If a license of broad scope is being sought (under 10 CFR 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"), also refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

Table 8.1 Types of Radioactive Materials.

Type of Material	Covered by This Report	Examples
Byproduct (reactor-produced)	Yes	H-3, C-14, Co-60, I-131, I-125, S-35, Sr-89, Sr-90, P-32, P-33, Pd-103, Ca-45, Ni-63, Cd-109, Cs-137
Source material	Yes	U, Th, Depleted Uranium
Special nuclear material	Yes	Pu, etc.
Naturally occurring radioisotopes	No	Ra-226
Accelerator-produced radioisotopes	No	Co-57, Na-22, Tl-201, Ga-67, Pd-103

The applicant should list each requested radioisotope by its element name and its mass number (e.g., carbon-14 [C-14]) in Item 5. It is necessary to specify whether the material will be acquired and possessed and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not required. For volatile radioactive material, however, it is necessary to specify whether the requested radioisotope will be acquired in free (volatile) or bound (non-volatile) form, because additional safety precautions are required when handling and using volatile material. For example, when requesting authorization to possess and use iodine-125 (I-125), the applicant must specify whether the material will be acquired in free form or bound form. If a radioisotope will be acquired in both free and bound forms, then separate possession limits for each form must be requested. The applicant must provide evidence (or information) which demonstrates that the material obtained will be non-volatile. NRC may issue the license with separate or combined possession limits depending on the reviewer's analysis of the information provided.

Applicants requesting an authorization to possess and use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling such material.

If you plan to possess radioactive materials in excess of the quantities listed in 10 CFR 30.72 (Schedule C), then you must provide with the application either: (1) an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent (EDE) or 0.05 Sv (5 rem) to the thyroid;, or (2) an emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i). Refer to Regulatory Guide 3.67 and Policy and Guidance Directive (P&GD) 84-14 for additional information regarding emergency plans.

The anticipated possession limit in megabecquerels (MBq) (millicuries) or gigabecquerels (GBq) (curies) for each radioisotope should also be specified. Possession limits must cover 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. If materials are expected or requested to be returned from customers, then these materials must be factored into the inventory. 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 Section 8.5.2, Financial Assurance and Decommissioning.

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. The safety evaluation is documented in an SSD registration certificate. Information on SSD registration certificates may be obtained by calling NRC's toll-free number, (800) 368-5642, extension 415-7231. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to possess and use those sources and devices specifically listed on their licenses. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSD registration certificate or specifically approved on a license. See also NUREG-1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the SSD designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining NRC's prior permission in a license amendment. To ensure that applicants possess and use sources and devices according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer. It is not acceptable to use multiple exempt quantities in a single device, as set forth in 10 CFR 32.19.

Materials Not Subject to NRC Licensing

Requests to license naturally-occurring radioactive material (NORM) and accelerator-produced radioactive material should be made to the appropriate State Regulatory Agency. NRC does not regulate NORM or accelerator-produced radioactive material.

Response from Applicant:

- For unsealed materials:
  - — Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit.

- For potentially volatile materials (e.g., I-125, I-131, H-3, Kr-85):
  - — Specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form.
- For sealed radioactive materials:
  - — 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 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.
- Identify the largest quantity of each radionuclide to be possessed at one time under the license, including receipts, in-process materials, and waste.
- 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).

References: See the Notice of Availability (on the inside front cover of this report) to obtain copies of Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities." Regulatory Guide 3.67 is available on NRC's web site at <http//www.nrc.gov>.

Policy and Guidance Directive 84-14, Revision 1, "Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licensees."

8.5.2 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Regulations: 10 CFR 30.32(h); 10 CFR 30.34(b); 10 CFR 30.35; 10 CFR 30.36(e); 10 CFR 30.36(g)(4)(v); 10 CFR 30.51(d); 10 CFR 30.51(e); 10 CFR 30.51(f); 10 CFR 40.31(i); 10 CFR 40.36; 10 CFR 40.41(b); 10 CFR 40.42(e); 10 CFR 40.42(g)(4)(v); 10 CFR 40.61(d); 10 CFR 40.61(e); 10 CFR 40.61(f); 10 CFR 70.22(a)(9); 10 CFR 70.25; 10 CFR 70.32(a)(3); 10 CFR 70.38(e); 10 CFR 70.38(g)(4)(v); 10 CFR 70.51(b)(6); 10 CFR 70.51(b)(7).

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35, 10 CFR 40.36, and/or 10 CFR 70.25 must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance for decommissioning (F/A).

Even if no financial assurance is required, all licensees are required to maintain, in an identified location, decommissioning records important to the decommissioning of a facility. Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g), licensees must transfer these records to either of the following:

- The new licensee before licensed activities are transferred or assigned according to 10 CFR 30.34(b), 10 CFR 40.41(b), and 10 CFR 70.32(a)(3).
- 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). There are two parts to the rule: financial assurance that applies to **SOME** licensees, and recordkeeping that applies to **ALL** licensees.

NRC regulations requiring an F/A or a DFP 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 an F/A or a DFP when the possession of radioactive material of half-life (T1/2) 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 an F/A (or neither) are stated in 10 CFR 30.35, 10 CFR 40.36, and /or 10 CFR 70.25. 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.

Acceptable financial assurance includes prepayment options (trusts, escrow accounts, government funds, certificates of deposit, or deposits of government securities); surety, insurance, or other guarantee methods (letters of credit, surety bonds, lines of credit, parent company guarantees, insurance policies); and statements of intent for Government entities. Criteria for parent company guarantees and self-guarantees can be found in 10 CFR 30, Appendix A, Appendix C, Appendix D, and Appendix E. Refer to 10 CFR 30.35(d) for a table of required amounts of financial assurance for decommissioning by quantity of material.

NUREG-1727, “NMSS Decommissioning Standard Review Plan,” dated September 2000, provides guidance acceptable to the NRC staff on the information to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information. NUREG-1727, “NMSS Decommissioning Standard Review Plan,” dated September 2000, also describes the information required to be submitted for a DFP.

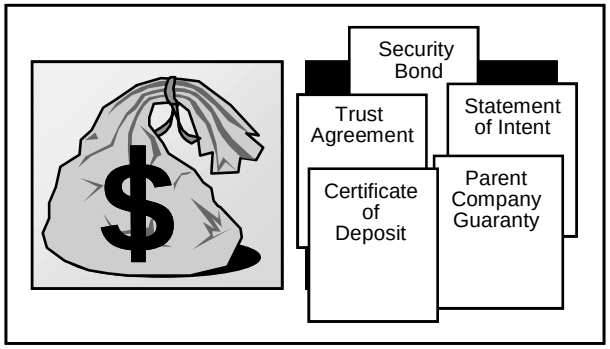

Figure 8.2 Financial Assurance for Decommissioning. *Most manufacturer licensees do not need to provide financial assurance for decommissioning. Large manufacturers may need one of several approved financial mechanisms.*

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(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. When the license is terminated, these records must be transferred to NRC. Careful recordkeeping of radionuclides possessed and used, including form, amount, and area used, will facilitate area release and license termination.

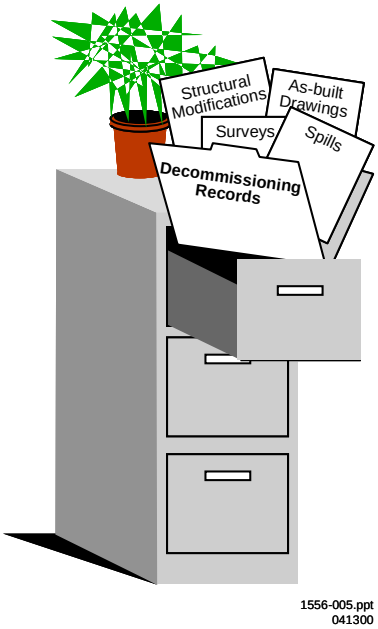

Figure 8.3 Records Important to Decommissioning. *All possession for manufacturing and distribution licensees must maintain records important to decommissioning, regardless of whether they need financial assurance for decommissioning.*

Response from Applicants: No response is needed from most applicants. If an F/A or a DFP is required, submit the required documents as described in NUREG-1727, "NMSS Decommissioning Standard Review Plan," dated September 2000.

References: See the Notice of Availability (on the inside front cover of this report) to obtain copies of NUREG-1727, "NMSS Decommissioning Standard Review Plan," dated September 2000.

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

Regulations: 10 CFR 30.4; 10 CFR 30.33(a)(1); 10 CFR 32.2; 10 CFR 32.11; 10 CFR 32.14; 10 CFR 32.17; 10 CFR 32.18; 10 CFR 32.21; 10 CFR 32.22; 10 CFR 32.26; 10 CFR 32.51; 10 CFR 32.53; 10 CFR 32.57; 10 CFR 32.61; 10 CFR 32.71; 10 CFR 32.72; 10 CFR 32.74; 10 CFR 32.210; 10 CFR 40.4; 10 CFR 40.32(a); 10 CFR 51.21; 10 CFR 51.22; 10 CFR 70.4; 10 CFR 70.39; 10 CFR 70.42; 10 CFR 110.2; 10 CFR 110.20; 10 CFR 110.42; 10 CFR 110.43; 10 CFR 110.50.

Criteria: Requested radioisotopes must be possessed and used for purposes authorized by the Atomic Energy Act of 1954, as amended. Sealed sources and devices containing licensed material must be possessed and used only for the purpose for which they are designed and according to manufacturer's (distributor's) instructions and recommendations for possession and use as specified in the SSD Registration Certificate.

In order to have a license for distribution of sources and devices containing radioactive materials, the applicant must first apply for and receive a Sealed Source and Device (SSD) registration in accordance with the procedures in NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

Note: If distributing sealed sources and devices to medical use licenses, also see Appendix U, Medical Distribution.

Discussion: Applicants should clearly specify the purpose for which each radioisotope will be used. The description should be detailed enough to allow NRC to determine the potential for exposure to radiation and radioactive materials to those working with radioactive materials and members of the public.

Applicants should pay particular attention to the applicable regulations listed above when applying for a license to manufacture and distribute licensed material (see Figure 8.4). However, this list is not exhaustive, nor does it relieve the applicant from complying with applicable Federal, State, and local requirements. Applicants considering research and development can include the requested licensed materials in this application and should refer to NUREG-1556,

Vol. 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope." Applicants intending to possess and use licensed materials for medical research involving humans must be authorized to do so pursuant to a license issued under 10 CFR Part 35, and should refer to NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." Applicants intending to become a broad scope licensee should refer to NUREG-1556, Vol. 11, "Consolidated Guidance for Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," for instructions.

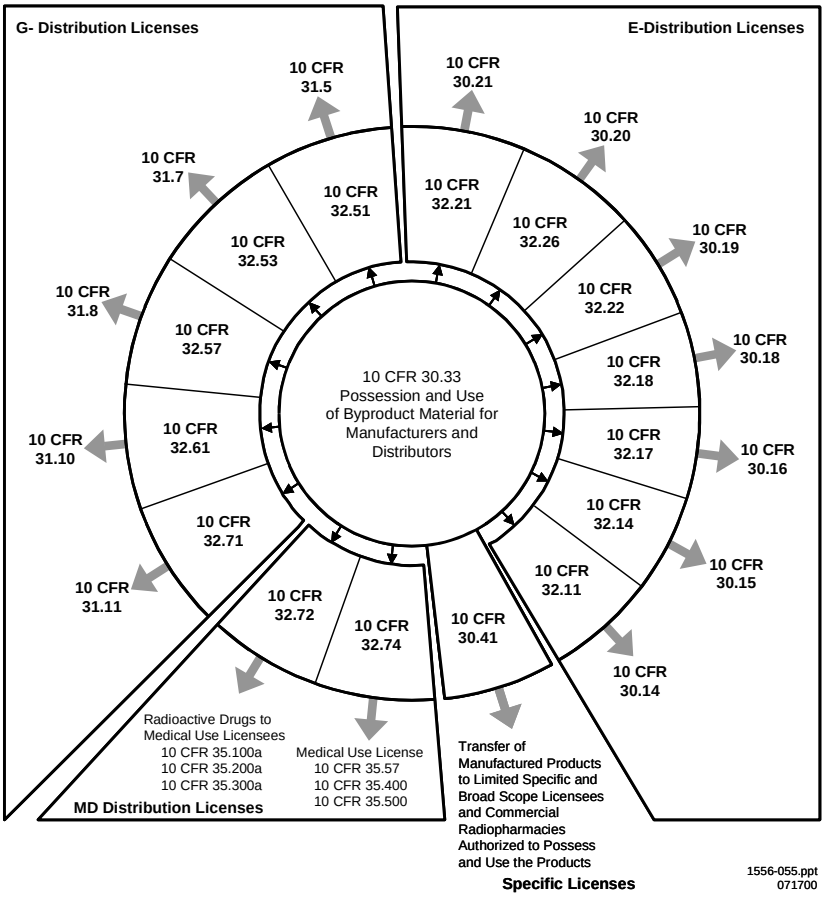

Figure 8.4 Regulation Wheel for Byproduct Material. *Possession for manufacturing and distribution of radioactive materials is authorized by several distinct regulations. The appropriate regulations to refer to depends on the nature of the material, the purpose(s) for which it will be possessed and used, and to whom it is sent.*

Applicants may use the format given in Table 8.2 to provide the requested information.

Table 8.2 Sample Format for Providing Information About Requested Radioisotopes.

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Manufacturing – Internal Uses			
Any byproduct material with atomic numbers 1 through 83	Any	Not to exceed 10 curies per radionuclide and 100 curies total	Research and development as defined in 10 CFR 30.4
Hydrogen-3	Unbound/volatile	100 millicuries	Labeling of compounds
Hydrogen-3	Bound/non-volatile	100 millicuries	*In vitro* studies; studies in small lab animals
Phosphorus-32	Any	30 millicuries	*In vitro* studies; labeling of compounds
Iodine-125	Unbound/volatile	30 millicuries	Protein iodination
Iodine-125	Bound/non-volatile	50 millicuries	*In vitro* studies; studies in small lab animals; calibration of instruments
Cesium-137	Sealed source, Mfg. name/model number	20 millicuries	Calibration of instruments
Manufacturing and Distribution			
Hydrogen-3	Unbound/volatile	100 millicuries	Labeling of compounds
Iodine-125	Unbound/volatile	30 millicuries	Protein iodination
Any byproduct material with atomic numbers 1 through 83	Any	Not to exceed 10 curies per radionuclide and 100 curies total	For possession, use, and processing incident to manufacture of radiochemicals, radiopharmaceuticals, and sealed sources

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Any byproduct material with atomic numbers 84 through 94	Any	Not to exceed 50 millicuries per radionuclide and 2 curies total	For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources
Hydrogen 3 Carbon 14 Phosphorus 32 Phosphorus 33 Sulfur 35	Any Any Any Any Any	100,000 curies 500 curies 100 curies 20 curies 400 curies	For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources
Hydrogen 3 Carbon 14 Phosphorus 32 Phosphorus 33 Sulfur 35	Any Any Any Any Any	100,000 curies 500 curies 100 curies 20 curies 400 curies	For packaging and distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses
Molybdenum 99/Technetium 99m	Any	500 curies	For possession, use, and processing incident to the manufacture of radiochemicals and radiopharmaceuticals
Distribution			
Xenon 133	Prepackaged Units	50 curies	For possession incident to commercial redistribution of unopened containers to authorized recipients

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Hydrogen 3	Any	100,000 curies	Distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources
Carbon 14	Any	500 curies	
Phosphorus 32	Any	100 curies	
Phosphorus 33	Any	20 curies	
Sulfur 35	Any	400 curies	

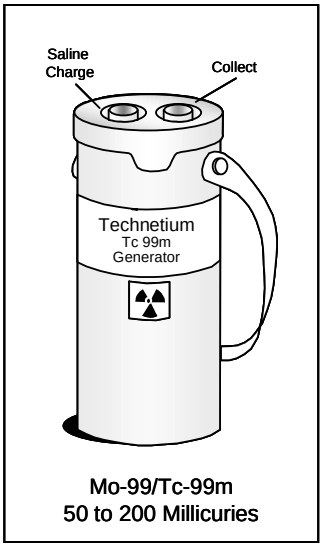

Figure 8.5 Example of a Product Produced Under Possession for Manufacturing and Distribution Authorization. *Other designs of technetium generators can contain up to 4 curies of Mo-99/Tc-99m.*

Applicants should clearly specify if the licensed material will be used in animal studies and/or tracer studies as part of manufacturing. Use of licensed material in animals may be in quality control or research studies. Applicants should also state whether the studies will be limited to small animals (e.g., rats, mice) or may also include larger animals (e.g., pigs, dogs, horses). See NUREG-1556, Vol. 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope."

Applicants requesting a license for distribution-only may need to refer to the information in Appendix F, which describes the different types of distribution licenses (i.e., General "G" Distribution License, Medical "MD" Distribution License, and Exempt "E" Distribution License), in order to determine whether this guidance document should be used for their application. Applicants for medical distribution licenses must refer to 10 CFR 32.72 and 32.74, in addition to the guidance specified in Appendices F and U. The applicant should also see the sample "MD" distribution licenses in Appendix D.

Some "manufacturers" are importers of materials and devices from abroad and do not require the same extent of information submission and review as a facility that produces an item. However, they are required to have a manufacturer/distributor license as the initial importer and distributor in the United States. The device distributor may be the sponsor of the "Sealed Source and Device Registry" certificate. The manufacturer/distributor license is separate from the "G" or "E" distribution license.

The general distribution only license ("G") and the exempt distribution only license ("E") application requirements are not covered in this document. Applicants for these licenses are referred to NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees," and NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses."

Response from Applicant: List the specific use or purpose of each radioisotope that will be possessed and used. Use of the suggested table format will facilitate review of the application.

- Identify each device, manufactured article, or material that becomes the product by manufacturer and model number.
- Identify the SSD registration certificate number of each sealed source proposed for possession and use or incorporation into a manufactured article.
- Submit information requesting authorization to possess and use any other licensed materials in support of the manufacturing and distribution license.

Note: Applicants intending to manufacture sealed sources or devices should refer to Appendix U, Item 10.2 for sealed source and device licensing criteria for evaluation of design and construction.

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

Regulations: 10 CFR 30.33(a)(3); 10 CFR 40.32(b); 10 CFR 70.22(a)(6); 10 CFR 70.23(a)(2).

Criteria: Executive management, the Radiation Safety Officer (RSO) (and his/her staff, as necessary), and users work as a team to implement the Radiation Protection Program. Each individual and position plays a critical role within his/her area of responsibility. The roles and responsibilities of executive management, the RSO, the Radiation Safety Office staff, users, and others in restricted areas are discussed in the sections that follow. Refer to the subsequent sections specific to the RSO and Authorized Users described above.

Note: NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," describes the role of executive management and the RSO at medical facilities, but

contains information that may be of help to the possession for manufacturing and distribution licensee.

Discussion: You must be qualified by training and experience to possess and use the material for the purpose 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. In a small program, the responsibility may be combined with or assigned to (or assumed by) the same individual using radioactive materials, therefore an authorized user may serve as an RSO. In a medium-sized program, the responsibility may be assigned to an individual on a part-time basis, with that person's primary responsibility being in another area of work. In a large program, the many facets of occupational and environmental radiation safety require that responsibility for the Radiation Safety Program be assigned to a qualified individual on a full-time basis. His or her 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 large program may have some or all of the following characteristics:

- In-house calibration of radiation survey, monitoring, and measurement instruments;
- The possession and use of multiple chemical and physical forms of multiple radionuclides for various purposes;
- Program flexibility with regard to the possession and use of radionuclides, their chemical and physical form, and the uses to be made of such radionuclides;
- 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, etc.;
- The need for the selection, evaluation, design, fabrication, maintenance, and use of radioactive effluent treatment systems;
- The need for the selection, evaluation, and maintenance of radiation measurement and analysis equipment;
- 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 Protection 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 underemphasized 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.

If a license of broad scope is being sought (under 10 CFR 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"), also refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

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

Regulations: 10 CFR 30.33(a)(3); 10 CFR 40.32(b); 10 CFR 70.23(a)(2).

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 Protection Program is called the Radiation Safety Officer (RSO). This individual may also be called the Radiation Protection Officer (RPO). 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 8.6 and described in Appendix G. 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.

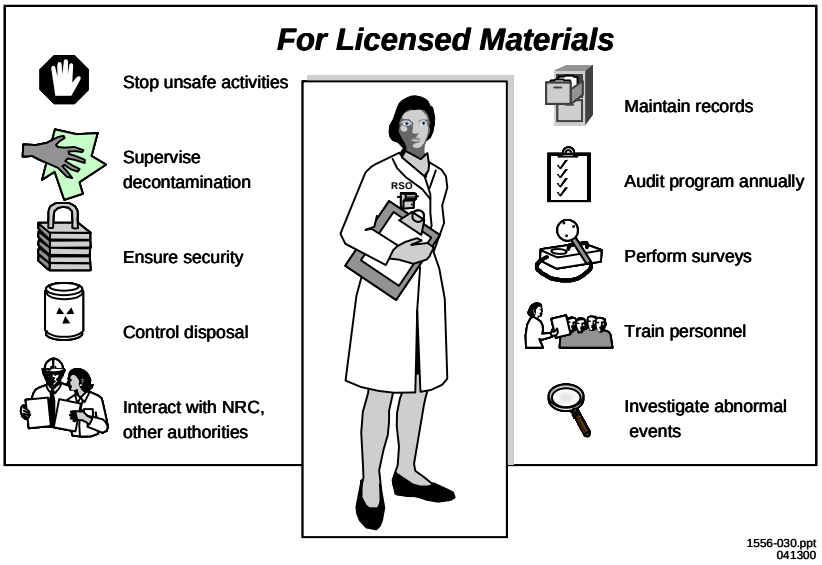

Figure 8.6 RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

NRC believes that to demonstrate adequate training and experience, the RSO should 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
- Hands-on Use of Radioactive Materials.

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 a manufacturing company where workers handle curie quantities of radioactive material should be specialists in the field of radiation protection and may need 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. On the other hand, RSOs at “manufacturers” who are importers of timepieces containing tritium that are received in the U.S. as completed products that will be distributed as exempt quantities may only require a few hours of radiation safety training and no prior experience with timepieces containing tritium

to be qualified as an 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;
- 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 only serves to slow 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 must be submitted to NRC as part of an amendment request.

8.7.2 AUTHORIZED USERS

Regulations: 10 CFR 19.12; 10 CFR 20.1101(b); 10 CFR 30.33(a)(3); 10 CFR 40.32(b); 10 CFR 70.23(a)(2); 10 CFR 71.5; 10 CFR 110.26; 10 CFR 110.27; 10 CFR 110.28; 10 CFR 110.29; 10 CFR 110.30; 10 CFR 110.42; 10 CFR 110.43; 10 CFR 110.44; 49 CFR Parts 170 through 189 (appropriate to the mode of transport).

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

Discussion: Applicants must name at least one individual who is qualified to use the requested licensed materials. An AU 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. The AU's primary responsibility is to ensure that radioactive materials are used safely and according to regulatory requirements. The AU is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

AUs must have adequate and appropriate training to provide reasonable assurance that they will use 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.

NRC believes that to demonstrate adequate training and experience, the AU 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. 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 the types and forms of byproduct material to be used)
- Hands-on Use of Radioactive Materials.

The amount of training and experience needed will depend upon the type, form, quantity, and proposed use of the licensed material requested, but it should cover the subjects stated. For instance, in addition to a college degree, authorized users at a manufacturing company where workers handle curie quantities of radioactive material should have 40 hours of radiation safety training and a minimum of 6 months of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be an authorized user. On the other hand, authorized users at "manufacturers" who are importers of timepieces containing tritium that are received in the U.S. as completed products that will be distributed as exempt quantities may only require a few hours of radiation safety training and no prior experience with timepieces containing tritium to be qualified as an authorized user. In general, AUs must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities 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 gamma emitters may not have appropriate experience for high energy beta emitters.

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

Response from Applicant: Provide the following:

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

Applicants should provide information about the proposed AU's training and experience relative to the licensed material 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, etc. Submittal of unrelated material only serves to slow 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 users without amending the license.

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

Regulations: 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 30.7; 10 CFR 30.9; 10 CFR 30.10; 10 CFR 30.33(a)(3); 10 CFR 30.34(e); 10 CFR 40.32(b); 10 CFR 40.41(e); 10 CFR 70.23(a)(2); 10 CFR 70.32(b).

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 their duties and responsibilities, as required by 10 CFR 19.12.

Discussion: Before beginning work with licensed material, individuals must 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 H, 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 30.33(a)(2); 10 CFR 30.35(g); 10 CFR 40.27(b); 10 CFR 40.28(b); 10 CFR 40.31(h); 10 CFR 40.32(c); 10 CFR 40.34(a); 10 CFR 51.20(b); 10 CFR 70.23(a)(3); 10 CFR 70.39(a).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. They 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 its 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 that may be subject to contamination;
- 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 I, Facilities and Equipment.

Response from Applicant: Describe the facilities and equipment to be made available at each location where radioactive material will be possessed or possessed and used (see Appendix I for topics to consider). Include a description of the area(s) assigned for the receipt, shipping, storage, preparation, security, and measurement of radioactive materials. A diagram should be submitted showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety (see Figures 8.7 and 8.8). When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. This information should be from the point of view of performance criteria. For example, state the purpose of your filtration equipment and the associated acceptance criteria to accomplish this purpose (such as the ventilation flow rate you are trying to maintain). If radioactive materials will be used with animals, include a description of the animal handling housing facilities. Appendix G to NUREG-1556, Vol. 7 may also be used as guidance.

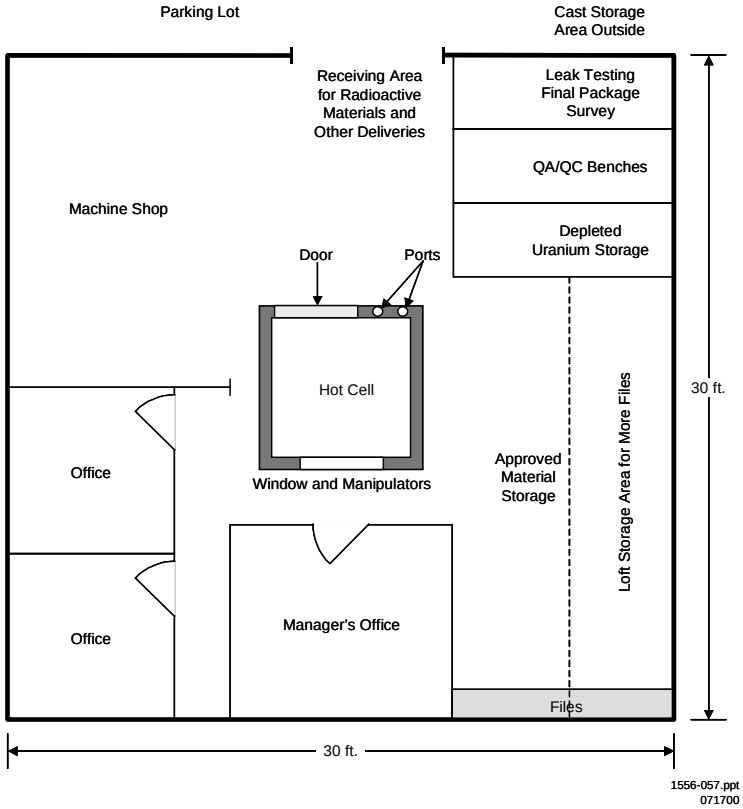

Figure 8.7 Facility Diagram for a Radiography Source Manufacturer.

Figure 8.8 Shielded Protective Enclosure (Hot Cell) With Remote Manipulator.

8.10 ITEM 10: RADIATION SAFETY PROGRAM

8.10.1 AUDIT PROGRAM

Regulations: 10 CFR 20.1101; 10 CFR 20.2102; 10 CFR 21.21(a).

Criteria: Licensees must review the content and implementation of their Radiation Protection 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 to ensure that
3. Operating procedures are in place for activities which 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 and an example audit form are described below.

Audit Objectives. NRC holds the licensee responsible for the Radiation Protection 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 licensee's: (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 their Radiation Safety Program including the role of senior management and the RSO; and (5) implementation of their 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 authorized user (See Section 8.7.2) 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 sources or frequent handling of intermediate activity sources. 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 Radiation Safety Officer (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. Note whether the licensee has permanent field offices and or temporary job sites, and if those sites were visited during the audit. Indicate any findings noted at these additional sites, and if these sites were not visited, give an explanation as to why these sites were not audited.

Materials. Verify that the license authorizes the quantities and types of byproduct material that the licensee possesses.

Leak Tests. Verify that all sealed/plated foil 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 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 are within regulatory limits and in accordance with 10 CFR 20.2103. Verify compliance with 10 CFR 20.1301. Records of surveys must be retained for 3 years after the record is made.

Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing byproduct material, received from others, are received, opened, and surveyed in accordance with 10 CFR 20.1906. Ensure that transfers are performed in accordance with 10 CFR 30.41, 40.51, and 70.42. Records of surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103**,** 30.51, 40.61, 70.51, and 70.54.

Transportation. Determine compliance with Department of Transportation (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 must 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 (If Made). The auditor should make independent survey measurements and compare the results with those made or used by the licensee.

Notification and Reports. Check for compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, 21, 30, 40, and 70. 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, 20.1904, and 10 CFR 21.6.

Recordkeeping for Decommissioning. Check to determine compliance with 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g).

Bulletins and Information Notices. Check to determine if bulletins, information notices, NMSS Newsletters, etc., 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 must 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. NRC has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records must be maintained for inspection by NRC.

Appendix J, Example Audit Form, contains an example audit form for manufacturer licensees. All areas indicated in Appendix J may not apply to every licensee, and all items may not need to be addressed during each audit. For example, licensees need not address areas that do not apply to their activities. Conversely, other licensee specific activities may need to be added to the form. Activities that have not occurred since the last audit need not be reviewed at the next audit.

Response from Applicant: The applicant must provide a description of its audit program that addresses the following:

- Objectives of audits;
- Scope of audits;
- Qualifications of auditors;
- Frequency of audits including a justification of that frequency;
- Audit techniques;
- Process to deal with and correct problems or deficiencies; and
- Records to be maintained.

References: See the Notice of Availability on the inside front cover of this report to obtain copies of:

- Inspection Procedure 87110, Appendix A, "Industrial/Academic/Research Inspection Field Notes," dated February 3, 1997;
- NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions";
- Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996;
- Information Notice 2000-10, "Recent Events Resulting In Extremity Exposures Exceeding Regulatory Limits," dated July 18, 2000;
- Inspection Procedure 87110, Appendix A, NUREG-1600, and Information Notices 96-28 and 2000-10 are available on the Internet at <http://www.nrc.gov>.

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:

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

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

- Portable or stationary count rate meters;
- Portable or stationary dose rate or exposure rate meters;
- Single or multichannel analyzers (MCA);
- Liquid scintillation counters (LSC);
- Gamma counters;
- Proportional counters;
- Solid state detectors;
- Neutron detectors.

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 8.9 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.

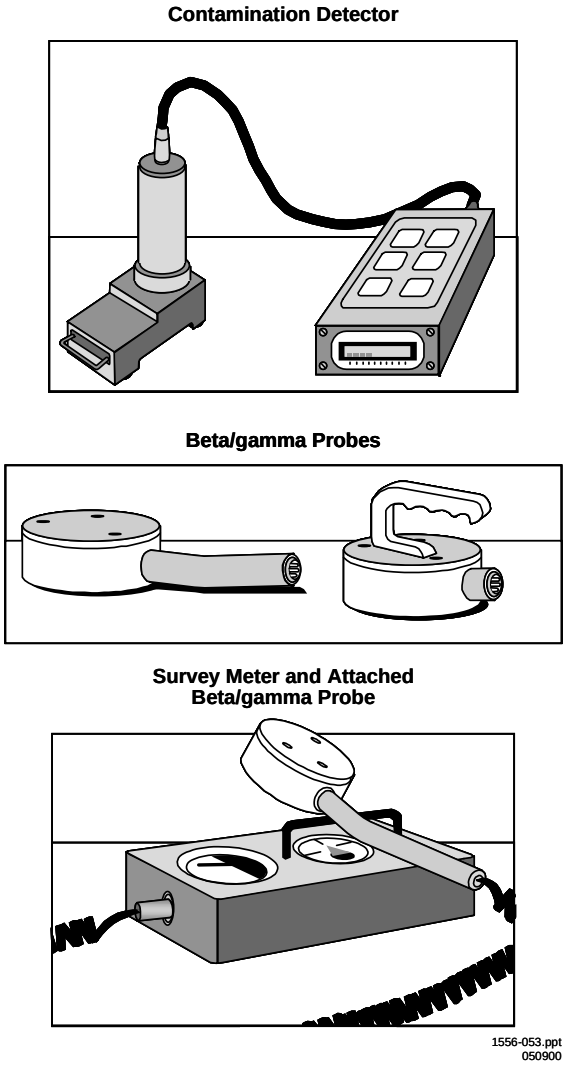

Figure 8.9 Examples of Portable Instruments Used in Laboratory Settings.

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 a calibration with appropriate radioactive sources, as described in Appendix K, Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program.

NRC requires that calibrations 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 must submit procedures for review. Appendix K 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. Instrumentation for counting smear wipes to detect contamination and/or leakage need calibration sources that may be listed on the manufacturing 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 K to NUREG-1556, Vol. 12. We reserve the right to upgrade our survey instruments as necessary."

OR

- 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 K to NUREG-1556, Vol. 12. Additionally, we will implement the model survey meter calibration program published in Appendix K to NUREG-1556, Vol. 12. We reserve the right to upgrade our survey instruments as necessary."

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 must be verified to have authorization to calibrate instruments for others. Further, the statement "We reserve the right to upgrade our survey instruments as necessary and change calibration services to other authorized providers" should be added to the response.

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 RECEIPT AND ACCOUNTABILITY

Regulations: 10 CFR 20.1501(a); 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2001; 10 CFR 20.2201; 10 CFR 30.34(e); 10 CFR 30.35(g); 10 CFR 30.41; 10 CFR 30.51; 10 CFR 31.11; 10 CFR Part 32; 10 CFR Part 40; 10 CFR 40.13; 10 CFR Part 70.

Criteria: Licensees must do the following:

- Develop, implement, and maintain written procedures for safely opening packages;
- Develop, implement, and maintain written procedures to ensure security and accountability of licensed material;
- Maintain records of receipt, transfer, and disposal of licensed material.

Discussion: Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with 10 CFR 20.1906. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

Licensees need to make arrangements to receive radioactive packages when they are delivered or to be notified when radioactive packages arrive at the carrier's terminal, so that the licensee can pick up the package expeditiously.

A model procedure for safely opening packages containing licensed materials is included in Appendix L, Material Receipt and Accountability.

In limited scope Radiation Safety Programs, the RSO or his/her staff usually receives the incoming package directly from the carrier, and performs all verification, surveying, opening, and documentation for inventory. The package is then delivered to the AU, or the AU retrieves the package from the RSO. If the package is transported over public roads by the licensee, it must be repackaged and transported in accordance with DOT regulations.

If the package of licensed material is delivered to the licensed facility's receiving department (Receiving), individuals working in that department should be trained to do the following:

- Identify the package as radioactive by labeling and shipping papers;
- Segregate the package from other incoming items in a secured area until released by the RSO;
- Notify the RSO.

When notified by Receiving that a package of licensed material has arrived, the RSO or his/her staff should retrieve the package and follow the safe opening procedures.

NRC regulations in 10 CFR 20.1906(b) and (c) state the requirements for monitoring packages containing licensed material. These requirements are described in Table 8.3.

Table 8.3 Package Monitoring Requirements.

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

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

Note: Additional information on DOT regulations is contained in this NUREG in Section 8.10.9, Transportation, and Appendix R, Transportation.

10 CFR 20.1906(d) requires that the licensee immediately notify the final delivery carrier and, by telephone, telegram, mailgram, or facsimile, the Administrator of the appropriate NRC Regional Office listed in Appendix D to 10 CFR Part 20 when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i), or external radiation levels exceed the limits of 10 CFR 71.47.

As illustrated in Figure 8.10, licensed materials must be tracked from “receipt to disposal” in order to ensure accountability and to ensure that possession limits listed on the license are not exceeded.

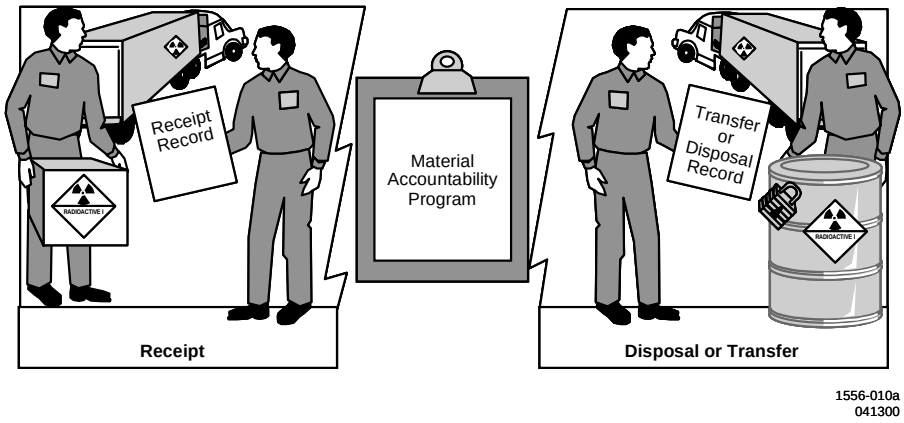

Figure 8.10 Material Receipt and Accountability. *Licensees must maintain records of receipt, transfer, and disposal of licensed material.*

NRC must be notified when licensed material is lost or stolen. The RSO must be proactive in evaluating whether NRC notification is required. Refer to Appendix O, Typical Notification and Reporting Requirements, and the regulations (10 CFR 20.2201-20.2203, 10 CFR 30.50, and 10 CFR 21.21) for a description of when and where notifications are required.

Accountability for Materials Not Included in the Manufactured Products

Licensees frequently possess radioactive material, which is generally licensed or distributed to them as an exempt quantity in addition to that which is specifically listed on their license. 10 CFR Part 31 provides information regarding generally licensed devices. Any person who acquires, receives, possesses, uses, or transfers a generally licensed device must do so in accordance with the provisions of the general license. Generally licensed material possessed by a specific licensee may continue to be possessed under a general license. A specific license does not automatically remove general licensee status nor automatically "move" generally licensed material to the specific license. NRC recognizes that multiple authorizations can create some confusion and, therefore, a specific licensee always has the option of receiving and possessing radioactive materials that "qualify" for a general license by adding these to its specific license.

Similarly, radioactive material received by a specific licensee, that is distributed to them under an exemption from the requirements for a license, is not subject to the terms and conditions of the specific license. Any person may receive byproduct material that is exempt from the requirements of a license pursuant to the regulations in 30.11 through 30.21. Such materials may include "exempt quantities" of byproduct materials that do not exceed the applicable quantity listed in 10 CFR 30.71, as well as items such as smoke detectors and self-luminous watches, that are distributed in accordance with other NRC regulations. Most licensees do not possess or control these type of devices under the provisions of their specific license and NRC does not

require or encourage this practice; however, as stated above, the specific licensee always has the option of adding these materials to its license and controlling them under the conditions of the specific license. In any case, licensees are required to ensure that dose limits are not exceeded, whether or not the dose results from licensed sources or unlicensed sources.

The possession limits of 7.4 MBq (200 microcuries) for generally licensed materials specified in 10 CFR 31.11 only apply to any one location of storage or use. The general licensee cannot possess at any one time, at any one location of storage or use (i.e., a location that is physically and administratively separate), a total amount of iodine-125 (I-125), iodine-131 (I-131), selenium-75 (Se-75), and/or iron-59 (Fe-59) in excess of 7.4 MBq (200 microcuries). The licensee may have more than one location of storage or use at its facility, and therefore may possess a total of more than 7.4 MBq (200 microcuries) at any one time, as long as there is not greater than 7.4 MBq (200 microcuries) at any one location.

It is recognized that loss, theft, or misplacement of licensed material can occur. However, licensees must have an accountability and control system in place for detecting losses of licensed material.

Accountability for Materials Included in the Manufactured and Distributed Products

Licensees who use and/or possess sealed sources are required by license condition to perform inventories of sealed sources every 6 months (see Condition Nos. 15 and 16, respectively, in the sample manufacturing licenses, in Appendix D). Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should, at least every 6 months, confirm that these sealed sources have not been disturbed. Licensees are also required to conduct leak tests of sealed sources, not in storage, at 6-month intervals (or at longer intervals as specified in the SSD Registration Certificate). 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.

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

To ensure that only trained, experienced, and authorized individuals possess or possess and use or supervise the possession or possession and use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be established for the procurement of licensed materials that may be obtained outside normal channels (e.g., through the loan or other transfer of materials without purchase, or through surplus). A model procedure for Ordering and Receiving Radioactive Material is included in Appendix L, Material Receipt and Accountability.

NRC regulations applicable to transfers are stated in 10 CFR 30.41. Sample policy transfer statements are included in Appendix L. Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components, including refrigerators and freezers, may become contaminated. Surveys of and removal of these items for maintenance, repair, or disposal should also be carefully controlled.

Licensees must maintain records of receipt, use, transfer, and disposal (as waste) of all licensed material. Table 8.4 lists each type of record and how long the record must be maintained. Other records, such as transfer records, could be linked to radioactive material inventory records. Receipt records should also document cases where excessive radiation levels or radioactive contamination were found on packages or containers of material received and describe the action taken.

Manufacturers/distributors must also make reports to regulatory agencies for exempt and general licensed devices distributed so that these can be accounted for and registered in some cases. Please refer to NUREG-1556, Vol. No. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," and NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees."

Table 8.4 Record Maintenance.

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

Receipt, transfer, and disposal 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 affected radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number);
- For licensed materials disposed of as waste, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.).

See Section 8.11, Waste Management, 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), 10 CFR 40.36(f), and 10 CFR 70.25(g). See also Section 8.5.2, Financial Assurance and Recordkeeping for Decommissioning.

Response from Applicant:

- Develop a procedure(s) for ensuring material accountability.

AND

- Provide either of the following:
  - A statement that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."

OR

  - A description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced.

***Note*:**

- No response is needed from applicants for package opening procedures. Package opening procedures will be reviewed during NRC inspections.
- Alternative responses will be evaluated using the criteria listed above.

References:

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

- NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities";
- NUREG-1556, Vol. 8, "Program Specific Guidance About Exempt Distribution Licenses";
- NUREG 1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope";

- NUREG-1556, Vol. 16, "Program Specific Guidance About Licenses Authorizing Distribution to General Licensees."

Additional References:

- Larson, William A., *A Health Physics Management Program for the Receipt and Shipment of Radioactive Materials*, Proceedings of the Ninth Midyear Topical Symposium of the Health Physics Society on "Operational Health Physics," Denver, CO, USA (1976);
- NCRP Report No. 114, "Maintaining Radiation Protection Records," (1992)[2];
- NCRP Report No. 105, "Radiation Protection For Medical and Allied Health Personnel," (1989)[2];
- NCRP Report No. 59, "Operational Radiation Safety Program," (1978)[2];
- NCRP Report No. 48, "Radiation Protection For Medical and Allied Health Personnel," (1976)[2];
- NCRP Report No. 32, "Radiation Protection in Educational Institutions," (1966)[2].

8.10.4 OCCUPATIONAL DOSE

Regulations: 10 CFR 19.13; 10 CFR 20.1003; 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 20.1501; 10 CFR 20.1502; 10 CFR 20.1703; 10 CFR 20.2104; 10 CFR 20.2105; 10 CFR 20.2106; 10 CFR 20.2206; 10 CFR 20, Appendix B.

Criteria: The use of individual monitoring devices for external dose is required for:

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - — 5 mSv (0.5 rem) deep-dose equivalent;
  - — 15 mSv (1.5 rem) eye dose equivalent;
  - — 50 mSv (5 rem) shallow-dose equivalent to the skin;
  - — 50 mSv (5 rem) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - — 1 mSv (0.1 rem) deep-dose equivalent;

[2] Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814-3095 or ordered electronically at <http://www.nrpc.com>.

  - — 1.5 mSv (0.15 rem) eye dose equivalent;
  - — 5 mSv (0.5 rem) shallow-dose equivalent to the skin;
  - — 5 mSv (0.5 rem) shallow-dose equivalent to any extremity.
- Declared pregnant women who are likely to receive, during the entire pregnancy, a deep-dose equivalent in excess of 1 mSv (0.1 rem).
- Individuals entering a high or very high radiation area.

Internal exposure monitoring (not necessarily individual monitoring devices) is required for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable Annual Limit on Intake (ALI) for ingestion and inhalation.
- Minors likely to receive in 1 year a CEDE in excess of 1 mSv (0.1 rem).
- Declared pregnant women likely to receive, during the entire pregnancy, a CEDE in excess of 1 mSv (0.1 rem).

Discussion:

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

According to 10 CFR 20.1502, if an adult (individual) is likely to receive in one year a dose greater than 10% of any applicable limit (See Figure 8.11 for annual dose limits), monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. When working at an NRC-licensed facility, in addition to exposure to material regulated by NRC, a worker may be exposed to radiation and to radioactive material (e.g., radiation emitted by accelerators or accelerator produced radioisotopes such as indium-111 and thallium-201) 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.” 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, in performing an evaluation of likely dose, you should consider these types of radiation exposures. 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. According to 10 CFR 20.1502, if an adult (individual) is likely to receive in one year a dose greater than 10% of any applicable limit (see Figure 8.11 for annual dose limits), monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose.

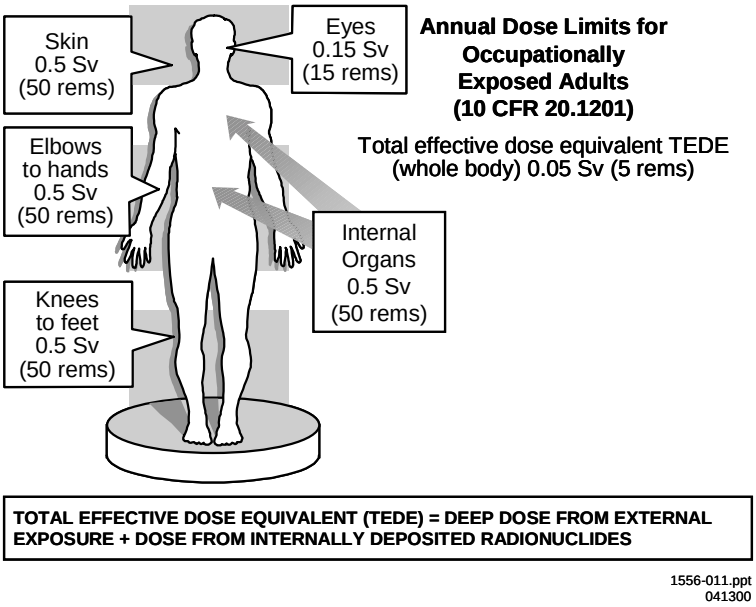

Figure 8.11 Annual Dose Limits for Occupationally Exposed Adults.

If this prospective evaluation shows that the individual's dose is not likely to exceed 10% of any applicable regulatory limit, there are no recordkeeping or reporting requirements. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. When determining the need for monitoring, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered, including any recordkeeping and reporting requirements. If an evaluation determined that monitoring was not required and a subsequent evaluation indicated that the 10% regulatory threshold may or will be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported (if required). 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.

If monitoring is not required to demonstrate compliance with all limits, but is required relative to one or more specific limits, the licensee should enter "NR," for "Not Required" in the blocks on NRC Forms 4 and 5 to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter "ND," for "Not Detectable."

If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit, monitoring is required (10 CFR 20.1502). Recordkeeping of the results of monitoring performed, regardless of the actual dose received, is required by 10 CFR 20.2106 (a).

Licensees are required to provide individual radiation exposure data to each worker annually and as otherwise described in 10 CFR 19.13.

A common method for dose evaluation is to monitor workers' doses with whole body and extremity dosimetry (TLDs, film, sign badge, etc.) provided by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved dosimetry service. If these devices are used, the licensee is responsible for exchanging and processing them in a timely manner. Also, the licensee is 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 must 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.

Workers are typically monitored for a year or more to determine 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, isotopes used, etc. 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 P, Radiation Safety Survey Topics, Bioassay Monitoring, for information on bioassay monitoring for internal exposure assessment.

Table 8.5 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

Additional References for Further Reading:

- U.S. Department of Energy DOE G 441.1-2, "Occupational ALARA Program Guide," March 17, 1999[3].
- U.S. Department of Energy DOE G 441.1-3, "Internal Dosimetry Program Guide," March 17,1999[3].
- U.S. Department of Energy DOE G 441.1-4, "External Dosimetry Program Guide," March 17, 1999[3].
- U.S. Department of Energy DOE G 441.1-8, "Air Monitoring Guide," March 17, 1999[3].
- U.S. Department of Energy DOE G 441.6-1, "Evaluation and Control of Radiation Dose to the Embryo/Fetus," April 1998[3].

Response from Applicant: Provide either of the following:

- A statement that: "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20, or we will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program – Occupational Dose' in NUREG-1556, Vol. 12, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.'"

OR

- A description of an alternative method for demonstrating compliance with the referenced regulations.

Note:

[3] Most DOE documents are available through the National Technical Information Service and the Superintendent of Documents, Government Printing Office. See the inside of the front cover of this document for details.

- Alternative responses will be evaluated using the criteria listed above.
- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with NRC requirements (e.g., to respond 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.

Criteria: Licensees must ensure that licensed material will be possessed or possessed and used, transported, stored or disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations. In addition, the licensee must ensure that air emissions of radioactive material to the environment will not result in a TEDE in excess of 10 millirem (0.1 mSv) per year to individual members of the public.

Discussion: "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, from medical procedures, and from licensees' release of radioactive materials into sanitary sewerage. 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, please refer to Appendix M, Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits.

Figure 8.12 shows the steps to calculate the annual dose to an individual member of the public.

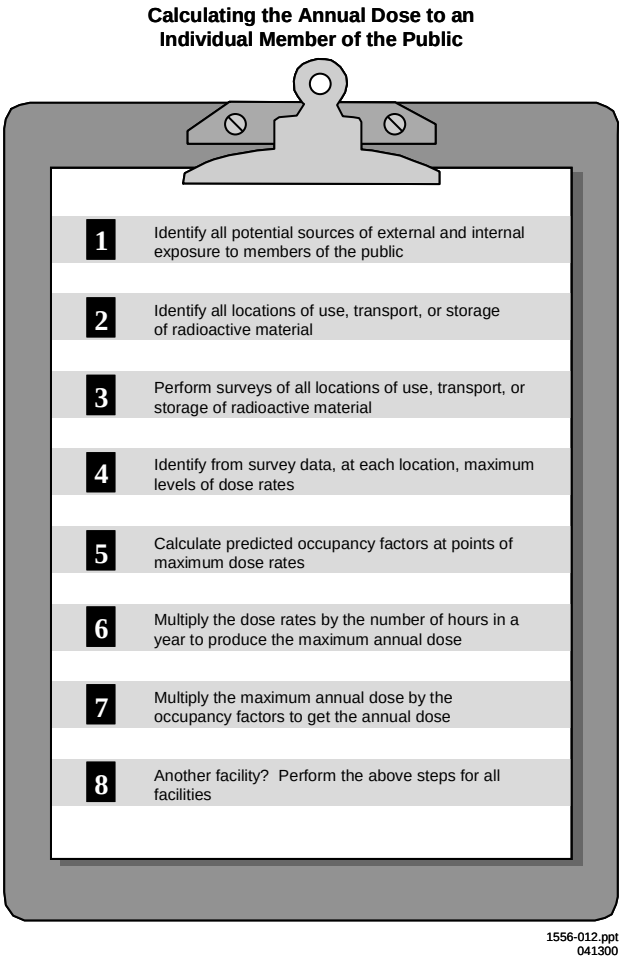

Figure 8.12 Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public (see Appendix M for more information about occupancy factors).*

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 radioactive exposure.

The licensee should review these major pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with 10 CFR 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 Section 8.10.7, Radiation Safety Program – Surveys and Leak Tests.

10 CFR 20.2107 requires that licensees maintain records sufficient to demonstrate compliance with the dose limits for members of the public until the Commission terminates the license.

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 millirem). 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 total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix M for examples of methods to demonstrate compliance.

8.10.6 OPERATING AND EMERGENCY PROCEDURES

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2201-2203; 10 CFR 21.21; 10 CFR 30.34(e); 10 CFR 30.50; 10 CFR Part 32; 10 CFR Part 40; 10 CFR Part 70.

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

Discussion: Licensees are responsible for the security and safe possession and use of all licensed material from the time it arrives at their facility until it is used, transferred, and/or disposed. Licensees should develop written procedures to ensure safe 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 and Manufacturing Process 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
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Use of appropriate shielding (see Figure 8.13);
- 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 N, General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures and Appendix P, Radiation Safety Survey Topics. Applicants should use these guidelines to develop procedures for the safe use of radioisotopes.

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.

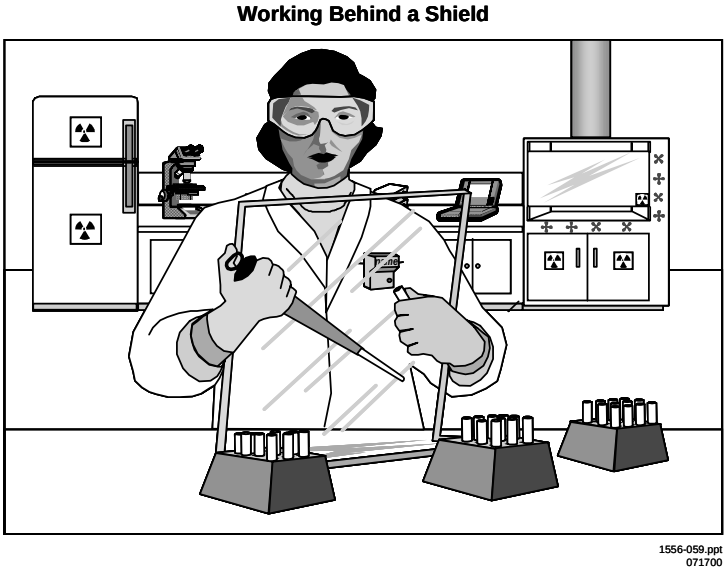

Figure 8.13 Use of Appropriate Shielding. *This worker is using high density plastic shielding, which is appropriate for radioisotopes that emit beta radiation.*

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 materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can 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 which 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, loss or theft of licensed material, sabotage, fires, floods, etc., can jeopardize the safety of personnel and members of the public. It is therefore 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 8.14) to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of 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 N includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

Figure 8.14 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 must state that operating and emergency procedures will be developed and documented before receipt of licensed material. In addition, the applicant must 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 your license pursuant to 10 CFR 30.32(i), 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; 10 CFR 40.63; 10 CFR 70.56; 10 CFR 70.57.

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 8.15). 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. 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.

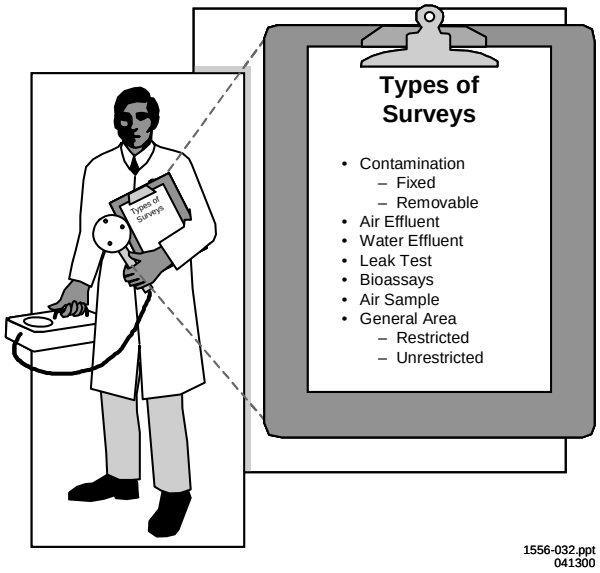

Figure 8.15 Types of Surveys. *There are many different types of surveys performed by manufacturer and distribution licensees.*

Radiation surveys are used to detect and evaluate contamination of:

- Facilities;
- Equipment;
- Personnel (during use, possession, transfer, or disposal of licensed material) (see Figure 8.16);
- Restricted and unrestricted areas;
- Packages;
- 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.

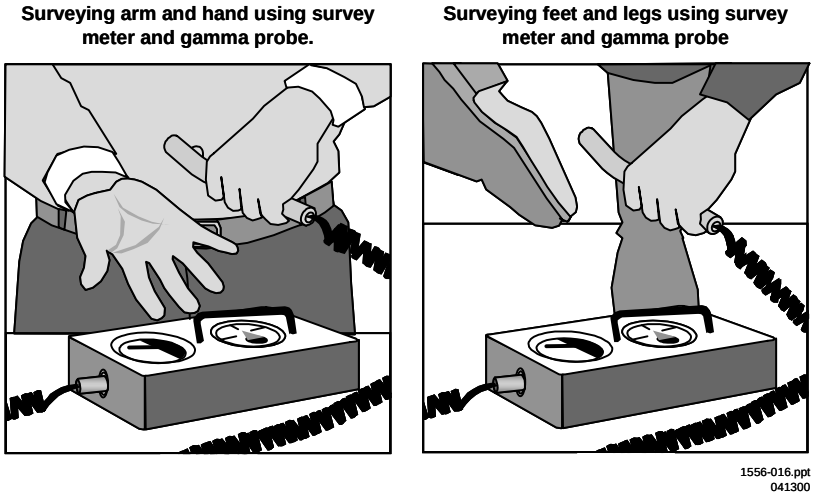

Figure 8.16 Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the area of use.*

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, production line, packages, 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).
- 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 P, 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 K.1 in Appendix K 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 fabricated sources. Table P.5 in Appendix P 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 SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcuries) of radioactivity.

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 is expected to 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 H-3;
- 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 Q, Model Leak Test Program.

Service Licenses

If a licensee wants to perform leak tests for its customers, it must obtain a service license. This may also be accomplished by amending an existing license. For more information regarding service license applications, see NUREG-1556, Vol. 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

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 P to NUREG-1556, Vol. 12." If applicable, state: "We will perform contamination checks on all fabricated sealed sources prior to distribution. Leak tests 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."

OR

- State: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R to NUREG-1556, Vol. 12." If applicable, state: "We will perform contamination checks on all fabricated sealed sources prior to distribution. Leak tests 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 Q to NUREG-1556, Vol. 12."

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 foil.

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.

- When dealing with special nuclear material, the applicant should refer to 10 CFR 70.57 for additional requirements.

Reference: See the Notice of Availability (on inside front cover of this report) to obtain a copy of NUREG-1556, Vol. 18, "Program-Specific Guidance About Service Provider Licenses."

8.10.8 MAINTENANCE

Regulations: 10 CFR 20.1101; 10 CFR 30.34(e).

Criteria: Maintenance of devices and facilities that use radioactive materials 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. Manufacturing a product incorporating 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 manufacturing process. As examples: (1) a radioisotope hot cell should have its contents moved or shielded before any maintenance requiring entry is begun, and the staff should survey the hot cell working area prior to entry; and (2) a maintenance procedure should direct the shutdown and lockout of applicable process control gauges before beginning work in the area, which may be in the direct beam of the gauge, whether inside the process vessel, or outside the vessel. 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 20.1101; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; 10 CFR 71.47; 10 CFR 71.87; Subpart H of 10 CFR Part 71; 49 CFR Parts 171-178.

Criteria: Applicants who will 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 U.S. Department of Transportation (DOT) regulations.

Discussion: Packages shipped by licensees frequently meet the "Limited Quantity" criteria described in 49 CFR 173.421 and therefore could be exempt from certain DOT requirements. However, they may be subject to other, less restrictive, DOT requirements (e.g., 49 CFR 173.422 and 173.424; also see Appendix R, Transportation, for more information).

If they are not exempted, however, licensed material, including radioactive waste, must be packaged and transported in accordance with NRC and DOT requirements if the transportation involves common carriers or the use of public highways. Licensees should 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. (See NUREG-1660/RAMREG-002, "U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments," November 1998.)

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.

All domestic shipping papers and labels must be in SI units only **OR** must be in SI units first, with English units in parenthesis.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation.

The general license in 10 CFR 71.12 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 71.12 or 10 CFR 71.14, as appropriate, is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. Licensees who use another manufacturers' Type B package must ensure that the other manufacturer (or service licensee):

- Is authorized to possess the licensed material at temporary job sites (i.e., at the facility location);
- Actually takes possession of the licensed material under its license;
- Uses an approved Type B package;
- Is registered with NRC as a user of the Type B package;
- Has an NRC-approved QA plan.

For each shipment, it must be clear who possesses the licensed material and 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 71.12 general license. For information about QA plans, see Revision 1 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986. For further information about registering as a user of a package or submitting a QA program for review, contact NRC's Spent Fuel Project Office (SFPO) by calling NRC's toll-free number, 800-368-5642, extension 415-8500. For information about associated fees, contact NRC's Office of the Controller by calling NRC's toll-free number, 800-368-5642, extension 415-7554.

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a "Memorandum of Understanding with DOT on the Transportation of Radioactive Material," signed June 6, 1979, to examine and enforce various DOT requirements, listed in Appendix R.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own in 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 issues will be reviewed during inspection.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials," 1983 revision, can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training, at (202) 366-4425. See the Notice of Availability (on the inside front cover of this report) to obtain a copy of the "Memorandum of Understanding with DOT on the Transportation of Radioactive Material," signed June 6, 1979; and Revision 1 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986.

8.10.10 MINIMIZATION OF CONTAMINATION

Regulations: 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.

Manufacturing activities that produce sealed sources should be aware that a common business option is to accept damaged, unwanted, and replaced sources from their customers or salvagers. Sealed sources that may be returned to the facility present an unknown risk to the receiving department staff and to the persons charged with evaluating the condition of received materials.

The manufacturing and distribution applicant may also be requested by customers to provide recovery and shipping services for unwanted, damaged, and replacement sources. As such, the applicant 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 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 non-porous materials for laboratory bench tops, flooring, etc.;
- Ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction;
- Air flows appropriate to the work being conducted;

- Use of appropriate plumbing materials with minimal pipelengths and traps;
- 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 SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must 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 – Sealed Sources and Devices or Unsealed Radioactive Material," Section 8.9, "Facilities and Equipment," Section 8.10.6, "Radiation Safety Program – Operating 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 20.1904; 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 30.51; 10 CFR 61.52; 10 CFR 70.42.

Criteria: Radioactive waste generated as part of the manufacturing and distribution process must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained. Waste licensed materials (such as glove, rags, tools) may not be received from others. Licensed materials which were distributed (such as decayed sources or devices at end of useful life) may be accepted from others, received, and sent for disposal properly.

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. 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 non-radioactive, 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 has concluded that materials with half-lives of less than or equal to 120 days are appropriate for decay-in-storage (DIS). The minimum holding period for DIS is ten half-lives of the longest-lived radioisotope in the waste. Care should be taken that the waste form should not degrade or adversely interact with the waste container. Also, care should be taken to group waste packages by half-life. Waste packages having mixed half-lives must be held for 10 half-lives of the longest lived radionuclide in the package. Therefore, waste with a 65-day half-life (held in storage for 650 days), should not be held in the same container for the 1,200 days as required for material with a 120-day half-life. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

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 For 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 S, 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 8.17). 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.

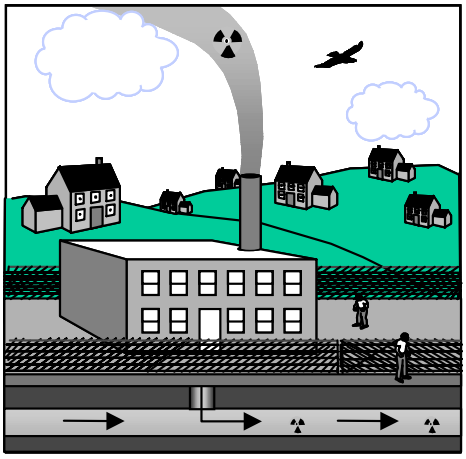

Figure 8.17 Air and water effluents from manufacturing facility. *Also note the fence, creating a "controlled area."*

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 biologic 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 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. A model procedure for disposal of radioactive waste via sanitary sewer is described in Appendix S.

If your facility maintains a private sewerage treatment system, a septic system, or leach fields, the regulations of 10 CFR 20.2003 are not applicable for releases to these systems. You may make releases of liquids to private sewerage systems, septic systems, or leach fields as effluents released to unrestricted areas pursuant to 10 CFR 20.1302(b)(2)(i).

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 your application. Contaminated sludges will be required to 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 Commission 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. Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997, provides guidance relative to the disposal of ash. A model procedure for incineration of waste is described in Appendix S. 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 that could create a radiological hazard to licensee employees or the general public must be described in detail in the application. A model procedure for waste compaction is described in Appendix S.

Disposal of Specific Waste As If It Were Not Radioactive

The following radioactive wastes may be disposed of as non-radioactive waste:

- Liquid scintillation medium containing no more than 1.85 kBq (0.05 microcuries) of H-3 or C-14 per gram of the medium;
- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 microcuries) of H-3 or C-14 per gram averaged over the weight of the entire animal.

Applicants should have procedures that will ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or animals. Applicants must maintain accurate records of these disposals.

Burial

Licensees who were previously authorized to bury radioactive materials pursuant to 10 CFR 20.304 prior to January 28, 1981 should describe the locations, condition, and current status of these former sites in their license application under waste management (i.e., controlled or uncontrolled, active monitoring of the site, and current condition of burial site)[20.2108]. Licenses will not ordinarily be written to allow this option; however, an applicant can submit a request pursuant to 10 CFR 20.2002.

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.

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 Appendix B, Table II, 10 CFR Part 20. 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 program.

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: Applicants do not need to provide information to NRC if they plan to dispose of LLW via transfer to an authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14 as authorized by 10 CFR 20.2005.

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 must 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 Protection 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

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. 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, 10 CFR 30.36(a), 10 CFR 40.43(a), and 10 CFR 70.38(a)).

Applicants for license renewal and amendment must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request.
- Submit, in duplicate, either NRC Form 313 or a letter requesting amendment or renewal.
- 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 Protection Program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

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); 10 CFR 40.14(a); 10 CFR 70.14(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, 10 CFR 30.11(a), 10 CFR 40.14(a), and 10 CFR 70.14(a)). These regulations state that NRC may grant an exemption, either acting on its own initiative or on an application from an interested person.

Exemptions always require an amendment request. Until NRC has granted an exemption in writing, NRC expects strict compliance with all applicable regulations and license conditions. 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 must 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;
- Alternative methods for complying with the regulation and why they are not feasible.

As an example, exemptions to certain regulations are necessary when teletherapy-type units are converted from human use to use for irradiation of materials or objects. See NUREG-1556, Vol. 6, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses," for more information about this special case.

Reference: See the Notice of Availability (on the inside cover of this report) to obtain copies of NUREG-1556, Vol. 6, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses."

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); 10 CFR 30.51(f); 10 CFR 40.36; 10 CFR 40.42; 10 CFR 40.51; 10 CFR 40.62(e); 10 CFR 70.38.

Criteria: Pursuant to the regulations described above, 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;
  - — 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), 10 CFR 40.36, and 10 CFR 70.38.
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j), 10 CFR 40.42, and 10 CFR 70.38.
- 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).
- 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), 10 CFR 40.51, 10 CFR 40.62(e), and 10 CFR 70.38, 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, Version 1.0, which is available for download from NRC's web site at http://www.nrc.gov/RES/rescodes.htm. 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.

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

Document Identification	Title	Date
RG 10.7	Guide for the Preparation of Applications for Licenses for Laboratory and Industrial Use of Small Quantities of Byproduct Material	08/79
P&GD FC 84-1*	Review Responsibility-Manufacturing and Distribution of Products to Persons Exempt Pursuant to 10 CFR 32.11 through 32.26	04/84
PG 8-10	Disposal of Incinerator Ash as Ordinary Waste	01/97
P&GD FC 85-6*	Standard Review Plan for Applications for Licenses and Approvals to Authorize Distribution of Various Items to Group Medical Licenses	02/85
NUREG/BR-0241	NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses	03/97
NUREG-1575	Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)	12/97
NUREG-1400	Air Sampling in the Workplace	09/93
NUREG-1516	Management of Radioactive Material Safety Programs at Medical Facilities	05/97
NUREG-1600, Rev. 1	General Statement of Policy and Procedures for NRC Enforcement Actions	05/98
NUREG-1727	NMSS Decommissioning Standard Review Plan	09/00
NUREG/CR-4884	Interpretation of Bioassay Measurements	07/87
Draft NUREG-1562	Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt from the Requirements for an NRC License	12/88

* When this report is issued in final form, these documents will be considered superseded and should not be used.

Document Identification	Title	Date
Draft RG FC 413-4	Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments	6/85
RG 3.66	Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72	06/90
RG 7.10 Rev. 1	Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material	06/86
PG 3-16	Licensing of Certain Sealed Sources and Devices for Medical Use in Accordance with 10 CFR 35.49	09/95
Draft RG DG-0005	Applications for Licenses of Broad Scope	10/94
P&GD FC 90-02 Rev. 1	Standard Review Plan for Evaluating Compliance with Decommissioning Requirements	04/30/91
P&GD PG 1-26	Processing of Exemptions for Material Licensees	07/25/97
P&GD PG 8-11	NMSS Procedures for Reviewing Declarations of Bankruptcy	08/08/96
RG 3.4 Rev. 2	Nuclear Criticality Safety in Operations with Fissionable Materials at Fuels and Materials Facilities	03/86
RG 3.65	Standard Format and Content of Decommissioning Plans for Licenses Under 10 CFR Parts 30, 40 and 70	08/89
RG 4.13 Rev. 1	Performance Testing, and Procedural Specifications for Thermoluminescence Dosimetry: Environmental Applications	07/77
RG 4.15 Rev. 1	Quality Assurance for Radiological Monitoring Programs (Normal Operations)-Effluent Streams and the Environment	02/79
RG 4.20	Constraint on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors	12/96
RG 5.11 Rev. 1	Nondestructive Assay of Special Nuclear Material Contained in Scrap and Waste	04/84
RG 5.13	Conduct of Nuclear Material Physical Inventories	11/73

Document Identification	Title	Date
RG 5.53 Rev. 1	Qualification, Calibration, and Error Estimation Methods for Nondestructive Assay	02/84
RG 6.1 Rev. 1	Leak Testing Radioactive Brachytherapy Sources	07/74
RG 6.2 Rev. 1	Integrity and Text Specifications for Selected Brachytherapy Sources	07/74
RG 6.3	Design, Construction, and Use of Radioisotopic Generators for Certain Land and Sea Applications	03/74
RG 6.4 Rev. 2	Classification of Containment Properties of Sealed Radioactive Sources	08/80
RG 6.5	General Safety Standard for Installations Using Non-medical Sealed Gamma-Ray Sources	06/74
RG 6.6	Acceptance Sampling Procedures for Exempted and Generally Licensed Items Containing Byproduct Material	06/74
RG 6.7 Rev. 1	Preparation of an Environmental Report to Support a Rule Making Petition Seeking an Exemption for a Radioactive-Containing Product	06/76
RG 6.9	Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material	02/95
Draft RG TP 102-5	Safety Features of Gauges Containing Radioactive Material	11/80
RG 7.1	Administrative Guide for Packaging and Transporting Radioactive Material	06/74
RG 7.2	Packaging and Transportation of Radioactively Contaminated Biological Materials	06/74
RG 7.3	Procedures for Picking Up and Receiving Packages of Radioactive Material	05/75
RG 7.4	Leakage Tests on Packages of Radioactive Material	06/75
RG 7.5 Rev. O-R	Administrative Guide for Obtaining Exemptions from Certain NRC Requirements over Radioactive Material Shipments	05/77

Document Identification	Title	Date
RG 7.6 Rev. 1	Design Criteria for the Structural Analysis of Shipping Cask Containment Vessels	03/78
RG 7.7	Administrative Guide for Verifying Compliance with Packaging Requirements for Shipments of Radioactive Materials	08/77
Draft RG TP 914-4	Measurement of Radiation Levels on Surfaces of Packages of Radioactive Materials	12/79
RG 8.4	Direct-Reading and Indirect-Reading Pocket Dosimeters	02/73
RG 8.5 Rev. 1	Criticality and Other Interior Evacuation Signals	03/81
RG 8.6	Standard Test Procedure for Geiger-Muller Counters	05/73
RG 8.7 Rev. 1	Instructions for Recording and Reporting Occupational Radiation Exposure Data	06/92
RG 8.9 Rev. 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program	07/93
RG 8.10 Rev. 1-R	Operating Philosophy for Maintaining Occupational Exposures As Low As is Reasonably Achievable	05/77
RG 8.11	Applications of Bioassay for Uranium	06/74
RG 8.12 Rev. 2	Criticality Accident Alarm Systems	10/88
RG 8.13 Rev. 2	Instruction Concerning Prenatal Radiation Exposure	12/87
RG 8.14 Rev. 1	Personnel Neutron Dosimeters	08/77
RG 8.15	Acceptable Programs for Respiratory Protection	10/76
RG 8.20 Rev. 1	Applications of Bioassay for I-125 and I-131	09/79
RG 8.23 Rev. 1	Radiation Safety Surveys at Medical Institutions	01/81
RG 8.25 Rev. 1	Air Sampling in the Workplace	06/92
RG 8.26	Applications for Bioassay for Fission and Activation Products	09/80
RG 8.28	Audible-Alarm Dosimeters	08/81
RG 8.29 Rev. 1	Instruction Concerning Risks from Occupational Radiation Exposure	02/96
RG 8.32	Criteria for Establishing a Tritium Bioassay Program	07/88

Document Identification	Title	Date
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
Draft RG DG-8014	Proposed Rev. 3-Instruction Concerning Prenatal Radiation Exposure	10/94
Draft RG OH 940-4	Proposed Rev.2-Personnel Neutron Exposures	02/80
Draft RG OP 032-5	Test and Calibration of Radiation Protection Instrumentation	09/84
Draft RG OP 722-4	Qualifications for the Radiation Safety Officer in a Large-Scale Non-Fuel-Cycle Radionuclide Program	04/82
RG 10.3 Rev. 1	Guide for the Preparation of Applications for Special Nuclear Materials Licenses of Less Than Critical Mass Quantities	04/77
RG 10.4 Rev. 2	Guide for the Preparation of Applications for Licenses to Process Source Material	12/87
RG 10.12	Preparation of Petitions for Rulemaking Under 10 CFR 2.802 and Preparation and Submission of Proposals for Regulatory Guidance Documents	12/96
Draft RG FC 406	Guide for the Preparation of Applications for Licenses and Approvals to Authorize Distribution of Various Items to Group Medical	2/85
Draft RG FC 411-4	Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Servicing Pre-registered Gauges, Measuring Devices, and Sealed Sources Used in Such Devices	06/85
Draft RG FC 413-4	Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments	06/85
Draft RG FC 412-4	Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Leak-Testing Services	06/85

Table A.2 List of Information Notices.

Document Identification	Title	Date
IN 84-94	Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)	12/84
IN 88-10	Material Licensees': Lack of Management Controls Over Licensed Programs	03/28/88
IN 89-25 Rev. 1	Unauthorized Transfer of Ownership or Control of Licensed Activities	12/07/94
IN 93-14	Clarification of 10 CFR 40.22, Small Quantities of Source Material	02/18/93
IN 93-77	Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities	10/04/93
IN 93-100	Reporting Requirements for Bankruptcy	12/22/93
IN 94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20	01/28/94
IN 94-16	Recent Incidents Resulting in Off-site Contamination	03/03/94
IN 94-15	Radiation Exposures During an Event Involving a Fixed Nuclear Gauge	03/02/94
IN 94-21	Regulatory Requirements When No Operations Are Being Performed	03/18/94
IN 94-23	Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program	03/25/94
IN 94-47	Accuracy of Information Provided to NRC During the Licensing Process	06/21/94
IN 94-64**	Reactivity Insertion Transient and Accident Limits for High Burnup Fuel	08/31/94
IN 94-64 Supplement 1**	Reactivity Insertion Transient and Accident Limits for High Burnup Fuel	04/06/95
IN 94-70	Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals	09/29/94

** These documents were reviewed but are not relevant to this NUREG.

Document Identification	Title	Date
IN 94-73	Clarification of Criticality Reporting Criteria	10/12/94
IN 95-01	DOT Safety Advisory: High Pressure Aluminum Seamless and Aluminum Composite Hoop-Wrapped Cylinders	01/04/95
IN 95-51	Recent Incidents Involving Potential Loss of Control of Licensed Material	10/27/95
IN 96-04	Incident Reporting Requirements for Radiography Licensees	01/10/96
IN 96-18	Compliance With 10 CFR Part 20 for Airborne Thorium	03/25/96
IN 96-20	Demonstration of Associated Equipment Compliance With 10 CFR 34.20	04/04/96
IN 96-33	Erroneous Data from Defective Thermocouple Results in a Fire	05/24/96
IN 96-28	Suggested Guidance Relating to Development and Implementation of Corrective Action	05/01/96
IN 96-35	Failure of Safety Systems on Self-Shielded Irradiators because of Inadequate Maintenance and Training	06/11/96
IN 96-51	Residual Contamination Remaining in Krypton-85 Handling System after Venting	09/11/96
IN 96-54	Vulnerability of Stainless Steel to Corrosion When Sensitized	10/17/96
IN 96-63	Potential Safety Issue Regarding the Shipment of Fissile Material	12/05/96
IN 96-70	Year 2000 Effect on Computer System Software	12/24/96
IN 97-03	Defacing of Labels to Comply with 10 CFR 20.1904(b)	02/20/97
IN 97-23	Evaluation and Reporting of Fires and Unplanned Chemical Reaction Events at Fuel Cycle Facilities	05/07/97
IN 97-30	Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises	06/03/97
IN 97-36	Unplanned Intakes by Workers of Transuranic Airborne Radioactive Materials and External Exposure Due to Inadequate Control of Work	06/20/97

Document Identification	Title	Date
IN 97-24**	Failure of Packing Nuts on One-Inch Uranium Hexafluoride Cylinder Values	05/08/97
IN 97-47	Inadequate Puncture Tests for Type B Packages Under 10 CFR 71.73(c)(3)	06/27/97
IN 97-50	Contaminated Lead Products	07/10/97
IN 97-56	Possession Limits for Special Nuclear Material at the Envirocare of Utah Low-Level Radioactive Waste Disposal Facility	06/28/97
IN 97-61	U.S. Department of Health and Human Services Letter, to Medical Device Manufactures, on the Year 2000 Problem	08/06/97
IN 97-72	Potential for Failure of the Omega Series Sprinkler Heads	09/22/97
IN 97-75	Enforcement Sanctions Issued as a Result of Deliberate Violations of NRC Requirements	09/24/97
IN 97-89	Distribution of Sources and Devices Without Authorization	12/29/97
IN 98-01	Thefts of Portable Gauges	01/15/98
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

** These documents were reviewed but are not relevant to this NUREG.

Document Identification	Title	Date
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

Table A.3 Miscellaneous NRC Documents.

Document Identification	Title	Date
IP 87111, Appendix A	Materials Processor/Manufacturer Inspection Record	06/11/98
IP 87111, Appendix B	Materials Processor/Manufacturer Inspection References	06/11/98
IMC 2800	Material Inspection Program	04/17/95
IP 87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing	06/11/97
IP 87104	Decommissioning Inspection Procedure for Materials Licensees	06/04/97
IP 87104, Appendix A	Materials Decommissioning Inspection Field Notes for Facilities Needing Significant Decommissioning Effort	06/04/97
MOU	Memorandum of Understanding with DOT on the Transportation of Radioactive Material	06/06/79
MOU	Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Health and Safety Administration; Worker Protection at NRC-Licensed Facilities	10/21/88

Appendix B

United States Nuclear Regulatory Commission Form 313

NRC FORM 313 (8-1999) 10 CFR 30, 32, 33 34, 35, 36, 39 and 40	U. S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120	EXPIRES:08/31/2002

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory information collection request: 7.4 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 Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@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, 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:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

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 SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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(ES) 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. LICENSEE 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 CONTAINED 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	

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 Manufacturing and Distribution licenses. 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 is then expected to describe its program or submit its procedures for the particular item.

For broad scope usage applications, refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

Item No.	Suggested Response	Agree to Use	Description Attached
5.	**RADIOACTIVE MATERIAL** **Unsealed and/or Sealed Sources**		
	• For unsealed materials: – Provide radionuclide (element name and mass number), chemical and/or physical form, and maximum requested possession limit. – For potentially volatile materials (e.g., I-125, I-131, H-3), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form.	N/A	❒
	• For sealed materials: – 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 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.	N/A	❒
	• Provide an Emergency Plan (if required).	N/A	❒

Item No.	Suggested Response	Agree to Use	Description Attached
5.	**RADIOACTIVE MATERIAL *(Cont'd)***		
	Financial Assurance and Recordkeeping for Decommissioning No response is needed from most applicants. If an F/A or a DFP is required, submit the required documents as described in NUREG-1727.	N/A	❒
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED**		
	List the specific use or purpose of each radioisotope.	N/A	❒
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**		
	RSO Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.	N/A	❒
	AUs Provide the name of each proposed AU, with the types and quantities of licensed material to be used. Also provide information demonstrating that each proposed AU is qualified by training and experience to use 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	❒

Item No.	Suggested Response	Agree to Use	Description Attached
9.	**FACILITIES AND EQUIPMENT**		
	Describe the facilities and equipment to be made available at each location where radioactive material will be used.	N/A	❒
	Include a description of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials.		❒
	Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety.		❒
	When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems.		❒
	Diagrams should be drawn to a specified scale, or dimensions should be indicated.		❒
	For facilities where it is anticipated that more than one area of use or room may be used, a generic area or room diagram may be submitted.		❒
10.	**RADIATION SAFETY PROGRAM** **Audit Program**		
	The applicant is required to submit its audit program and frequency of audits to NRC for review during the licensing phase. It should be noted in the program whether or not operating procedures which can potentially affect the use of radioactive material or occupational dose have been developed, documented, implemented, and maintained to demonstrate compliance with 10 CFR 20.1101(a).	N/A	❒

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)***		
	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 K to NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.' We reserve the right to upgrade our survey instruments as necessary."	❒	❒
	OR		
	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 K to NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.' Additionally, we will implement the model survey meter calibration program published in Appendix K to NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.' We reserve the right to upgrade our survey instruments as necessary."	❒	❒
	Material Receipt and Accountability		
	State that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."	❒	❒

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)***		
	Occupational Dose		
	State that: "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20."	❒	N/A
	OR		
	"We will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program – Occupational Dose' in NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.'"	❒	N/A
	Public Dose		
	Initially, a response is not required from the applicant in a license application.	N/A	N/A

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)***		
	Safe Use of Radionuclides and Emergency Procedures	N/A	❒
	Develop and maintain procedures for safe use and emergencies. State that such procedures have been developed.	❒	❒
	If an emergency response plan is needed, submit it as a separate part of the application.	❒	N/A
	Procedures may be revised without submission to NRC if: • The changes are reviewed and approved by licensee management and the RSO. • Licensee staff is trained in the revised procedures before they are implemented. • The changes are consistent with the procedures submitted with the license application. • The changes do not degrade the effectiveness of the program.		

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)***		
	Surveys		
	"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix P to NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.' Leak tests 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."	❒	N/A
	OR		
	"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix P to NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.' Leak tests 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 Q to NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.'"	❒	N/A

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM** ***(Cont'd)***		
	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. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: "Radioactive Material – Sealed Sources and Devices or Unsealed Radioactive Material," "Facilities and Equipment," "Radiation Safety Program – Operating and Emergency Procedures," "Radiation Safety Program – Surveys and Leak Tests," and "Waste Management."	N/A	N/A
11.	**WASTE MANAGEMENT**		
	State that: "We will use the model waste procedures published in Appendix S to NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.'"	❒	N/A
	OR		
	"We will use the (specify either (1) Decay-In-Storage; or (2) Disposal of Liquids Into Sanitary Sewerage) model waste procedures that are published in Appendix S to NUREG-1556, Vol. 12, 'Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.'"	❒	

Appendix D

Sample Licenses

Sample Licenses appear on the following pages.

Note: For an example of a distribution license for generally licensed products, see NUREG-1556, Vol. 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees." For an example of a distribution license for exempt products, see NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses."

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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Manufacture License, Inc.	3. License Number 01-23456-78
2. 1234 Anywhere Street Anytown, State 01234	4. Expiration Date February 28, 2008
	5. Docket No. 030-01234 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. Any byproduct material with atomic numbers 1 through 83	A. Any	A. Not to exceed 370 gigabecquerels (GBq) (10 curies (Ci)) per radionuclide and 3.7 terabecquerels (TBq) (100 Ci) total
B. Any byproduct material with atomic numbers 84 through 94	B. Any	B. Not to exceed 1.85 GBq (50 millicuries (mCi)) per radionuclide and 74 GBq (2 Ci) total
C. Hydrogen-3	C. Any	C. 3.7 petabecquerels (PBq) (100,000 Ci)
D. Carbon-14	D. Any	D. 18.5 TBq (500 Ci)
E. Phosphorus-32	E. Any	E. 3.7 TBq (100 Ci)
F. Phosphorus-33	F. Any	F. 740 GBq (20 Ci)
G. Sulfur-35	G. Any	G. 14.8 TBq (400 Ci)

9. Authorized Use

A. through G.

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

(2) For possession, use, and processing incident to manufacture of radiochemicals, radiopharmaceuticals and sealed sources. (Sealed sources are not identified by specific manufacturer model numbers because they will be distributed under a G-, E-, or MD-distribution license, and will be identified on that license.)

(3) For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals and sealed sources.

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License Number
01-23456-78

Docket or Reference Number
030-01234

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(4) For packaging and distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement States.

(5) For use in calibration of Sample Manufacture License, Inc. instruments.

(6) For storage as radioactive wastes.

(7) For return of spent generators, radiopharmaceuticals, and sealed sources to the Sample Manufacture License, Inc. facility in Anytown, State, for storage prior to disposal and/or processing.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 1234 Anywhere Street, 5678 East Anyplace Street, and 0123 and 4567 West Any Road, Anytown, State.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, John Q. Public, Ph.D., CHP, Chairperson.

    B. The Radiation Safety Officer for this license is John Doe, M.S., CHP

12. This license does not authorize commercial distribution of licensed material pursuant to 10 CFR 32.72 or 10 CFR 32.74 to persons generally licensed pursuant to 10 CFR Part 31 or equivalent regulations of any Agreement State; or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.20 inclusive, or equivalent regulations of any Agreement State.

13. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to be exceed three months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

    D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

    E. Sealed sources and detector cells need not be leak tested if:

        (i) they contain only hydrogen-3; or

        (ii) they contain only a radioactive gas; or

        (iii) the half-life of the isotope is 30 days or less; or

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(iv) they contain not more than 100 μCi of beta and/or gamma emitting material or not more than 10 μCi of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test intervals, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 μCi of radioactive material on the test sample. If the test reveals the presence of 0.005 μCi or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.52(b)(2), and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region___, ATTN: Chief, Nuclear Materials Safety Branch, (insert appropriate Regional address). The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

14. Licensed material shall not be used in or on human beings.

15. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

16. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

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

18. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

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C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. 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 enclosure, 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 October 23, 1997
B. Radiological Contingency Plan dated February 6, 1998

For the U.S. Nuclear Regulatory Commission

Date: _____ By: _____

Division of Nuclear Materials Safety
Region ___
City, State Zip Code

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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Smoke Detector Company	3. License number 12-34567-89
2. 12345 South Any Street Any Town, State 12345-6789	4. Expiration date August 31, 2008
	5. Docket No. 030-12345 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. Americium-241	A. Foil sources (Amersham Int., Inc. Model No. AMM 1001H)	A. No single foil to exceed 33.3 kilobecquerels (kBq) (0.9 μCi), 1.665 gigabecquerels (GBq) (45 millicuries) total

9. Authorized Use:

A. To be used for possession and storage in Sample Smoke Detector Company XY Series ionization smoke detectors incident to distribution in accordance with the conditions of NRC Byproduct Material License No. 12-34567-89E.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 12345 South Any Street, Any Town, State.

11. Licensed material shall be used by, or under the supervision of, Named Person One or Named Person Two.

12. This license does not authorize commercial distribution of licensed material.

13. Licensed material shall not be used in or on human beings.

14. Sealed sources containing licensed material shall not be opened.

15. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

16. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

17. 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

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License Number
34-23772-01

Docket or Reference Number
030-31617

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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 July 25, 1998.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____

By: _____
Reviewer's Name
Materials Licensing Branch
Region ____

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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Medical Calibration Source Distribution Company	3. License number 01-23456-78MD
2. 01234 North Any Street Any Town, State 01234-5678	4. Expiration date September 30, 2008 5. Docket No. 030-01234 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. As specified in Condition 10	A. As specified in Condition 10	A. Not applicable

Authorized Use:

A. Pursuant to 10 CFR Part 32.74, the licensee is authorized to distribute the sources specified in Condition 10 of this license to persons licensed pursuant to 10 CFR Part 35.57, or under equivalent licensees of Agreement States.

CONDITIONS

10. Each sealed source distributed under this license shall not contain, as of the assay date, more than the quantity of byproduct material listed in the following table:

Byproduct Material	Model No.	Chemical and/or Physical Form	Maximum Quality
A. Cobalt-60	NES-354	Dose calibrator reference source Solid epoxy matrix in vial E	1 millicurie
B. Cesium-137	NES-356	Dose calibrator reference source Solid epoxy matrix in vial E	1 millicurie
C. Barium-133	NES-358	Dose calibrator reference source Solid epoxy matrix in vial E	1 millicurie
D. Barium-133	NES-8060	Spot Marker reference source	200 μCi
E. Cesium-137	NES-8021	Dose calibrator reference source	50 μCi
F. Cesium-137	NES-8023	Dose calibrator reference source	50 μCi
G. Gadolinium-153	NES-8412 through NES-8425	Reference sources to be used in gamma cameras for medical imaging	1 curie

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01-23456-78MD

Docket or Reference Number
030-01234

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11. The licensee is authorized to distribute the licensed materials listed in Condition 10 of this license from 01234 North Any Street, Any Town, State.

12. This license does not authorize possession or use of licensed material.

13. Any proposed changes in packaging, labeling, shielding, or instructions for use and storage shall be submitted for review to the Nuclear Materials Safety Branch, U.S. Nuclear Regulatory Commission, Region ____, (insert appropriate Region and address) and approval of the changes shall be received by the licensee prior to implementing the change.

14. 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 August 28, 1998

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____ By: _____

Division of Nuclear Materials Safety
Region ____
City, State Zip Code

APPENDIX D

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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated April 13, 1995,
1. Sample Radiopharmaceutical Distribution Only License, Inc.	3. License number 01-23456-04MD is amended in its entirety to read as follows:
2. P.O. Box 191 City, State Zip Code	4. Expiration date March 31, 2008
	5. Docket No. 030-56789 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. Chromium-51	A. Sodium Chromate (NDA 13-993)	A. Not applicable
B. Iodine-131	B. Sodium Iodohippurate (NDA 16-666)	B. Not applicable
C. Iodine-131	C. Sodium Iodide (NDA 10-929/S-01, S-002)	C. Not applicable

9. Authorized Use:

A. through C.

Pursuant to Section 32.72 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Sections 35.100, 35.200 and 35.300 of 10 CFR Part 35, or under equivalent licenses of Agreement States.

CONDITIONS

10. Each product distributed under this licensee shall not contain as of the assay date, more than the quantity of byproduct material listed in the following table.

Byproduct Material	Product Name	Maximum Quantity
A. Chromium-51	Chromitope Sodium Injection	37 megabecquerels (MBq) (1.0 millicurie (mCi))
B. Iodine-131	Hippuran I 131 Injection	74 MBq (2.0 mCi)
C. Iodine-131	Iodotope Therapeutic Capsules	5.55 gigabecquerels (Gbq) (150 mCi)
D. Iodine-131	Iodotope Therapeutic Oral	3.959 GBq (107 mCi)

11. The licensee may distribute material from licensee's facilities located at 1 Medical Drive, Any Town, Any State.

License Number
01-23456-04MD

Docket or Reference Number
030-56789

MATERIALS LICENSE
SUPPLEMENTARY SHEET

12. This license does not authorize possession or use of licensed material.

13. 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 January 27, 1998
    B. Letter dated February 10, 1998
    C. Letter dated March 2, 1998

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____ By: _____

Division of Nuclear Materials Safety
Region ____
City, State Zip Code

Appendix E

Information Needed for Transfer of Control Application

For information on the transfer of control application, refer to 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."

Appendix F

License Types – Guidance

XX (state code)-XXXXX (institution code – a unique identifier for each licensee)-XX (sequential number of license for that licensee).

Letters that follow the license number on distribution licenses include: E, G, MD. No letters indicates a possession license.

Manufacturer's Possession License XX-XXXXX-XX

This specific license is issued to a manufacturer to possess, use, manufacture, etc. licensed material for distribution and for use by the licensee in process controls. It can include distribution to other specific licensees who are also specifically authorized to receive the materials pursuant to their specific license. The manufacturer's possession license contains conditions that prohibit distribution pursuant to 10 CFR 32.72, 32.74, and prohibit distribution to general licensees and to persons exempt from licensing.

Importer's Possession License XX-XXXXX-XX

This specific license is issued to an importer to possess (only) licensed material for transfer. It only authorizes transfers to other specific licensees authorized by license condition to receive the materials. The importer's possession license contains conditions that prohibit distribution pursuant to 10 CFR 32.72, 32.74, and prohibit distribution to general licensees and to persons exempt from licensing.

General Distribution License XX-XXXXX-XXG

This specific license is issued to manufacturers and/or distributors to distribute approved materials to persons who are generally licensed to possess and use the materials. This license does not authorize the possession of byproduct, source, or special nuclear material.

The most common products distributed to general licensees are:

10 CFR 32.51/51a/52

> Certain measuring, gauging, or controlling devices, including: fixed gauges including density, thickness, etc. and may include multi-curie sources; gas chromatograph ECDs, X-ray fluorescence or other analytical devices; curie-quantity tritium light sources for exit signs; and similar devices. For possession and use by persons authorized by a General License pursuant to 10 CFR 31.5.

10 CFR 32.71

> Kits for *in vitro* clinical or laboratory testing, e.g., microcurie quantities of H-3, C-14, Fe-55, I-125, etc. For possession and use by persons authorized by a General License pursuant to 10 CFR 31.11.

Exempt Distribution License XX-XXXXX-XXE

Specific license to distribute approved materials to persons who are not required to have any license in order to possess or use the material. Exempt Distribution is authorized by a Specific License ISSUED BY NRC HEADQUARTERS in Washington, D.C. This license does not authorize the possession of byproduct, source, or special nuclear material.

Medical Distribution License (XX-XXXXX-XXMD)

10 CFR 32.72 and 32.74

> Sources/devices for medical use pursuant to 10 CFR 35.57/400/500 for radiopharmaceuticals for medical use pursuant to 10 CFR 35.100/200/300 (since the "new pharmacy rule," which eliminated regulation of cold kits; regulation of distribution of generators is also included). This license does not authorize the possession of byproduct, source, or special nuclear material.

Manufacturers of medical devices may wish to plan for return shipments of licensed materials. Manufacturers of sealed source devices such as eye applicators or bone densitometers may wish to provide a return at end of useful life service. Radiopharmaceutical manufacturers may wish to receive spent generator assemblies from their customers and dispose of them by decay-in-storage. The manufacturer should prepare return shipping procedures for customers to use. The shipper is responsible for the proper preparation for shipment. Many licensees request assistance from manufacturers about shipments. These instructions may be included with this license application. Returned materials are possessed pursuant to the manufacturer's possession license.

Appendix G

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 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 delivery, receipt, and conduct of 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, regulations, etc.;
- 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 receipts, 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, etc.), 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;
- 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 H

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;

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 users and supervised users.

B. Worker-specific manufacturing process tasks.

C. Shipping.

D. Ordering and receiving radioisotopes.

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 N).

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:
   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. Procedures for opening and examining packages:
   1. leakage and contamination;
   2. monitoring packages;
   3. monitoring packing materials;
   4. gloves;
   5. transferring material to users.

U. Animal experiments:
   1. description of facilities;
   2. safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages;
   3. security.

V. Sealed sources:
   1. leak-test requirements;
   2. inventory requirements;
   3. exempt quantities;
   4. records.

W. NRC/State/Licensee audit findings

X. Other topics.

Y. 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, etc.

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

Appendix I

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.
- Benchtop 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 non-porous, 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 or glove boxes 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 required in 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.
- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.

- Plumbing and ductwork 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 beta radiation; the type, quality and configuration of local shielding in place; and the duration of personnel exposure in conducting the operation with a high-energy beta emitting radionuclide.
- Generally, when the exposure is likely to be small, shielding material(s) (usually plastic) of low atomic number, in sufficient thickness to absorb all the beta radiation, will be all that is needed to eliminate direct exposure to betas and minimize the generation of secondary bremsstrahlung.
- In operations using large quantities (i.e., multi-millicurie quantities) of high-energy beta-emitting radionuclides and/or longer exposure times, it may be necessary to also reduce the bremsstrahlung by adding shielding containing high-atomic number material such as lead. These shields generally are low-atomic number materials closest to the source, enclosed by high-atomic number material.
- In use of quantities of high-energy beta radionuclides (generally above 100 millicuries), it may be more practical to use lead for the outer shield, and to use an indirect viewing method such as mirrors to view the source or the process.
- 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.

- 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 J

Example Audit Form

The following audit form 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). Attachment A may be used by licensees that distribute radioactive drugs. These forms are not intended to be all inclusive. During an audit, the auditor needs to keep in mind not only the requirements of NRC's regulations, but also the licensee's commitments in its applications and other correspondence with NRC. Licensees are encouraged to modify the audit form as needed to include items specific to their licensed program and should ensure that radiation safety audits include activities conducted during all shifts. References are also included.

EXAMPLE AUDIT FORM

1. AMENDMENTS AND PROGRAM CHANGES:
(Amendments to the license were properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition)

AMENDMENT #	DATE	SUBJECT

2. MANAGEMENT OVERSIGHT:
(Management support to radiation safety; Radiation Safety Committee (RSC); Radiation Safety Officer (RSO); program audits, including annual reviews of program and as low as is reasonably achievable (ALARA) reviews; control by authorized users)

3. FACILITIES:
(Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding; air flow)

4. EQUIPMENT AND INSTRUMENTATION:
(Operable survey equipment; procedures; 10 CFR Part 21 procedures; process and storage systems)

5. MATERIAL USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses)

7. TRAINING AND INSTRUCTIONS TO WORKERS:
(Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency situations; and supervision by authorized users)

8. RADIATION PROTECTION:
(Radiation Protection Program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

9. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents and compactors; license conditions for special disposal method)

10. DECOMMISSIONING:
(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

11. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

12. NOTIFICATIONS AND REPORTS:
(Reporting and follow-up of theft; loss; incidents; overexposures; change in RSO, authorized user; and radiation exposure reports to individuals)

13. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

14. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed and measurements made; comparison of data with staff's results and regulations)

15. AUDIT FINDINGS:

16. SOURCE OR DEVICE REVIEW:
(Device registration documents; changes; quality assurance/quality control program)

REFERENCES

1. AMENDMENTS AND PROGRAM CHANGES:

   Applicable license conditions.

2. MANAGEMENT OVERSIGHT:

   A. Radiation Safety Committee

      Applicable license conditions.

   B. Radiation Safety Officer

      Applicable license conditions.

   C. Audits, Reviews, or Inspections

      10 CFR 20.1101, Radiation Protection Programs.
      10 CFR 20.2102, Records of Radiation Protection Programs.
      Applicable license conditions.

   D. ALARA

      10 CFR 20.1101, Radiation Protection Programs.

   E. Authorized Users

      Applicable license conditions.

3. FACILITIES

   A. Access Control

      10 CFR 20.1601, 1602, Control of access to high/very high radiation areas.
      10 CFR 20.1801, Security of stored material.
      10 CFR 20.1802, Control of material not in storage.
      Applicable license conditions.

B. Engineering Controls

10 CFR 20.1101, Radiation Protection Programs.
10 CFR 20.1701, Use of process or other engineering controls.
Applicable license conditions.

4. EQUIPMENT AND INSTRUMENTATION:

A. Survey Instruments

10 CFR 20.1501, General.
10 CFR 20.1701, Use of Process or Other Engineering Controls.
10 CFR 20.2103, Records of Surveys.
Applicable license conditions.

B. Safety Component Defects

10 CFR 21.21, Notification of failure to comply or existence of a defect and its evaluation.

5. MATERIAL USE, CONTROL AND TRANSFER:

A. License and applicable license conditions.

B. Security and Control

10 CFR 20.1003, Definitions (restricted area and unrestricted area).
10 CFR 20.1801, Security of stored material.
10 CFR 20.1802, Control of material not in storage.

C. Receipt and Transfer of Licensed Material

10 CFR 20.1302, Compliance with dose limits for individual members of the public.
10 CFR 20.1906, Procedures for receiving and opening packages.
10 CFR 20.1501, Surveys.
10 CFR 20.2103, Records of surveys.
10 CFR 30.41, Transfer of byproduct material.
10 CFR 30.51, Records of receipt and transfer.

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:

A. Area Surveys

10 CFR 20.1302, Compliance with dose limits for individual members of the public.
10 CFR 20.1501, General.
10 CFR 20.2103, Records of surveys.
10 CFR 20.2107, Records of dose to individual members of the public.
Applicable license conditions.

B. Leak Tests and Inventories

Applicable license conditions.

7. TRAINING AND INSTRUCTIONS TO WORKERS:

10 CFR 19.12, Instruction to workers.
Knowledge of 10 CFR Part 20 radiation protection procedures and requirements.
Applicable license conditions.

8. RADIATION PROTECTION:

A. Radiation Protection Program

1. Exposure evaluation

10 CFR 20.1501, General.

2. Programs

10 CFR 20.1101, Radiation Protection Programs.

B. Dosimetry

1. Dose Limits

10 CFR 20.1201, Occupational dose limits for adults.
10 CFR 20.1202, Compliance with requirements for summation of external and internal doses.
10 CFR 20.1207, Occupational dose limits for minors.
10 CFR 20.1208, Doses to an embryo/fetus.

2. External

10 CFR 20.1203, Determination of external dose from airborne radioactive material.

10 CFR 20.1501, General.

10 CFR 20.1502, Conditions requiring individual monitoring of external and internal occupational dose.

Applicable license conditions.

3. Internal

10 CFR 20.1204, Determination of internal exposure.

10 CFR 20.1502, Conditions requiring individual monitoring of external and internal occupational dose.

10 CFR 20, Subpart H, Respiratory protection and controls to restrict Subpart H internal exposure in restricted areas.

C. Records

10 CFR 20.2102, Records of Radiation Protection Programs.

10 CFR 20.2103, Records of surveys.

10 CFR 20.2104, Determination of prior occupational dose.

10 CFR 20.2106, Records of individual monitoring results.

9. RADIOACTIVE WASTE MANAGEMENT:

A. Disposal

10 CFR 20.1904, Labeling containers.

10 CFR 20.2001, General requirements.

10 CFR 20.2103, Records of surveys.

10 CFR 20.2108, Records of waste disposal.

10 CFR 20.2003, Disposal by release into sanitary sewerage.

B. Effluents

1. General

Regulatory Guide 8.37, ALARA Levels for Effluents from Materials Facilities.

2. Release to septic tanks

   10 CFR 20.1003, Definitions (sanitary sewerage).
   10 CFR Part 20, Effluent Concentrations.
   App. B, Table 2.

3. Incineration of waste

   10 CFR 20.2004, Treatment or disposal by incineration.

4. Control of air effluents and ashes

   10 CFR 20.1201, Occupational dose limits for adults.
   10 CFR 20.1301, Dose limits for individual members of the public.
   10 CFR 20.1501, General.
   10 CFR 20.1701, Use of process or other engineering controls.
   Applicable license conditions.

C. Waste Management

1. General

   10 CFR 20.2001, General requirements.

2. Waste compacted

   Applicable license conditions.

3. Waste storage areas

   10 CFR 20.1801, Security of stored material.
   10 CFR 20.1902, Posting requirements.
   10 CFR 20.1904, Labeling containers.
   Applicable license conditions.

4. Packaging, Control and Tracking

   10 CFR Part 20, Requirements for Low-Level Waste Transfer.
   Appendix F for Disposal at Land Disposal Facilities and Manifests.
   10 CFR 20.2006, Transfer for disposal and manifests.

10 CFR 61.55, Waste classification.
10 CFR 61.56, Waste characteristics.

5. Transfer

10 CFR Part 20, Requirements for Low-Level Waste Transfer.
Appendix F for Disposal at Land Disposal Facilities and Manifests.
10 CFR 20.2001, General requirements.
10 CFR 20.2006, Transfer for disposal and manifests.

6. Records

10 CFR 20.2103, Records of surveys.
10 CFR 20.2108, Records of waste disposal.

10. DECOMMISSIONING:

10 CFR 30.35, Financial assurance and recordkeeping for decommissioning.
10 CFR 30.36, Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.
NUREG/BR-0241NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees.

11. TRANSPORTATION:

A. General

10 CFR 71.5, Transportation of licensed material.
49 CFR Parts 100-179, Transportation of licensed material.

B. Shippers – Requirements for Shipments and Packaging

1. General Requirements

49 CFR Part 173, Class 7 (radioactive) materials.
Subpart I.
49 CFR 173.24, General requirements for packagings and packages.
49 CFR 173.448, General transportation requirements.
49 CFR 173.435, Table of A_1 and A_2 values for radionuclides.

2. Transport Quantities

10 CFR 71.4, Definitions.

a. All quantities

10 CFR 71.4, Definitions.

49 CFR 173.410, General design requirements.

49 CFR 173.441, Radiation level limitations.

49 CFR 173.443, Contamination control.

49 CFR 173.475, Quality control requirements prior to each shipment of Class 7 (radioactive) materials.

49 CFR 173.476, Approval of special form Class 7 (radioactive) materials.

b. Limited quantities

49 CFR 173.421, Excepted packages for limited quantities of Class 7 (radioactive) materials.

49 CFR 173.422, Additional requirements for excepted packages containing Class 7 (radioactive) materials.

c. Type A quantities

49 CFR 173.412, Additional design requirements for Type A packages.

49 CFR 173.415, Authorized Type A packages.

49 CFR 178.350, Specification 7A; general packaging, Type A.

d. Type B quantities

10 CFR 71

e. LSA material and SCO

49 CFR 173.403, Definitions.

49 CFR 173.427, Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO).

3. HAZMAT Communication Requirements

49 CFR 172.200-205, Shipping papers.
49 CFR 172.300-338, Marking.
49 CFR 172.400-450, Labeling.
49 CFR 172.500-560, Placarding.
49 CFR 172.600-604, Emergency response information.

C. HAZMAT Training

49 CFR 172.702, Applicability and responsibility for training and testing.
49 CFR 172.704, Training requirements.

D. Transportation by Public Highway

49 CFR 171.15, Immediate notice of certain hazardous materials incidents.
49 CFR 171.16, Detailed hazardous materials incident reports.
49 CFR 177.800, Purpose and scope of this part and responsibility for compliance and training.
49 CFR 177.816, Driver training.
49 CFR 177.842, Class 7 (radioactive) material.

12. NOTIFICATIONS AND REPORTS:

10 CFR 19.13, Notifications and reports to individuals.
10 CFR 20.2201, Reports of theft or loss of licensed material.
10 CFR 20.2202, Notification of incidents.
10 CFR 20.2203, Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.
10 CFR 30.50, Reporting requirements.

13. POSTING AND LABELING:

10 CFR 19.11, Posting of notices to workers.
10 CFR 21.6, Posting requirements.
10 CFR 20.1902, Posting requirements.
10 CFR 20.1903, Exemptions to posting requirements.

10 CFR 20.1904, Labeling containers.
10 CFR 20.1905, Exemptions to labeling requirements.

14. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

No references.

15. AUDIT FINDINGS:

No references.

16. SOURCE OR DEVICE REVIEW:

10 CFR 32.210, Registration of product information.

ATTACHMENT A RADIOACTIVE DRUG DISTRIBUTORS

1. Indicate type of operation:

   A. Registered or licensed with U.S. Food and Drug Administration as a drug manufacturer . . . . . ❒

   B. Registered or licensed with State Agency as a drug manufacturer . . . . . ❒

2. Periodically reviews work of supervised individuals preparing drugs, and records kept to reflect work. [License condition (L/C)] . . . . . ❒ Y ❒ N

   Basis for Findings:

3. Radioactive drugs are measured (assayed) by direct measurement or combination of measurement and calculation before commercial distribution [10 CFR 32.72(c)] . . . . . ❒ Y ❒ N

   Basis for Findings:

4. Instrumentation Used to Measure Radioactivity of Drugs

   A. List type of equipment used to assay alpha and beta particles.

   B. Procedures for instrument use developed and implemented [10 CFR 32.72(c)] . . . . . ❒ Y ❒ N

   C. Calibration tests performed before initial use, periodically, and following repair for accuracy, linearity, and geometry dependence, as appropriate for use of the instrument [10 CFR 32.72(c)(1); L/C] . . . . . ❒ Y ❒ N

   D. Adjustment to instrumentation made when necessary [10 CFR 32.72(c)(1); L/C] . . . . . ❒ Y ❒ N

E. Instruments are checked for constancy and proper operation at the beginning of each day of use [10 CFR 32.72(c)(2); L/C] . . . . . ❒ Y ❒ N

Basis for Findings:

5. Transport radiation shield (on transfers for distribution) labeled with radiation symbol, "CAUTION [or DANGER], RADIOACTIVE MATERIAL," name, and quantity at specified date and time[1] [10 CFR 32.72(a)(4)(I); L/C] . . . . . ❒ Y ❒ N

6. Syringes, vials, or other containers labeled with radiation symbol, "CAUTION [or DANGER], RADIOACTIVE MATERIAL," and an identifier to correlate with the information on the transport radiation shield label [10 CFR 32.72(a)(4)(ii); L/C] . . . . . ❒ Y ❒ N

Basis for Findings:

[1] The time may be omitted for drugs with a half-life greater than 100 days.

Appendix K

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

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

Table K.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	Gamma, X-ray	R-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 will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and 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;
- Biological effects of radiation.

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

- Observing authorized personnel performing survey instrument calibration;
- 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 should wear assigned dosimetry.
- Individuals conducting calibrations should use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments

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

- Approximate a point source;

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

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows[2]:

- 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.
- Meters with a digital display device shall be calibrated the same as meters with a linear scale.
- Readings above $2.58 \text{ X } 10^{-4}$ coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.
- 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]

- Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.
- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately

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

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

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

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

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a national standard (standard certified by National Institutes of Standards and Technology (NIST));
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

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

Calibration Records

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

- The owner or user of the instrument;
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date;
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument;
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);

- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
- The exposure rate or count rate from a check source, if used;
- 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;
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

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

The publication entitled *Air Sampling Instruments, 7th Edition*, American Conference of Governmental Industrial Hygienists, 1989, (available from the American Conference of Governmental Industrial Hygienists, Inc., 1330 Kemper Meadow Drive, Cincinnati, Ohio 45240-1634) provides guidance on total air sample volume calibration methods acceptable to NRC staff, as supplemented below. *Air Sampling Instruments, 8th Edition,* American Conference of Governmental Industrial Hygienists, 1995 is also available. The *8th Edition* has not been reviewed for acceptability by NRC for licensing purposes. NRC license applicants may submit materials based upon the *8th Edition*, but be aware that the review will require more time than if using the *7th Edition* and the NRC-developed information.

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

[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.

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%.[3]

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 & 0 C)
V1 = volume measured at conditions P1 and T1
T1 = temperature of V1 in K
P1 = pressure of V1 in mm Hg

Documentation of Calibration of Air Metering Devices

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

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

- Draft Regulatory Guide FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985. This document is available under the heading of Regulatory Guide Group 10 from References at <http://www.nrc.gov>.
- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992.
- NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Additional References:

- The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, dated 1992.
- 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: <http://www.ansi.org>.
- *Air Sampling Instruments for Evaluation of Atmosphere Contaminant, 7th Edition*, Cincinnati: American Conference of Governmental Industrial Hygienists, 1989.

Appendix L

Material Receipt and Accountability

Sample Model Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) shall be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or another designated trained individual) should unlock the door, place the package in the designated secured storage area, and re-lock the door.

Radiation Safety Officer (RSO):_____

Office Phone:_____

Home Phone:_____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Ask the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries will usually be handled by security personnel (or other trained individuals) as described in the above procedures. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

Name:_____

Phone:_____

For additional information on worker training, see Section 8.8, Training for Individuals Working In or Frequenting Restricted Areas.

Sample Model Procedure for Safely Opening Packages Containing Licensed Materials

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

- Wear gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO.
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, to ensure that the shipment does not exceed license possession limits.

- Monitor the external surfaces of a labeled package according to specifications in Appendix R, Part 2.
- Open the outer package (following supplier's directions, if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Again check that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO.
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final carrier and notify the Administrator of the appropriate NRC Regional Office listed in 10 CFR 20, Appendix D by telephone, telegram, mailgram, or facsimile when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) or external radiation levels exceed the limits of 10 CFR 71.47.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or AU's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the license. All transfers shall be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material shall not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with DOT, NRC, or U.S. Postal Service Regulations, whichever is applicable.

Gifts

On occasion, licensees may be offered or have donated licensed materials by other individuals as gifts (e.g., a retiring medical practitioner donating his cesium needles to the university medical center). All such gifts of radioactive materials must be transferred to the licensee and handled in accordance with NRC requirements and the conditions of the license. In any case, the RSO should approve the gift prior to the transfer.

Appendix M

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 millirem (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.
- Air emissions of radioactive material to the environment will not result in a TEDE in excess of 10 millirem (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 • Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, but the licensee may control access to these areas for other reasons, such as security.

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 Table 2 of Appendix B to Part 20; 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.

- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1mSv (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.

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

Calculation Method

Using a calculation method, the licensee must determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous

and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. 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 M.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.

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 M.1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table M.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 N

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 used 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 used.
- 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 N.1).
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Store radioactive solutions in clearly labeled containers.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

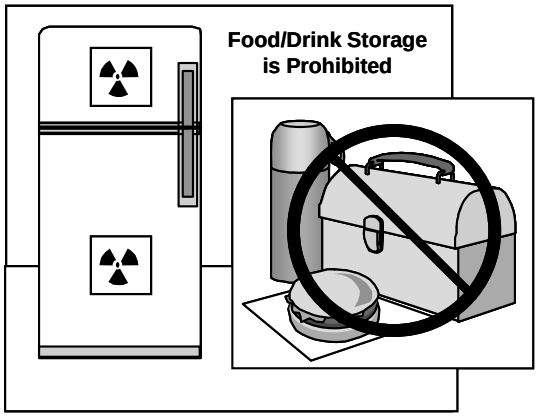


Figure N.1 Storage of Food and Drink. *Food or drink shall not be stored in refrigerators with radioisotopes.*

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-125 or iodine-131, special safety instructions should be provided to users, including 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;
- Procedures for measuring the concentration of radioiodine effluents from the hoods.

Example 2:

If requesting more than 37 MBq (1 mCi) of phosphorus-32, special safety instructions should be provided to users, including the following:

- The use of low-density plastic shielding and high-density materials, layered properly, in order to keep bremsstrahlung radiation 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;
- 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;
- The use of eye protection for procedures that involve 10 millicuries or more.

Model Procedures for Handling 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 it is 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;
  - — Pencil;
  - — Appropriate 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 Radiation Safety Officer (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).
  - — 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.
  - — 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).
- — 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 need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin.
  - — If necessary, notify NRC.

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

- Instructions to Workers
  - — Notify all personnel to vacate the room immediately.
  - — Shut down 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).
  - — 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 need for 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 need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident.
  - — If necessary, notify NRC.

Minor Fires

- Instructions to Workers
  - — Immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if other fire hazards or radiation hazards are not present.
  - — Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO).
  - — Once the fire is out, isolate the area to prevent the spread of possible contamination.
  - — 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.
  - — Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
  - — Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - — Supervise decontamination activities.
  - — 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 assure that there are no other possibilities of another fire starting.
  - — Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident.
  - — 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.
  - — Notify the RSO and other facility safety personnel.
  - — 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, etc.
  - — Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
  - — Allow no one to return to work in the area unless approved by the RSO.
  - — Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - — Coordinate activities with facility's industrial hygienist or environmental health and safety office, and with local fire department.
  - — Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.

- Once the fire is extinguished, do not allow the firefighters to enter the radiation area until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas.
- Perform thorough contamination surveys of the firefighters 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, inhaled, and/or absorbed through the skin. Document incident.
- Notify NRC.

Copies of emergency procedures should be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.

Appendix O

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 O.1 Typical NRC Notifications and/or Reports.

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(I)
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)
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)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)

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

Appendix P

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 will 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;
- Biological effects of radiation.

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

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples;
- 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 will 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.

- 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, 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;
- 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 annual limit on intake (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 P.1 contains suggested contamination survey frequency from Regulatory Guide 8.23. (See Tables P.2, P.3, and P.4 for alternate survey frequencies).

Table P.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 P.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 are to be used for more than one isotope.

Table P.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 non-occupational 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 LOW, MEDIUM, and HIGH survey frequency in Table P.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
- High – Not less than once per normal working day.

Table P.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 C1-38 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-l91 Pt-193 Pt-197 Au-196 Au-198 Au-l99 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 must ensure that the amounts do not exceed the contamination levels listed in Table P.5.

Table P.5 Acceptable Surface Contamination Levels.

Nuclide[1]	Average[2,3]	Maximum[2,4]	Removable[2,5]
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 P.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;
- Name of the person making the evaluation and recording the results and date.

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.

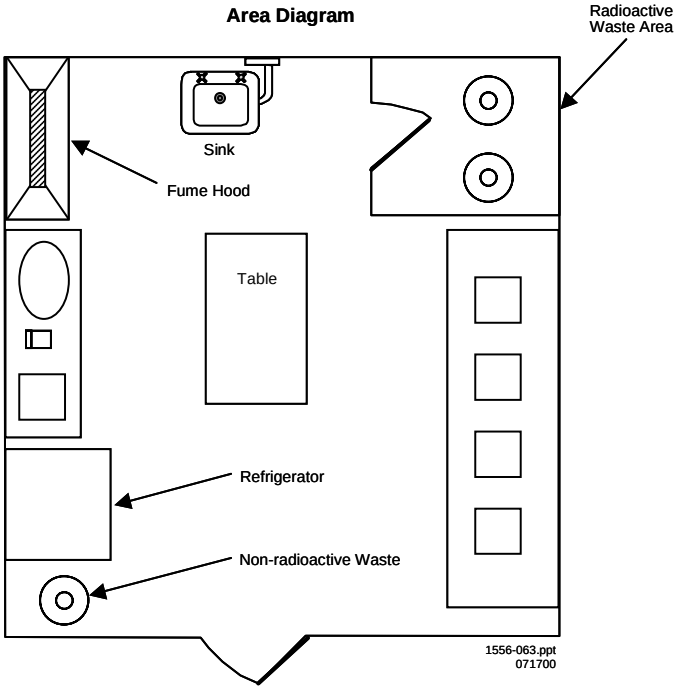


Figure P.1 Area Diagram. *This is an example of a laboratory survey map.*

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;
- 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 anytime 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 Q.

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;
- 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, urinalysis, etc.) 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 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 became contaminated and radioactive material was 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 may be required. Frequently, this estimate is made by performing 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 your 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 (24-hour urine collection?);
- Ease/difficulty of sample collection;
- 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;
- 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 8.23, Revision 1, “Radiation Safety Surveys at Medical Institutions,” dated January 1981.
- Regulatory Guide 8.25, Revision 1, “Air Sampling in the Workplace,” dated June 1992.
- Regulatory Guide 8.32, “Criteria for Establishing a Tritium Bioassay Program,” dated July 1988.
- 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 N13.30-1996, “Performance Criteria for Radiobioassay,” dated 1996.

- ANSI N42.18, “Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents,” 1991.
- NCRP Commentary No. 3, “Screening Techniques for Determining Compliance with Environmental Standards,” published in January 1989 and the addendum published in October 1989.
- U.S. Department of Energy, DOE G 441.1-8, “Air Monitoring Guide,” dated March 17, 1999.
- U.S. Department of Energy, DOE G 441.1-3, “Internal Dosimetry Program Guide,” dated March 17, 1999.
- U.S. Department of Energy, DOE G 441.1-4, “External Dosimetry Program Guide,” dated March 17, 1999.
- U.S. Department of Energy, DOE G 441.1-2, “Occupational ALARA Program Guide,” dated March 17, 1999.

Appendix Q

Model Leak Test Program

This appendix provides applicants and licensees with model leak test procedures and sample calculations for determining activity on a wipe test sample.

Frequency for Conducting Leak Tests of Sealed Sources

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

Procedure for Performing Leak Testing and Analysis

For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclide, and 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 (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the radionuclide and ensure that its calibration is current.
- Using the selected instrument, count and record background count rate.
- Calculate efficiency of the detector. A sample calculation is shown below.
- Count the sample.

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

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

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

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

- Sign and date the list of sources, data and calculations. Retain records for 3 years (10 CFR 20.2103(a)).
- If the wipe test activity is 185 Bq (0.005 mCi) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly.
- Also notify NRC.

Appendix R

Transportation

Part 1 – Regulations

Transportation

The major areas in the DOT regulations that are most relevant for transportation of licensed material shipped as Type A quantities are contained in NUREG-1660/RAMREG-002, "U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments," dated November 1998.

Appendix R
Transportation

Part 2
Sample Shipping Documents, Placards, and Labels

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Entries Always Required Unless Excepted	Additional Entries Sometimes Required	Optional Entries
! The basic description, in sequence: Proper Shipping Name, Hazard Class (7), U.N. Identification Number ! 24 hour emergency response telephone number ! Name of shipper ! Proper page numbering (Page 1 of 4) ! Except for empty and bulk packages, the total quantity (mass, or volume for liquid), in appropriate units (lbs, mL....) ! If not special form, chemical and physical form ! The name of each radionuclide (95% rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). However, for domestic shipments, the activity *may* be expressed in terms of customary units only, until 4/1/97. ! For each labeled package: - The category of label used; - The transport index of each package with a Yellow-II or Yellow-III label ! Shipper's certification (not required of private carriers)	Materials-Based Requirements: ! If hazardous substance, "RQ" as part of the basic description ! The LSA or SCO group (e.g., LSA-II) ! "Highway Route Controlled Quantity" as part of the basic description , if HRCQ ! Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)]) ! If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982) ! "Radioactive Material" if not in proper shipping name Package-Based Requirements: ! Package identification for DOT Type B or NRC certified packages ! IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473) Administrative-Based Requirements: ! "Exclusive Use-Shipment" ! Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-tight or NRC certified LSA (§ 173.427) ! If a DOT exemption is being used, "DOT-E" followed by the exemption number	! The type of packaging (e.g., Type A, Type B, IP-1, ...) ! The Technical/chemical name may be in included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description) ! Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information ! For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used *in place of* activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered *in addition to* activity units [see § 172.203(d)(4)] ! Emergency response hazards and guidance information (§§ 172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§ 172.602(b)]

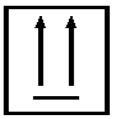
Some Special Considerations/Exceptions for Shipping Paper Requirements

! Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste (40 CFR 262).
! Shipping papers must be in the pocket on the left door, or readily visible to person entering driver's compartment and within arm's reach of the driver.
! For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color.

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Markings Always Required Unless Excepted	Additional Markings Sometimes Required	Optional Markings
Non-Bulk Packages ! Proper shipping name ! U.N. identification number ! Name and address of consignor or consignee, *unless*: (A) highway only and no motor carrier transfers, or B. part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)]	Materials-Based Requirements: ! If in excess of 110 lbs (50 kg), Gross Weight ! If non-bulk liquid package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking]  ! If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name Package-Based Requirements: ! The package type if Type A or Type B (½" or greater letters) ! The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)] ! For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...) ! If Type B, the trefoil (radiation) symbol per Part 172 App. B [*size*: outer radius ≥ 20 mm (0.8 in)] ! For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85) Administrative-Based Requirements: ! If a DOT exemption is being used, "DOT-E" followed by the exemption number ! If an export shipment, "USA" in conjunction with the specification markings or certificate markings	! "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended ! Both the name and address of consignor and consignee are recommended ! Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling
Bulk Packages (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment) ! U.N. identification number, on orange, rectangular panel (see §172.332) – some exceptions exist		

Some Special Considerations/Exceptions for Marking Requirements

! Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the HAZMAT contents of the package.
! Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
! Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking.
! Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of each non-bulk package must be marked "Radioactive-LSA" or "Radioactive-SCO," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
! For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a)).

Hazard Communications for Class 7 (Radioactive) Materials

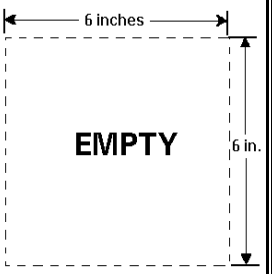
Labeling Packages (49 CFR 172.400-450)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Placement of Radioactive Labels

! Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the package.
! For labeling of radioactive materials packages, two labels are required on opposite sides excluding the bottom.

Determination of Required Label

Size: *Sides:* ≥ 100 mm (3.9 in.) *Border:* 5-6.3 mm (0.2-0.25 in.)	 49 CFR 172.436	 49 CFR 172.438	 49 CFR 172.440	 49 CFR 172.450
Label	**WHITE-I**	**YELLOW-II**	**YELLOW-III**	**EMPTY LABEL**
Required when:	Surface radiation level < 0.005 mSv/hr (0.5 mrem/hr)	0.005 mSv/hr (0.5 mrem/hr) < surface radiation level ≤ 0.5 mSv/hr (50 mrem/hr)	0.5 mSv/hr (50 mrem/hr) < surface radiation level ≤ 2 mSv/hr (200 mrem/h) [*Note:* 10 mSv/hr (1000 mrem/hr) for exclusive-use closed vehicle (§173.441(b)]	The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to §173.428. It must cover any previous labels, or they must be removed or obliterated.
Or:	**TI = 0** [1 meter dose rate < 0.0005 mSv/hr (0.05 mrem/hr)]	**TI ≤ 1** [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)]	**TI ≤ 10** [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [*Note:* There is no *package* TI limit for exclusive-use]	
Notes:	! Any package containing a Highway Route Controlled Quantity (HRCQ) must bear a YELLOW-III label ! Although radiation level transport indices (TIs) are shown above, for fissile material, the TI is typically determined on the basis of criticality control			

Content on Radioactive Labels

! RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):
(1) The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
(2) The activity in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis. However, for domestic shipments, the activity *may* be expressed in terms of customary units only, until 4/1/97.
(3) The Transport Index (TI) in the supplied box. The TI is entered *only* on YELLOW-II and YELLOW-III labels.

Some Special Considerations/Exceptions for Labeling Requirements

! For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label *may* not be required on opposite sides, and must not display the hazard class number
! Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classed for that hazard. Hazard communication requirements for the other class are required
! Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use
! The “Cargo Aircraft Only” label is typically required for radioactive materials packages shipped by air [§ 172.402(c)]

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Visibility and Display of Radioactive Placard

! Placards are required to be displayed:
- C. on four sides of the vehicle
- D. visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized)
- E. clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins)
- F. at least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness
- G. upright and on-point such that the words read horizontally
- H. in contrast with the background, or have a lined-border which contrasts with the background
- I. such that dirt or water from the transport vehicle's wheels will not strike them
- J. securely attached or affixed to the vehicle, or in a holder.

! Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

! Placards are required for any vehicle containing package with a RADIOACTIVE Yellow-III label.

! Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel *marking* with the UN Identification number is not required.

! Placards are required any vehicle containing package with a Highway Route Controlled Quantity **(HRCQ)**. In this case, the placard must be placed in a square background as shown below (see §173.507(a)).

Radioactive Placard

Size Specs:

Sides: ≥ 273 mm (10.8 in.)

Solid line Inner border: About 12.7 mm (0.5 in.) from edges

Lettering: ≥ 41 mm (1.6 in.)

Square for HRCQ: 387mm (15.25 in.) outside length by 25.4 mm (1 in.) thick

49 CFR 172.556

RADIOACTIVE PLACARD (Domestic)

Base of yellow solid area: 29 ± 5 mm (1.1 ± 0.2 in.) above horizontal centerline

IAEA SS 6 (1985) paras. 443-444

RADIOACTIVE PLACARD (International)

See 49 CFR 172.527 AND 556

RADIOACTIVE PLACARD FOR HIGHWAY ROUTE CONTROLLED QUANTITY
(either domestic or international placard could be in middle)

Some Special Considerations/Exceptions for Placarding Requirements

! Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.

! Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [*NOTE:* except for LSA/ SCO exclusive use under §173.427, as above].

! If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexafluoride (UF_6) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding.

! For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE – YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera).

Minimum Required Packaging For Class 7 (Radioactive) Materials

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Quantity:	< 70 Bq/g (< 0.002 µCi/g)	Limited Quantity (§173.421)	A_1/A_2 value	1 rem/hr at 3 m, unshielded (§173.435)	(§173.427)

Non-LSA/SCO:	**Excepted**	**Type A**	**Type B** [3]	
Domestic or International LSA/SCO: LSA-I solid, (liquid)[1] SCO-I	**Excepted**	**IP-I**		**Type B** [3]
LSA-I Liquid LSA-II Solid, (liquid or gas)[1] (LSA-III)[1] SCO-II		**IP-II**		**Type B** [3]
LSA-II Liquid or Gas LSA-III		**IP-III**		**Type B** [3]
Domestic (only) LSA/SCO: LSA-I, II, III; SCO-I, II	**Excepted**	**Strong-tight** [2]	**DOT Spec. 7A Type A**	**Type B** [3] **NRC Type A LSA** [3,4]

1. For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive use consignment)
2. Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
3. Subject to conditions in Certificate, if NRC package
4. Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

Package and Vehicle Radiation Level Limits (49 CFR 173.441) [A]

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Transport Vehicle Use:	**Non-Exclusive**	**Exclusive**		
Transport Vehicle Type:	Open or Closed	Open (flat-bed)	Open w/Enclosure [B]	Closed
Package (or freight container) **Limits:**				
External Surface	2 mSv/hr **(200 mrem/hr)**	2 mSv/hr **(200 mrem/hr)**	10 mSv/hr **(1000 mrem/hr)**	10 mSv/hr **(1000 mrem/hr)**
Transport Index (TI) [C]	10	no limit		
Roadway or Railway Vehicle (or freight container) **Limits:**				
Any point on the outer surface	N/A	N/A	N/A	2 mSv/hr **(200 mrem/hr)**
Vertical planes projected from outer edges		2 mSv/hr **(200 mrem/hr)**	2 mSv/hr **(200 mrem/hr)**	N/A
Top of . . .		load: **(200 mrem/hr)**	enclosure: 2 mSv/hr **(200 mrem/hr)**	vehicle: 2 mSv/hr **(200 mrem/hr)**
2 meters from. . .		vertical planes: 0.1 mSv/hr **(10 mrem/hr)**	vertical planes: 0.1 mSv/hr **(10 mrem/hr)**	outer lateral surfaces: 0.1 mSv/hr **(10 mrem/hr)**
Underside		2 mSv/hr **(200 mrem/hr)**		
Occupied position	N/A [D]	0.02 mSv/hr **(2 mrem/hr)** [E]		
Sum of package TI's	50	no limit [F]		

A. The limits in this table do not apply to excepted packages – see 49 CFR 173.421-426.
B. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures.
C. For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1 m (3.3 feet) from the exterior package surface, in millirem/hour.
D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages.
E. Does not apply to private carrier wearing dosimetry if under Radiation Protection Program satisfying 10 CFR 20 or 49 CFR 172 Subpart I.
F. Some fissile shipments may have combined conveyance TI limit of 100 – see 10 CFR 71.59 and 49 CFR 173.457.

Package and Vehicle Contamination Limits (49 CFR 173.443)

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm^2
Sufficient measurements must be taken in the appropriate locations to yield representative assessments

$\beta\gamma$ means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters
A means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)

The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11	**General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)**
	$\beta\gamma$: **0.4 Bq/cm^2 = 40 Bq/100 cm^2 = 1x10^{-5} µCi/cm^2 = 2200 dpm/100 cm^2**
	A: **0.04 Bq/cm^2 = 4 Bq/100 cm^2 = 1x10^{-6} µCi/cm^2 = 220 dpm/100 cm^2**

The following exceptions and deviations from the above basic limits exist:

Deviation from Basic Limits	**Regulation 49 CFR §§**	**Applicable Location and Conditions Which must Be Met:**
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	On any external surface of a package in an exclusive use shipment, during transport including end of transport. Conditions include: (1) Contamination levels at beginning of transport must be below the basic limits. (2) Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination.
10 times the basic limits	173.443(d) Also see 177.843 (highway)	On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include: (1) A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). (2) Exterior of vehicle must be conspicuously stenciled, "For Radioactive Materials Use Only" in letters at least 76 mm (3 inches) high, on both sides. (3) Vehicle must be kept closed except when loading and unloading.
100 times the basic limits	173.428	**Internal** contamination limit for excepted package-empty packaging, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: (1) The basic contamination limits (above) apply to **external** surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5) Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.

In addition, after any incident involving spillage, breakage, or suspected contamination, the modal-specific DOT regulations (§177.861(a), highway; §174.750(a), railway; and §175.700(b), air) specify that vehicles, buildings, areas, or equipment have "no significant removable surface contamination," before being returned to service or routinely occupied. The carrier must also notify offer or at the earliest practicable moment after incident.

SAMPLE CERTIFICATE ENCLOSED IN, OR ON PACKAGE, INCLUDED WITH THE PACKING LIST, OR OTHERWISE FORWARDED WITH THE PACKAGE

This package conforms to the conditions, and limitations specified in 49 CFR 173.424 for radioactive material, excepted package-instruments or articles, UN2910.

(Signed) Radiation Safety Officer

Appendix S

Waste Disposal

General Discussion

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal into non-radioactive 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)

Applicants should assure that adequate space and facilities are available for the storage of waste for 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 shall 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 must be stored separately.
5. Filled containers must be sealed. Sealed containers shall 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, the date when ten half-lives of the longest-lived radioisotope will have transpired, 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. The contents of the container should be allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container.
8. 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).
    f. If the surveys indicate residual radioactivity, return the container to the DIS area and contact the RSO for further instructions.
9. 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.

All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels/containers; the waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container prior to incineration.

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 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 must 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 must be discharged only via designated sinks or toilets.
9. Discharge liquid waste slowly to minimize splashing, with water running to dilute it and to be sure 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 remained 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 (i.e., incineration of a licensee's own waste). You do not need specific NRC approval 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 you review your program and confirm that you have waste which requires specific NRC approval for incineration, please provide the following information in your 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 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 your method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe your procedures for collection, handling, and disposal of the ash residue.

5. Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incineration, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must 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 must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant must describe how any ash generated exceeding regulatory limits will be disposed of.

NRC Policy and Guidance Directive PG 8-10: Disposal of Incinerator Ash as Ordinary Waste, is excerpted below for your convenience.

This policy and guidance directive (P&GD) provides guidance for granting authorizations for disposal of incinerator ash as ordinary waste to municipal landfills.

Policy and Guidance

Pursuant to 10 CFR 20.2002, licensees may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1-83, except those noted as ordinary waste in a landfill, provided the

concentrations of the radionuclides at the time of disposal, when expressed in units of uCi per gram of ash, are numerically no greater than the values in Table II, Column 2, 10 CFR Part 20, Appendix B. The above policy does not apply to the following isotopes, for which the corresponding disposal limits are 10% of the values listed in Table II, Column 2, 10 CFR Part 20, Appendix B: H-3 (hydrogen-3), C-14 (carbon14), Al-26 (aluminum-26), Cl-36 (chlorine-36), Ag-108m (silver-108m), Nb-94 (niobium94), I-129 (iodine-129), Tc-99 (technetium-99), and Tl-204 (thallium-204). In applying the above limits to ash containing more that one radioactive isotope, the sum of fractions approach must be used.

To show compliance with the ash release limits specified, appropriate surveys or calculations must be conducted pursuant to 10 CFR 20.1501(a)(2), to determine that the average concentration of licensed material in the ash does not exceed the permissible values. In the case of disposal of H-3, the licensee may assume that all the tritium that was in the incinerator feed is converted to tritiated water and released via the stack as an air effluent, with none remaining in the ash. For disposal of C-14, the licensee may assume that 5% of the C-14 contained in the incinerator feed remains in the ash, the balance being converted to C-14 dioxide and released via the stack as an air effluent. The licensee may be permitted to make similar assumptions for other radionuclides, but these must be approved on a case-by-case basis by the Division of Industrial and Medical Nuclear Safety, NMSS. To obtain such approval, the licensee must provide reliable data supporting the proposed assumptions. Authorizations for disposal of incinerator ash pursuant to this guidance does not excuse the licensee from compliance with other applicable Federal, State, and local regulations.

Dilution of incinerator ash produced from incineration of waste containing licensed material with ash from non-radioactive burns prior to determination of compliance with the release limits is not permitted. The concentrations required to show compliance must be determined prior to mixing with other materials for disposal. The reason for this position is that the generic studies on which this policy is based assume a certain total activity being disposed of at a landfill per year. Permitting dilution with clean waste before showing compliance with the release limits could increase the total activity received by the landfill by a substantial margin, thereby invalidating these studies. In addition, in assessing the volume of ash used in the generic studies, ash generated by commercial low-level waste incinerators and waste water treatment plants was not considered. Therefore, this policy is not applicable to either of these two incinerator classes. Requests by such facilities must be handled on a case-by-case basis.

As an alternative to the policy, and pursuant to 10 CFR 20.2002, facility-specific release limits for incinerator ash can be submitted based on site-specific dose assessments. The calculations and assumptions used in NRC's "Generic Dose Assessment for Disposal of Incinerator Ash in a Landfill," dated January 1994, may be used for the site-specific assessments, but other methods may also be used. The staff will evaluate these submissions on a case-by-case basis, which should be forwarded to the Division of Industrial and Medical Nuclear Safety, NMSS via technical assistance requests for review.

The following license condition should be used for granting authorization to dispose of ash containing licensed material to a landfill:

> Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1-83 other than those isotopes listed below, as ordinary waste in a landfill, provided the concentrations of the isotopes, expressed in uCi per gram of ash, at the time of disposal, do not exceed the numerical values listed in Table II, Column 2, 10 CFR 20, Appendix B. Isotopes not included are hydrogen-3, carbon-14, aluminum-26. chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thalium-204, for which the concentrations must not exceed 10% of the values listed in Table II, Column 2, 10 CFR Part 20, Appendix B.

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, etc.).
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.
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 examining containers for defects.

Appendix T

Using the Internet to Obtain Copies of NRC Documents and Other Information

In an effort to make its documents and information readily available to licensees and the general public, NRC is placing documents and information on its web site.

Many of the reference sections of this NUREG refer to the NRC home page <http://www.nrc.gov>. Applicants and licensees who have Internet access may use this address to find more information on a topic, the referenced document, or information on obtaining the referenced document.

To access the site, type the address into the location box of the Internet browser software and press the Enter key. Sometimes the given address does not go directly to the necessary page; however, the addressed page will have links to the information referenced in this NUREG. Generally, links appear either as blue text or as a picture in the document. To use a link, place the pointer on the blue text or picture. The pointer will change from an arrow to a hand with the index finger extended. By single-clicking the mouse on the blue text or picture, the Internet browser will go to the selected page. For example, if you wanted to review the definitions in 10 CFR Part 20, type http://www.nrc.gov in the location box of your browser and press the Enter key. After the NRC home page comes up, place the pointer on the Reference Library icon. The arrow will change to a hand with the index finger extended. Single-click the pointing device button. Next, place the pointer on the blue text, “Title 10 of the Code of Federal Regulations,” and single-click the mouse. Place the pointer on the blue text, “20,” and single-click. Finally, place the pointer on the blue text “Definitions,” and single-click.

Appendix U

Medical Distribution

1. INTRODUCTION

1.1 PURPOSE OF APPENDIX

The purpose of this appendix is to provide assistance to you, the applicant or licensee, in preparing applications for new licenses, license amendments, and renewals of medical distribution licenses under 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material" (i.e., licenses that authorize the distribution of radioactive drugs and sealed sources containing byproduct material to the Nuclear Regulatory Commission's (NRC's) and Agreement States' medical use licensees). Medical distribution by applicants registered or licensed with the U.S. Food and Drug Administration or State Agency as a drug or sealed source manufacturer is provided for in 10 CFR 32.72 and 32.74 or equivalent provisions of an Agreement State. The medical distribution license only authorizes distribution; it does not authorize the possession of byproduct material. NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," contains much of the information needed in preparing applications for medical distribution licenses. In order to avoid duplication, many sections in this appendix will refer you to Vol. 13. Some applications for manufacture and distribution of radioactive drugs require a separate application. Nuclear pharmacy applicants should refer to NUREG-1556, Vol. 13 in the preparation of an application for transfer for distribution of radioactive drugs for medical use.

Holders of licenses to manufacture and conduct broad scope research and development, who were authorized on January 1, 1995 to distribute radio labeled drugs to medical use licensees by specific license conditions or under the authorized use item of the license, but who did not have a 10 CFR Part 32 medical distribution license, may continue to distribute the radio labeled drugs pursuant to the authorization without obtaining a medical distribution license. However, when the licensee wishes to amend or renew this authorization, a new 10 CFR Part 32 medical distribution license or authorization will be needed. This appendix describes the application procedures for broad scope licenses to manufacture and distribute radio labeled drugs to medical use licensees and conduct research and development.

Several words and phrases used in this guide should be explained. The phrase "byproduct material" means any radioisotope produced by a nuclear reactor. The term "distribution" has the same meaning as in 10 CFR Part 32, i.e., the routine transfer of licensed materials to others. For organizations licensed in accordance with 10 CFR 32.72 and 32.74, these transfers of licensed material are to specific licensees in accordance with the requirements of 10 CFR 30.41; these organizations' principal customers are medical use licensees. The phrase "medical use licensee" means a physician, podiatrist, dentist, or medical institution licensed under 10 CFR Part 35 for "medical use," as defined in 10 CFR 35.2.

1.2 FILING AN APPLICATION FOR BROAD SCOPE LICENSES TO MANUFACTURE AND DISTRIBUTE RADIO LABELED DRUGS TO MEDICAL USE LICENSEES FOR RESEARCH

A request for an exemption from 10 CFR 32.72(a)(2) should be made from broad scope research and development licensees who are requesting to manufacture and distribute drugs containing byproduct material, pursuant to 10 CFR 32.72, to authorized recipients for human use research. An exemption may be granted if the applicant or licensee specifically requests an exemption from 10 CFR 32.72(a)(2) and provides the following supporting information with regard to the requirements of 10 CFR 32.72(a)(2):

1. 32.72(a)(2)(i) – The applicant or licensee must confirm that *only* radioactive drugs for which the FDA has accepted an IND application containing microcurie quantities of hydrogen-3 or carbon-14 will be prepared and distributed. (The FDA, in 21 CFR 207.10(d), exempts classes of persons who manufacture or process drugs not for sale, but solely for use in research, teaching, and chemical analysis, from registering with the FDA as a drug manufacturer.)
2. 32.72(a)(2)(ii) – The applicant or licensee must confirm that it is not registered with the State or the FDA as a drug manufacturer.
3. 32.72(a)(2)(iii) – The applicant or licensee must confirm that it is not licensed as a pharmacy (in order to operate as such you would need to employ an Authorized Nuclear Pharmacist (ANP)). The risk imposed by the radioactive drugs containing only microcurie quantities of hydrogen-3 or carbon-14 does not warrant imposing the additional burden of hiring an ANP for the license. The applicant or licensee may also have proprietary concerns with hiring an ANP for short periods of time to work on the development of new drugs.
4. 32.72(a)(2)(iv) – The applicant or licensee must confirm that it is neither a nuclear pharmacy nor located within a Federal institution.
5. The applicant or licensee must agree to meet all other *applicable* sections of 10 CFR 32.72.

If the exemption is granted, the following authorized use will be added to the license for Hydrogen-3 and Carbon-14:

- Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72.

In addition, the following license condition will be added to the license:

- Notwithstanding 10 CFR 32.72(a)(2), the licensee is authorized to prepare radioactive drugs in accordance with an accepted U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) application protocol; and to distribute them to medical use licensees in accordance with 10 CFR 32.72.

Since this exemption applies to broad scope research and development licensees, the broad scope licensee will not require an exemption from 33.17(a)(4,) which restricts broad scope licensees from adding byproduct material to drugs designed for human use when applying for 10 CFR 32.72 authorization. The addition of authorization to manufacture, prepare, or transfer radioactive drugs containing byproduct material for medical use (10 CFR 32.72) to a license authorizes Part 32 activities in addition to Part 33 (broad scope) activities. Preparation of radioactive drugs is done under the Part 32 authorization and not the Part 33 authorization.

2. CONTENTS OF AN APPLICATION

The following paragraphs are numbered as on NRC Form 313 "Application for Material License," Appendix B.

Item 1: LICENSE ACTION TYPE
See Section 8.1.

Item 2: APPLICANT'S NAME AND MAILING ADDRESS
See Section 8.2.

Item 3: LOCATIONS OF USE
See Section 8.3.

Item 4: PERSON TO BE CONTACTED ABOUT APPLICATION
See Section 8.3.

Items 5 and 6: RADIOACTIVE MATERIALS AND USES

Identify the materials you wish to be authorized to distribute to NRC's and the Agreement States' medical use licensees. The regulatory requirements and the subsequent information that is needed are different for radioactive drug and for sealed source licenses.

For radioactive drugs, specify the radionuclide and chemical form (for generators, specify the parent and daughter radionuclides and the name and model number, if appropriate, of the generator).

For sealed sources, specify the radionuclide, manufacturer's name and model number of each source, the maximum activity in each source, and the anticipated use of the sources. NRC needs to know the anticipated use of the source to perform its safety evaluation. If the sealed sources are usually used in a device (e.g., bone mineral analyzer), specify the manufacturer's name and the model number of the device.

The following examples show appropriate responses to Items 5 and 6.

Radioactive Drugs:
Chromium-51 as Sodium Chromate
Molybdenum-99 as Molybdenum-99/Technetium-99m Generator (Model MTG-1)

Sealed Sources:
Cesium-137, XYZ Corp., Model 1234
Maximum activity per source: 100 FCi
To be used by medical use licensees as dose calibrator reference sources as authorized in 10 CFR 35.57.

Strontium-90, ABC Corp., Model 567
Maximum activity per source: 150 millicuries
To be used as a strontium-90 beta eye applicator for treatment of superficial eye conditions.

Iodine-125, FGH Corp., Model 890
Maximum activity per source: 300 millicuries
To be used in an FGH Corp. Model BMA-1 device for bone mineral analysis.

Item 7 INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE
Enter "Not Applicable."

Item 8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
Enter "Not Applicable."

Item 9 FACILITIES AND EQUIPMENT
Enter "Not Applicable."

Item 10 RADIATION SAFETY PROGRAM

According to 10 CFR 32.72 and 32.74, certain radiation safety information must be submitted regarding licensed material to be distributed to medical use licensees. The information to be submitted for each type of licensed material to be distributed to medical use licensees is identified in the following sections and in NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

Item 10.1 Radioactive Drugs

If you wish to distribute radioactive drugs to medical use licensees pursuant to 10 CFR 35.100, 35.200, or 35.300, you need to provide the information identified below or in NUREG-1556,

Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," for nuclear pharmacy license applicants.

Item 10.1.1 Radioactive Drugs – Commercial Distribution

According to 10 CFR 32.72(a)(2), you must provide evidence that you are registered or licensed with either the U.S. Food and Drug Administration (FDA) or a State Agency as a drug manufacturer. See NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," for nuclear pharmacy license applicants.

Item 10.1.2 Radioactive Drugs – Instrumentation

According to 10 CFR 32.72(c), you must possess and use instrumentation to measure the radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. Measurements may be made by direct measurement or a combination of direct measurement and calculation (calculation only may be used for alpha and beta radiation). See NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses,." for nuclear pharmacy license applicants.

Item 10.1.3 Radioactive Drugs – Packaging and Shielding Licensing Criteria

See NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

Item 10.1.4 Radioactive Drugs – Licensing Criteria for Labeling

See NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

Item 10.1.5 Generators – Return Program

Some licensees offer a generator return program. In this program, customers may return used or spent generators to the licensee. Experience has shown that customers who do not ship radioactive materials frequently may not be familiar with the DOT regulations governing such shipments; the manufacturer's or distributor's instructions to customers have not been sufficiently detailed for these inexperienced shippers. As a result, when some spent generators were shipped back to the manufacturer or distributor, the shipment was not in accordance with applicable regulations.

Item 10.1.5.1 Licensing Criteria

If you wish to offer a generator return program, the instructions (including instructions on labeling and shipping documents) you have developed and will supply to your customers should be sufficiently detailed to ensure that the shipper can comply with 10 CFR 71.5 and with DOT regulations. As a minimum, these instructions are to:

1. Establish the user's responsibility and liability as the shipper;
2. Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
3. Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189.

Item 10.1.5.2 Return Program Procedures

If you do not plan to offer a generator return program, so state; no additional information is necessary. However, if you plan to offer a generator return program, copies or facsimiles of all forms, labels, and instructions you will provide to customers for shipping the spent generators back to your facility should be provided. To avoid the problems experienced in the past by inexperienced shippers, you should ensure that your instructions achieve the objectives outlined in Items 1 through 3 above. The discussion of the customer's responsibilities mentioned in Item 3 should include (but is not limited to):

- The requirements for surveying and wipe-testing the packages;
- The distance at which to survey packages;
- The action levels for the package wipe-test results;
- The dose rate limitations on the particular shipping label that you provide; and
- The need for sealing tape or another mechanism to fulfill the security seal (tamper-indicating) requirement.

Item 10.2 Sealed Sources

If you intend to distribute sealed sources to medical use licensees, provide the information identified in NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

Item 10.2.1 Sealed Sources in Devices – Licensing Criteria for Evaluation of Design and Construction

If you are a manufacturer or initial distributor of sealed sources (or devices containing sealed sources), you may need to submit a separate application for authorization to distribute the sealed sources or devices. This separate application will facilitate NRC's review and evaluation of the radiation safety information for the sealed source or device and its certificate of registration. To

submit a source or device design for a safety evaluation and registration use NUREG-1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," dated July 1998. This safety evaluation is required by 10 CFR 32.74 prior to the source or device being approved for distribution and medical use.

Item 10.2.2 Sealed Sources – Labeling

Item 10.2.2.1 Licensing Criteria

Your product labeling must fulfill the requirements of 10 CFR 20.1901, 20.1904, 20.1905 and of 10 CFR 32.74(a)(2)(viii) and 32.74(a)(3).

A label, leaflet, or brochure accompanying the sealed source or device must contain appropriate instructions from a radiation safety standpoint for handling and storing the source or device. For example, the instructions may specify the use of extremity monitors, the use of tongs or other devices (rather than bare hands) to pick up sources, storage within auxiliary shielding, and any special procedures needed in the handling and sterilizing of "fragile" sources (e.g., iodine-125 seeds).

A label, leaflet, or brochure must also contain the licensing statement required by 10 CFR 32.74(a)(3). For sources, the statement should read, "The (name of source or device) is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to [10 CFR 35.57, 35.400, or 35.500] or under equivalent licenses of Agreement States."

For *each* type of sealed source or device you intend to distribute, you should:

1. Submit copies or facsimiles of the labels that will accompany the product and specify where each label will be placed (e.g., on the device, on the source shield); and
2. Submit copies of all leaflets and brochures that will accompany the product.

For *each* type of source or device to be distributed, you should provide a copy of correspondence to and from the FDA that clearly shows that the FDA finds the source or device to be safe and effective or "substantially equivalent" to sources or devices offered for sale in the United States before May 1976. (***Note:*** An NRC registration will not be issued unless the applicant has submitted to NRC a substantially equivalent letter pursuant to Section 510(K) of the Food, Drug, and Cosmetic Act, as amended, or a similar indication of premarketing approval by FDA.)

Devices and sources used in conjunction with medical applications involving computers and patient planning systems are within FDA jurisdiction and must also have a substantially equivalent letter pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act, as amended, or a similar indication of premarketing approval by FDA.

Item 10.2.2.2 FDA and NRC Coordination

FDA and NRC signed a Memorandum of Understanding on August 26, 1993, to coordinate existing FDA and NRC regulatory programs for medical devices, drugs, and biological products that make use of byproduct, source, or special nuclear materials. The principal statute under which the FDA regulates devices is the Food, Drug, and Cosmetic Act, as amended by the Safe Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the Memorandum of Understanding, the Agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of potential public health problems involving products of mutual regulatory concern. Further, the Agencies will share information to the extent practicable. For NRC's Office of Nuclear Materials Safety and Safeguards (NMSS), this includes information on the design, manufacture, testing, quality assurance, and control, etc., used by FDA and NRC for its product approval.

Item 10.2.3 Sealed Sources – Return Program and Device Service

Item 10.2.3.1 Experience with Returns

Some licensees offer a source return program or a device service or both. In this program, customers may return unused sources for credit or may return used sources or devices for disposal, service, or replacement. Similar programs have been offered by manufacturers of other products. Experience with these other products indicates that customers who do not ship radioactive materials frequently are often not familiar with Department of Transportation (DOT) regulations governing such shipments. Unless the manufacturer's or distributor's instructions to customers were sufficiently detailed for these inexperienced shippers, some shipments were not in accordance with applicable regulations. Similar problems may arise with sealed sources or devices that are being returned.

Item 10.2.3.2 Licensing Criteria

If you do not plan to offer a source return program or device service, so state; no additional information is necessary. However, if you offer a source return program or device service, you must have developed, and must supply to your customers, sufficiently detailed instructions (including instructions on labeling and shipping documents) to ensure that the shipper can comply with 10 CFR 71.5 and with DOT regulations. You must also submit to NRC copies or facsimiles of all forms, labels, and instructions that you will provide to customers for shipping sources back to your facility. As a minimum, the instructions must:

1. Establish the user's responsibility and liability as the shipper;
2. Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
3. Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189. This discussion of the customer's responsibilities should include (but is not limited to):

- The requirements to survey and wipe-test packages;
- The distance at which to survey packages;
- The action levels for the package wipe-test results;
- The dose rate limitations on the particular shipping label that you will provide; and
- The need for sealing tape or another mechanism to fulfill the security seal requirement.

Item 10.2.4 Calibration or Reference Sources For Medical Use – Compatibility with 10 CFR 35.57 Licensing Criteria

You must request authorization to distribute calibration or reference sources that are described in 10 CFR 35.57. These calibration or reference sources must not exceed the activity limits of 10 CFR 35.57, and according to 10 CFR 32.74, you must confirm this in your license application.

If a source to be distributed contains byproduct material exceeding the activity limits of 10 CFR 35.57, source material, or special nuclear materials, it may not be distributed to medical licensees under the provisions of 10 CFR 35.57. In such cases, medical use licensees may purchase such sources only if their licenses specifically authorize possession and use of them. In these cases, you may not use a license issued under 10 CFR 32.74 to distribute the sources; rather, you need a license issued pursuant to 10 CFR Part 30, 40, or 70, as appropriate, that authorizes you to distribute such sources to your proposed customers.

Item 11 WASTE MANAGEMENT
Enter "Not Applicable."

Item 12 LICENSE FEES
See Section 8.12.

Item 13 CERTIFICATION
See Section 8.13.

TERMINATION OF ACTIVITIES
See Section 11.

The distribution license does not authorize the possession and use of byproduct material. Therefore, termination of your distribution license only requires a letter notifying NRC of the termination. If you are also terminating your possession license, 10 CFR 30.36(b) requires that a licensee notify NRC promptly and request termination of the license. This notification normally requires: (1) a completed form NRC-314, "Certificate of Disposition of Materials," certifying that all sources have been disposed of properly; and (2) the results of a final radiation survey of the premises where the licensed activities were carried out.

Appendix V

Addendum: Summary of Comments Received on Draft NUREG-1556, Vol. 12

Location	Subject	Comment
Section 8.10.6, Figure 8.13	Caption may be misleading	This worker is using a high density plastic shielding, which may be appropriate for radioisotopes that emit beta radiation and some gamma-ray emitting radioisotopes.
NRC Response: Comment accepted, caption made less specific.		
Appendix I	Paragraph may be less precise than needed	• Optimal shielding requirements will depend on the intensity and energy of the beta radiation, the type, quality and configuration of local shielding in place, and the duration of personnel exposure in conducting the operation with a high-energy beta-emitting radionuclide. • Generally, when the exposure is likely to be small, shielding materials (usually plastic) of low-atomic number in sufficient thickness to absorb all the beta radiation shall be all that is needed to eliminate direct exposure to betas and minimize the generation of secondary bremsstrahlung. • In operations using large quantities (i.e., multi-millicurie quantities) of high-energy beta-emitting radionuclides and/or longer exposure times, it may be necessary to also reduce the bremsstrahlung by adding shielding containing high-atomic number material such as lead. These shields generally are low-atomic number materials closest to the source, enclosed by high-atomic number material. • In use of quantities of high-energy beta radionuclides (generally above 100 millicuries), it may be more practical to use lead for the outer shield, and use an indirect viewing method such as mirrors to view the source or the process.
NRC Staff Response: Added three new bullets incorporating the comments in the Council on Radionuclides and Radiopharmaceuticals, Inc. letter.		

Location	Subject	Comment
Appendix N	Paragraph may be made more precise	If requesting more than 37 MBq (1 mCi) of phosphorus-32, special safety instructions should be provided to users, including the following: • The use of low-density plastic shielding and high-density materials, layered properly, in order to keep bremsstrahlung radiation 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; • 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; • The use of eye protection for procedures that involve 10 millicuries or more.
NRC Staff Response: Added selected words to emphasize sequence and density.		
Section 5.1		**Comments from Illinois Department of Nuclear Safety** 1) Clarify that procedures submitted ensure compliance. Use of the suggested wording of responses and a commitment to use the model procedures in this report will expedite NRC's review. Applicants need not adopt the model procedures; however, if they choose not to do so, they must submit procedures that, if followed, will ensure compliance with radiation protection requirements.
NRC Staff Response: Comment accepted, changes made.		

Location	Subject	Comment
Section 8.5		2) Clarify that procedures submitted ensure compliance. As indicated on NRC Form 313 (Appendix B), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C for this purpose and should note that use of the suggested wording of responses and a commitment to use the model procedures in this report will expedite NRC's review. Applicants need not adopt the model procedures; however, if they choose not to do so, they must submit procedures that if followed, will ensure compliance with radiation protection requirements.
NRC Staff Response: Comment accepted, changes made.		

Location	Subject	Comment
Section 8.5.1		3) Include reference to not allowing use of multiple exempt quantity sources in a single device. Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the SSD designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining NRC's prior permission in a license amendment. To ensure that applicants possess and use sources and devices according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer. It is not acceptable to use multiple exempt quantities in a single device, as set forth in 10 CFR 32.19.
8.7.1, Appendix G		4) Include discussion of delegation of RSO duties.
8.9, Appendix I		5) Include, in this section, waste storage areas and security/access control measures, etc.
8.10.3		6) In Section 8.10.3, manufacturers/distributors must also make reports to regulatory agencies for exempt and general licensed devices distributed so that these can be accounted for and registered in some cases. These requirements should be referenced in this section.
8.10.2 and 8.10.7		7) Several sections of the guide which should be separate and distinct sections have been combined into one section. In Section 8.10.2, you have included calibration procedures. This should be a separate section. This occurs again in Section 8.10.7, which combines area surveys with leak tests. It will be clearer to licensees to separate these items, particularly when certain of these services may be provided by a consultant/service vendor.

Location	Subject	Comment
8.10.5		8) In Section 8.10.5, the Department requires that applicants submit evidence to demonstrate that doses to the public will not be exceeded from exposure to radiation or releases of radioactive material. The "Response from Applicant" section states that no detailed response is needed. Information, such as that required by the Department, should be submitted with the application.
8.10.6		9) In Section 8.10.6, the applicant should be required to submit "General Rules for Safe Use." Also in this section, licensees are asked to "commit to establishing appropriate operating and emergency procedures." These procedures should be submitted for review. A commitment is not adequate if the procedures are flawed.
8.10.8		10) In Section 8.10.8, maintenance procedures for devices and facilities need to be submitted initially for review.
8.10.9		11) In Section 8.10.9, the Department believes that the applicant must submit package designs for review with the application. Packages should not only be evaluated to ensure that they meet DOT requirements. Package review is also necessary to evaluate the transportation environmental conditions to ensure that they do not exceed those of the ANSI classifications for that product. The experiences of the Amersham CKC.LSA irradiator sources becoming heat sensitized in transit and the problems with the Omnitron afterloader source being affected by the transport container illustrate the importance of enhanced regulatory review in this area. Reviews limited to the DOT transport container requirements are not adequate to address all safety concerns.

Location	Subject	Comment
8.10.10		12) In regards to Section 8.10.10, the Department believes that this section can be omitted entirely. As you have stated in the response section, this item is covered in detail in other sections of the guide.
8.11		13) In Section 8.11, again the applicant is asked to commit to establishing procedures for waste disposal. This is an especially critical item to ensure public health and safety. The applicant must submit these in the application for review rather than simply commit to developing them.
Appendix A		14) In Appendix A, there are no references to the ANSI standards used for classification of sources or devices. These should be included.
Appendix H		15) In Appendix H, the Department found the detailed training agenda which included additional topics for these complex licensees very useful.
Appendix I		16) In Appendix I, it would be useful to include a sample diagram for applicants to have as a reference in preparing depictions of their own facilities.
Appendix K		17) In Appendix K, a statement indicating when electronic calibrations will be acceptable should be included. Also in Appendix K, the Department found the inclusion of air calibration procedures in this guide very useful.
Appendix P		18) In Appendix P, the Department found the inclusion of frequencies/action levels for surveys to be very useful. This provides a thorough summary of previous guidance.

Location	Subject	Comment

NRC Staff Response:

4) Not accepted. The staff believes that licensee management and the RSO should have the freedom to delegate such responsibilities as are needed to accomplish the licensed program. The annual review of the program should provide acceptable demonstration that the program is being accomplished or where the program is not being implemented properly.

5) Not accepted. The staff believes that these matters are already appropriately discussed in other sections, such as Appendix I for Facilities and Equipment, Appendix S for Waste Disposal, and Appendix L for Material Receipt and Accountability.

6) Manufacturers/distributors must also make reports to regulatory agencies for exempt and general licensed devices distributed so that these can be accounted for and registered in some cases. Please refer to NUREG-1556, Vol. 8, "Program-Specific Guidance About Exempt Distribution Licenses and NUREG-1556, Vol. 16, "Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees."

7) Not accepted. The staff believes that these matters are already appropriately discussed in Section 8.10.2, Radiation Monitoring, with reference to Appendix K and Section 8.10.7, Surveys and Leak Tests, and with references to Appendix L and Appendix P.

8) Not accepted. The staff believes that these matters are already appropriately discussed in Section 8.10.5, Public Dose, with reference to Appendix M for examples of methods to demonstrate compliance.

9) Not accepted. The staff believes that these matters are already appropriately discussed in Section 8.10.6, Operating and Emergency Procedures, with references to Appendix N, General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures, and Appendix O, Notification Requirements.

10) Not accepted. The staff believes that these matters are already appropriately discussed in Section 8.10.8, Maintenance. 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.

11) Your comment is beyond the scope of NUREG-1556, Vol. 12, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution." You may wish to discuss your concern directly with the Office of Nuclear Material Safety and Safeguards (NMSS).

Location	Subject	Comment
12) Not accepted. Section 8.10.10, Minimization of Contamination, is an important NRC criteria and regulation (10 CFR 20.1406). 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: "Radioactive Material – Sealed Sources and Devices or Unsealed Radioactive Material," "Facilities and Equipment," "Radiation Safety Program – Operating and Emergency Procedures, Radiation Safety Program – Surveys and Leak Tests," and "Waste Management." 13) Comment accepted. Response from Applicant: Applicants should commit to establish procedures for waste collection, storage, and disposal by any of the authorized methods described in this section (Section 8.11, Waste Management). 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. Appendix S, Waste Disposal, has Model Procedures for Decay-in-Storage (DIS), Disposal of Liquids Into Sanitary Sewerage, Incineration, and Compaction. 14) Not accepted. Appendix A, List of Documents Considered in Development of this NUREG, was limited to NRC documents, including lists of NUREG Reports, Regulatory Guides, Policy and Guidance Directives, Information Notices, Manual Chapters, Inspection Procedures, Memoranda of Understanding, and Technical Assistance Requests. 15) Comment accepted.		

Location	Subject	Comment

16) Not accepted. Rather than including a sample diagram for applicants in Appendix I, NRC considered it more appropriate to increase the facility descriptions as shown below:

- 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. Similarly, shielding of low-atomic number material, such as plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.
- Optimal shielding requirements will depend on the intensity and energy of the beta radiation, the type, quality and configuration of local shielding in place, and the duration of personnel exposure in conducting the operation with a high-energy beta emitting radionuclide.
- Generally, when the exposure is likely to be small, shielding materials (usually plastic) of low-atomic number in sufficient thickness to absorb all the beta radiation shall be all that is needed to eliminate direct exposure to betas and minimize the generation of secondary bremsstrahlung.
- In operations using large quantities (i.e., multi-millicurie quantities) of high-energy beta-emitting radionuclides and/or longer exposure times, it may be necessary to also reduce the bremsstrahlung by adding shielding containing high- atomic number material such as lead. These shields generally are low-atomic number materials closest to the source, enclosed by high-atomic number material.
- In use of quantities of high-energy beta radionuclides (generally above 100 millicuries), it may be more practical to use lead for the outer shield, and use an indirect viewing method such as mirrors to view the source or the process.

17a) In Appendix K, a statement indicating when electronic calibrations will be acceptable should be included. *Response:* An acceptable electronic calibration was not developed for this NUREG.

17b) Also in Appendix K, the Department found the inclusion of air calibration procedures in this guide very useful. *Response:* We are pleased that the Department found the inclusion of air calibration procedures in this guide very useful.

18) In Appendix P, the Department found the inclusion of frequencies/action levels for surveys to be very useful. This provides a thorough summary of previous guidance. *Response:* We are pleased that the Department found the inclusion of frequencies/action levels for surveys in Appendix P to be very useful.