

# **Consolidated Guidance About Materials License: Program-Specific Guidance About Service Provider Licenses (NUREG 1556v18)**

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## **Abstract**

As part of its redesign of the materials licensing process, NRC is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," also dated April 1996. NUREG-1556, Vol. 18, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses," dated November 2000, is the eighteenth 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 the following draft regulatory guides: "Guide for the Application for a License for the Use of Radioactive Materials for Calibrating Radiation Survey and Monitoring Instruments," dated June 1985; "Guide for the Application for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985; and "Guide for the Applications for the Use of Radioactive Materials in Servicing Preregistered Gauges, Measuring Devices, and Sealed Sources Used in Such Devices," dated June 1985. Additionally, NRC staff included information contained in the corresponding Standard Review Plans for these three draft regulatory guides.

This report takes a more risk-informed, performance-based approach to licensing service

providers, and reduces the information (both the amount and the level of detail) needed to support an application for these activities.

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## **Foreword**

The United States Nuclear Regulatory Commission (NRC) is using business process redesign 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 consolidating and updating numerous guidance documents into a NUREG series of reports. Below is a listing of volumes currently included in the NUREG-1556 series: "Consolidated Guidance About Materials Licenses":

<b>Vol. No.</b>	<b>Volume Title</b>	<b>Status</b>
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Industrial 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 Irradiator Licenses	Final Report
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses	Final Report
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope	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 Materials Licenses	Draft
11	Program-Specific Guidance About Licenses of Broad Scope	Final Report
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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
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees	Draft
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 About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance For NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)	Final Report
20	Guidance About Administrative Licensing Procedures	Draft

The current document, NUREG-1556, Vol. 18, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses," dated November 2000, is the eighteenth program-specific guidance developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel.

A team composed of NRC staff from Headquarters and Regional Offices drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to service provider licenses. A representative of NRC's Office of the General Counsel provided a legal perspective.

Since this report takes a risk-informed, performance-based approach to licensing, it specifies the

amount of information needed from an applicant seeking to use sealed and unsealed byproduct material. NRC's considerable experience with these licensees indicates that radiation exposures to workers are generally low, if the workers follow basic safety procedures. This NRC report represents a step in the transition from the current paper-based process to the new electronic process. This document is available on NRC's web site at the following address: (<http://www.nrc.gov/NRC/NUREGS/SR1556/v18/index.html>).

NUREG-1556, Vol. 18, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses," dated November 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 only.

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## Abbreviations

A L A R A	as low as is reasonably achievable
A L	annual limit of intake
A N S	American National Standards Institute
A U	authorized user
B q	Becquerel
C E D E	committed effective dose equivalent
C F R	Code of Federal Regulations
cp m	counts per minute
D an d D	Decontamination and Decommissioning software code
D FP	decommissioning funding plan
D O T	United States Department of Transportation
DI S	decay-in-storage

E P A	United States Environmental Protection Agency
F A	certification of financial assurance
G B q	gigabecquerel
G M	Geiger-Mueller
G P O	Government Printing Office
H E P A	high efficiency particulate air
IN	Information Notice
L L W	low level waste
L S A	low specific activity
M B q	megabecquerel
M C	Manual Chapter
M O U	Memorandum of Understanding
m R	milliroentgen
m e m	millirem
m Sv	millisievert

N C R P	National Council on Radiation Protection and Measurements
N S T	National Institute of Standards and Technology
N M S S	Office of Nuclear Material Safety and Safeguards
N O R M	naturally-occurring radioactive material
N R C	United States Nuclear Regulatory Commission
N V L A P	National Voluntary Laboratory Accreditation Program
O C F O	Office of the Chief Financial Officer
O C R	optical character reader
O M B	Office of Management and Budget
O S L	optically stimulated luminescence
Q A	quality assurance
R	Roentgen
R G	Regulatory Guide



R	reportable quantities
Q	
R	radiation safety officer
S	
O	
SF	Spent Fuel Program Office
P	
O	
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
S	special nuclear material
N	
M	
S	Sealed Source and Device
S	
D	
st	standard
d	
S	Office of State and Tribal Programs
T	
P	
Sv	Sievert
T	total effective dose equivalent
E	
D	
E	
TI	transportation index
T	thermoluminescent dosimeters
L	
D	

## 1 Purpose of Report

This report provides guidance to an applicant in preparing a service provider license application, as well as providing NRC with the appropriate criteria for evaluating such applications.

Service providers provide commercial services to both specific and general licensees, and in some instances, recover both licensed and unlicensed material from the public domain. Customers who possess such radioactive material may require commercial services to manage materials at concentrations and activities they are not authorized to handle. In these unique situations, a service provider licensee is authorized to possess these radioactive materials under

its license incident to performing specific services required by its customers. Optionally, licensees may elect to transfer licensed material such as radioactive waste and contaminated materials to service providers (e.g., radioactive waste brokers, decontamination and decommissioning service providers or nuclear laundry operators).

Licensees who in the course of doing business, receive physical samples and possess equipment containing licensed materials related to the performance of service activities such as leak test and environmental sample analyses, survey instrument and dosimetry calibration services are also included in the service provider category.

Service providers addressed in this NUREG are limited to licensed entities providing the following types of commercial services:

- Installation, relocation, removal from service, disposal, radiation surveys, routine and preventive maintenance, adjustment of equipment, training of personnel or repair of devices containing licensed materials.
  
- Installation, relocation, removal from service, disposal, radiation surveys, routine or preventive maintenance, adjustment, training or repair of Part 36 irradiators.
  
- Installation, radiation surveys, routine and preventive maintenance, adjustment or repair of remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic components that could expose the sealed source, reduce the shielding, or compromise the radiation safety of the device or safety systems.
  
- Calibration of survey instruments and personnel dosimetry equipment.
  
- Leak testing of sealed sources, including analyzing the leak test kits or smears.
  
- Environmental sample analysis.
  
- Training of personnel using sealed sources.
  
- Calibration of medical dose calibrators.
  
- Nuclear laundry services.

- Waste management services including:
  - Commercial incineration
  - Compaction, Super Compaction
  - Solidification or vitrification
  - Packaging and repackaging of radioactive waste for transportation.
- Decontamination and decommissioning services.
  
- Site characterization services.

This report identifies the information needed to complete NRC Form 313 (Appendix B), "Application for Material License." The information collection requirements in 10 CFR Part 20 and Part 30 and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0014, 3150-0017, and 3150-0120, respectively.

The format within this document for each item of technical information is as follows:

- 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.
  
- 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.

NRC Form 313 does not provide sufficient space for applicants to include full responses to Items 5 through 11; as indicated on the form, the answers to those items are to be provided on separate sheets of paper and submitted with the completed NRC Form 313. For the convenience of applicants and for streamlined handling of applications for service provider licenses, use Appendix C to provide supporting information, attach it to NRC Form 313, and submit it to NRC.

Appendix D is a checklist that NRC staff uses to review applications and applicants can use to check for completeness. Appendix E contains samples of the different types of licenses for service providers, each license contains the conditions most often found on these type of license, although not all licenses issued to service providers will have all conditions.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. These terms are defined in 10 CFR Part 20. Rem, and its International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites) equivalent Sievert (1 rem = 0.01 Sievert (Sv)), 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 rad or roentgen, and the sealed sources that emit beta and gamma rays, which means that 1 roentgen = 1 rad = 1 rem.

## 2 Agreement States

Certain states, called Agreement States (see Figure 2.1), have entered into agreements {Section 274b, Atomic Energy Act, 1954, as amended} 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. File these applications with Agreement State officials, not with NRC. Refer to the reference paragraph below for information for submitting an application to a particular state.

NRC's materials licensees who wish to conduct operations under reciprocity at temporary job sites in an Agreement State should contact that state's Radiation Control Program Office for information about state regulations. To ensure compliance with Agreement State reciprocity requirements, licensees should request authorization well in advance of scheduled use.

Under the provisions of 10 CFR 150.20, NRC can recognize and grant a general license to Agreement State licensees. This general license authorization allows Agreement State licensees to conduct licensed operations identified on the Agreement State license in non-Agreement States, areas of exclusive Federal jurisdiction within Agreement States, and offshore waters provided:

- The Agreement State license does not limit authorized activity to a specific installation or location.
- The Agreement State license contains no provisions to the contrary.

Activities, other than those in offshore waters, including storage of materials, are limited to a total of 180 days in any calendar year. Offshore activities, as specified in 10 CFR 150.20(b)(4), are authorized for an unlimited period of time.

NRC must be notified in accordance with the provision of 10 CFR 150.20(b)(1).

Licensees who are requesting generally-licensed activities in offshore waters of Louisiana, and are licensed by the State of Louisiana, can notify the State of Louisiana in lieu of notifying NRC. Notification to the State of Louisiana must be completed in accordance with the provisions of 10 CFR 150.20(c)(1).

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 as indicated below.

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 and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, US 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 <i>not</i> subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

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

All Agreement States Letter, SP-96-022, on determining jurisdictional status at a Federal facility, dated February 16, 1996, is available on STP's web site at (<http://www.hsr.d.ornl.gov/nrc/home.html>); choose "NRC-State Letters," then scroll down to "Other Information - 1996" for SP-96-022. You can also request the letter from STP by calling NRC's toll free number (800) 368-5642, extension 415-3340.

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

### 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 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 meticulous compliance with regulations is maintained.
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program.
- Prohibition against discrimination of employees engaged in protected activities (10 CFR 30.7).
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10, respectively.
- Obtaining NRC's prior written consent before transferring control of the license.
- Notifying 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 "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600,

and Inspection Procedure 87110, Appendix A, "Industrial/Academic/Research Inspection Field Notes"; see the Notice of Availability (on inside front cover of this report). In addition, NUREG-1600 and Inspection Procedure 87110, Appendix A may be found on NRC's web site at (<http://www.nrc.gov> ).

## 4 Applicable Regulations

It is the applicant's or licensee's responsibility to obtain up-to-date copies of applicable regulations, read and understand the requirements of each of these regulations, and comply with each applicable regulation.

The following Parts of 10 CFR Chapter I contain regulations applicable to service provider licensees:

- 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 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

10 CFR Part 71 requires that licensees or applicants who transport licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport shall comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189 appropriate to the mode of transport. Copies of DOT regulations can be ordered from the Government Printing Office (GPO) whose address and telephone number are listed below.

- 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274"
- 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" and "Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC."

To request copies of the above documents, call GPO's order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of *Title 10, Code of Federal Regulations, Parts 0-50 and 51-199* from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. You may also contact the GPO electronically at (<http://www.gpo.gov>). Additionally, Title 10, Code of Federal Regulations, Parts 0-50 and 51-199, is available electronically on NRC's Reference Library page on NRC's web site at (<http://www.nrc.gov>). Individuals may request single hard copies of the above documents from NRC's Regional Offices (see Figure 2.1 for addresses and telephone numbers).

Note that NRC publishes amendments to its regulations in the *Federal Register*.

## 5 How to File

### 5.1 Paper Application

Applicants for a materials license should do the following:

- Be sure to use the most recent information 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.
- 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, 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.
- Do not submit personal information about employees.
- Do not submit copies of NRC licenses.
- Submit an original, signed application and one copy.
- Retain one copy of the license application for future reference.

As required by 10 CFR 30.32(c), applications shall be signed by a duly authorized management representative; see Section 8.13, "Certification."

Using the suggested wording of responses and committing to using the model procedures in this NUREG-1556, Vol. 18 will expedite NRC's review.

All license applications will be available for review by the general public in NRC's Public Document or Electronic Reading Rooms. 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.

- Do not submit personal information about employees.
- Do not submit copies of NRC licenses.

As explained in the "Foreword," NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. NRC will continue to accept paper applications; however, these will be scanned and put through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition, 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.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Universe; the text of this document is in a serif font called Times New Roman.
- Choose 12-point or larger font size.
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

## **5.2 Electronic Application**

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes or CD-ROM, and through the Internet. Additional filing instructions will be provided as these new mechanisms become 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 shows NRC's four Regional Offices and their respective areas for licensing purposes, and identifies Agreement States.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State, not NRC. If work will be conducted at Federally controlled sites in Agreement States, however, 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, including applications for new licenses and license

amendments, must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the new license prior to fee receipt. An application for a new license or an amendment to an existing license requesting authorization to conduct field flood studies requires that an environmental assessment be performed. Fees for a licensing action that requires an environmental assessment are charged at an hourly rate. Full cost fee recovery is assessed by the professional staff time expended, as described in footnote e.3. to 10 CFR 170.31. Once technical review begins, no fees will be refunded; application fees will be charged regardless of NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for 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 toll-free at (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 to License No.	XX-XXXXXX-XX

          C. Renewal of License No.	XX-XXXXXX-XX
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Check box A if the application is for a new license.

Check box B if the application is for an amendment<sup>(1)</sup> to an existing license, and provide the license number.

Check box C if the application is for the renewal<sup>(1)</sup> of an existing license, and provide the 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 use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address.

Notify NRC of changes in 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. NRC Information Notice (IN) 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

### Timely Notification of Transfer of Control

**Regulations:** 10 CFR 30.34(b).

**Criteria:** Licensees must provide full information and obtain NRC's prior written consent before transferring control of the license, or, as some licensees call it, "transferring the license."

**Discussion:** Transfer of 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 NRC's written consent before the transaction is finalized. This is to ensure the following:

- 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 disposition of records and licensed material;
- Public health and safety are not compromised by the use of such materials.

**Response from Applicant:** None from an applicant for a new license; Appendix F, excerpted from IN 89-25 (Revision 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, identifies the information to be provided about transferring control.

**References:** See the Notice of Availability on the inside front cover of this report to obtain hard copies of INs. Electronic copies are available in the "Reference Library" on NRC's web site at (<http://www.nrc.gov> ).

- Information Notice 89-25 (Revision 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994.
- Information Notice 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997.

### **Notification of Bankruptcy Proceedings**

**Regulation:** 10 CFR 30.34(h).

**Criteria:** Immediately following filing of 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 all licensed material is accounted for and adequately controlled, and 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 at time of application for a new license. Generally, licensees should notify NRC within 24 hours of filing a bankruptcy petition.

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

- Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing." Inspection Procedure 87103 is available on NRC's web site at (<http://www.nrc.gov> ).
- Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," (dated August 8, 1996).

INs are available in the "Reference Library" on NRC's web site at (<http://www.nrc.gov>). For hard copies, see the Notice of Availability (on the inside front cover of this report).

### **8.3 Item 3: Address(es) Where Licensed Material Will Be Used or Possessed**

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility at which licensed material will be used, stored, or dispatched, and list the specific activities to be conducted at each location. As illustrated in Fig. 8.1, a post office box or drawer address is not acceptable.

**Figure 8.1 Location of Use.** *An acceptable location of use specifies street address, city, state, and zip code and does not include a post office box number.*

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

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

### **8.4 Item 4: Person to Be Contacted about this Application**

Identify the name of the individual who can answer specific administrative or technical 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 the contact person's 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 unless the notification involves a change in the contact person who is also the RSO.

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

## 8.5 Item 5: Radioactive Material

**Regulations:** 10 CFR 30.14; 10 CFR 30.15; 10 CFR 30.18; 10 CFR 30.19; 10 CFR 30.21; 10 CFR 30.32(g); 10 CFR 30.32(i); 10 CFR 30.33; 10 CFR 31.5; 10 CFR 31.8; 10 CFR 31.11; 10 CFR 32.210.

**Criteria:** An application for a license will be approved if the requirements in 10 CFR 30.33 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.

**Discussion:** 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 E. Table 8.1 below lists the type of radioactive material covered by this report.

**Note:** Additional safety equipment and precautions are required when handling and using unsealed free-form volatile radioactive materials. Volatile means that a liquid, and in rare cases a solid, becomes a gas at a relatively low temperature when exposed to the environment.

**Table 8.1 Types of Radioactive Materials.**

Type of Material	Covered by this Report	Examples
Byproduct (reactor-produced)	Yes	H-3, C-14, *Na-22, I-131, I-125, S-35, P-32, P-33, Ca-45, Ni-63, *Cd-109, Cs-137
Source material	Yes	U, Th
Special nuclear material	Yes	Pu-238, Pu-239, U-233, U-235
Naturally occurring radioisotopes	No	Rn-222, Ra-226
Accelerator-produced radioisotopes	No	Co-57, *Na-22, *Cd-109, Tl-201, Ga-67

\* Accelerator or Reactor Produced

The applicant should list each requested radioisotope by its element name and its mass number [e.g., cobalt-60 (Co-60)] in Item 5. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not required.

Service providers requesting authorization to possess and use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures necessary to handle such materials.

The anticipated possession limit in megabecquerel (MBq)/millicuries or gigabecquerel (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. 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 8.5.3, "Financial Assurance and Recordkeeping for Decommissioning."

When requesting authorization for possession limits in excess of the quantities listed in Schedule C of 10 CFR 30.72, you must provide in conjunction with the license 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 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)(3). For additional information regarding emergency plans, refer to Regulatory Guide 3.67 and Policy and Guidance Directive 84-14.

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:** No response required, unless an emergency plan is required. For NRC to grant authorization to possess quantities equal to the activities specified in Schedule C of 10 CFR 30.72, it is necessary to provide the information outlined in 10 CFR 30.32(i) sufficient to evaluate the need for an emergency plan.

**References:**

- Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities." The document is available on NRC's web site at (<http://www.nrc.gov>). To obtain hard copies, see the Notice of Availability on the inside front cover of this report.
- Policy and Guidance Directive 84-14, Revision 1, "Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licensees." To obtain copies, see the Notice of Availability on the inside front cover of this report.

### **8.5.1 Unsealed And/or Sealed Byproduct Material**

**Regulations:** 10 CFR 30.32(g); 10 CFR 30.33(a)(2); 10 CFR 32.210.

**Criteria:** Applicants for a service provider license must provide the manufacturer's or distributor's name and model number for each requested sealed source and device that it will possess, use, and service. Service provider licensees in most circumstances will possess, use, or service only those sealed sources and devices specifically approved or registered by NRC or an Agreement State. However, some sealed sources and/or devices not registered by NRC or an Agreement State may be possessed or used by service providers or individual clients needing services. Possession and use of these unique types of sealed sources result from, either of the

following:

- Custom sealed sources and/or devices built to unique specifications of a given custom user.

**OR**

- Calibration and reference sources that:
  - Contain beta and/or gamma emitting material in amounts not exceeding either 3.7 MB (100 microcuries) or ten times the quantity specified in 10 CFR 30.71, Schedule B, whichever is greater.
  - Contain alpha emitting material in amounts not exceeding 0.37 MB (10 microcuries).

**OR**

- Sealed sources or devices containing radioactive material intended only for use under research and development or broad scope licenses.

When requesting authorization to possess or provide services involving these unique sealed sources see Section 8.5.2, "Unsealed Radioactive Material."

**Discussion:** NRC or an Agreement State performs a safety evaluation of sealed sources and/or devices before authorizing distribution to general or specific licensees. This safety evaluation is documented in a certificate in NRC's Sealed Source and Device (SSD) Registry. Before the SSD registration process was formalized by NRC, some older sealed sources and/or devices may have been evaluated, but not formalized in a separate document. However, these sealed sources and/or devices were specifically approved on a license. Service licensees, in possession of these devices, can continue to use these devices provided they are specifically listed on their licenses, or optionally, if they are authorized to possess equivalent amounts of unsealed material. Examples of the types of devices that are possessed, used, or serviced by service provider licensees are shown in Figure 8.2.

**Figure 8.2 Examples of Sealed Sources and/or Devices Possessed, Used, or Serviced.**

Service providers, when possessing, using, or servicing sealed sources and/or devices, should consult with the manufacturer or distributor to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with NRC or an Agreement State. Licensees, unless approved by NRC or an Agreement State, 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.

Sealed Source and Device registration certificates may be obtained by contacting the SSD Registration Assistant by calling NRC's toll-free number (800) 368-5642, extension 415-8140, or visiting NRC's web site at (<http://www.nrc.gov>). To ensure that service providers possess and use sealed sources and/or devices according to the registration certificates, they may want to get a copy of the SSD certificate and review it or discuss use and service with the manufacturer.



"Conditions of Normal Use" and "Limitation and Other Considerations of Use" are described in most SSD Registration Certificates. These certificates generally include limitations derived from conditions imposed by the manufacturer or distributor, including particular conditions of use that would reduce radiation safety of the device, or circumstances unique to the sealed source and/or device. Information may include environmental conditions such as working life of the device, temperature, vibrations, corrosive atmospheres, etc. Except as specifically approved by NRC or Agreement States, licensees are required to use devices according to their respective SSD Registration Certificates. For additional information about the SSD registration process, see the current version of NUREG-1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration." See Appendix G for a copy of the standard NRC SSD registration certificate format.

Service providers who remove for disposal/transfer, or dispose of fixed gauges at customer facilities may wish to perform this service for device models and sealed sources not specifically identified on their license. Specific authorization to provide these limited services for devices that are similar in design and activity to those listed on their license from other manufacturers will be included in the license.

**Response from Applicant:**

- Identify each radionuclide that will be possessed in each sealed source and/or device.
- Identify the manufacturer or distributor and model number of each type of sealed source and/or 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 per device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State.
- Identify the special circumstances under which sealed sources and/or devices that are not registered by NRC or an Agreement State may be possessed, used, or serviced.

*Note:* For more information about the SSD registration process, see the current version of NUREG-1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration." It is available electronically in the "Reference Library" on NRC's web site at (<http://www.nrc.gov>); for a hard copy, see the Notice of Availability on the inside front cover of this report.

## **8.5.2 Unsealed Radioactive Material**

**Regulations:** 10 CFR 30.14; 10 CFR 30.15; 10 CFR 30.18; 10 CFR 30.19; 10 CFR 30.21; 10 CFR 30.32(i); 10 CFR 30.33; 10 CFR 31.11.

**Criteria:** An application for a license will be approved if the requirements of 10 CFR 30.32, 10 CFR 30.33, 10 CFR 33.11, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, and 10 CFR 33.17 are met.

**Discussion:** Applicants who request unsealed licensed material typically:

- Request authorization to possess and use any form of byproduct material with atomic numbers from 1 through 83.
- State the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. When establishing individual radionuclide and total cumulative quantities, all materials possessed under the license should be included (i.e., materials received awaiting use, materials in use/process, and that categorized as waste awaiting disposal). The maximum quantity for each individual radionuclide and total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and demonstrated experience/capability. If certain individual radionuclides will be needed in much larger quantities than that described in the atomic number 1-83 request, they should be listed separately rather than increasing the possession limit for all radionuclides, e.g., 37,000 GBq (1000 curies) of strontium-90; or
- Request broad scope authorization for types and quantities of licensed materials as specified in 10 CFR Part 33. Applicants for a broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR Part 33. If needed, an applicant for a broad scope license may request authorization to possess byproduct materials with atomic numbers greater than 83 (e.g., atomic numbers 84 to 96). See NUREG-1556, Vol. 11, "Program-Specific Guidance About Broad Scope Licenses."

For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.

**Note:** Authorization to possess byproduct materials with atomic numbers 84 through 96 does not include authorization to possess uranium, thorium, or plutonium. Even though these elements have atomic numbers within the range of 84 through 96, they are designated source or special nuclear material, not byproduct material, and should be requested individually. Quantities of SNM addressed in this guide are limited to small activities that cannot under any circumstances achieve critical mass configuration.

**Response from Applicant:** Possession requests by service provider applicants should be categorized into general areas of use, e.g., survey instrument and personnel dosimeter calibrations, leak test sample analysis, equipment maintenance, environmental sample analysis, decommissioning, waste management, nuclear laundry services, commercial incineration, etc.

- Request any form of byproduct material with atomic numbers from 1 through 83 and 84 through 104. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. If a broad scope license authorization is requested, refer to the types and quantities of licensed materials specified in 10 CFR Part 33.
- For source material, specify the number of kilograms of natural uranium, depleted uranium and thorium requested.
- For special nuclear material (SNM), specify the number of grams of material requested for each isotope.

### 8.5.3 Financial Assurance and Recordkeeping for Decommissioning

**Regulations:** 10 CFR 30.34(b); 10 CFR 30.35; 10 CFR 40.36; 10 CFR 70.25.

**Criteria:** Financial assurance is not required for many service providers; however, each licensee is obligated to maintain, in an identified location, decommissioning records related to facilities where licensed material is used, stored, or dispatched. Pursuant to NRC regulations when terminating the license, licensees must transfer records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned.
- The appropriate NRC Regional Office before the license is terminated.

Decommissioning records described above are not required for temporary job site locations.

**Discussion:** NRC regulations, when applicable, require the applicant, when not operating at temporary job sites, to provide certification of financial assurance (F/A) or a decommissioning funding plan (DFP). This is to provide reasonable assurance that after the technical and environmental components of decommissioning are carried out, that unrestricted use of the facilities specifically identified in the license is possible at the termination of licensed activities. NRC's primary objective is to ensure that decommissioning will be carried out with minimum impact on the health and safety of the public and occupationally exposed individuals, and the environment (53 FR 24018). These requirements specify that a licensee either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available (see Figure 8.3). Before a license is issued, applicants are required to submit an F/A or a DFP when requesting authorization to possess any sealed or unsealed radioactive material with half life (T1/2 ) greater than 120 days exceeding certain the limits. Criteria for determining whether an applicant must submit a DFP or has an option of submitting either a DFP or an F/A are described in 10 CFR 30.35, 10 CFR 40.36, or 10 CFR 70.25.

**Figure 8.3** Methods of Certification of Financial Assurance for Decommissioning.

**Note:** There are two parts to the financial assurance and recordkeeping for decommission rule: (1) Financial assurance that applies to some licensees; and (2) Recordkeeping that applies to all licensees.

Regulatory Guide (RG) 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each mechanism authorized by the regulation to guarantee or secure funds except for the Statement of Intent for government licensees.

### **Recordkeeping**

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 10 CFR Parts 30, 40 and 70. All licensees are required to maintain these records in an identified location until the site is released for unrestricted use (see Figure 8.4). In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee before transferring the licensed activities.

The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records shall be transferred to NRC.

10 CFR Part 30, 40, and 70 "Requirements for Disposition of Records Important to Decommissioning" requires that:

- Before licensed activities are transferred, the licensee must transfer or otherwise assign all decommissioning records to the new licensee.

**OR**

- Before the license is terminated, transfer records to the appropriate NRC Regional Office.

**Response from Applicants:** Financial assurance is not required for most service provider applicants. Applicants need only indicate that they will maintain and transfer decommissioning records as specified in 10 CFR 30.35(g). NRC may require financial assurance for waste brokers who provide services or store radioactive waste prior to disposal at locations specifically identified on the license. If an F/A or a DFP is required, submit the required documents as described in Regulatory Guide 3.66.

**Figure 8.4** Types of Records That Must Be Maintained for Decommissioning.

*Note:* With the exception of temporary job site locations, licensees must maintain permanent records on locations where licensed materials are used or stored while the license is in force. These permanent records are important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable permanent records include sketches, written descriptions of specific locations where radioactive material is used or stored, and records of any leaking sealed sources, radioactive material spills, contaminated waste storage areas, or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

**References:** See the Notice of Availability (on the inside front cover of this report) to obtain copies of RG 3.66 and Policy and Guidance Directive FC 90-2 (Rev. 1), "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991.

## **8.6 Items 6: Purpose(s) for Which Licensed Material Will Be Used**

**Regulations:** 10 CFR 30.33(a)(1).

**Criteria:** Radioisotopes and sealed sources requested in the application must be used for purposes authorized by the Atomic Energy Act of 1954, as amended.

**Discussion:** The licensee must specify the purpose for which each radioisotope or sealed source listed in Item 5 is to be used or possessed incident to providing a specific service. Sealed sources

and devices containing licensed materials shall be used only for the purpose for which they are designed, and according to manufacturer's (distributor's) instructions and recommendations for use as specified in the SSD Registration Certificate.

Use of sealed sources and devices other than those listed in the SSD Registration Certificate require review and approval by NRC or an Agreement State. Only a person specifically licensed by NRC or an Agreement State shall install, maintain, adjust or repair a device that involves work on the sealed source(s) shielding, the source(s) driving unit, or other electrical or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

**Response from Applicant:**

- Leak Test Service Providers:
  - State that possession will be for use in performing commercial leak test services.
- Environmental Laboratories:
  - State that the material will be used for performing commercial laboratory analysis of environmental samples.
- Instrument and/or Dosimetry Calibration Service Providers:
  - State that possession of sealed sources will be used for commercial calibration of radiation survey instruments and/or personnel dosimetry.
- Service Provider Licensees Providing Services on Devices Containing Sealed Sources:
  - State that possession "incident to performing services" on sealed sources and/or devices will be used for purpose of performing commercial:
    - Installation;
    - Radiation surveys;
    - Removal;
    - Disposal;
    - Relocation;
    - Repair;
    - Source exchange;
    - Maintenance;
    - Source retrieval;
    - Transportation;
    - Leak test sample acquisition;
    - Customer training and instruction in the proper use of device(s) and for conducting routine, and in some situations, non-routine maintenance of device(s);
    - Packaging, repackaging, and transportation;
    - Other services not identified above, but excluding activities involving critical mass quantities.
- Services Other Than Leak Test Service Providers and Environmental Laboratories Involving Unsealed Materials:

- State that use, possession, and "possession incident to performing commercial services" on unsealed materials will be used for the purpose of performing:
  - Nuclear laundry services.
  - Waste management services:
    - Incineration;
    - Compaction/Supercompaction;
    - Solidification or vitrification;
    - Packaging, repackaging or radioactive waste;
    - Transportation of radioactive waste.
- Decontamination and decommissioning services.
- Site characterization services.
- Radiation protection or health physics training and instruction.
- Other service providers not identified above excluding activities involving critical mass quantities of SNM.

## **8.7 Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience**

### **8.7.1 Radiation Safety Office (RSO)**

**Regulations:** 10 CFR 30.33(a)(3).

**Criteria:** Service provider licensees must have an RSO who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters. The RSO's training and experience must include the uses of licensed material identified on the license so that the RSO is able to oversee the radiation safety program during normal and emergency conditions.

**Discussion:** Service provider licensees must appoint an RSO who is responsible for radiation safety and compliance with the regulations for the use of radioactive material, that may include byproduct, source, and special nuclear material. The RSO must ensure that radiation safety activities are being performed safely according to approved policies and procedures, and that all regulatory requirements are met. The RSO should have full access to all activities involving the use of licensed material and the authority to terminate any activity in which health and safety appear to be compromised without consulting with executive management.

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).

**Figure 8.5** *RSO Responsibilities. Typical duties and responsibilities of RSOs.*

Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped;
- Radiation exposures are as low as is reasonably achievable (ALARA);
- Development, distribution, implementation, and maintenance of up-to-date operating and emergency procedures;
- Possession, installation, relocation, use, storage, repair and maintenance of sealed sources, devices and radioactive wastes are consistent with the limitations in the license, individual Sealed Source and Device Registration Certificate(s), and the manufacturer's specific recommendations and instructions;
- Evaluations of occupationally exposed individuals are performed to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel monitoring devices are provided;
- When necessary, National Voluntary Laboratory Accreditation Program (NVLAP)-approved personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed materials are properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public that is likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as damage to sealed sources/devices, loss of licensed material, fire, theft, etc.;
- Unusual occurrences are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Radiation safety program audits are performed and documented at least annually;
- When the licensee identifies violations of NRC requirements or program weaknesses, the licensee develops, implements, and documents corrective actions;
- Licensed material is transported in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained;
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner;
- Monitoring and surveys of all areas in which radioactive material is used;
- Ordering, receipt, surveys, and delivery of byproduct material;
- Packaging, labeling, surveys, etc. of all shipments of byproduct material leaving the institution;
- Implementing personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits;
- Effluent monitoring;
- Training personnel;
- Administering waste disposal program;
- Performing/overseeing the inventory and leak testing of sealed sources;
- Overseeing decontamination activities;

- Investigating any incidents and responding to any emergencies;
- Serving as a point of contact for NRC's and licensee's management during routine operations, emergencies, or incidents;
- Maintaining records required that are necessary to support the license and satisfy NRC regulations.

The responsibilities of the RSO may not be transferred to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals; however, the responsibility for these tasks and duties remains with the RSO. NRC recognizes that a qualified individual will on occasion fill in for the RSO when the RSO is away for short periods of time, e.g. professional conferences, vacation, illness, etc. Absences that have a major impact on licensed activities should not occur for extended or indefinite periods of time. Consideration should be given to how individuals temporarily delegated the duties and tasks of the absent RSO could contact the RSO in the event of an emergency.

When management selects an RSO, they should keep in mind the duties and responsibilities of the position, and select an individual who is qualified to serve as the RSO. The RSO will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with licensed materials under his or her responsibility. The individual selected as RSO should have sufficient training and experience to perform the duties required by his or her position. Executive management should ensure that the RSO has sufficient time is allocated to carry out the responsibilities of the position.

**Response from Applicant:** Provide the following:

- The name of the proposed RSO who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

**AND**

- Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position, demonstrating day-to-day oversight of the radiation safety activities.

**AND EITHER**

- The specific training and experience of the RSO.
- Include the specific dates of training in radiation safety.

**OR**

- Alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g., Board Certification by the American Board of Health Physicists, completion of a bachelor's and/or master's degree in the sciences with at least one year of experience in the conduct of a radiation safety program of comparable size and scope).

**Note:** It is important to notify NRC, as soon as possible, typically within 30 days, 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. Applicants should review the regulations for program areas which have specific requirements regarding changes in the RSO.

### **8.7.2 Authorized Users**

**Regulations:** 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 30.33(a)(3); 10 CFR 30.34(e); 10 CFR 40.32; 10 CFR 70.22.

**Criteria:** Authorized users (AUs) must have adequate training and experience to use, possess, or provide services involving licensed materials. Duration of training and experience should be commensurate with the expected hazards service provider personnel may encounter during routine and emergency conditions. Successful completion of training as described in Appendix H is evidence of adequate training and experience. Experience requirements could consist of on-the-job training done under the supervision of a qualified individual (AU, RSO, or manufacturer's representative that is authorized by NRC or an Agreement State for the purpose(s) or activities that will be authorized in the license, when issued.).

#### **Frequency of Training**

**Discussion:** An AU is a person whose training and experience meet NRC criteria specified in Appendix H, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed materials. An AU must ensure the proper use of licensed materials possessed under the license. AUs must have training to provide reasonable assurance that they will use, possess, or provide services involving licensed materials in a safe manner, maintain security, prevent unauthorized access, and respond appropriately to emergencies. The classroom part of the training for AUs could range from a few hours to several days or more.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving licensed material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records, conducting routine maintenance), the AU remains responsible for safe use of licensed material. An individual's supervised hands-on experience should be adequate to address routine licensed activities and include a discussion or drill on emergency procedures.

**Response from Applicant:** Provide either of the following:

- The statement: "Before using licensed material, authorized users will receive the training described in Appendix H in NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000."

**OR**

- A description of the training and experience for proposed authorized users.

**Note:** Alternative response will be evaluated using the criteria listed above.

### 8.7.3 Ancillary Personnel

**Regulations:** 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 30.7; 10 CFR 30.9; 10 CFR 30.10; 10 CFR 30.33.

**Criteria:** Ancillary personnel may include individuals whose assigned duties involve exposure to radiation and/or radioactive material, and individuals who in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 millisievert (mSv) = (100 mrem). These individuals must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12.

Ancillary personnel may include clerical, housekeeping, security, any customers' personnel or staff member working under the supervision and direction of the service provider's RSO or AU at the time licensed materials are possessed (incident to providing services) under the service provider's license, and other similar types of personnel whose duties may require them to work in the vicinity of radioactive material, whether they are escorted or not by authorized users. These individuals should be informed about radiation hazards and the appropriate precautions they should take when working in the vicinity of licensed material. The licensee should assess each individual's involvement with licensed material and provide appropriate training.

**Discussion:** Before beginning work with licensed material, most individuals must receive radiation safety training commensurate with their assigned duties. Each individual should also receive periodic refresher training.

Licensees should not assume that safety instruction has been adequately covered by previous radiation safety training. Particular attention should be given to individuals performing work or in the immediate vicinity or work being performed with radioactive materials that may require special procedures, e.g., sealed source exchange, service operations that create high radiation areas, etc. Training may be in the form of lecture, demonstrations, videotape, or self-study, and should emphasize practical subjects important to the safe use of licensed material. The guidance in Appendix H may be used to develop a training program. The program should consider both the topics pertinent for each group of workers and the method and frequency of training.

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:** Provide either of the following:

- The statement: "Before using licensed materials, ancillary personnel will have successfully completed the Classroom Training portion of the training course described in Appendix H in NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,' dated November 2000."

**OR**

- 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.

## **8.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)**

**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 millirem (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. If a licensee's prospective analysis determines that the potential exposure is greater than 5 mSv (500 mrem), then more extensive training commensurate with the potential radiological health protection problems is appropriate.

**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.

Licenses 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 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 may be used to develop a training program. The program should consider all topics pertinent for each group of workers and also the method and frequency of training. The program should evaluate whether or not the audience understands the materials presented.

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:** 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; 10 CFR 30.33(a)(2); 10 CFR 30.35(g); 10 CFR 40.32(c); 10 CFR 70.23(a)(3).

**Criteria:** Facilities and equipment must be adequate to protect health, minimize danger to life or property, minimize the possibility of contamination, and keep exposure to occupationally exposed workers and the public ALARA.

**Discussion:** Applicants must demonstrate that proposed facilities and equipment provide adequate storage capabilities, appropriate shielding, maintain radiation exposures ALARA, and minimize the possibility of contamination or release of licensed materials as a result of normal and emergency conditions including fire, floods, and wind damage.

Licensed materials located in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee. Licensed materials should be accessible only by authorized persons and secured or locked when an authorized person is not physically present. If accessible by unescorted, unauthorized persons, use or storage areas cannot be considered restricted areas for purposes of radiation safety.

Applicants may elect to delay completing permanent facilities that will be specifically listed on its license and acquiring equipment described in the application until the technical review of the application is completed by the licensing staff. Delaying the acquisition allows for changes identified as a result of the technical review of the application.

In all cases, the applicant cannot possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.
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### **Response from Applicant:**

For permanent facilities specifically identified on the license:

Applicants requesting the use of sealed radioactive material in the following commercial applications:

- Leak Test Service Providers and Environmental Laboratories: No response required for facilities.
- Instrument Calibration: If only sealed sources are possessed in registered devices designed to emit a collimated beam for the purpose of instrument calibration, no response required.
- Services that involve handling of sealed sources in an shielded container: No response required.
- Services that involve handling of sealed sources outside a shielded container:

- Submit a drawing or sketch of the proposed permanent facility identifying areas where radioactive materials, including radioactive wastes, will be used or stored.
- Show in the drawings the relationship and distance between restricted areas and adjacent unrestricted areas.
- Specify in the drawings shielding materials (concrete, lead, etc.) and means for securing radioactive materials from unauthorized removal.
- Drawings, sketches, diagrams, etc. should indicate the scale, or include dimensions on each drawing or sketch.
- Describe engineered safety systems e.g. area monitors, interlocks, alarms, etc.

Applicants requesting the use of unsealed radioactive material in the following applications:

- Leak Test Services and Environmental Laboratories: No response required for facilities.
- Other services that involve handling of unsealed radioactive material:
  - Describe the permanent facilities and equipment to be made available at each location where unsealed radioactive material will be used or handled.
  - Include a description of the area(s) assigned for the receipt, storage, security, preparation, handling, waste storage and measurement of radioactive materials.
  - Submit a facility diagram showing the proximity of licensed materials to unrestricted areas.
  - Drawings, sketches, diagrams, etc. should indicate the scale, or include dimensions on each drawing or sketch.
  - Submit a diagram, sketch, or drawing, when applicable, that identifies areas where radioactive materials may become airborne. The diagram should contain descriptions of the ventilation systems, with pertinent airflow rates, filtration equipment, sample collection points, and monitoring systems.
  - Submit a diagram of radioactive waste handling equipment that includes incinerators, compactors, solidification equipment, hold-up tanks, sample collection points, etc.
  - Describe proposed laundry facilities, if applicable, used for contaminated protective equipment and clothing. Specify how the contaminated waste water from the laundry machines or sinks is disposed. Operating and emergency procedures should address decontamination of the laundry area and equipment.
  - Describe protective clothing (such as rubber gloves, coveralls, respirators, and face shields), auxiliary shielding, absorbent materials, secondary containers for waste water

storage for decontamination purposes, plastic bags for storing contaminated items, etc., that will be available.

- Identify specialized handling tools, facility safety interlocks designed to prevent operation of radiological safety systems in the event that operation of a system could result in accidental exposure or release of material (e.g., high efficiency particulate air (HEPA) filters, ventilation system, safety door interlocks, etc.) or equipment.

**For temporary job sites:**

- No facility description is required.
  - For applicants requesting the use of licensed sealed radioactive sources that do not require the use of specialized handling tools.
- No facility description is required.
  - For applicants requesting the use of licensed sealed radioactive material that requires the use of specialized handling tools.
- Applicants requesting the use of licensed sealed radioactive material that requires the use of specialized equipment or handling tools should provide a description, photograph, sketch, or drawing.

**For applicants requesting the use of unsealed radioactive material:**

- Describe protective clothing (such as rubber gloves, coveralls, respirators, and face shields), auxiliary shielding, absorbent materials, secondary containers for waste water storage for decontamination purposes, plastic bags for storing contaminated items, etc., that will be available for use when handling unsealed or uncontained radioactive materials.

## **8.10 Item 10: Radiation Safety Program**

**Regulations:** 10 CFR 20.1101; 10 CFR 20.2102; 10 CFR 30.32.

A radiation safety program must be established and submitted to NRC as part of the application. The program must be commensurate with the scope and extent of activities for the use of licensed materials in service operations. Each applicant must develop, document, and implement a radiation protection program-specific to its types of operations. Radiation safety programs should address the following elements:

- Development and implementation of an ALARA program;
- Description of equipment and facilities adequate to protect personnel, the public and the environment;
- Confirmation that licensed activities are conducted only by individuals qualified by training and experience;
- Development and maintenance of written operating and emergency procedures;
- Implementation of an audit program to ensure that, at least annually, the radiation safety program is reviewed;

- Description of organization structure and individuals responsible for ensuring day-to-day oversight of radiation safety program;
- Establishment and management of a radiation safety and decommissioning records system.

**Discussion:** Individual components of a radiation safety program are addressed in the topics found in this NUREG. Some topics will not require the applicant to submit information as part of an application, but simply provide the applicant with guidance to comply with a specific NRC requirement.

Applicants who plan to provide services using sealed or unsealed materials should submit their operating and emergency procedures for NRC approval or, optionally, provide an outline or summary of each procedure that includes the important radiation safety aspects of each individual procedure. Additionally, radiation safety programs that include authorization for handling unsealed or uncontained licensed materials should include in its operating and emergency procedures radiation safety practices that addresses the specific concerns listed below:

- Methods or procedures for preventing the release of contaminated material and equipment;
- Methods or procedures for preventing personnel contamination;
- Radiation safety procedures and the authorized users responsibilities unique to each type of service operation requested in the application;
- Equipment, techniques, and corresponding radiation safety procedures associated with providing services involving either sealed sources or unsealed materials.

**Response from Applicant:** The applicant must establish and submit its radiation protection program. Each item listed above should be addressed in the corresponding sections of this guide.

### 8.10.1 Audit Program

**Regulations:** 10 CFR 20.1101; 10 CFR 20.2102; 10 CFR 71.5.

**Criteria:** Licensees must review the content and implementation of their radiation protection programs at least annually to ensure the following elements are satisfied:

- Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA; and
- Records of audits and other reviews of program content are maintained for at least three years from the date of the record.

**Discussion:** A review of the content and implementation of the radiation protection program by the licensee or its consultant is required at least annually. Appendix I contains a suggested audit checklist that is specific to Service Provider licensees who perform activities within the scope of this document. All areas indicated in Appendix I may not be applicable to every licensee. For example, licensees do not need to address areas which do not apply to their activities.

If an audit identifies violations of NRC requirements, the licensee should first evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of

Corrective Action," dated May 1, 1996, 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 there is any uncertainty regarding a reporting requirement. NRC routinely reviews licensee's records to verify if appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in a licensee best interest to identify potential violations of regulatory requirements and take necessary steps to correct them. NRC can exercise discretion and elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented. Additionally, NRC policy allows licensees with a good regulatory performance, as shown by a licensee's inspection history, to be inspected less frequently than licensees where NRC staff identify significant violation(s) during an inspection. For information on NRC's use of discretion on issuing a notice of violation, refer to NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions." Currently, NRC's emphasis in inspections is to perform actual observations of work in progress. As a part of the audit programs, licensee are encouraged to perform unannounced audits of authorized users to determine if, for example, operating and emergency procedures are available and followed. When conducting inspections, NRC routinely reviews corrective actions to ensure they were implemented in a timely manner following a self-identified violation and in such a manner prevent recurrence. Licensees must maintain records of these audits and other reviews of program content and implementation for at least 3 years from the date of the record.

Audit records should include the following information: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

**Response from Applicant:** The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, but should not be submitted in the license application.

**References:** The current version of NUREG-1600 is available electronically on NRC's web site at (<http://www.nrc.gov/OE> ). INs are available in the "Reference Library" on NRC's web site at (<http://www.nrc.gov>). For hard copies of NUREG-1600, IN 96-28, and Manual Chapter (MC) 87110, Appendix A, "Industrial/Academic/Research Inspection Field Notes," see the Notice of Availability (on the inside front cover of this report).

### **8.10.2 Radiation Monitoring Instruments**

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

**Criteria:** Licensees must possess and periodically calibrate radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

**Discussion:** Licensees must ensure that an adequate number of calibrated radiation detection and measurement instruments are available to make radiation measurements. Instruments should be calibrated periodically for the types of radiation being measured. In this document, survey



instruments are defined as any device used to measure radiological conditions. Figure 8.6 illustrates some common survey instruments used for making contamination surveys and to taking direct radiation measurements.

**Figure 8.6 Examples of Portable Instruments.**

Service provider applications should include:

- Criteria used in determining what radiation detection and monitoring equipment will be required for the type of measurement to be taken (count rate, dose rate, etc.);
- Type of use;
- Number and availability of a sufficient quantity of these calibrated radiation detection and measurement instruments:
  - Ion-chambers;
  - Geiger-Muellers (G-Ms);
  - Liquid scintillation counters;
  - Pocket ion chambers;
  - Alarming ratemeters;
  - Area monitors.

NRC requires that radiation monitoring devices used to determine compliance with regulatory requirements be calibrated periodically by the instrument manufacturer or persons specifically authorized by NRC or an Agreement State. Radiation monitoring devices and personnel dosimetry devices (PIC, alarming ratemeters, etc.) should be calibrated at least annually (every 12 months) unless otherwise specified by regulation or license condition. Licensees seeking authorization to perform radiation monitoring instrument calibrations will need to submit procedures for review or commit to implementing the procedure in Appendix J. The licensee may wish to review available industry standards for calibration of instruments such as American National Standards Institute (ANSI) N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments."

**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 J to NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,' dated November 2000.' 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 J to NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,' dated November 2000. Additionally, we will implement the model survey meter calibration program published in Appendix J to NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,' dated November 2000. 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. Further, the statement "We reserve the right to upgrade our survey instruments as necessary" should be added to the response.

*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.

**Criteria:** Licensees must do the following:

- Develop, implement, and maintain written procedures for radioactive material package receipt and shipment;
- Ensure control, 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 containing licensed material may require special opening procedures based on the types, quantities, or half-lives of the nuclide being delivered. Arrangements should be made to receive radioactive packages expeditiously when they are delivered to your permanent facility or at temporary job sites at a customer's facility that will receive packages. Alternatively, arrangements may be made for you to be notified when radioactive packages arrive at the carrier's terminal. A model procedure for safely opening packages containing licensed materials is included in Appendix K.

Individuals that will receive packages containing licensed material 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;
- Notify the RSO or AU.

When notified that a package of licensed material has arrived, the RSO or AUs should retrieve the package and follow radioactive material receipt 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 8.2 below.

**Table 8.2 Package Monitoring Requirements.**

Package	Contents	Survey Type	Survey Time*
Low Specific Activity (LSA-I)	Ores, U, Th, Non-fissile Spent A2	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package LSA II

LS A II	Tritiated water, Solid U/Th mixed compound, Non-fissile unlimited A2	Con tami nati on Rad iatio n Lev el	As soo n as pra ctic abl e, but not late r tha n 3 hou rs afte r rece ipt of pac kag e
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LS A III	Uniformly distributed insoluble material	Con tami nati on Rad iatio n Lev el	As soo n as pra ctic abl e, but not late r tha n 3 hou rs afte r rece ipt of pac kag e
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SC O I/II Sur fac e Co nta mi nat ed Ob jec ts	Contaminated objects, or on accessible surfaces	Con tami nati on Rad iatio n Lev el	As soo n as pra ctic abl e, but not late r tha n 3 hou rs afte r rece ipt of pac kag e
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La bel ed (W hit e I, Ye llo w II, Ye llo w III)	Gas or Special Form  Greater Than Type A	Rad iatio n Lev el	As soo n as pra ctic abl e, but not late r tha n 3 hou rs afte r rece ipt of pac kag e
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La bel ed (W hit e I, Ye llo w II, Ye llo w III)	Not Gas Nor Special Form Greater Than Type A	Con tami nati on  Rad iatio n Lev el	As soo n as pra ctic abl e, but not late r tha n 3 hou rs afte r rece ipt of pac kag e
La bel ed (W hit e I, Ye llo w II, Ye llo w III)	Gas or Special Form Less Than Type A	Non e	No ne



La bel ed (W hit e I, Ye llo w II, Ye llo w III)	Not Gas Nor Special Form Less Than Type A	Con tami nati on	As soo n as pra ctic abl e, but not late r tha n 3 hou rs afte r rece ipt of pac kag e
No t La bel ed	Licensed Material	Non e	No ne

Da ma ge d	Licensed Material	Con tami nati on Rad iatio n Lev el	As soo n as pra ctic abl e, but not late r tha n 3 hou rs afte r rece ipt of pac kag e
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\* 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.

If removable radioactive surface contamination on the package exceeds the limits of 10 CFR 71.87(i); or external radiation levels exceed the limits of 10 CFR 71.47, 10 CFR 20.1906(d) requires that the licensee immediately notify the final delivery carrier. Additionally, the administrator of the appropriate NRC Regional Office listed in Appendix D to 10 CFR Part 20 must be notified immediately (within 24 hours).

As illustrated in Figure 8.7, licensed materials must be tracked from receipt to disposal in order to ensure accountability and to confirm that possession limits are not exceeded.

**Figure 8.7 Material Receipt and Accountability.** *Licensees must maintain records of receipt, transfer, and disposal of licensed material.*

Licensed material possessed at customers' facilities may be received by the customer in advance of the service provider licensee performing services. In certain circumstances, this material is received and possessed by the customer under the auspices of the customer's license until a licensed service provider can take possession incident to performing services. Licensees must have in place an accountability and control system for promptly detecting missing licensed

material at permanent facilities, customer’s facilities, temporary job sites, or any other locations where loss, theft, or misplacement of licensed material can occur. Operating and emergency procedures should address how you will maintain control and accountability of licensed material possessed incident to performing commercial services at customer’s facilities.

Licensees who use and/or possess sealed sources are required by license condition to perform inventories of sealed sources every six months. Service provider licensees must account for all sealed sources, including those that have been taken out of service and await disposal, sources placed in storage prior to use or installation, and sources in the control of the licensee. At six month frequency, licensees should confirm that the sealed sources and devices that have been placed in storage or removed from service have not been lost, misplaced, and that radiological conditions have not deteriorated. Because licensees are required to conduct periodic leak tests of sealed sources, records of leak tests may serve as an inventory record provided the leak test records include necessary information to identify the source and location. If leak tests are performed at intervals of greater than six months, additional inventories aside from those associated with leak tests must be performed. Licensees may use various methods (e.g., computer programs, manual ledgers, log books) to account for receipt, use, transfer, disposal, and decay of licensed material.

To ensure that only the RSO or AUs use or supervise the 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. A model procedure for ordering and receiving radioactive material is included in Appendix K.

Licensees must maintain records of receipt, use, transfer, and disposal (as waste) as indicated in Table 8.3.

**Table 8.3 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

Licensed material possessed incident to performing services at customer’s facilities is not normally transferred to the service provider during the time service is being performed. One notable exception is when the service provider is preparing the shipment to be shipped and is designated as the shipper of record (i.e., signing the Shipper’s Certification on the shipping paper).

**Response from Applicant:**

- State: "Ordering licensed material and package receipt and opening will follow the model

procedures in NUREG-1556, Vol. 18, Appendix K."

**OR**

- Submit a description of procedure(s) for ordering licensed material and package receipt and opening.

**AND**

- For unsealed licensed material, submit a description of procedure(s) for ensuring material accountability.

**Note:**

- Your license will be conditioned to require physical inventories to be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.
- 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-1660/RAMREG-002, "Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments."

**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).
- National Council on Radiation Protection (NCRP) Report No. 114, "Maintaining Radiation Protection Records," (1992)<sup>(2)</sup>.
- NCRP Report No. 59, "Operational Radiation Safety Program," (1978)<sup>2</sup>.

### **8.10.4 Occupational Dose**

**Regulations:** 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 20.2106; 10 CFR 20 Appendix B.

**Criteria:** The use of individual monitoring devices for external dose is required for service personnel with the potential of receiving 10% of the annual dose identified in Figure 8.8.

**Discussion:** The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose (prospective evaluation). When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received. For individuals who have received doses at other facilities in the current

year, the previous dose need not be considered in the prospective evaluation if monitoring was not required at the other facilities. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

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

Licensees shall monitor worker exposures for:

- Adults who are likely to receive an annual dose in excess of any of the following:
  - 5 mSv (0.5 rem) deep-dose equivalent;
  - 15 mSv (1.5 rems) eye dose equivalent;
  - 50 mSv (5 rems) shallow-dose equivalent to the skin;
  - 50 mSv (5 rems) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of any of the following:
  - 1.0 mSv (0.1 rem) deep-dose equivalent;
  - 1.5 mSv (0.15 rem) eye dose equivalent;
  - 5 mSv (0.5 rem) shallow-dose equivalent to the skin;
  - 5 mSv (0.5 rem) shallow-dose equivalent to any extremity.
- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.

Internal exposure monitoring is required for:

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

If an individual is likely to receive in 1 year a dose greater than 10% of any applicable limit (See Figure 8.8 for annual dose limits for adults), monitoring for occupational exposure is required.

**Figure 8.8 Annual Dose Limits for Occupationally Exposed Individuals.**

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).

A common method for dose evaluation is to monitor workers' dose with whole body and extremity dosimetry (thermoluminescent dosimeters (TLD), optically stimulated luminescence dosimeters (OSLs), film badges, ring badge, etc.) provided by an NVLAP-approved dosimetry service. 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.

Licensees may not permit any individual to provide services requiring dosimetry unless, at all times during the handling of these materials, each individual wears on the trunk of the body a NVLAP-approved personnel dosimetry sensitive to the type of radiation(s) to which the individual is exposed. Film badges should be replaced at intervals not to exceed one month, and TLDs or OSL at intervals not to exceed three months.

### **Internal Radiation Dose:**

Bioassays are required when individuals work with airborne radioactive material in the quantities, chemical and physical forms, and activities that make it likely that the radionuclide will be ingested, inhaled, or absorbed resulting in an intake in excess of 10% of the applicable annual limit on intakes (ALIs) in Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20. One ALI results in a committed effective dose equivalent (CEDE).

Guidance on bioassay programs for iodine-131, including the levels and types of handling for which bioassays are indicated, is provided in Regulatory Guide 8.20, Rev. 1, "Applications of Bioassay for I-125 and I-131." Copies may be obtained from NRC's Regional Offices or at locations identified on the inside cover of the report in the Notice of Availability.

Bioassay services are available and provided by local hospitals, universities, or other vendors specifically approved to provide such services.

### **Response from Applicant:** Provide 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 'Occupational Dose' in NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,'" dated November 2000.

**OR**

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

**AND/ADDITIONALLY FOR UNSEALED OR UNCONTAINED MATERIALS**

- Provide a bioassay program when using unsealed radioactive materials. If an applicant elects to provide a bioassay program that is less conservative than recommended in Regulatory Guide 8.20, its rationale should be stated.

**OR**

- Bioassay programs must include what the applicant considers an acceptable interval or schedule for conducting bioassays, identify action levels or guidelines, and describe specific actions to be taken when action levels are exceeded. Because of the complex nature of bioassay and corresponding data analysis, it is acceptable for applicants to make reference to the procedures in NRC guidance documents. Contract with an outside group for bioassay services. Provide a commitment that each vendor is licensed or otherwise authorized by NRC or Agreement State to provide required bioassay services.

For guidance about methodologies for determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses," dated July 1992, and Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993. NRC also has additional Regulatory Guides that have been developed for specific isotopes such as H-3 and iodine. For copies of these guidance documents contact the appropriate NRC Regional Office or contact NRC's web site at (<http://www.nrc.gov>).

**Response from Applicant:** Provide either of the following:

- State: "NVLAP-accredited dosimetry (film badge, TLD, OSL, etc.) will be processed by a NVLAP-accredited entity. NVLAP-accredited dosimetry will be exchanged at the frequency specified in Section 8.10.4 of NUREG-1556, Vol. 18."

**OR**

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

To obtain a copy of the National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program, 1997 Directory," contact the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9225. (For information on the program, call NIST at (301) 975-3679). Also, NVLAP maintains a directory of accredited laboratories on its web site at (<http://ts.nist.gov/nvlap>). The directory is updated quarterly.

**Note:**

- 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).

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

- Regulatory Guide 8.7, Revision 1, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."
- Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program."
- Regulatory Guide 8.20, Rev. 1, "Applications of Bioassay for I-125 and I-131."
- Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses."

### 8.10.5 Public Dose

**Regulations:** 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2107.

**Criteria:** Licensees must do the following:

- Ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.
- Control/maintain constant surveillance of licensed material when in use and not in storage.
- Secure stored licensed material from access, removal, or use by unauthorized personnel.

**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 and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties and not on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

For guidance about accepted methodologies for determining dose to members of public, please refer to Appendix M.

Members of the public include persons who work in or may occupy locations where licensed material is used or stored. Employees whose assigned duties do not include the use of licensed material and work in the vicinity where it is used or stored are also included as members of the public. Public dose is controlled, in part, by ensuring that licensed material is secured (e.g., located in a locked area) to prevent unauthorized access or use. Sealed and unsealed materials are usually restricted by controlling access to the keys needed to gain access to storage locations, including storage bunkers. Only the RSO or authorized user should have access to keys. Public dose is also affected by the choice of storage and use locations at temporary job sites. Licensed material must be located so that the resulting public dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv



(2 mrem) in any one hour. Applicants should use the concepts of controlling time, distance, and shielding when choosing storage and use locations. Decreasing the time that an individual is exposed, increasing the distance from the radioactive material, and adding shielding that is appropriate for the specific type of radiation (e.g., brick, concrete, lead, hydrogenous materials, etc.) will reduce the radiation exposure.

Information provided on anticipated radiation levels of sealed sources and unsealed materials both inside their respective transport containers and outside the transport container at given distances is the type of information needed to make public dose calculations. Licensees may assess radiation levels located in adjacent areas to radioactive material either by making calculations or by using a combination of direct measurements and calculations. After obtaining anticipated radiation levels or by making direct radiation measurements using an appropriate survey instrument an applicant can use the "inverse square" law to evaluate the effect on the public, and use this information to determine operating and emergency procedures for using radioactive materials. See Appendix M for an example demonstrating that individual members of the public will not receive doses exceeding the allowable public limits.

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

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

- Airborne radioactive material;
  
- Waterborne radioactive material;
  
- External radioactive exposure.

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

If, after making an initial public dose evaluation, a licensee changes the conditions used for the evaluation (e.g., relocates radioactive material within a designated storage area, increases the amount of radioactive materials in storage, changes the frequency radioactive material is in use, or changes the occupancy of adjacent areas) the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, if required.

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 specific needs.

**Figure 8.9** *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).*

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. Refer to Appendix M for additional guidance regarding compliance with the recordkeeping requirements.

**Response from Applicant:** No response is required from the applicant in a license application, but compliance will be examined during inspection.

During NRC inspections, licensees must be able to provide documentation demonstrating, either by measurement, calculation, or a combination of both, that the total effective dose equivalent to any individual member of the public that is likely to receive the highest dose from licensed operations is less than 1 mSv (100 mrem) in one year, and any unrestricted area does not exceed 0.02 mSv (2 mrem) in any one hour. See Appendix M for examples of methods to demonstrate compliance.

### **8.10.6 Safe Use of Radionuclides And Emergency Procedures**

**Regulations:** 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1902-1905; 10 CFR 20.2201-2203; 10 CFR 21.21; 10 CFR 30.32(i); 10 CFR 30.34(e); 10 CFR 30.50; 10 CFR 30.72.

**Criteria:** As part of the application package, the licensee must develop, implement, and maintain operating and emergency procedures and submit a summary of the procedures to NRC. This summary should address the important radiation safety aspects of each procedure.

**Discussion:** The purpose of operating and emergency procedures is to provide personnel specific guidance for all operations they will perform. The operating and emergency procedures should include each topic important to safe operation and use considered applicable to the materials and uses proposed in the application.

Each licensee must develop, implement, and maintain operating and emergency procedures, which should include the items outlined below:

- Procedure for obtaining an agreement with customers outlining the responsibilities of both the customer and service provider, when performing service operations at a customer's facility;
- Instructions for handling and using licensed materials;
- Instructions for maintaining security during storage and transportation;
- Instructions to keep licensed material under control and immediate surveillance during use;
- Steps to take to keep radiation exposures ALARA;
- Steps to maintain accountability during use;
- Steps to control access to work sites;
- Steps to take and whom to contact when an emergency occurs;
- Instructions for using remote handling tools when handling sealed sources, except low-activity calibration sources;
- Methods and occasions for conducting radiation surveys, including surveys for detecting contamination;

- Procedures to minimize personnel exposure during routine use and in the event of an incident, including exposures from inhalation and ingestion of licensed unsealed materials;
- Methods and occasions for locking and securing stored licensed materials;
- Procedures for personnel monitoring, including bioassays, and the use of personnel monitoring equipment;
- Procedures for transporting licensed materials to temporary job sites, packaging of licensed materials for transport in vehicles (private or common carrier), placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;
- Procedures for picking up, receiving, and opening packages containing licensed materials, in accordance with 10 CFR 20.1906;
- Instructions for maintaining records in accordance with the regulations and the license conditions;
- Procedures for identifying and reporting to NRC defects and noncompliance as required by 10 CFR 21.21(a) of this chapter;
- Procedures and actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments;
- Instructions for the proper storage and disposal of radioactive waste;
- Procedures to be followed in the event of uncontrolled release of radioactive unsealed licensed material to the environment, including notification of the RSO, NRC, and other Federal and state agencies;
- Procedures for identifying and reporting to NRC defects and noncompliance (see Table 8.4 for a description of the typical incident notifications required by NRC regulations);
- Procedures for the implementation and adherence to good health physics practices while performing service operations:
  - Minimization of distance to areas, to the extent practicable, where licensed materials are used and stored;
  - Maximization of survey frequency, within reason, to enhance detection of contamination;
  - Segregation of radioactive material in waste storage areas;
  - Segregation of sealed sources and tracer materials to prevent cross-contamination;
  - Separation of radioactive material from explosives;
  - Separation of potentially contaminated areas from clean areas by barriers or other controls.

**Note:** Service providers who perform specific operations involving sealed sources such as inspection and maintenance of devices, and removal and replacement of sealed sources, should include appropriate procedures and instructions for these operations in the applicant's operating and emergency procedures;

**OR**

The licensee should provide a commitment to follow the manufacturer's procedures for inspection, maintenance, source exchange, and operations that involve access to the sealed source(s) and safety systems, if applicable.

**Table 8.4 Typical NRC Incident Notifications Required for Service Provider Licensees.**

<b>Event</b>	<b>Telephone Notification</b>	<b>Written Report</b>	<b>Regulatory Requirement</b>
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)
Filing petition for bankruptcy under 11 U.S.C.	none	immediately after filing petition	10 CFR 30.34(h)
Expiration of license	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities at entire site	none	60 days	10 CFR 30.36(d)

Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months at the entire site	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
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) 816-5100 or (301) 951-0550.

**Response from Applicant:** Applicants should either submit their operating and emergency

procedures or an outline or summary in responding to subsequent sections.

### 8.10.7 Surveys

**Regulations:** 10 CFR 30.53; 10 CFR 20.1501; 10 CFR 20.2103.

**Criteria:** Licensees are required by 10 CFR 20.1501 to make surveys of potential radiological hazards in their workplace. Records of surveys and leak tests results must be maintained.

**Discussion:** Surveys are evaluations of radiological conditions and potential hazards (See Figure 8.10). These evaluations may be measurements (e.g., radiation levels measured with survey instrument 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 8.10 Types of Surveys.

Radiation surveys are used to detect and evaluate contamination of:

- Facilities;
- Equipment;
- Personnel (during use, transfer, or disposal of licensed material) (See Figure 8.11);
- Restricted and Unrestricted Areas.

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 8.11 Personnel Surveys.** *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the laboratory or any area with potential contamination.*

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, 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.

- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

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. Refer to Appendix J for a listing of the types of radiation survey instruments available.

Ambient survey and routine contamination survey frequencies depend on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation. NRC regulations do not provide specific limits for surface contamination in restricted areas, only that ALARA considerations must prevail. Each applicant should propose and justify fixed and removable surface contamination limits allowable in a work area before decontamination is required.

### Contamination Survey Frequency

Personnel working with, in, or around unsealed forms of radioactive material should survey for contamination. Contamination surveys should be conducted at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest ALI (for either inhalation or ingestion) as identified in 10 CFR Part 20, Appendix B, then documented surveys should be performed at least daily in accordance with 10 CFR 20.2103.

**Table 8.5** contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

**Table 8.5 Suggested Contamination Survey Frequency.**

	<b>&lt; 0.1 ALI   0.1 ALI &lt; 1.0   1.0 ALI</b>		
<b>In Use</b>	Monthly	Weekly	Daily
<b>Not in Use</b>	Every 6 Months		

### 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 8.6.

**Table 8.6 Acceptable Surface Contamination Levels for Equipment.**

Nuclide (a)	Average (b)(c)	Maximum (d)	Remarks (e)
I-125, I-129	1.7 Bq/*1000 cm <sup>2</sup> (1000 dp m/1000 cm <sup>2</sup> )	5.0 Bq/1000 cm <sup>2</sup> (3000 dp m/1000 cm <sup>2</sup> )	0.3 Bq/1000 cm <sup>2</sup> (2000 dp m/1000 cm <sup>2</sup> )
I-126, I-131, I-133, Sr-90	16.7 Bq/1000 cm <sup>2</sup> (1000 dp m/1000 cm <sup>2</sup> )	50.0 Bq/1000 cm <sup>2</sup> (3000 dp m/1000 cm <sup>2</sup> )	3.3 Bq/1000 cm <sup>2</sup> (2000 dp m/1000 cm <sup>2</sup> )



Beta	83.	25	16.
-gam	3	0	7
ma	Bq	Bq/	Bq
emitt	*/1	10	/10
ers	00	0	0
(nucl	cm <sup>2</sup>	cm	cm
ides	(5,0	cm	cm
with	00	(15	(1,
deca	dp	,00	00
y	m/1	0 d	0
mod	00	pm	dp
es	cm <sup>2</sup>	/10	m/
other	)	0	10
than		cm	0
alph		<sup>2</sup> )	cm
a			<sup>2</sup> )
emis			
sion			
or			
spon			
tane			
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(a) 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.

(b) 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.

(c) Measurements of average contaminant should not be averaged over more than 1 square meter.

For objects of less surface area, the average should be derived for each such object.

(d) The maximum contamination level applies to an area of not more than 100 cm<sup>2</sup> .

(e) The amount of removable radioactive material per 100 cm<sup>2</sup> 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.

\* 1 Bq = 1 Disintegration per second

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, Table 8.6 provides the maximum acceptable residual levels for equipment. 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 equipment and facilities 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<sup>2</sup> is acceptable to indicate levels of removable contamination.

### **Survey Record Requirements**

Each survey record should include the following:

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

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

### **Air Monitoring in the Workplace**

Air sampling can be used to do the following:

- Determine whether the confinement of radioactive materials is effective;
- Measure airborne radioactive material concentrations in the workplace;

- Estimate worker intakes of radioactive material;
- Determine posting requirements;
- Determine what protective equipment and measures are appropriate;
- Warn of significantly elevated levels of airborne radioactive materials.

**Note:** 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 may eliminate 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 for further guidance on the 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 on 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 sewerage releases is more fully discussed in Appendix N.

**Response from Applicant:** Choose 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 NUREG-1556, Vol. 18, "Program-Specific Guidance About Service Provider Licenses," dated November 2000."

**OR**

- Submit description of alternative method for demonstrating how to evaluate a radiological hazard.

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

**References:**

- Regulatory Guide DG-4006, "Demonstrating Compliance with the Radiological Criteria for License Termination."
- Federal Register Notice, "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination," Volume 63, Number 222, Page 64132, dated November 18, 1998.
- Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors."
- Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."
- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace."
- Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program."
- Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities."
- NUREG-1400, "Air Sampling in the Workplace."
- NUREG-1549, "Decision Methods for Dose Assessment to Comply With Radiological Criteria for License Termination."
- NUREG/CR-5512, Vol. #3, "Residual Radioactive Contamination From Decommissioning, Parameter Analysis."
- ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities."
- ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents."
- NCRP Commentary No. 3, "Screening Techniques for Determining Compliance with Environmental Standards," published in January 1989, and the addendum published in October 1989.

### **8.10.8 Leak Tests**

**Regulations:** 10 CFR 20.2103(a)(4); 10 CFR 30.53.

**Criteria:** NRC requires testing of sealed sources containing greater than 3.7 MBq (100 microcuries) of beta/gamma or 0.37 MBq (10 microcuries) of alpha radioactive material in order to determine whether there is any radioactive leakage from sealed sources. Requirements for leak tests are based on the type of radiation escaping from the inner capsule. Records of test results must be maintained.

**Discussion:** Sealed sources and devices that are approved by NRC or an Agreement State and used according to the respective SSD Registration Certificate usually pose little risk of contamination. Leak tests performed at the frequency specified in the SSD Registration Certificate should identify leaking sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to NRC requirements. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

NRC licenses will require the performance of leak tests on sealed sources at intervals approved by NRC or an Agreement State and specified in the SSD Registration Sheet. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Becquerel (0.005 microcurie) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by NRC or an Agreement State to either 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 gauge manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Licensees may also be authorized to conduct the entire leak test sequence themselves.

If you will be providing leak tests as a service to others, you may wish to distribute commercial leak test kits.

Leak test kits should contain:

- Swabs, wipes, absorbent-tipped sticks, etc., that are to be used to make the wipes on the specified sources or devices;
- Envelopes, vials, etc., where wipe sample will be placed after sample has been taken;
- Step-by-step instructions for safe use of the particular kit (these instructions will be specific to the types of devices/sealed sources that the kit is designed);
- Procedures for returning the wipes to you for analysis;
- Label for the customer to fill out that identifies:
  - Customer's name;
  - License number;
  - Source or device (by manufacturer, model number, nuclide and activity) wiped; and
  - The name of the individual who made the wipes.

**Response from Applicant:** Do one of the following:

- State: "Leak tests, when required by the license, will be performed at intervals approved by NRC or an Agreement State and specified in the Sealed Source and Device Registration Sheet. 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 kit supplier's instructions."

**OR**

- State: "Leak testing will follow the model procedures in Appendix O."

**OR**

- State: "Leak testing procedures and analysis will be done by the applicant." Provide the information in supporting a request to perform leak testing. Appendix O may serve as guidance.

In addition, if you will distribute leak test kits to customers, either:

- State: "We will provide leak test kits as described in the model leak test kit description in Section 8.9.8 of NUREG-1556, Vol. 18."

**OR**

- Provide a sample of the kits that will be distributed for each type of sealed source/device combination for which you will provide analysis.

*Note:* Requests for authorization to perform leak testing and sample analysis will be reviewed on a case-by-case basis and, if approved, NRC staff will authorize via a license condition. Alternative procedures submitted by the applicant will be evaluated against Appendix O criteria.

**References:** Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," is available from NRC upon request.

### **8.10.9 Maintenance**

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

**Criteria:** This section applies to individuals who perform maintenance on their own licensed devices. Service providers who perform maintenance as a commercial service to other licensees should refer to Section 8.10.8, "Leak Tests." Licensees must maintain devices (e.g., survey instrument calibrators, self-shielded irradiators, etc.) according to the manufacturer's written recommendations and instructions; see Figure 8.12.

"Routine maintenance" of the device includes, but is not limited to, cleaning, lubrication, changing batteries, relays or fuses. "Non-routine maintenance" is the repair, removal, replacement, or alteration involving activities during which personnel could receive radiation doses exceeding NRC limits. These activities could include maintenance on electrical and

mechanical systems that directly control source or shielding movement, the device's shielding or sealed source, safety interlocks, any component that may affect safe operation of the device, or any other Non-routine maintenance must be performed by the device manufacturer (or distributor) or a person specifically licensed by NRC or an Agreement State; see Figure 8.12.

**Discussion:** Before any maintenance or repair work is done on your licensed devices, you need to ensure that you:

- Are specifically authorized by your license to perform the activity;
- Follow the manufacturer's procedures describing the activity;
- Have individuals qualified by their training and experience to perform the activity;
- Use approved parts and components;
- Have specialized equipment to perform these activities;
- Test the device before it is returned to routine use to ensure that it functions as designed;
- Test the device before it is returned to routine use to ensure that it functions as designed.

The NRC license will require that non-routine maintenance be performed only by the manufacturer (or distributor) or other persons specifically licensed by NRC or an Agreement State to perform such services. Applicants seeking authorization to perform non-routine maintenance must submit specific procedures for review. See Appendix P for more information.

**Figure 8.12 Routine Maintenance and Lubrication.** *To ensure proper operation of the unit, licensees need to perform routine maintenance according to the manufacturer's (or distributor's) written instructions and recommendations.*

**Response from Applicant:**

For performance of routine maintenance, submit either of the following:

- The statement: "We will implement and maintain procedures for routine maintenance of our device according to each manufacturer's (or distributor's) written recommendations and instructions."

**OR**

- Alternative procedures for NRC's review.

For performance of non-routine maintenance, submit either of the following:

- The statement: "We will have the device manufacturer (or distributor) or other person authorized by NRC or an Agreement State perform non-routine maintenance."

**OR**

- The information listed in Appendix P supporting a request for authorization to perform this work.

**Note:** Alternative procedures submitted by the applicant for performing routine maintenance will be reviewed using the criteria in Appendix P.

Information requested in Appendix P will be reviewed on a case-by-case basis; if approved, the license will contain a specific condition authorizing the licensee to perform non-routine maintenance.

**References:** INs are available in the "Reference Library" on NRC's web site at (<http://www.nrc.gov>). For hard copies, see the Notice of Availability (on the inside front cover of this report).

### **8.10.10 Minimization of Contamination**

**Regulations:** 10 CFR 20.1406.

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

**Discussion:** When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. 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;
- Appropriate filtration of effluent streams;
- Use of non-porous materials for laboratory bench tops, flooring, etc.;
- Ventilation stacks and duct work with minimal lengths and minimal abrupt changes in direction;
- Use of appropriate plumbing materials with minimal pipe lengths and traps;
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed.

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: "Radioactive Material - Unsealed and/or Sealed Sources," "Facilities and Equipment," "Radiation Safety Program - Safe



Use of Radioisotopes and Emergency Procedures," "Radiation Safety Program - Surveys," and "Radiation Safety Program - Waste Management."

### **8.10.11 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; Subpart H of 10 CFR Part 71; 49 CFR Parts 171-178.

**Criteria:** Applicants must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and DOT regulations.

**Discussion:** 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. Licensees should consider the safety of all individuals who may handle or may come into contact with the transport containers or packages containing licensed material. The primary consideration in packaging licensed material should be to ensure that the package integrity is not compromised during transport, and that the radiation levels or removable contamination levels at the package surfaces meet the regulatory requirements of 10 CFR 71.47. In all cases, ALARA concerns are addressed prior to, during, and after transporting any radioactive material.

Service provider personnel are authorized to prepare packages for shipment at customer facilities. Regardless of who prepares the package for shipment the shipper (i.e., the individual signing the Shipper's Certification on the shipping papers) is responsible for proper package preparation. If a service provider licensee becomes the shipper, the material will be transferred to the service provider's license. HAZMAT training (49 CFR 172, Subpart H-Training) is required for individuals that prepare packages for shipment.

Transporting licensed materials originating at certain facilities (e.g., irradiators) may involve quantities of radioactive material that require a Type B package that involve special requirements. In many cases, this material will be transferred to your license and you will act as the shipper. In these cases, you must ensure that you:

- Are authorized to possess the licensed material at temporary job sites (i.e., at the facility in question);
- Take possession of the licensed material and that it is transferred to you;
- Use an approved Type B package;
- Are registered with NRC as a user of the Type B package;
- Have an NRC-approved quality assurance (QA) plan.

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 toll-free at (800) 368-5642, extension 415-8500. For information about associated fees, contact NRC's Office of the Controller by calling NRC toll-free at (800) 368-5642, extension 415-7554.

**Note:** Licensees shipping radioactive waste for disposal must prepare the shipment and its shipping manifest as required by 10 CFR Part 20, Appendix F.

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. See Appendix Q for a Schedule Summary of the Principal Requirements for Transport of Specified Types of Radioactive Material Consignments.

**Response from Applicant:** No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials in Type B packages, a licensee must 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:** "Radioactive Materials Regulations Review" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-2301. 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," the current version of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," and NUREG-1660/RAMREG-002, "U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments."

## 8.11 Item 11: Waste Management

**Regulations:** 10 CFR 20.1904; 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.

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

**Discussion:** This section applies to service providers who generate radioactive waste as a result of services operations, but does not include licensees providing waste management services to customers. Waste management service may include, but is not limited to, commercial incineration, compaction, solidification/vitrification, and packaging, repackaging, and transportation of radioactive waste. Service providers who perform these activities as a service to other licensees should refer to Section 8.9.6, "Operating and Emergency Procedures."

Radioactive waste generated or handled when conducting licensed activities may include contaminated samples, sealed sources, and unusable items contaminated with radioactive material, e.g., absorbent paper, gloves, filters, tools, etc. You may also be called upon to package radioactive waste at customer facilities for disposal by the customer.

Service providers may not receive radioactive waste from other licensees for processing, storage

or disposal, unless specifically authorized to do so by NRC. If customers wish to dispose of radioactive waste including sealed sources, service provider licensees may assist them only by transferring licensed material to any person authorized to possess these materials. Individuals authorized to possess materials include:

- The original manufacturer;
- The distributor;
- Commercial firms licensed by NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material.

All radioactive waste must be stored in appropriately labeled containers until it is disposed. During the period between storage and disposal container integrity must be assured. All radioactive waste must be secured against access or removal by unauthorized personnel. NRC regulations require that all licensees must dispose of radioactive waste as follows:

- Decay-in-storage (DIS);
- Release into sanitary sewerage;
- Transfer to an authorized recipient;
- Extended interim storage;
- Obtaining prior approval from NRC of an alternate method;
- Disposal of waste as if it were not radioactive (specific wastes);
- Release in effluents to unrestricted areas, other than into sanitary sewerage;
- Incineration.

Additionally, radioactive waste management programs can include compaction, solidification/vitrification, and packaging, repackaging of radioactive waste.

With service provider licensees, NRC's experience is that most dispose of radioactive waste by transfer to an authorized recipients. Applicants requesting authorization to dispose of radioactive waste by incineration should refer to Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997.

**Note:** Compliance with NRC regulations does not relieve a licensee for the responsibility of complying with any other applicable Federal, State, or local regulations. Furthermore, some radioactive waste called "mixed waste" may include additional hazards (e.g., biohazard or chemical hazard). The storage and disposal of "mixed waste" must also comply with all other applicable Federal, state, and local regulatory requirements.

Applicants should describe their radioactive waste management program. This program should include procedures for handling and storing, characterization and minimization, and disposal of radioactive waste. The U.S. Environmental Protection Agency (EPA) issued guidance for development of a comprehensive program to reduce hazardous waste, including radioactive waste. NRC transmitted these guidelines to licensees in IN-94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994.

### **Disposal By Decay-in-storage (DIS)**

NRC has concluded that materials with half-lives of less than or equal to 120 days may be disposed of by DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. 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.

Procedures for management of waste being held for DIS should include methods of segregation according to half life, surveys prior to disposal, and maintenance of records of disposal. Records should include the date when the waste was put in storage for decay, date when ten half-lives of the longest-lived radioisotope have transpired, date of disposal, and results of final survey before disposal as ordinary trash. Appendix N provides a model procedure for disposal of radioactive waste by DIS that incorporates the above guidelines.

### **Release Into Sanitary Sewerage**

10 CFR 20.2003 authorizes disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is easily dispersible biological material) in water;
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in 10 CFR Part 20, Appendix B, Table 3;
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 cannot exceed unity;
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.

Licensees are responsible to demonstrate that licensed materials discharged into the public sewerage system are indeed readily soluble 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 acceptable criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be "readily dispersible." Careful consideration should be given to the possibility of reconcentration of radioisotopes that are released into the sewer. 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.

The regulations in 10 CFR 20.2003 are not applicable for releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas pursuant to 10 CFR 20.1301. However, if licensed

material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludge may be required to be disposed of as radioactive waste, using one of the methods described in this section.

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 regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A model program for disposal of radioactive waste via sanitary sewer is described in Appendix N.

## **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 that requires specific NRC approval for incineration, a description of the following should be provided.

- Training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations, if different from the RSO.
- Chemical and/or physical form of the waste.
- How the waste is segregated, packaged and labeled for transfer from the generation site to the incinerator.
- Methods for determining concentration of radioactivity averaged over the weight of the material to be incinerated (micro curies per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn. Describe procedures for ensuring that environmental release limits specified in 10 CFR 20 will not be exceeded and remains ALARA.
- Procedures for packaging, handling, securing and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property.
- Method for measuring or estimating the concentration of radioactive material remaining in the ash residue.
- Procedures for collection, handling and disposal of the ash residue.
- Records that document receipts, incinerations, environmental releases of effluents, and disposals of ash generated in the incineration process that include the units that will be used in



these records (e.g., Ci/ml).

- Characteristics of the site location and incinerator 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.

- Methods for evaluating airborne and liquid concentration of radionuclides released from the stack, scrubbers, condensers, and associated systems.
- 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 the disposal method for any ash generated that exceeds regulatory limits.
- 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.

**Note:** Incinerators must also be authorized by other federal, state and local authorities to operate.

### **Model Procedure for Compaction**

The following information should be provided from licensees who propose to compact waste. These guidelines apply to noncommercial compaction, i.e., compaction of a licensee's own waste. A description of the following should be provided.

- Describe the type, quantities, and concentrations of waste to be compacted.
- The compaction system that demonstrates 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.). Identify 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.
- An analysis of the potential for airborne release of radioactive material during compaction activities.
- Methods used to monitor and control exposure to airborne radioactive material and contamination.
- 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.

### **Transfer to an Authorized Recipient**

When transferring radioactive waste, it is the licensee's responsibility to verify that the intended recipient is authorized to receive the radioactive waste prior to making any shipment. The radioactive waste must be packaged in approved containers for shipment, and each container must identify the radioisotopes and the amounts contained in the waste. Additionally, packages must comply with the requirements of the particular burial site's license and state requirements. Each shipment must comply with all applicable NRC and DOT requirements. In some cases, the waste handling contractor may provide guidance to the licensee for packaging and transportation requirements; however, the licensee is ultimately responsible for ensuring compliance with all