



NUREG-1556,  
Volume 4, Rev. 1

# **Consolidated Guidance about Materials Licenses**

Program-Specific Guidance  
about Fixed Gauge Licenses

Draft Report for Comment

Office of Federal and State Materials and  
Environmental Management Programs

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# **Consolidated Guidance about Materials Licenses**

## **Program-Specific Guidance about Fixed Gauge Licenses**

### **Draft Report for Comment**

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## **ABSTRACT**

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for fixed gauges. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

### **Paperwork Reduction Act Statement**

This NUREG contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collection requirements were approved by the Office of Management and Budget, approval numbers 3150-0044, 3150-0014, 3150-0017, 3150-0008, and 3150-0120.

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## FOREWORD

The U.S. Nuclear Regulatory Commission's (NRC's) NUREG-1556 technical report series provides a comprehensive source of reference information about various aspects of materials licensing and materials program implementation. These reports, where applicable, describe a risk-informed, performance-based approach to licensing consistent with the current regulations. The reports are intended for use by applicants, licensees, license reviewers, and other NRC personnel. The NUREG-1556 series currently includes the following volumes:

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

<b>Volume No.</b>	<b>Volume Title</b>
<b>17</b>	Program-Specific Guidance about Special Nuclear Material of Less Than Critical Mass Licenses
<b>18</b>	Program-Specific Guidance about Service Provider Licenses
<b>19</b>	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)
<b>20</b>	Program-Specific Guidance about Administrative Licensing Procedures
<b>21</b>	Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator
<b>22</b>	Reserved

The current document, NUREG-1556, Volume 4, Revision 1, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses,” is intended for use by applicants, licensees, and NRC staff. This revision provides a general update to the previous information contained in NUREG-1556, Volume 4, issued October 1998.

This report takes a risk-informed, performance-based approach to licensing fixed gauges. A team composed of staff from NRC Headquarters, NRC regional offices, and Agreement States prepared this document, drawing on their collective experience in radiation safety in general and as specifically applied to fixed gauges.

NUREG-1556, Volume 4, Revision 1, is not a substitute for NRC regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if they include a basis for the staff to make the determinations needed to issue or continue a license.

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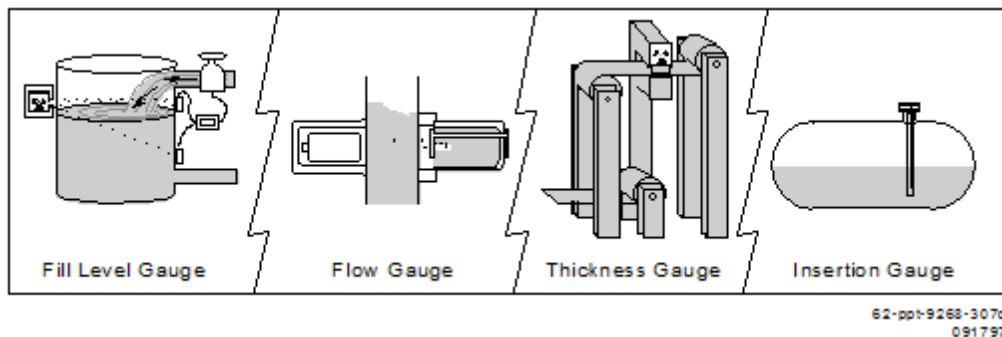
## ABBREVIATIONS

ALARA	as low as is reasonably achievable
ANSI	American National Standards Institute
AU	authorized user
CFR	<i>Code of Federal Regulations</i>
DOT	United States Department of Transportation
FSME	Office of Federal and State Materials and Environmental Management Programs
G-M	Geiger-Mueller
hazmat	hazardous materials
IAEA	International Atomic Energy Agency
IN	Information Notice
MDA	minimum detectable activity
mrem	millirem
mSv	millisievert
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NSTS	National Source Tracking System
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
R	Roentgen
Rev.	revision
RIS	regulatory issue summary
RQ	reportable quantity
RSO	radiation safety officer
SSD	sealed source and device
TI	transportation index
U.S.C.	United States Code

# 1. PURPOSE OF REPORT

This report provides guidance to an applicant applying for a fixed gauge license and provides the U.S. Nuclear Regulatory Commission (NRC) criteria for evaluating a fixed gauge license application. It is not intended to address the research and development of fixed gauges or the commercial aspects of manufacturing, distributing, and non-routine servicing of such devices. Within this document, the phrases or terms “fixed gauge,” “gauging devices,” or “gauges” are used interchangeably.

This report addresses a variety of radiation safety issues associated with fixed gauges of many designs. Typically, gauges are used for process control (e.g., to measure the thickness of paper, the density of coal, the level of material in vessels and tanks, and volumetric flow rate). Figure 1.1 illustrates various examples of different types of fixed gauges. Because of differences in design, manufacturers provide appropriate instructions and recommendations for proper operation and maintenance. In addition, with gauges of varying designs, the sealed sources may be oriented in different locations within the devices, resulting in different radiation safety problems.



**Figure 1.1 Examples of several different types of fixed gauges**

Chapter 8, “Contents of an Application,” of this report identifies the information needed to complete NRC Form 313, “Application for Material License” (see Appendix A), for the use of sealed sources in fixed gauges. The Office of Management and Budget (OMB) has approved the information collection requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” and NRC Form 313 under OMB Clearance Nos. 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 evaluate the applicant’s response
- Discussion—provides additional information about the topic
- Response from Applicant—provides suggested response or responses, offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process

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

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11, as indicated on the form. Applicants should address those items on separate sheets of paper and submit them along with the completed NRC Form 313. For the convenience and streamlined handling of fixed gauge applications, Appendix B, "Suggested Format for Providing Information Requested in Items 5 through 11 of U.S. Nuclear Regulatory Commission Form 313," may be used to provide supporting information.

## 2. AGREEMENT STATES

Certain States, called Agreement States (see Figure 2.1), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, and special nuclear materials, in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive federal jurisdiction within an Agreement State, NRC continues to be the regulatory authority.

Locations of NRC Offices and Agreement States

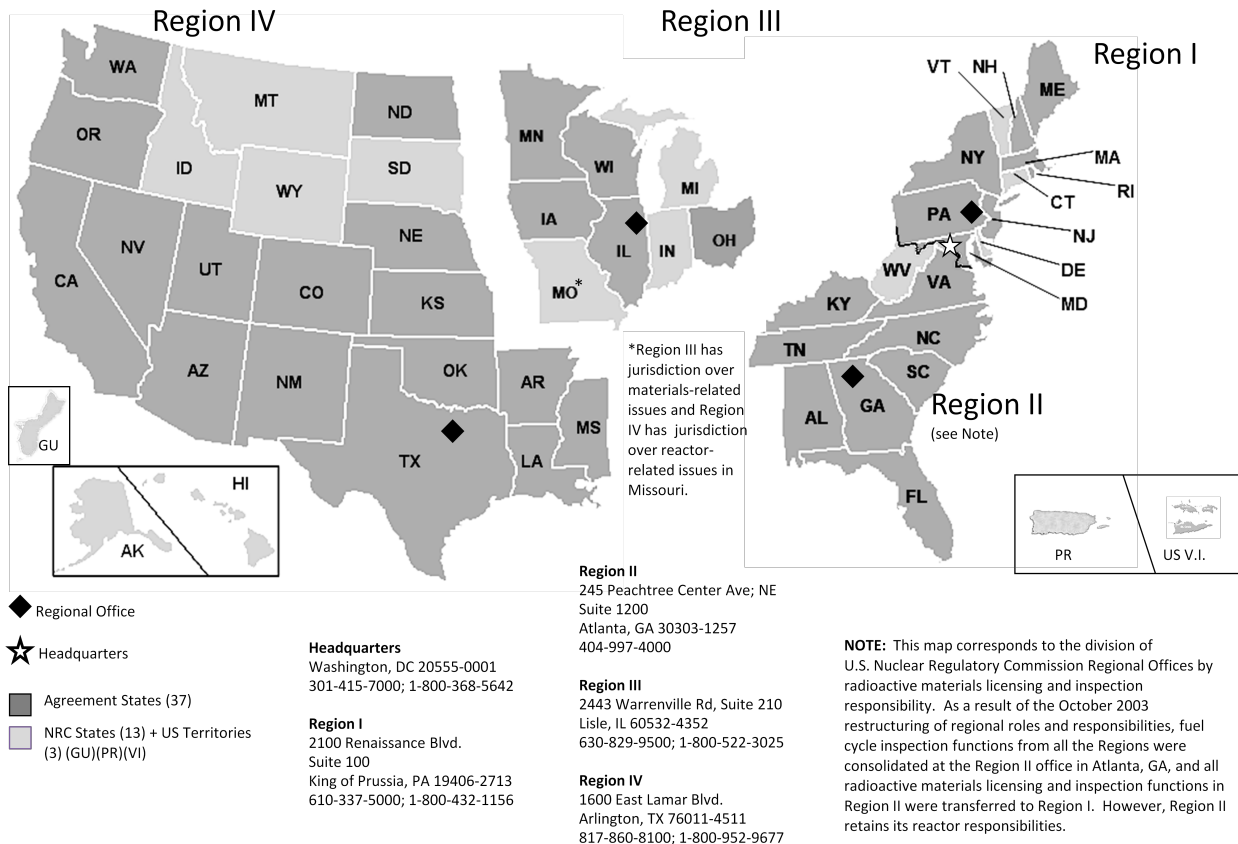


Figure 2.1 U.S. map: Locations of NRC offices and Agreement States

In the special situation of work at Federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the land to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include tribal lands of federally recognized Indian Tribes.<sup>1</sup> The NRC has regulatory authority over land determined to be “exclusive Federal jurisdiction,” while the Agreement State has jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for determining in advance the jurisdictional status of the

<sup>1</sup> For the purposes of this guidance, an “Indian tribe” is defined as an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994. A list of federally recognized tribes is available at [www.bia.gov](http://www.bia.gov).

specific areas where they plan to conduct licensed operations. The NRC recommends that applicants contact their local office of the Federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) for assistance in determining the jurisdictional status of the land and to provide the information in writing to ensure compliance with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in the All Agreement States Letter (SP-96-022), dated February 16, 1996, which is available at <http://nrc-stp.ornl.gov/>. Once on the Web site, use the link for “FSME Letters” in the left hand column under “Resources & Tools.” The link will take you to another Web page where you can search for letters to the Agreement States.

Table 2.1 provides a quick way to check on whether the NRC or an Agreement State has regulatory authority.

**Table 2.1 Who Regulates the Activity?**

<b>Applicant and Proposed Location of Work</b>	<b>Regulatory Agency</b>
Federal agency regardless of location (except the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with 10 CFR 30.12, “Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts”)	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or tribal member on Indian Tribal land	NRC
Non-federal entity on Federally recognized Indian Tribal land	NRC <sup>2</sup>
Federally recognized Indian Tribe or tribal member outside of Indian Tribal land in Agreement State.	Agreement State

<sup>2</sup> The NRC can exercise jurisdiction as the regulatory authority on tribal land of a Federally recognized Indian Tribe. Section 274b. Agreements do not give States the authority to regulate nuclear material in these areas. However, there are few States that exercise regulatory authority over these areas based on treaties or agreements with specific tribes. Companies owned or operated by Federally recognized Indian Tribe members or non-Indians that wish to possess or use licensed material on tribal lands should contact the appropriate NRC regional office to determine the jurisdictional status of the tribal lands and identify the appropriate regulatory agency for licensing and reciprocity.



Applicant and Proposed Location of Work	Regulatory Agency
Non-Federal entity in Agreement State	Agreement State <sup>3</sup>
Non-Federal entity in Agreement State at Federally controlled site not subject to exclusive Federal jurisdiction	Agreement State <sup>3</sup>
Non-Federal entity in Agreement State at Federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials not directly connected with Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State <sup>3</sup>

**Reference:** A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available at the Office of Federal and State Materials and Environmental Management Programs' public Web site, <http://nrc-stp.ornl.gov>. As an alternative, a request for the list can be made to an NRC regional office.

<sup>3</sup> Section 274m. of the AEA gives the NRC regulatory authority over radioactive materials covered under the Section 274b. Agreement when the activity can affect the Commission's authority to protect the common defense and security, to protect restricted data, or guard against the loss or diversion of special nuclear material at a site. (This is an uncommon situation which NRC usually evaluates on a case-by-case basis.) Companies that wish to possess or use licensed material at these sites should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use at the site.



### 3. MANAGEMENT RESPONSIBILITY

The NRC recognizes that effective radiation safety program management is vital to achieving safe, secure, and compliant operations. Consistent compliance with NRC regulations provides reasonable assurance that licensed activities will be conducted safely and that effective management will result in increased safety, security, and compliance.

“Management” as used in this volume refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

#### 3.1 Commitments and Responsibilities

Pursuant to 10 CFR 30.32(c), each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on the behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual that signed the application is duly authorized to act for and on the behalf of the applicant or licensee. The signature on an application acknowledges the licensee’s commitments and responsibilities 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 the NRC (10 CFR 30.9, “Completeness and accuracy of information”);
- Knowledge about the contents of the license and application;
- Compliance with current NRC and U.S. Department of Transportation (DOT) regulations and the licensee’s operating, emergency, and security procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained;
- Selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities;
- Commitment to ensure that radiation workers have adequate training;
- Prevention of discrimination of employees engaged in protected activities (10 CFR 30.7, “Employee protection”);

- Commitment to provide information to employees about the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10, “Deliberate misconduct,” respectively;
- Commitment to obtain the NRC’s prior written consent before transferring control of the license (see Section 9.1, “Timely Notification of Transfer of Control,” of this report); and
- Notification of the appropriate NRC regional administrator in writing, immediately following the filing of a petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)), as discussed further in Section 8.2.1, “Notification of Bankruptcy Proceedings,” of this report.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of the NRC’s Enforcement Policy and Inspection Procedures available in the NRC’s online library at <http://www.nrc.gov/reading-rm.html>.

### **3.2 Safety Culture**

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority.

“Nuclear safety culture” is defined in the Safety Culture Policy Statement as *the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment*. Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to Table 3.1 for the traits of a positive safety culture from NRC’s safety culture policy statement.

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, NRC’s safety culture policy statement and traits are not incorporated into the regulations. Many of the safety culture traits may be inherent to an organization’s existing radiation safety practices and programs. For instance, many fixed gauges include shutters that allow the source to be shielded. If the fixed gauge shutter fails and cannot be closed, licensees are required to notify the NRC Headquarters Operations Center within 24 hours of discovery of an event involving licensed material in which equipment is disabled or fails to function when it is required to be available and operable to prevent exposures exceeding regulatory limits. The need to recognize an equipment failure and make a 24-hour report may correspond with the “Problem Identification and Resolution” (issues potentially impacting safety are promptly identified, fully

evaluated, and promptly addressed and corrected commensurate with their significance) safety culture trait.

Refer to Appendix N for the NRC's safety culture policy statement. More information on NRC activities relating to safety culture can be found at: <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

**Table 3.1 Traits of a Positive Safety Culture**

<b>Leadership Safety Values and Actions</b>	<b>Problem Identification and Resolution</b>	<b>Personal Accountability</b>
Leaders demonstrate a commitment to safety in their decisions and behaviors	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance	All individuals take personal responsibility for safety
<b>Work Processes</b>	<b>Continuous Learning</b>	<b>Environment for Raising Concerns</b>
The process of planning and controlling work activities is implemented so that safety is maintained	Opportunities to learn about ways to ensure safety are sought out and implemented	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination
<b>Effective Safety Communications</b>	<b>Respectful Work Environment</b>	<b>Questioning Attitude</b>
Communications maintain a focus on safety	Trust and respect permeate the organization	Individuals avoid complacency and continually challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action



## 4. APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR) contain regulations applicable to fixed gauges. These parts will apply to many, if not all, licensees.

The current versions of these parts can be found under the "Basic References" link at the NRC's online library at <http://www.nrc.gov/reading-rm.html>; if viewing in a browser, the following list includes direct links to the rules:

- [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 71](#), "Packaging and Transportation of Radioactive Material"

In 10 CFR Part 71, the NRC requires that licensees or applicants who transport licensed material, or who may offer such material to a carrier for transport, must comply with the applicable DOT requirements that are found in 49 CFR Parts 170 through 189.
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- [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 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 the NRC"

Copies of the above documents may be obtained by calling the Government Printing Office order desk toll-free at (866) 512-8600, in Washington, DC, at (202) 512-1800 or online at <http://bookstore.gpo.gov>.

A single copy of the above documents may be requested from the NRC's regional offices (see Figure 2.1 for addresses and telephone numbers). In addition, 10 CFR Parts 1 through 199 can be found on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/> under "Regulations (10 CFR)."

NRC regulations and amendments can also be accessed from the "NRC Library" link on the NRC's public Web site at <http://www.nrc.gov>. The NRC and all other Federal agencies publish amendments to their regulations in the *Federal Register*.



## 5. HOW TO FILE

### 5.1 Paper Application

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete NRC Form 313 (Appendix A) 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 B.
- Provide sufficient detail for the NRC to determine that equipment, facilities, training, experience, and the radiation safety program are adequate to protect health and safety and minimize danger to life and property.
- For each separate sheet other than NRC Form 313 and Appendix B submitted with the application, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Submit all documents, typed, on 8-1/2 x 11-inch paper.
- Avoid submitting proprietary information and personally identifiable information.
- If submitted, proprietary information and other sensitive information (e.g., personal privacy and security related) should be clearly identified per 10 CFR 2.390, "Public inspections, exemptions, requests for withholding" (see Chapter 6, "Identifying and Protecting Sensitive Information").
- Submit an original, signed application.
- Retain one copy of the license application for future reference.

Applications must be signed by the applicant, licensee, or a person duly authorized as required by 10 CFR 30.32(c) (see Section 8.13, "Certification").
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### 5.2 Where to File

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

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State and not with the NRC. However, if work will be conducted at federally controlled sites, or federally recognized Indian Tribal lands, in Agreement

States, applicants must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. See Chapter 2, “Agreement States,” for additional information.

### **5.3 Transfer to Electronic Format**

Paper applications received by the NRC are scanned through an optical character reader and converted to an electronic format. To ensure a smooth transfer to an electronic format, applicants should do the following:

- 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, Future, or Univers (the text of this document is in the Arial font).
- Use 12-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

It is anticipated that the NRC may provide mechanisms for filing applications through the Internet. If this occurs, the NRC will provide additional filing instructions as the agency implements these new mechanisms.

## 6. IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

All licensing applications, except for portions containing sensitive information, will be made available for review in the NRC's Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit [www.nrc.gov](http://www.nrc.gov).

The licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. Licensing applications that contain sensitive information should be marked as indicated below in accordance with 10 CFR 2.390 before the information is submitted to the NRC. Key examples are as follows:

- **Proprietary Information/Trade Secrets:** If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application.
- **Personally Identifiable Information:** Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, which can be found on the NRC's Generic Communications webpage under "Regulatory Issue Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC changed its procedures to avoid release of information that terrorists could use to plan or execute an attack against facilities or citizens in the United States. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: "Security Related—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g. an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005, which can be found on the NRC's Generic Communications webpage under "Regulatory Issue Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional information on procedures and any updates is available at <http://www.nrc.gov/reading-rm/sensitive-info.html>.



## 7. APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 10 CFR 170.31, "Schedule of fees for materials licenses and other regulatory services, including Inspections, and import and export licenses," to determine the amount of the fee. The NRC will not issue a license until the fee is received. Consult 10 CFR 170.11, "Exemptions," for information on exemptions from these fees. Once the technical review has begun, no fees will be refunded; application fees will be charged regardless of the 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, "Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC." Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

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



## 8. CONTENTS OF AN APPLICATION

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

All items in the application should be completed in enough detail for the NRC to determine that the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. Consideration shall be given, when developing the application, to the concepts of keeping exposure as low as is reasonably achievable (ALARA), minimizing contamination, and maintaining control of radioactive materials.

Refer to Appendix M for guidance regarding the definition of construction and the consideration of activities that can be performed by materials license applicants and potential applicants, and licensees before the NRC has concluded its environmental review of the proposed licensing action. The vast majority of materials licensing actions will meet the criteria in 10 CFR 51.22(c) for a categorical exclusion. This means that the licensing action will not require an environmental assessment or environmental impact statement in accordance with 10 CFR 51.22(b), since the NRC has already determined that the licensing action does not have a significant impact on the environment. It is the applicant's responsibility to review the guidance in Appendix M to determine whether the categorical exclusion applies to the licensing action.

10 CFR 20.1101(b) states: "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA concepts and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

10 CFR 20.1406, "Minimization of contamination," requires applicants for licenses to describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste. As with ALARA considerations, applicants should address concerns for all aspects of their programs.

10 CFR 20.1801, "Security of stored materials," states that licensees shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

10 CFR 20.1802, "Control of material not in storage," states that licensees shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

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

### 8.1 **Item 1: License Action Type**

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

Type of Action	License No.
<input type="checkbox"/> A. New License	Not Applicable
<input type="checkbox"/> B. Amendment	XX-XXXXX-XX
<input type="checkbox"/> C. Renewal	XX-XXXXX-XX

Check Box A for a new license request. Note that a pre-licensing visit may be required prior to issuance of the license. Also note that an initial security inspection may be conducted in accordance with NRC Inspection Manual Chapter 2800, "Materials Inspection Program," before issuance of the license.

Check Box B for an amendment to an existing license and provide the license number.

Check Box C for a renewal of an existing license and provide the license number.

Licensees are required to request and obtain an amendment to the license before making changes to their radiation safety programs. The following are examples of changes that require amendment:

- a change of RSO
- changes in the mailing address
- changes in the address(es) of storage locations
- changes in licensed material, including increases in the possession limit of byproduct material and adding new types of gauges

See "Amendments and Renewals to a License" in Chapter 9 of this report.

### 8.2 **Item 2: Name and Mailing Address of Applicant**

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



**Note:** The NRC must be notified before control of the license is transferred (see Section 9.1, “Timely Notification of Transfer of Control”) or when bankruptcy proceedings have been initiated (see Section 8.2.1, “Notification of Bankruptcy Proceedings”).

### 8.2.1 Notification of Bankruptcy Proceedings

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

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

**Discussion:** Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. The NRC must be notified 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). The 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 is required at the time of application for a new license. Licensees must immediately notify the NRC in writing follow the filing of a voluntary or involuntary petition for bankruptcy by or against the licensee.

**Reference:** See NUREG-1556, Volume 15, “Consolidated Guidance about Materials Licenses: Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses.”

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

Specify the street address, city, and State or other descriptive address (e.g., Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable. In addition, applicants are encouraged to provide global positioning system coordinates, as appropriate.

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. This applies whether the gauge is an additional device or a relocation of an existing device.

An NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements).
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To conduct operations at temporary job sites (i.e., locations where work is conducted for limited periods of time), refer to the section in Section 8.10.10 of this report called “Fixed Gauges Used at Temporary Job Sites.” That section offers examples of operations where fixed gauges might be used at temporary job sites and identifies information that should be provided to the NRC to support a request for these operations.

Documents that give the exact location of use and storage for materials greater than or equal to International Atomic Energy Agency (IAEA) Category 2 quantities should be marked “Security-Related Information—Withhold under 10 CFR 2.390.”

The applicant need *not* submit sketches or identify the specific location of the fixed gauge within the facility with the application. The NRC will review the acceptability of the gauge’s location during the inspection process.

**Note:** As discussed later in Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning,” licensees must maintain permanent records describing where licensed material was used or stored while the license was in effect. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For fixed gauge licensees, acceptable records are leak test records, sketches, and written descriptions of specific locations where each gauge was used or stored and any information relevant to damaged devices or leaking radioactive sources.

#### **8.4 Item 4: Person To Be Contacted about This Application**

Identify the individual who can answer questions about the content of the application, and include a telephone number where the individual may be contacted. Also include business cell phone numbers and e-mail addresses. This individual, usually the RSO, will serve as the point of contact during the review of the application. If this individual is not a full-time employee of the licensed entity, his or her position and relationship to the licensee should be specified. The NRC should be notified if the person assigned to this function changes or if his or her telephone number, cell phone number, or e-mail address changes. Notification of a contact change is only in order to provide information and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

As indicated on NRC Form 313 (see Appendix A), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix B for this purpose and should note that using the suggested wording of responses and committing to use the model procedures in this report will facilitate the NRC’s review.

#### **8.5 Item 5: Radioactive Material**

##### **8.5.1 Sealed Sources and Devices**

**Regulations:** 10 CFR 30.32(g), 10 CFR 30.33(a)(2), and 10 CFR 32.210

**Criteria:**

Applicants must provide the manufacturer’s name, model number, radionuclide, quantity, and nominal activity for each requested sealed source and the manufacturer’s name and model number for each device.

Licensees will be authorized to possess and use only those sealed sources and devices specifically approved and registered by the NRC or an Agreement State.

**Discussion:** The NRC and Agreement States perform safety evaluations of gauges before authorizing manufacturers to distribute fixed gauges to licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) registration certificate.

Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining NRC's prior permission in a license amendment. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSD registration certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce the radiation safety of the device, or by circumstances unique to the sealed source or device. For example, the working life of the device or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by the NRC, licensees are required to use gauges according to their respective SSD registration certificates. Accordingly, applicants should obtain a copy of the certificate and review it with the manufacturer or distributor, or with the NRC or the issuing Agreement State.

Fixed gauges could potentially be at or above Category 2 quantities described in the IAEA's "Code of Conduct on the Safety and Security of Radioactive Sources." Applicant/licensee information on manufacturers, model numbers, and possession limits is sensitive and should be marked accordingly (see Chapter 6, "Identifying and Protecting Sensitive Information"). Category 1 and Category 2 sources regulated by the NRC and Agreement States must be tracked in the National Source Tracking System (NSTS).

**Response from Applicant:**

- Identify each radionuclide and nominal activity in each gauge.
- Identify the manufacturer or distributor and model number of each type of gauge.
- State the total quantity of each type of gauge.

For existing licensees with Category 1 or 2 quantities of materials, mark the section related to the possession of sealed sources and devices that includes manufacturers, model numbers, and possession limits as follows: "Security-Related Information—Withhold Under 10 CFR 2.390."

**Reference:** For more information about the SSD registration process, see the current version of NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

## 8.5.2 Financial Assurance and Recordkeeping for Decommissioning

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

**Criteria:** Fixed gauge licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in 10 CFR 30.35, "Financial assurance and

recordkeeping for decommissioning,” must provide evidence of financial assurance for decommissioning.

Licensees are required to maintain, in an identified location, decommissioning records related to leaking sources and to structures and equipment where gauges are used or stored. Licensees must transfer these records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b) or to the appropriate NRC regional office before the license is terminated.

**Discussion:** The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most fixed gauge applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the thresholds in 10 CFR 30.35(d). The thresholds for typical radionuclides used for fixed gauge sealed sources are shown in Table 8.1.

**Table 8.1 Examples of Minimum Inventory Quantities Requiring Financial Assurance**

Radionuclide (Sealed Sources)	Activity in Gigabecquerels	Activity in Curies
Cobalt-60	$3.7 \times 10^5$	10,000
Krypton-85	$3.7 \times 10^7$	1,000,000
Strontium-90	$3.7 \times 10^4$	1,000
Cesium-137	$3.7 \times 10^6$	100,000
Americium-241	$3.7 \times 10^3$	100
Californium-252	$3.7 \times 10^3$	100

A licensee would need to possess tens to hundreds of gauges before the financial assurance requirements would apply. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance. Licensees should follow the guidance provided in NUREG-1757, Volume 3, “Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness.”

Applicants requesting more than one radionuclide may determine whether financial assurance for decommissioning is required by calculating, for each radionuclide possessed, the ratio between the activity possessed, in curies, and the radionuclide’s threshold activity requiring financial assurance, in curies. If the sum of such ratios for all of the radionuclides possessed exceeds “1” (i.e., “unity”), then applicants must submit evidence of financial assurance for decommissioning.

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All fixed gauge licensees need to maintain records of structures and equipment where each gauge was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the

room or building or a narrative description of the area) concerning the specific areas and locations. If no records exist regarding structures and equipment where gauges were used or stored, licensees shall make all reasonable efforts to create such records based on historical information (e.g., employee recollections). In addition, if fixed gauge licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For fixed gauge licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each gauge was used or stored.

**Response from Applicant:** No response is needed from most applicants. If financial assurance is required, submit the documentation required under 10 CFR 30.35.

**Reference:** See NUREG-1757, Volume 3, “Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness.”

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

**Regulation:** 10 CFR 30.33(a)(1)

**Criteria:** An application for a license will be approved if the proposed activity is authorized by the Atomic Energy Act of 1954, as amended, and devices will be used only for the purposes for which they were designed and according to the manufacturer’s recommendations for use as specified in an approved SSD registration certificate.

**Discussion:** Uses other than those listed in the SSD registration certificate require review and approval by the NRC or an Agreement State. Requests to use fixed gauges for purposes not listed in the SSD registration certificate will be reviewed on a case-by-case basis. Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the source integrity or shielding, or other components of the device critical to radiation safety. The NRC will evaluate the radiation safety program for each type and use of gauge requested.

An NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations.

**Response from Applicant:** Specifically describe how each device will be used. If the fixed gauge(s) will be used for the purposes listed on the SSD registration certificate, or as recommended by the manufacturer, the applicant may so state and provide a specific description of use for each type of gauge requested. If the fixed gauge will be used for purposes other than those listed on the SSD registration certificate, specify these other purposes and include a safety analysis supporting the request.

**Notes:**

- Allowed uses of fixed gauges normally include process control methods, such as measuring the thickness of paper, the density of coal, the level of material in vessels and tanks, etc.
- Unusual uses will be evaluated on a case-by-case basis, and the authorized use condition will reflect approved uses.

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

**8.7.1 Radiation Safety Officer**

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

**Criteria:** RSOs must have adequate training and experience. In the past, the NRC has found successful completion of one of the following to be evidence of adequate training and experience:

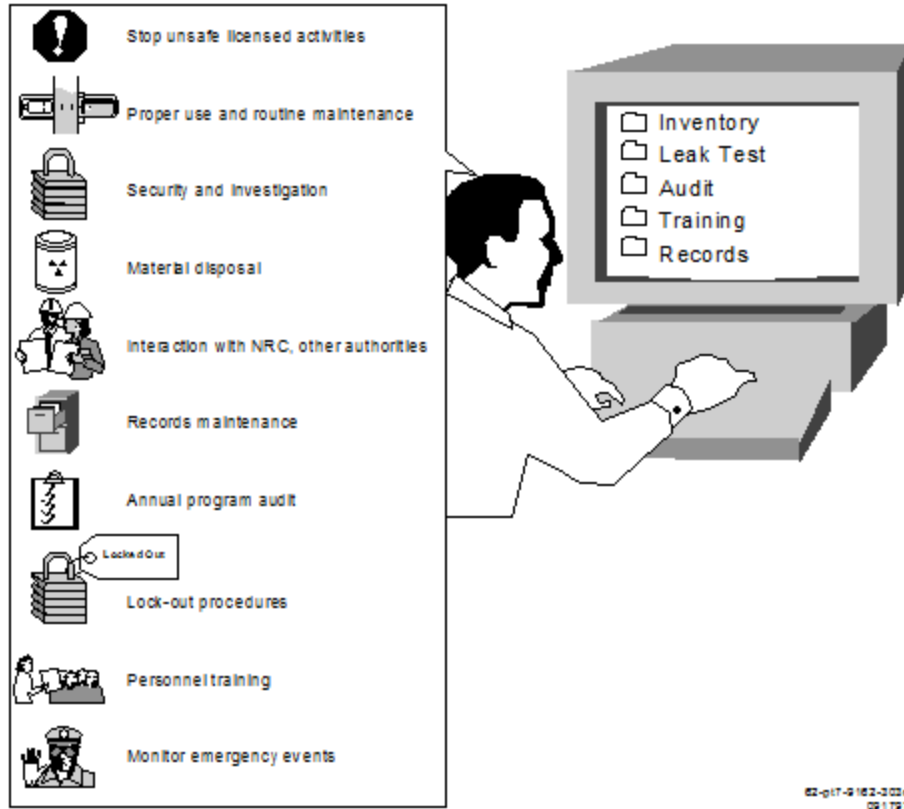
- fixed gauge manufacturer's or distributor's course for users or for RSOs

**OR**

- equivalent course that meets the criteria in Appendix D

Additional training is required for RSOs in programs that perform nonroutine operations. This includes repairs involving or potentially affecting components related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding) and any other activities during which personnel could receive radiation doses exceeding the NRC's regulatory dose limits (e.g., installation, initial radiation survey, gauge relocation, and removal of the gauge from service). See Section 8.10.8, "Maintenance," and Appendix J to this report for more information on nonroutine operations.

**Discussion:** The person responsible for the radiation protection program is the RSO. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are illustrated in Figure 8.1 and described in Appendix C. The NRC requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person appointed and that the named individual knows of his or her designation as RSO.



**Figure 8.1 Typical duties and responsibilities of RSOs**

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

- name of the proposed RSO.
- documentation demonstrating that the proposed RSO is qualified by training and experience (i.e., certificate of completion of the RSO's course or the authorized user's course).

**Notes:**

- Licensees must inform the NRC of changes in the designation of the RSO and request an amendment to the license to name a replacement RSO.
- The RSO may delegate responsibilities to another individual at any site listed on the license or at temporary job sites. If these responsibilities are delegated, then the delegate RSO should meet the same training and experience criteria as the RSO. Please note that only the primary RSO is named on an NRC license.

## 8.7.2 Authorized Users

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

**Criteria:** Authorized users (AUs) must have adequate training and experience in the use of fixed gauges. In the past, the NRC has found successful completion of one of the following to be evidence of adequate training and experience:

- fixed gauge manufacturer's or distributor's course for users

**OR**

- equivalent course that meets the criteria in Appendix D

Applicants requesting to perform nonroutine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service, must provide additional training. See Section 8.10.8, "Maintenance," and Appendix J to this report for more information.

**Discussion:** AUs have the responsibility to ensure the proper use, security, and routine maintenance of fixed gauges containing licensed material. AUs must attend the training and instruction given at the time of installation or receive equivalent training and instruction.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

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

- the statement "Before using licensed materials, authorized users will have successfully completed one of the training courses described in the 'Criteria' part of the section entitled 'Authorized Users' in the current version of NUREG-1556, Volume 4, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses.'"

**OR**

- a description of the training and experience for proposed AUs

**Note:** Records of the training of each AU must be maintained for at least 3 years after the last use of licensed material by the AU.



**8.8 Item 8: Training for Individuals who in the Course of Employment Are Likely To Receive Occupational Doses of Radiation in Excess of 1 Millisievert (100 Millirem) in a Year (Occupationally Exposed Workers) and Ancillary Personnel**

**Regulations:** 10 CFR 19.11, 10 CFR 19.12, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, and 10 CFR 30.33

**Criteria:** Individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 1 millisievert (mSv) (100 millirem (mrem)) in a year must receive training according to 10 CFR 19.12, "Instruction to workers." The extent of this training must be commensurate with potential radiological health protection problems present in the work place.

**Discussion:** Licensees need to perform a prospective evaluation to determine radiation doses likely to be received by different individuals or groups (see Section 8.10.4, "Occupational Dose"). AUs and individuals performing installations, relocations, nonroutine maintenance, or repairs would be most likely to receive doses in excess of 1 mSv (100 mrem) in a year. See the previous section for a discussion of training and experience for AUs.

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

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

**Response from Applicant:** No response is required from the applicant as part of the license application. The applicant's training program for individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 1 mSv (100 mrem) in a year (occupationally exposed workers) and ancillary personnel will be examined during inspections.

**8.9 Item 9: Facilities and Equipment**

**Regulations:** 10 CFR 20.1101(b), 10 CFR 20.1201, 10 CFR 20.1301, 10 CFR 20.1801, and 10 CFR 30.33(a)(2)

**Criteria:** Facilities and equipment must be adequate to protect health and to minimize danger to life or property. This may be demonstrated by the following:

- the location of the gauge is compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSD registration certificate,

**AND**

- the fixed gauge is secured to prevent unauthorized removal or access (e.g., located in a locked room, permanently mounted, or chained and locked to a storage rack).

**Discussion:** Fixed gauges incorporate many engineering features to protect the user from unnecessary radiation exposure in a wide variety of environments. Fixed gauges may be located in harsh environments involving variables such as pressure; vibration; mounting height/method; temperature; humidity; air quality; corrosive atmospheres; corrosive chemicals including process materials and cleaning agents; possible impact or puncture conditions; and fire, explosion, and flooding potentials. Applicants and/or licensees need to consult the sections on the SSD registration certificate entitled “Conditions of Normal Use” and “Limitations and/or Other Considerations of Use” to determine the appropriate gauge and location. In those instances when a proposed location is not consistent with the SSD registration certification, the applicant may ask the source or device manufacturer or distributor to request an amendment to modify the SSD registration certificate to include the new conditions. If the manufacturer or distributor does not request an amendment, the applicant must provide the NRC with specific information demonstrating that the proposed new conditions will not impact the safety or integrity of the source or device.

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

- A statement that “We will ensure that the location of each fixed gauge meets the criteria in Section 8.9, ‘Facilities and Equipment,’ in the current version of NUREG-1556, Volume 4, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses.’”

**OR**

- Confirmation that the fixed gauge is secured to prevent unauthorized removal or access and submittal of specific information demonstrating that the proposed conditions will not impact the safety or integrity of the source or device. Address any instances where the proposed conditions exceed any conditions listed in the SSD registration certificate.

**Note:** Any deviations from an SSD registration certificate will require specific NRC or Agreement State approval.

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

### **8.10.1 Audit Program**

**Regulations:** 10 CFR 20.1101 and 10 CFR 20.2102

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

- Programs comply with NRC and DOT regulations and the terms and conditions of the license.

- Occupational doses and doses to members of the public are ALARA (per 10 CFR 20.1101, “Radiation protection programs”).
- Records of audits and other reviews of program content are maintained for at least 3 years.

**Discussion:** Appendix E contains a suggested audit program that is specific to the use of fixed gauges and is acceptable to the NRC. All areas indicated in Appendix E may not be applicable to every licensee and may not need to be addressed during each audit.

Currently, the NRC’s emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of fixed gauge users to determine if, for example, operating and emergency procedures are available and are being followed, etc.

It is essential that once problems are identified comprehensive corrective action are taken in a timely manner; Information Notice (IN) 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” dated May 1, 1996, provides guidance on this subject. The NRC will review the licensee’s audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the NRC will normally exercise discretion and may elect not to cite a violation. The NRC’s goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies. For additional information on the NRC’s use of discretion in issuing violations, refer to the current version of the NRC Enforcement Policy.

With regard to audit records, 10 CFR 20.2102(a) requires, in part, that licensees maintain records of “audits and other reviews of program content and implementation” for 3 years from the date of the record. The NRC has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and followup.

**Response from Applicant:** The applicant is not required to submit its audit program to the NRC for review during the licensing phase. The applicant’s audit program will be reviewed during NRC inspections.

**References:** For information about NRC enforcement, see the current version of the NRC Enforcement Policy found on the NRC’s public website. IN 96-28 is available electronically in the “NRC Library” on the NRC’s Home Page at <http://www.nrc.gov>.

### 8.10.2 Instruments

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

**Criteria:** Licensees should possess, or have access to, radiation monitoring instruments, which 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:** Typically, fixed gauge licensees are not required to possess a survey meter; however, an applicant that plans to conduct nonroutine operations will need to conduct surveys in accordance with 10 CFR 20.1501, “General.” Nonroutine operations include installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement,

disposal of the sealed source, and nonroutine maintenance and repair of components related to the radiological safety of the gauge. See Section 8.10.8, "Maintenance," and Appendix J for more information on maintenance and nonroutine operations. Because some of these operations may increase the opportunity for radiation exposure, the areas where individuals will be performing these operations should be carefully monitored with a survey meter. Such survey meters must be properly calibrated. Proper calibration is particularly important for initial surveys, because the results can be used as a basis for public dose estimates. For those licensees requesting authorization to calibrate their own survey instruments, Appendix F contains calibration procedures acceptable to the NRC.

Each year, a number of gauges experience equipment failures because of corrosion caused by the harsh environmental conditions in which many gauges are operated. Following discovery of an equipment failure, it is important to determine if the shielding and source are intact. The most efficient and effective way to do this is by measuring the radiation levels in the vicinity of the gauge with an appropriate, calibrated survey instrument. Because many fixed gauge licensees are not required to possess a survey meter, applicants should preplan how they will obtain assistance in performing a radiation survey in the event of an emergency (e.g., obtain a survey instrument from the manufacturer, a consultant, another NRC or Agreement State licensee, or a local emergency response organization).

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

- A statement that "Surveys according to 10 CFR 20.1501 will be performed by a person specifically authorized by the NRC or an Agreement State to perform these surveys."

**OR**

- A statement that "We will use survey instruments that meet the criteria in Section 8.10.2, 'Instruments,' in the current version of NUREG-1556, Volume 4, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses,' and one of the following three choices:
  - "Each survey meter will be calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations."

**OR**

- "We will implement the model survey meter calibration program published in Appendix F, 'Model Survey Instrument Calibration Program' in the current version of NUREG-1556, Volume 4, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses.'"

**OR**

- "We will submit alternative calibration procedures for NRC review."

**OR, IN LIEU OF ALL OF THE ABOVE**

- Submit a description of an alternative method to perform surveys according to 10 CFR 20.1501.

**Notes:**

- Alternative responses will be reviewed against the criteria listed above.
- Regardless of whether an applicant is authorized to calibrate survey meters or contracts an authorized firm to perform calibrations, the licensee must retain calibration records for at least 3 years in accordance with 10 CFR 20.2103(a).

**8.10.3 Material Receipt and Accountability**

**Regulations:** 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201, 10 CFR 20.2207, 10 CFR 30.34(e), 10 CFR 30.41, 10 CFR 30.51

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

- Maintain records of receipt, transfer, and disposal of fixed gauges.
- Conduct physical inventories at intervals not to exceed 6 months (or some other interval justified by the applicant and approved by the NRC) to account for all sealed sources.
- Update transactions in the NSTS and perform an NSTS annual inventory reconciliation, if applicable.

**Discussion:** Licensed materials must be tracked from “cradle to grave” in order to ensure gauge accountability; identify when gauges could be lost, stolen, or misplaced; and ensure that possession limits listed on the license are not exceeded. Significant problems can arise from failure to ensure the accountability of gauges (see NRC IN 88-02, “Lost or Stolen Gauges,” dated February 2, 1988).

Receipt, inventory, transfer, and disposal records must be maintained for the times specified in Table 8.2. Typically, these records contain the following types of information:

- the radionuclide and the activity (in units of becquerels or curies) of byproduct material in each sealed source
- the manufacturer’s or distributor’s name, the model number, and the serial number (if appropriate) of each device containing byproduct material
- the location of each sealed source and device
- for inventories, the date of the inventory and signature of the individual conducting the inventory
- for materials transferred or disposed of, the date of the transfer or disposal, the name and license number of the recipient, and a description of the affected radioactive material (e.g., radionuclide, activity, manufacturer’s or distributor’s name and model number, serial number)

**Table 8.2 Record Maintenance**

Type of Record	How Long Record Must Be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Inventory	For 5 years from the date of the inventory
Transfer	For 3 years after transfer
Disposal	Until the NRC terminates the license
Important to Decommissioning*	Until the site is released for unrestricted use

\* See Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning,” for more details.

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

- A statement that “Physical inventories will be conducted at least every 6 months or at other intervals approved by the NRC, to account for all sealed sources and devices received and possessed under the license.”
- A statement that “We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.”

**Note:** The requirements of the NSTS apply to sealed sources containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E, “Nationally Tracked Source Thresholds,” to 10 CFR Part 20.

**References:** INs are available in the “NRC Library” on the NRC’s public website at <http://www.nrc.gov>.

#### 8.10.4 Occupational Dose

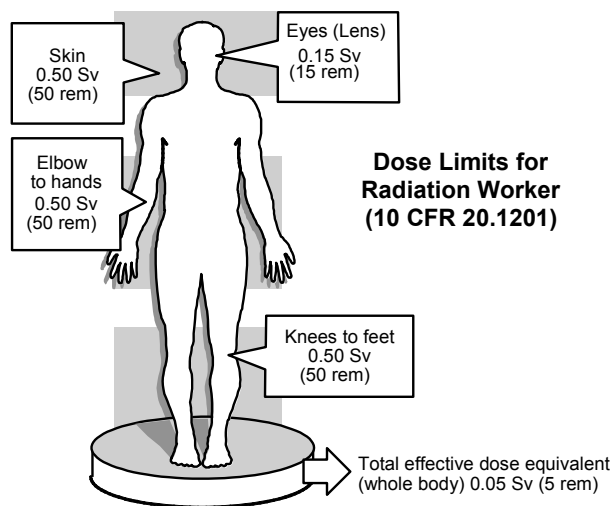
**Regulations:** 10 CFR 19.13, 10 CFR 20.1201, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, and 10 CFR 20.1502

**Criteria:** Applicants must do either of the following:

- Perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits, as shown in Figure 8.2, and maintain the record for inspection by the NRC.

**OR**

- Provide dosimetry processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor that is exchanged at a frequency recommended by the processor.



**Figure 8.2 Annual dose limits for radiation workers**

**Discussion:** Under conditions of routine use, the typical fixed gauge user does not require a personnel monitoring device (dosimetry). A gauge user also may not require dosimetry when proper emergency procedures are used. Appendix G provides guidance on performing a prospective evaluation demonstrating that fixed gauge users are not likely to exceed 10 percent of the limits shown in Figure 8.2 and thus are not required to have personnel dosimetry.

Individuals who perform nonroutine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service are more likely to exceed 10 percent of the limits shown in Figure 8.2. Applicants must provide dosimetry (whole body and perhaps extremity monitors) to individuals who perform nonroutine operations or must perform a prospective evaluation demonstrating that unmonitored individuals who perform nonroutine operations are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits as shown in Figure 8.2.

When personnel monitoring is needed, most licensees use dosimeters supplied by an NVLAP-approved processor. The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP-approved processor for its recommendations for exchange frequency and proper use of the dosimeter.

**Response from Applicant:** Provide any one of the following:

- A statement that “We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20.”

**OR**

- A statement that “We will provide dosimetry, processed and evaluated by an NVLAP-approved processor, that is exchanged at a frequency recommended by the processor.”

**OR**

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

**Notes:**

- Alternative responses will be evaluated against 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 or to maintain records of personal exposure).

**Reference:** The National Institute of Standards and Technology (NIST) maintains a directory of accredited laboratories at <http://ts.nist.gov>.

### **8.10.5 Public Dose**

**Regulations:** 10 CFR 20.1003, 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 fixed gauges will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.

**AND**

- Prevent unauthorized access, removal, or use of fixed gauges.

**Discussion:** Public dose is defined in 10 CFR Part 20 as “the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee.” Public dose excludes doses received from background radiation and medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual’s assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) where the individual is when he or she receives the dose.

In the case of fixed gauges, members of the public include persons who live, work, or may be near locations where fixed gauges are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where gauges are used or stored. Since a fixed gauge presents a radiation field, the applicant must use methods to limit the public dose such that the radiation level in an unrestricted area (e.g., a nearby walkway or



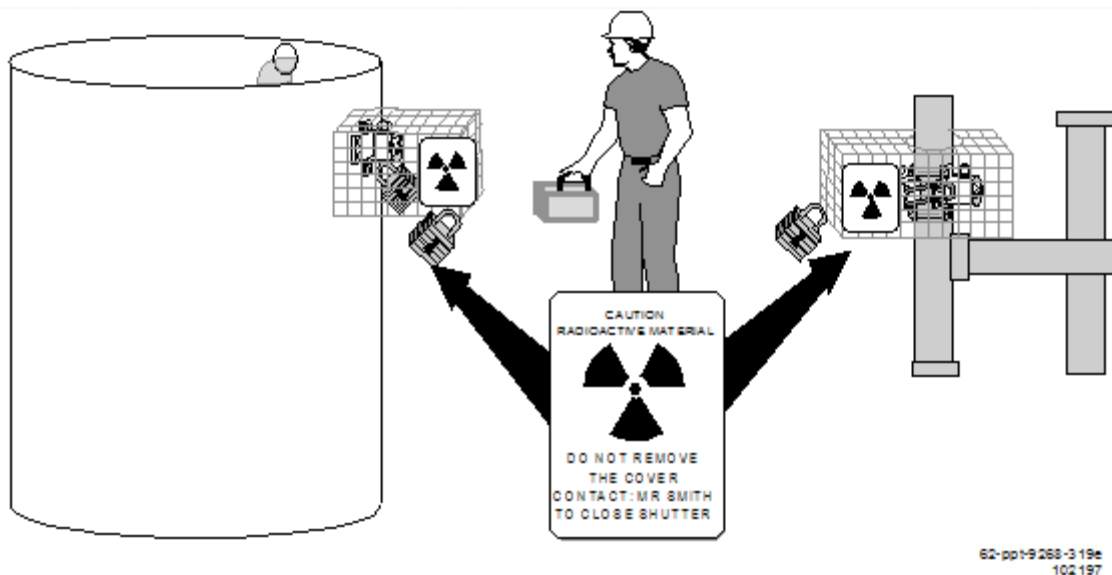
area near the gauge that requires frequent maintenance) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour.

Because fixed gauges are generally permanently mounted (e.g., chained and locked to a storage rack), they may not need to be in a locked area to prevent loss, theft, or unauthorized removal. Procedures regarding security and lock-out procedures specified in Section 8.10.6, "Operating and Emergency Procedures," of this document should be sufficient to limit the exposure to the public during use or storage and after accidents. IN 81-37, Revision 1, "Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices," dated February 9, 1982, provides information about an event that resulted or may have resulted in unnecessary radiation exposure to members of the public. IN 88-02 provides information about several events where fixed gauges were lost or stolen.

Public dose is also affected by the location of the gauge. Use the concepts of time, distance, and shielding when developing a method to limit public dose. Decreasing the time spent near a gauge, increasing the distance from the gauge, and using shielding will reduce the radiation exposure. The most effective way to limit public dose is to prevent members of the public from entering areas where gauges are used or stored. This may be accomplished by administrative or engineering controls.

Administrative controls include training and warning signs. In cases where gauges are located in harsh environmental conditions (e.g., high temperatures, caustic chemicals, etc.), warning signs may be difficult to maintain so requiring radiation awareness training to caution employees would be a good practice.

Engineering controls reduce radiation levels in areas that are accessible to the public. Shielding the gauge with a protective barrier (e.g., using brick, concrete, lead, or other solid walls) or placing the gauge within an enclosure to prevent access to higher radiation levels are examples of engineering controls (see Figure 8.3).



**Figure 8.3 Limiting Public Dose**

*When dose rates in an area are high enough that a member of the public could receive a dose in excess of 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year, licensees must take additional measures to prevent public access to these higher dose rates, such as building enclosures around the gauges.*

Public dose can be estimated in areas near the gauge by using radiation levels determined during initial surveys and applying the “inverse square” law to evaluate the effect of distance on radiation levels and occupancy factors to account for the actual presence of members of the public (see Appendix G for an example).

If, after making a public dose estimate, the conditions used to make the evaluation change (e.g., there are changes to the location of gauges, changes to the type or frequency of gauge use, addition of new gauges, or changes to the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the dose to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for individual members of the public (see Appendix G for examples of methods to demonstrate compliance).

**Response from Applicant:** No response is required from the applicant during the licensing phase. The NRC will examine this matter during inspection.

**References:** INs are available in the “NRC Library” on the NRC’s Home Page at <http://www.nrc.gov>.

### 8.10.6 Operating and Emergency Procedures

**Regulations:** 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201–2203, 10 CFR 20.2207, 10 CFR 21.21, 10 CFR 30.34(e), 10 CFR 30.50

**Criteria:** Each applicant should do the following:

- Develop, implement, and maintain operating procedures that contain the following elements for each type of fixed gauge:
  - instructions for using the gauge, including use at temporary job sites if requested and authorized on the license (see Section 8.10.10, “Fixed Gauges Used at Temporary Job Sites,” for more information on fixed gauges used at temporary job sites)
  - instructions for performing routine maintenance according to the manufacturer’s recommendations and instructions
  - instructions for testing each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the SSD registration certificate
  - instructions for lock-out procedures, if applicable, that are adequate to ensure that no individual or portion of an individual’s body can enter the radiation beam
  - steps to take to keep radiation exposures ALARA
  - steps to maintain accountability of gauges (i.e., inventory)
  - instructions to ensure that nonroutine operations such as installation, initial radiation survey, repair and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service are performed by the manufacturer, distributor, or person specifically authorized by the NRC or an Agreement State
  - steps to ensure that radiation warning signs are visible and legible
  - instructions for transporting radioactive material to ensure compliance with DOT regulations, if the applicant will be transporting gauges to temporary job sites.
- Develop, implement, and maintain emergency procedures for gauge malfunction or damage that contain the following elements for each type of fixed gauge:
  - instructions for how to stop the use of the gauge
  - instructions for restricting access to the area
  - contact information for safety/emergency personnel (telephone numbers for the RSO, AUs, the gauge manufacturer or distributor, fire department, or other emergency response organization)

- guidelines for reporting to the NRC pursuant to 10 CFR 20.2202, “Notification of incidents,” 10 CFR 20.2203, “Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits,” 10 CFR 21.21, “Notification of failure to comply or existence of a defect and its evaluation,” and/or 10 CFR 30.50, “Reporting requirements”
  - descriptions of additional actions or precautions based on the specific situation
  - guidelines to follow when a gauge is involved in a transportation accident, if the license authorizes temporary job sites.
- Develop, implement, and maintain security procedures to prevent theft, loss, or sabotage that contain the following elements:
    - instructions to prevent unauthorized access, removal, or use of fixed gauges, including at temporary job sites if authorized on the license
    - requirements for reporting to the NRC pursuant to 10 CFR 20.2201, “Reports of theft or loss of licensed material,” and 10 CFR 20.2207, “Reports of transactions involving nationally tracked sources,” as appropriate
    - guidelines to meet the security requirements of 10 CFR 20.1801, “Security of stored material,” 10 CFR 20.1802, “Control of material not in storage,” and any other applicable security requirements
  - Provide copies of operating, emergency, and security procedures to all gauge users and at each site.
  - Post copies of operating and emergency procedures at each location of use, or if posting procedures is not practicable, post a notice that briefly describes the procedures and states where they may be examined.

**Discussion:** Applicants must develop, implement, and maintain operating and emergency procedures. The NRC will permit an applicant greater flexibility when licensing certain types of gauges. For each gauge that is requested, if one or more of the following safety conditions are met, the applicant need *not* submit these procedures for NRC review during the licensing process:

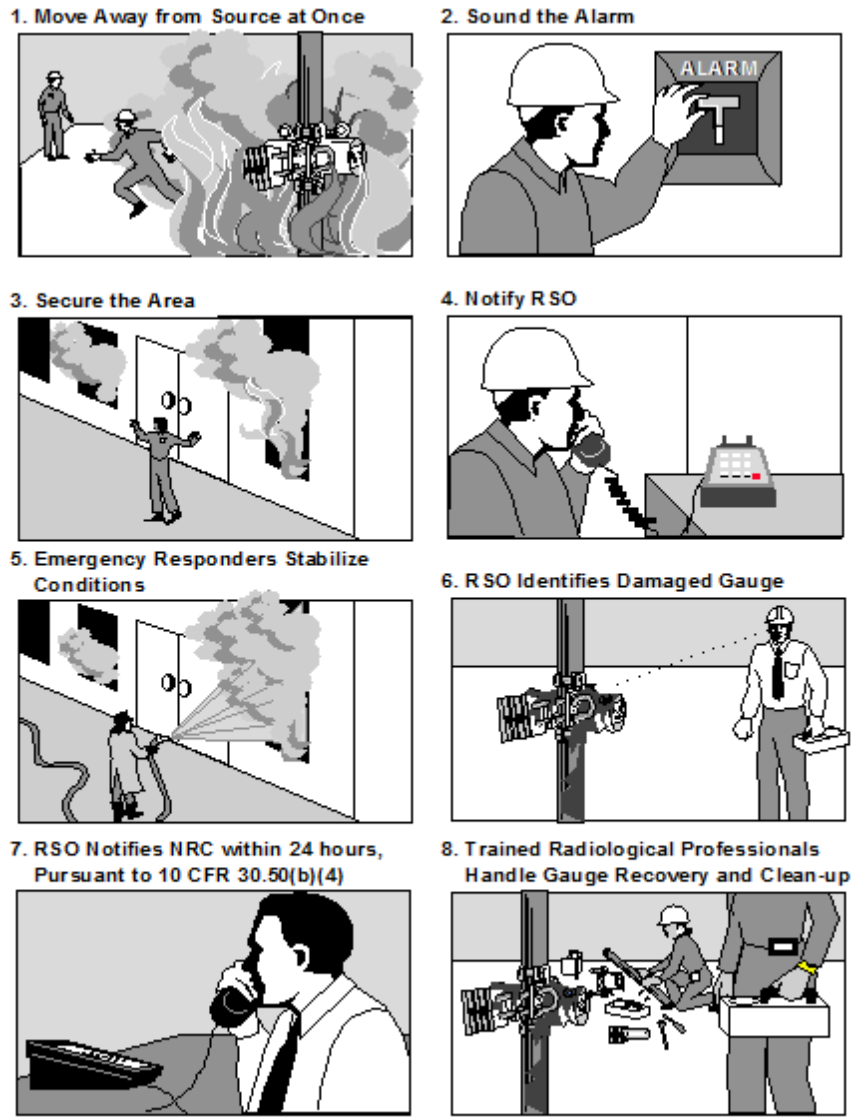
- The air gap between the radiation source and detector of the device is less than 45 centimeters (18 inches).
- The air gap of the device would not allow insertion of a 30-centimeters (12-inch) diameter sphere into the radiation beam of the device without removal of a barrier.
- The radiation dose rate in the radiation beam of the device at 45 centimeters (18 inches) from the radiation source with the device shutters, if any, in the open position does not exceed 1 mSv per hour (0.1 rem per hour).

- Entry into vessels (e.g., bins, tanks, hoppers, or pipes) with a gauge installed is not necessary under any foreseeable circumstances and is prohibited.

If the requested gauge does not meet any of the safety conditions above, then the applicant must submit its procedures to the NRC for review during the licensing process.

Operating, emergency, and security procedures should be developed, maintained, and implemented to ensure that gauges are used only as they were designed to be used, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA.

Improper operation could lead to the damage or malfunction of a gauge and elevated exposure rates in the gauge's immediate vicinity. A list of specific items that should be addressed in operating, emergency, and security procedures is contained in Appendix H. Figure 8.4 illustrates a proper response to a fire involving a fixed gauge. Emergency procedures should be developed to address a spectrum of incidents (e.g., fire, explosion, mechanical damage, flood, or earthquake).



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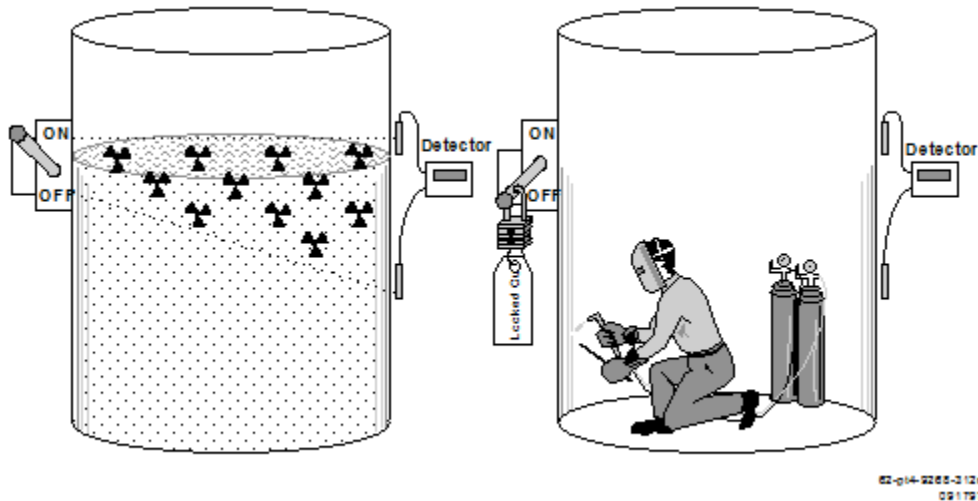
**Figure 8.4 Proper handling of incident**

*Licensee personnel implement emergency procedures when a fire melts the lead shielding of a gauge producing the potential for elevated exposure levels.*

The NRC considers the security of licensed material to be extremely important, and lack of security is a significant violation for which licensees may be fined. Although most fixed gauges are difficult to move, the licensee must prevent unauthorized access, removal, or use of the gauge. Licensees are responsible for ensuring that gauges are secured and accounted for at all times (e.g., during plant modifications, change in ownership, staffing changes, or after termination of activities at a particular location).

The NRC must be notified when gauges are lost or stolen or certain other conditions occur.

The RSO should be proactive in evaluating whether NRC notification is required. Refer to Appendix L to this report and the regulations (i.e., 10 CFR 20.2201–20.2203, 10 CFR 20.2207, 10 CFR 21.21, and 10 CFR 30.50) for a description of when and where notifications are required.



**Figure 8.5 Lock-out procedures**

*Typical lock-out procedures include locking the shutter into the “off” position and tagging the shutter control mechanism to indicate the gauge is locked out.*

When the distance or air gap between the source and detector permits entry of all or a portion of a person’s body into the primary radiation beam, licensees must develop lock-out procedures. Lock-out procedures encompass locking the on-off or shutter mechanism into the off position or otherwise controlling the radiation beam or using any other means of preventing an individual or a portion of an individual’s body from entering the radiation beam during maintenance, repairs, or work in, on, or around the process line (e.g., bin, tank, hopper, pipe, or conveyor belt) where the device is mounted. The on-off or shutter control mechanism should be tagged to indicate that the gauge is locked out. A warning sign should be posted at each entryway to an area where it is possible to be exposed to the radiation beam. In addition to providing a warning, the sign should give safety instructions (e.g., “contact the RSO before entering this vessel”). Lock-out procedures should specify who is responsible for performing them.

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

- If the gauge meets one or more of the safety conditions specified in “Discussion,” provide the following

A statement that “Operating, emergency, and security procedures will be developed, implemented, maintained, and distributed, and will meet the criteria in Section 8.10.6, ‘Operating, and Emergency Procedures’ in the current version of NUREG-1556, Volume 4, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses.’”

**OR**

- If the gauge does not meet any of the safety conditions specified in “Discussion,” provide your operating, emergency, security, and lock-out (if applicable) procedures to the NRC for review during the licensing process.

**Note:** When developing operating, emergency, and security procedures, applicants should consider the information contained in the following documents describing incidents involving fixed gauges:

- IN 81-37, Revision 1, “Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices,” dated February 9, 1982
- IN 86-31, “Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges,” dated May 5, 1986
- IN 88-02, “Lost or Stolen Gauges,” dated February 2, 1988
- IN 88-90, “Unauthorized Removal of Industrial Nuclear Gauges,” dated November 22, 1988
- IN 94-15, “Radiation Exposures during an Event Involving a Fixed Nuclear Gauge,” dated March 2, 1994

**References:** INs are available in the “NRC Library” on the NRC’s Home Page at <http://www.nrc.gov>.

### **8.10.7 Leak Tests**

**Regulations:** 10 CFR 20.1501, 10 CFR 20.2103, and 10 CFR 30.53

**Criteria:** The NRC requires testing to determine whether there is any radioactive leakage from the source in the fixed gauge. Records of the test results must be maintained for 3 years.

**Discussion:** Based on the conditions of the license, a licensee is required to perform leak tests at an interval approved by the NRC or an Agreement State in the device’s SSD registration certificate or at a more frequent interval that the licensee committed to in its license application.



The measurement of the leak test sample is a quantitative analysis that requires instrumentation capable of detecting 185 becquerels (0.005 microcuries) of radioactivity.

Manufacturers, distributors, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test sequence on behalf of licensees or provide leak test kits to licensees. In the latter case, the licensee takes the leak test sample according to the manufacturer's and/or the kit supplier's instructions and returns it to the leak test service provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves. Appendix I contains information to support a request to perform leak testing and sample analysis.

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

- A statement that "Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device registration certificate. Leak tests will be performed by an organization authorized by the 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 the NRC or an Agreement State to provide leak test kits to other licensees and according to the kit supplier's instructions. Records of leak test results will be maintained."

**OR**

- A statement that "We will implement the model leak test program published in Appendix I to the current version of NUREG-1556, Volume 4, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses.'"

**OR**

- A description of alternative equipment and/or procedures for determining whether there is any radioactive leakage from sources contained in gauges.

**Note:** Requests for authorization to perform leak testing and sample analysis will be reviewed and, if approved, will be authorized via a license condition.

#### **8.10.8 Maintenance**

**Regulations:** 10 CFR 20.1101, 10 CFR 30.33(a)(3), and 10 CFR 30.34(e)

**Criteria:** Licensees should routinely clean and maintain gauges according to the manufacturer's or distributor's written recommendations and instructions. Individuals performing routine maintenance must have adequate training and experience. Radiation safety procedures for routine cleaning and maintenance (e.g., removal of exterior residues from the gauge housing, shutter operation checks, external lubrication of shutter mechanism, calibration, and electronic repairs) must consider ALARA principles and ensure that the gauge functions as designed and source integrity is not compromised.

“Nonroutine maintenance or repair” (beyond routine cleaning, lubrication, calibration, and electronic repairs) means any maintenance or repair that involves or potentially affects components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control or shielding) and any other activities during which personnel could receive radiation doses exceeding the NRC’s regulatory dose limits.

The fixed gauge manufacturer or distributor, or a person specifically authorized by the NRC or an Agreement State, must perform nonroutine maintenance or repair. Appendix J presents information to support requests for specific authorization to perform nonroutine maintenance or repair.

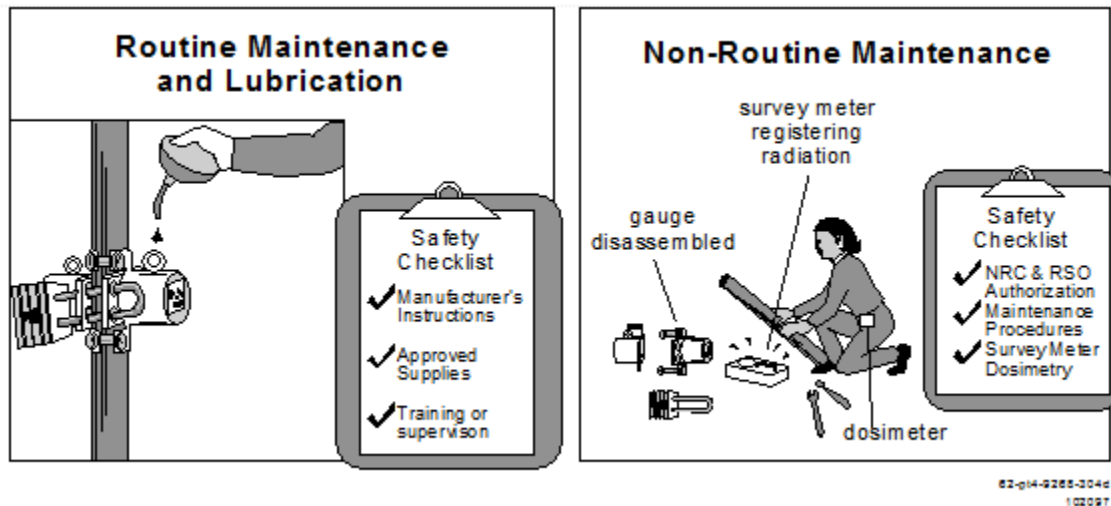


Figure 8.6 Maintenance

*Licensees need to perform routine maintenance to ensure proper operation of the fixed gauge. For nonroutine maintenance, most licensees use or contract the services of the gauge manufacturer, distributor, or a service company.*

**Discussion:** The NRC allows fixed gauge licensees to perform routine maintenance of the gauges. Licensees should follow the gauge manufacturer’s or distributor’s written recommendations and instructions provided with the gauge(s). Generally, before any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

- the tasks to be performed;
- the protocol or procedures to be followed;
- the radiation safety procedures including possible need for compensatory measures (i.e., steps taken to compensate for lack of or reduced shielding);
- ALARA considerations;
- training and experience of personnel performing the work;

- instructions for lock-out procedures;
- the qualification of parts, components, other materials to be used in the gauge; and
- the tests to be performed before the gauge is returned to routine use to ensure that it functions as designed.

Although manufacturers or distributors may use different terms, “routine maintenance” includes, but is not limited to, cleaning, lubricating, and calibrating the gauge and making electronic repairs. Routine maintenance also includes testing the proper operation of the gauge’s on-off mechanism (i.e., shutter checks) and indicator at intervals not to exceed 6 months or as specified in the SSD registration certificate. A standard license condition in all fixed gauge licenses imposes this requirement. Two NRC Information Notices: (1) IN 2009-18, “Performance of Required Shutter Checks and Reporting of Gauge Shutter Failures,” dated September 18, 2009, and (2) IN 2011-09, “Fixed Gauge Shutter Failures Due to Operating in Harsh Working Environments,” dated May 18, 2011, discuss the importance of performing shutter checks.

Routine maintenance does **not** include any activities that involve:

- components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control or shielding);
- installation, relocation, or alignment of the gauge;
- initial radiation surveys;
- replacement and disposal of sealed sources;
- removal of a gauge from service;
- a potential for any portion of the body to come into contact with the primary radiation beam; and
- any other activity during which personnel could receive radiation doses exceeding the NRC’s regulatory dose limits.

Mounting a gauge is unpacking or uncrating the gauge and fastening, hanging, or affixing the gauge into position before using. Mounting does not include electrical connection, activation, or operation of the gauge. Installing a gauge includes mounting, electrical connection, activation, and first use of the device. Specific NRC or Agreement State authorization on a license is required to install a gauge; however, a licensee may initially mount a gauge, without specific NRC or Agreement State authorization, if the gauge’s SSD registration certificate explicitly permits it. The conditions under which a licensee may initially mount a gauge will be specified on the license as a standard license condition if the licensee is not specifically authorized to install a gauge. The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person or entity specifically licensed by the NRC or an Agreement State to perform such operations.

A condition in the NRC license will state that operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service shall be performed only by the manufacturer, distributor, or other persons specifically licensed by the NRC or an Agreement State to perform such services. Most licensees do not perform nonroutine operations. Rather, these licensees use or contract the services of other licensees that have the specialized equipment and the technical expertise needed to perform these activities. Applicants seeking authorization to perform nonroutine operations must submit specific procedures for review. See Appendix J for more information.

**Response from Applicant:**

**For routine maintenance:** Submit either of the following:

- A statement that “We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer’s or distributor’s written recommendations and instructions.”

**OR**

- Alternative procedures for the NRC’s review.

**For nonroutine operations:** Submit either of the following:

- A statement that “The gauge manufacturer, distributor, or other person authorized by the NRC or an Agreement State will perform nonroutine operations such as installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources.”

**OR**

- Procedures using the information listed in Appendix J to support a request to perform nonroutine operations “in-house.”

**Notes:**

- Alternative procedures for performing routine maintenance will be evaluated using the criteria listed above.
- Requests for authorization to perform nonroutine operations will be reviewed and, if approved, will be authorized via a license condition.

**References:** INs are available in the “NRC Library” on the NRC’s Home Page at <http://www.nrc.gov>.

### 8.10.9 Transportation

**Regulations:** 10 CFR 20.1101, 10 CFR 71.5, and 49 CFR Parts 171–178

**Criteria:** Applicants must do one of the following:

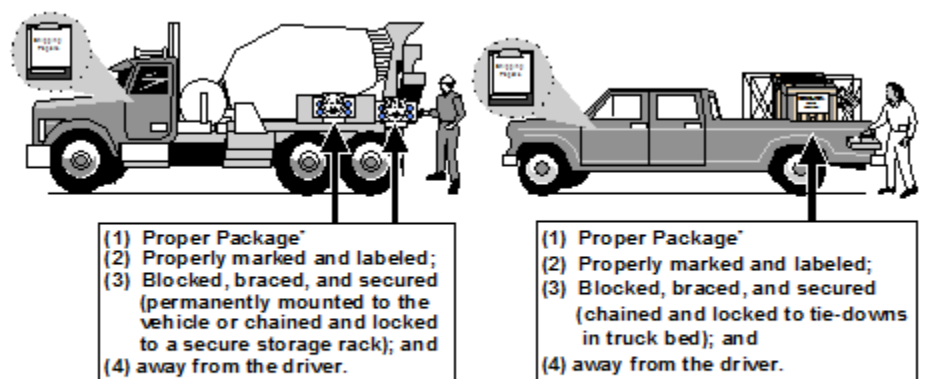
- Develop, implement, and maintain safety procedures for off-site transport of radioactive material to ensure compliance with DOT regulations.

**OR**

- Arrange for transportation of a gauge by the manufacturer, distributor, or other person specifically licensed to transport gauges by the NRC or Agreement State.

**Discussion:** Some fixed gauge licensees have the manufacturer, distributor, or other person specifically licensed to transport gauges by the NRC or Agreement State arrange for preparing and shipping licensed material. If licensees decide to transport their own gauges, they are responsible for compliance with DOT regulations including hazardous materials (hazmat) employee training.

Figure 8.7 illustrates some important DOT requirements for gauge licensees, and Appendix K lists applicable DOT regulations.



\*Many fixed gauges have been tested and certified as DOT Type A packages. Contact the gauge manufacturer for more information or to obtain copies of the performance test records.

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**Figure 8.7 DOT transportation requirements**

**Response from Applicant:** No response is needed from applicants during the licensing process; this issue will be reviewed during inspection.

**Reference:** “Radioactive Material Regulations Review,” published by DOT’s Pipeline and Hazardous Materials Safety Administration in December 2008, can be obtained at <http://www.phmsa.dot.gov>.

### 8.10.10 Fixed Gauges Used at Temporary Job Sites

**Regulations:** 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201–2203, 10 CFR 30.34(e), and 10 CFR 30.50.

**Criteria:** Each applicant requesting authorization to perform work with fixed gauges at temporary job sites must develop, implement, and maintain operating, emergency, and security procedures, as described in Section 8.10.6, "Operating and Emergency Procedures," and provide copies of those procedures to all gauge users and at each job site.

**Discussion:** A temporary job site is a location where work with licensed materials is conducted for a limited period of time. Temporary job sites are not specifically listed on a license. A gauge user may be dispatched to work at several temporary job sites in one day. A location is not considered a temporary job site if it is used to store *and* dispatch licensed material. The NRC considers such a location to be a field office. Licensees must apply for and receive a license amendment specifically listing each field office location.

There are two primary categories of fixed gauges used at temporary job sites: (1) gauges that are permanently mounted to vehicles or trailers and (2) gauges that are transported to industrial facilities and temporarily installed on process equipment to conduct short-term quality assurance and/or quality control studies (see Figure 8.8). The NRC also handles the licensing of sealed sources used for industrial diagnostic scanning at facilities and mobile nonintrusive scanning systems in the same manner as fixed gauges. These applications of radioactive materials may also be used at temporary job sites.

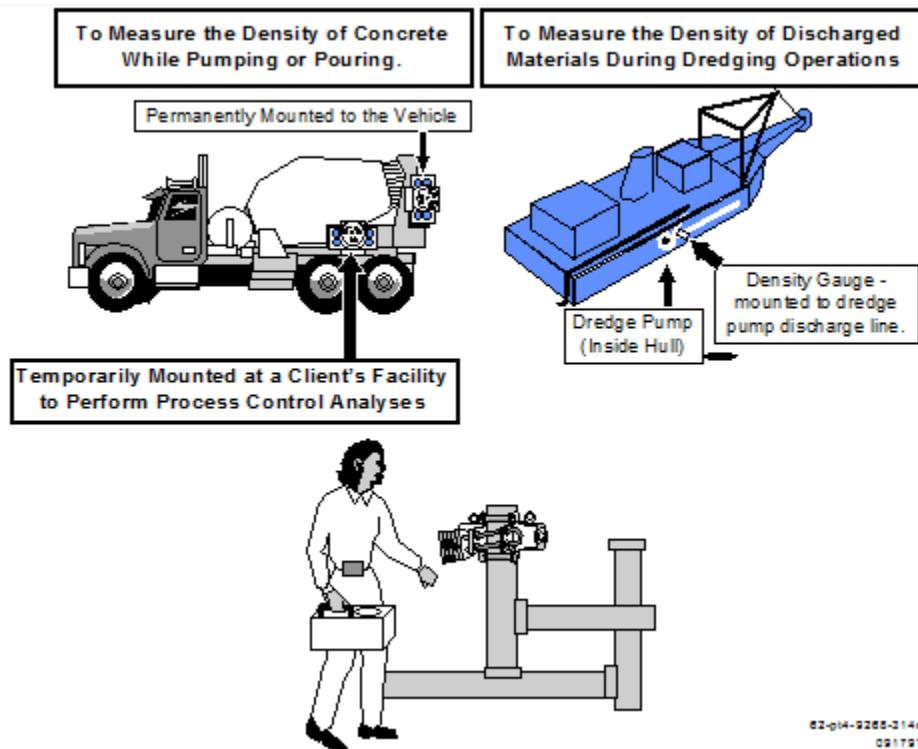
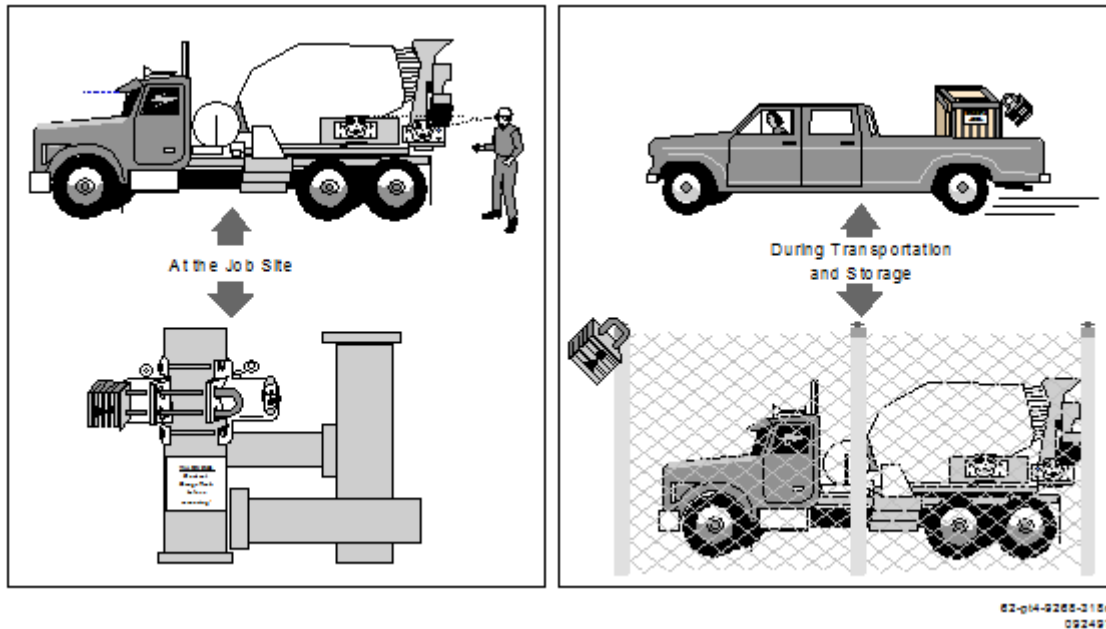


Figure 8.8 Examples of uses for fixed gauges at temporary job sites

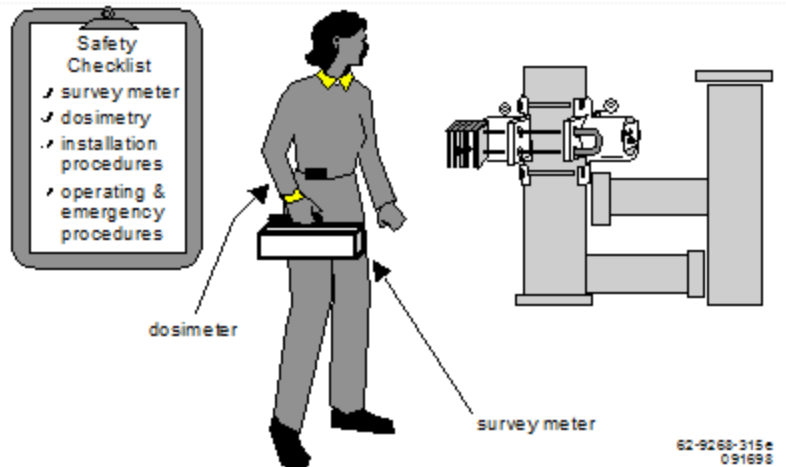
When working at a temporary job site, licensees generally have to follow the rules and procedures of the organization that owns or controls the site. Thus, licensees may not be able to restrict access to areas in the same manner that they can at their own facilities. Furthermore, non-licensee personnel may not be familiar with fixed gauges or radioactive material. Therefore, to avoid lost or stolen gauges and to prevent unnecessary radiation exposures to members of the public, licensees must keep gauges under constant surveillance, or secured against unauthorized use or removal (see Figure 8.9).



**Figure 8.9 Security**

*Examples of Methods Used To Secure Fixed Gauges at Temporary Job Sites.*

While installing gauges at a temporary job site, personnel could receive radiation doses exceeding NRC limits if they do not follow proper radiation safety principles. Licensee personnel performing installations should be assigned and wear dosimetry and use a survey meter to monitor radiological conditions (see Figure 8.10).



**Figure 8.10 Installation of fixed gauges at temporary job sites**

*Examples of the Additional Precautions Needed When Installing Fixed Gauges at Temporary Job Sites.*

After installing a gauge at a temporary job site, a radiation survey must be conducted to ensure that dose rates in unrestricted areas will not exceed 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year. If surveys indicate that a member of the public (e.g., client personnel) could receive a dose exceeding these limits, licensees would need to adopt additional measures to prevent public access, such as maintaining constant surveillance or erecting physical barriers.

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

- A statement that “We will not use fixed gauges at temporary job sites.”

**OR**

- A statement that “We will develop, implement, maintain, and distribute procedures that meet the criteria in Section 8.10.10, ‘Fixed Gauges Used at Temporary Job Sites,’ of NUREG-1556, Volume 4, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses.’ Copies of these procedures will be provided to all gauge users and will be available at all temporary job sites.”

**8.10.11 Security Program**

**Regulations:** 10 CFR 20.1801, 10 CFR 20.1802, and 10 CFR 20.2207

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

**Discussion:** The regulations in 10 CFR 20.1801, and 10 CFR 20.1802 require licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage. Depending on the quantity and type of radioactive materials used by fixed gauges, some licensees may be required to implement additional tracking and security requirements.



The regulations in 10 CFR 20.2207, “Reports of transactions involving nationally tracked sources,” require that each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NSTS). The NSTS is a major security initiative of the NRC. The NSTS is a secure, accessible and easy-to-use computer system that tracks high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern.

In addition to the regulations, the NRC in 2005 began issuing Orders imposing security requirements on licensees who possessed radioactive materials quantities of concern (RAMQC). The Orders required licensees to implement enhanced security to control access to RAMQC and to protect sensitive security-related information. In 2007, the NRC issued additional Orders to the same licensees requiring fingerprinting and criminal history records checks for unescorted access to RAMQC. The specific radionuclides and associated thresholds were based on the Category 1 and Category 2 quantities described in the IAEA’s “Code of Conduct on the Safety and Security of Radioactive Sources.”

Applicants and licensees should visit the NRC’s public Web site ([www.nrc.gov](http://www.nrc.gov)) and select the Nuclear Security tab at the top of the NRC home page for additional information regarding the security of licensed material or any enhanced security requirements imposed by Orders.

Please contact the appropriate regional office for questions regarding the security of licensed material or any enhanced security requirements imposed by the Orders.

### **8.11 Item 11: Waste Management—Gauge Disposal and Transfer**

**Regulations:** 10 CFR 20.2001, 10 CFR 20.2207, 10 CFR 30.36, 10 CFR 30.41, and 10 CFR 30.51

**Criteria:** Licensed materials must be disposed of in accordance with NRC requirements by transfer to an authorized recipient. Appropriate records must be maintained.

**Discussion:** When disposing of fixed gauges, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer or distributor of the device, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., its license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, the licensee must verify that the recipient is properly authorized to receive the licensed material using one of the methods described in 10 CFR 30.41, “Transfer of byproduct material.” In addition, all packages containing radioactive sources must be prepared and shipped in accordance with NRC and DOT regulations. Records of the transfer must be maintained by the licensee as required by 10 CFR 30.51, “Records.”

If source activity exceeds activities listed in Appendix E to 10 CFR Part 20, the transfer transaction must be reported in accordance with 10 CFR 20.2207.

**Response from Applicant:** The applicant does not need to provide a response to this item during the licensing process. However, the licensee should establish and include waste

disposal procedures in its radiation safety program.

**References:** See IN 86-31 and IN 88-02. INs are available in the “NRC Library” on the NRC’s Home Page at <http://www.nrc.gov>.

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

### **8.12 Item 12: License Fees**

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

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

### **8.13 Item 13: Certification**

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, a representative of the corporation or legal entity filing the application must sign and date NRC Form 313 and include his or her title. The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in Chapter 3, “Management Responsibility,” signing the application acknowledges management’s commitment to and responsibility for the radiation protection program. The NRC will return all unsigned applications for proper signature.

#### **Notes:**

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

## 9. AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109(a), 10 CFR 30.36(a)).

Applicants for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request.
- Submit either an NRC Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, the NRC's guidance, the licensee's organization, or the licensee's radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

### 9.1 Timely Notification of Transfer of Control

**Regulation:** 10 CFR 30.34(b)

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

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State 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:** No response is required from an applicant for a new license. However, current licensees should refer to NUREG-1556, Volume 15, for more information about transfer of ownership.

## 10. APPLICATIONS FOR EXEMPTIONS

**Regulations:** 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11

**Criteria:** Licensees may request exemptions from regulations. The licensee must demonstrate that the exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public interest.

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

Exemptions are not intended to revise regulations or apply to large classes of licensees and are generally limited to unique situations. Exemption requests must be accompanied by descriptions of the following:

- Exemption requested, basis, and justification for the requested exemption.
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested.
- Alternative methods for complying with the regulation and an explanation of why compliance with the existing regulation is not feasible.

Until the NRC has granted an exemption in writing, the agency expects strict compliance with all applicable regulations.
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## 11. TERMINATION OF ACTIVITIES

**Regulations:** 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36(d), 10 CFR 30.36(j)(1), 10 CFR 30.51(f)

**Criteria:** The licensee must do the following:

- Notify the NRC, in writing, within 60 days of the occurrence of any of the following:
  - Expiration of its license.
  - A decision to cease licensed activities permanently at the entire site.
  - A decision to cease licensed activities permanently in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements.
  - No principal activities under the license have been conducted for a period of 24 months.
  - No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements.
- Submit to the appropriate NRC regional office a completed NRC Form 314, “Certificate of Disposition of Materials” (or equivalent information), and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final leak tests).
- Before a license is terminated, send the records important to decommissioning to the appropriate NRC regional office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee in accordance with 10 CFR 30.35(g).

**Discussion:** Typically, a fixed gauge termination request will meet the above criteria if the licensee has performed the following steps:

- Dispose of or transfer the gauges to an NRC or Agreement State licensee authorized to possess these devices as described in Section 8.11, “Waste Management—Gauge Disposal and Transfer.”
- Copy applicable decommissioning records as described in Section 8.5.2 “Financial Assurance and Recordkeeping for Decommissioning.” Typically, this includes transfer records and final leak test records. See Section 8.5.2 for additional recordkeeping requirements if leaking sealed sources or other incidents that involve the spreading of contamination have occurred.
- Submit a completed NRC Form 314 and a copy of the applicable decommissioning records to the appropriate NRC regional office.

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

**Reference:** NRC Form 314 is available at <http://www.nrc.gov/reading-rm/doc-collections/forms>.



**APPENDIX A**

**U.S. NUCLEAR REGULATORY COMMISSION FORM 313**



## United States Nuclear Regulatory Commission Form 313

<b>NRC FORM 313</b> (05-2012) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40	<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	<b>APPROVED BY OMB: NO. 3150-0120</b>  Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.	<b>EXPIRES: (05/31/2015)</b>						
<b>APPLICATION FOR MATERIALS LICENSE</b>									
<b>INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.</b>									
<b>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</b>  OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001  <b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</b>  <b>IF YOU ARE LOCATED IN:</b>  ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,  <b>SEND APPLICATIONS TO:</b>  LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713	<b>IF YOU ARE LOCATED IN:</b>  ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, <b>SEND APPLICATIONS TO:</b>  MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352  ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,  <b>SEND APPLICATIONS TO:</b>  NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511								
<b>PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.</b>									
1. THIS IS AN APPLICATION FOR <i>(Check appropriate item)</i>  <input type="checkbox"/> A. NEW LICENSE  <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____  <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT <i>(Include ZIP code)</i>  _____  _____  _____								
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED  _____  _____  _____	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION  _____  BUSINESS TELEPHONE NUMBER _____ BUSINESS CELLULAR TELEPHONE NUMBER _____  BUSINESS EMAIL ADDRESS _____								
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.									
5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.  _____  _____								
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.  _____  _____								
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.  _____  _____								
11. WASTE MANAGEMENT.	12. LICENSE FEES <i>(See 10 CFR 170 and Section 170.31)</i>  <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%; border-bottom: 1px solid black;">FEE CATEGORY</td> <td style="width: 15%; border-bottom: 1px solid black; text-align: center;">AMOUNT</td> <td style="width: 15%; border-bottom: 1px solid black; text-align: center;">ENCLOSED \$</td> </tr> <tr> <td style="border-bottom: 1px solid black;"> </td> <td style="border-bottom: 1px solid black; text-align: center;"> </td> <td style="border-bottom: 1px solid black; text-align: center;"> </td> </tr> </table>			FEE CATEGORY	AMOUNT	ENCLOSED \$			
FEE CATEGORY	AMOUNT	ENCLOSED \$							
13. CERTIFICATION. <i>(Must be completed by applicant)</i> THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.  THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.									
CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE  _____		SIGNATURE  _____	DATE  _____						
<b>FOR NRC USE ONLY</b>									
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS				
			\$						
APPROVED BY				DATE					



**APPENDIX B**

**SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED  
IN ITEMS 5 THROUGH 11 OF U.S. NUCLEAR REGULATORY  
COMMISSION FORM 313**



**Items 5 & 6: Materials to be Possessed and Proposed Uses**

Yes	No	Radionuclide	Manufacturer or Distributor Model No.	Quantity	Use as Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Cobalt-60	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Require maximum possession limits per source or device and include the total possession limit.	Yes <input type="checkbox"/> Specific description of the gauge use: _____ _____ _____ _____	<input type="checkbox"/> Not applicable _____ <input type="checkbox"/> Uses are: _____ (Submit safety analysis supporting safe use)
		Krypton-85	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Require maximum possession limits per source or device and include the total possession limit.	Yes <input type="checkbox"/> Specific description of the gauge use: _____ _____ _____ _____	<input type="checkbox"/> Not applicable _____ <input type="checkbox"/> Uses are: _____ (Submit safety analysis supporting safe use)
		Strontium-90	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Require maximum possession limits per source or device and include the total possession limit.	Yes <input type="checkbox"/> Specific description of the gauge use: _____ _____ _____ _____	<input type="checkbox"/> Not applicable _____ <input type="checkbox"/> Uses are: _____ (Submit safety analysis supporting safe use)

Yes	No	Radionuclide	Manufacturer or Distributor Model No.	Quantity	Use as Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Cesium-137	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Require maximum possession limits per source or device and include the total possession limit..	Yes <input type="checkbox"/> Specific description of the gauge use: _____ _____ _____ _____	<input type="checkbox"/> Not applicable _____ <input type="checkbox"/> Uses are: _____ (Submit safety analysis supporting safe use)
		Americium-241	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Require maximum possession limits per source or device and include the total possession limit.	Yes <input type="checkbox"/> Specific description of the gauge use: _____ _____ _____ _____	<input type="checkbox"/> Not applicable _____ <input type="checkbox"/> Uses are: _____ (Submit safety analysis supporting safe use)
		Other Isotope (Specify):	Sealed source manufacturer or distributor and model number: _____ Device manufacturer or distributor and model number: _____	Require maximum possession limits per source or device and include the total possession limit.	Yes <input type="checkbox"/> Specific description of the gauge use: _____ _____ _____ _____	<input type="checkbox"/> Not applicable _____ <input type="checkbox"/> Uses are: _____ (Submit safety analysis supporting safe use)
Is financial assurance required? If yes, submit evidence of financial assurance						



**Items 7 Through 11: Training and Experience,  
Facilities and Equipment, Radiation Safety Program,  
and Waste Disposal**

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
7. Individual(s) Responsible For Radiation Safety Program and Their Training and Experience  7.1 Radiation safety officer  Name: _____	Provide documentation of the proposed radiation safety officer's training and experience.	Submit applicable documentation.	
7. Individual(s) Responsible For Radiation Safety Program and Their Training and Experience  7.2 Authorized users	Before using licensed materials, authorized users will have successfully completed one of the training courses described in the "Criteria" part of the section entitled "Authorized Users" in the current version of NUREG-1556, Volume 4, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses."	<input type="checkbox"/>	<input type="checkbox"/>
8. Training for Individuals Who in the Course of Employment are Likely to Receive Occupational Doses of Radiation in Excess of 1 mSv (100 mrem) in a Year (Occupationally Exposed Workers) and Ancillary Personnel	The applicant is <i>not</i> required to, and should not, submit its training program for individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 1 mSv (100 mrem) in a year (occupationally exposed workers) and ancillary personnel to the NRC for review during the licensing phase.	Need not be submitted with application.	





Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10. Radiation Safety Program – Leak Tests	<p>Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate. Leak tests will be performed by an organization authorized by the 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 the NRC or an Agreement State to provide leak test kits to other licensees and according to the kit supplier's instructions.</p> <p style="text-align: center;"><b>OR</b></p> <p>We will implement the model leak test program published in Appendix I of the current version of NUREG-1556, Volume 4, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses."</p>	<input type="checkbox"/>          <input type="checkbox"/>	<input type="checkbox"/>
10. Radiation Safety Program – Maintenance	<p><u>ROUTINE MAINTENANCE</u> We will implement and maintain procedures for routine maintenance of our fixed gauges according to each manufacturer's or distributor's written recommendations and instructions.</p> <p><u>NONROUTINE MAINTENANCE OPERATIONS</u> The gauge manufacturer, distributor, or other person authorized by the NRC or an Agreement State will perform nonroutine operations, such as installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources.</p>	<input type="checkbox"/>          <input type="checkbox"/>	<input type="checkbox"/>          <input type="checkbox"/> The information listed in Appendix J, "Information Needed to Support Applicant's Request to Perform Nonroutine Operations," is attached.
10. Radiation Safety Program – Transportation	The applicant is <i>not</i> required to submit its response about transportation during the licensing process. This issue will be reviewed during NRC inspections.	Need not be submitted with application.	

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10. Radiation Safety Program – Fixed Gauges Used at Temporary Job Sites	<p>We will not use fixed gauges at temporary job sites.</p> <p style="text-align: center;"><b>OR</b></p> <p>We will develop, implement, maintain, and distribute procedures that meet the criteria in Section 8.10.10, "Fixed Gauges Used at Temporary Job Sites," in the current version of NUREG-1556, Volume 4, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses," and provide copies of these procedures to all gauge users and make them available at all temporary job sites.</p>	<input type="checkbox"/>          <input type="checkbox"/>	<input type="checkbox"/>
10. Radiation Safety Program – Security Program	Licensees must ensure the security and control of licensed material. The regulations in 10 CFR 20.1801 and 20.1802 require licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.	Need not be submitted with application.	
11. Waste Management – Gauge Disposal & Transfer	The applicant is not required to submit a response to waste management during the licensing process; however, the licensee should develop, implement, and maintain gauge transfer and disposal procedures in its radiation protection program.	Need not be submitted with application.	



## **APPENDIX C**

### **TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER**





The RSO's duties and responsibilities (illustrated in Figure 8.2) typically include ensuring the following:

- Licensed activities that the RSO considers unsafe are stopped.
- Radiation exposures are kept as low as is reasonably achievable (ALARA).
- Up-to-date operating and emergency procedures are developed, implemented, maintained, and distributed.
- Individuals who use fixed gauges are properly trained.
- Possession, installation, relocation, use, storage, routine maintenance, and nonroutine operations of fixed gauges are consistent with the limitations in the license, the Sealed Source and Device registration certificate(s), and the manufacturer's or distributor's recommendations and instructions.
- Safety consequences of nonroutine operations are analyzed before conducting any such activities that have not been previously analyzed.
- Nonroutine operations are performed by the manufacturer, distributor, or person specifically authorized by the NRC or an Agreement State.
- Prospective evaluations are performed to demonstrate that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits or that personnel monitoring devices are provided.
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- Documentation is maintained to demonstrate, by measurement or calculation, that the dose to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in 10 CFR 20.1301, "Dose limits for individual members of the public."
- Fixed gauges are properly secured.
- Proper authorities are notified in case of accident, damage to, or malfunction of fixed-gauges, fire, loss, or theft.
- Unusual occurrences involving the fixed gauge (e.g., malfunctions or damage) are investigated, cause(s) are determined, and appropriate corrective action(s) are taken.
- Audits are performed and documented at least annually, and corrective actions are taken.
- When the licensee identifies violation(s) of regulations or license conditions or program weaknesses, corrective action(s) are developed, implemented, and documented.

- Licensed material is transported in accordance with all applicable NRC and DOT requirements.
- Licensed material is disposed of properly.
- All required records are maintained.
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.
- Posting of documents required by 10 CFR 19.11, "Posting of notices to workers," and 10 CFR 21.6, "Posting Requirements," or posting a notice indicating where these documents can be examined. Required documents include the following:
  - 10 CFR Part 19;
  - 10 CFR Part 20;
  - license documents;
  - operating procedures;
  - any notice of violation involving radiological working conditions, proposed imposition of civil penalty, order, or any licensee response;
  - NRC Form 3, "Notice to Employees";
  - 10 CFR Part 21;
  - Section 206 of the Energy Reorganization Act of 1974; and
  - procedures adopted under 10 CFR Part 21.

**Model Delegation of Authority to RSO**

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

You, \_\_\_\_\_, have been appointed radiation safety officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend \_\_\_\_\_ hours per week conducting radiation protection activities.

\_\_\_\_\_  
Signature of Management Representative

\_\_\_\_\_  
Date

I accept the above responsibilities,

\_\_\_\_\_  
Signature of Radiation Safety Officer

\_\_\_\_\_  
Date

**cc: Affected department heads**



## **APPENDIX D**

### **CRITERIA FOR ACCEPTABLE TRAINING FOR AUTHORIZED USERS AND RADIATION SAFETY OFFICERS**



## Course Content

Classroom training may be in the form of lectures, videos, computer-based sessions, or self-study lessons that emphasize practical subjects important to the safe use of the gauge including:

### Radiation Safety:

- radiation versus contamination
- internal versus external exposure
- biological effects of radiation
- types and relative hazards of radioactive material possessed
- ALARA concept
- use of time, distance, and shielding to minimize exposure
- location of sealed source within the gauge

### Regulatory Requirements:

- applicable regulations
- license conditions, amendments, and renewals
- locations of use and storage of radioactive materials
- material control and accountability
- annual audit of radiation safety program
- transfer and disposal
- recordkeeping
- prior events involving fixed gauges
- handling incidents
- recognizing and ensuring that radiation warning signs are visible and legible
- licensing and inspection by regulatory agency
- need for complete and accurate information
- employee protection
- deliberate misconduct

### Practical Explanation of the Theory and Operation for Each Gauge Possessed by the Licensee:

- operating and emergency procedures
- routine versus nonroutine maintenance
- lock-out procedures

### Supervised, Hands-On Experience (On-the-Job Training) Involving:

- operating procedures
- test runs of emergency procedures
- routine maintenance
- lock-out procedures

**Note:** On-the-job training must be done under the supervision of an AU or RSO.

## **Training Assessment**

Management will ensure that proposed AUs are qualified to work independently with each type of gauge with which they may work. Management will ensure that proposed RSOs are qualified to work independently with and are knowledgeable of the radiation safety aspects of all types of gauges that may be possessed by the applicant.

## **Course Instructor Qualifications**

Instructors should have, at a minimum, the following:

- successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent);
- successful completion of an 8-hour radiation safety course or radiation safety officer training course; and
- documentation of 8 hours of hands-on experience with fixed gauges.

**OR**

- The applicant may submit a description of alternative training and experience for the course instructor.

**Note:** Additional training is required for those applicants intending to perform nonroutine operations, such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service. See Appendix J, "Information Needed to Support Applicant's Request to Perform Nonroutine Operations."



## **APPENDIX E**

### **Suggested Fixed Gauge Audit Checklist**



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

Licensee's name \_\_\_\_\_ License No. \_\_\_\_\_

Date of This Audit \_\_\_\_\_ Date of Last Audit \_\_\_\_\_

Audit Date Range \_\_\_\_\_

\_\_\_\_\_  
Date \_\_\_\_\_

(Auditor Signature)

\_\_\_\_\_  
Date \_\_\_\_\_

(Management Signature)

## 1. **Audit History**

- A. Last audit of this location conducted on (date) \_\_\_\_\_
- B. Were previous audits conducted periodically (at least annually)? (10 CFR 20.1101)
- C. Were records of previous audits maintained? (10 CFR 20.2102)
- D. Were any deficiencies identified during the last two audits or two years, whichever is longer?
- E. Were corrective actions taken? (Look for repeated deficiencies).

## 2. **Organization and Scope of Program**

- A. If the mailing address or places of use changed, was the license amended?
- B. If ownership changed or bankruptcy was filed, did the licensee obtain prior NRC consent or notify the NRC?
- C. If the licensee changed the RSO, was the license amended?
- D. Sealed Sources and Devices
  - 1. Does the license authorize all of the NRC-regulated radionuclides contained in the gauges possessed?
  - 2. Are the gauges as described in the SSD registration certificate?
  - 3. Are copies of (or access to) SSD registration certificates available?
  - 4. Are manufacturers' or distributors' manuals for operation and

maintenance available? (10 CFR 32.210)

5. Are the actual uses of gauges consistent with the authorized uses listed on the license?
6. Are the locations of the gauges compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSD registration certificates?

### **3. Training and Instructions to Workers**

- A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per 10 CFR 19.12? Was refresher training provided, as needed? Were records maintained?
- B. Did each AU receive training and instruction given at the time of gauge installation or equivalent training and instruction before using gauges?
- C. Are training records maintained for each AU?
- D. Did individuals who perform nonroutine operations receive training before performing these operations?
- E. Did interviews with AUs reveal that they know the operating, emergency, and security procedures?
- F. Did this audit include observations of AUs using the gauge?
- G. Did this audit include observations of workers performing routine cleaning and lubrication on the gauge?
- H. Was DOT hazardous materials (HAZMAT) training provided, if required? (49 CFR 172.700, 172.701, 172.702, 172.704)

### **4. Radiation Survey Instruments**

- A. If the licensee is required to possess a survey meter, does it meet the NRC's criteria? (10 CFR 20.1501)
- B. Are calibration records maintained, if applicable? (10 CFR 20.2103(a))
- C. If the licensee does not possess a survey meter, are specific plans made to have one available?

### **5. Gauge Inventory**

- A. Is a record kept showing the receipt of each gauge? (10 CFR 30.51(a)(1))
- B. Are all gauges physically inventoried every 6 months?
- C. Are records of inventory results with appropriate information maintained?

## 6. Personnel Radiation Protection

- A. Are considerations for keeping doses as low as is reasonably achievable (ALARA) incorporated into the radiation protection program? (10 CFR 20.1101(b))
- B. Were prospective evaluations performed showing that unmonitored individuals receive  $\leq 10$  percent of the NRC limits in 10 CFR 20.1201(a)? (10 CFR 20.1502(a))
- C. Did unmonitored individuals' activities change during the year in a way that could put them over 10 percent of the NRC limit? If yes, was a new evaluation performed?
- D. If external dosimetry is required (i.e., when individuals are likely to receive  $> 10$  percent of the NRC limit), is dosimetry provided to these individuals? If yes, address the following:
  - 1. Is the dosimetry supplier approved by the National Voluntary Laboratory Accreditation Program? (10 CFR 20.1501(c))
  - 2. Are the dosimeters exchanged at the appropriate frequency?
  - 3. Are dosimetry reports reviewed and signed by the RSO when they are received?
  - 4. Are the records based on NRC Forms or the equivalent? (10 CFR 20.2104(d) and 20.2106(c))
    - a. Is NRC Form 4, "Cumulative Occupational Exposure History," completed?
    - b. Is NRC Form 5, "Occupational Dose Record for a Monitoring Period," completed?
  - 5. Are there any declared pregnant workers?
    - a. If a worker declared her pregnancy, did the licensee comply with 10 CFR 20.1208, "Dose equivalent to an embryo/fetus"?
    - b. Were records kept of doses to an embryo/fetus per 10 CFR 20.2106(e)?
- E. Are records of exposures, surveys, monitoring, and evaluations maintained? (10 CFR 20.2102, "Records of radiation protection programs"; 10 CFR 20.2103, "Records of surveys"; 10 CFR 20.2106, "Records of individual monitoring results")

**7. Public Dose**

- A. Is public access to gauges controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? (10 CFR 20.1301(a)(1))
- B. Has a survey or evaluation been performed per 10 CFR 20.1501(a)? Have there been any additions or changes to the storage, security, or use of the surrounding areas that would necessitate a new survey or evaluation?
- C. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour? (10 CFR 20.1301(a)(2))
- D. Is gauge access controlled in a manner that would prevent unauthorized use or removal? (10 CFR 20.1801)
- E. Are records of surveys maintained? (10 CFR 20.2103, 10 CFR 20.2107)

**8. Operating and Emergency Procedures**

**Note:** An ideal way to assess the adequacy and adherence to operating procedures is by observing work in progress.

- A. Have operating and emergency procedures been updated to incorporate any new elements, practices, or requirements?
- B. Does each individual working with the gauges have current copies of the operating and emergency procedures (including lock-out procedures and emergency telephone numbers)?
- C. Is a lock-out warning sign posted at each entryway to an area where it is possible to be exposed to the beam?
- D. Did any emergencies occur?
  - 1. If so, were they handled properly?
  - 2. Were appropriate corrective actions taken?

**9. Leak Tests**

- A. Were sealed source leak tests performed at the prescribed intervals?
- B. Was the leak test performed in accordance with license requirements?
- C. Are records of leak test results retained with all of the required information included?
- D. Were any sources found to be leaking and if yes, was the NRC notified?

## 10. Maintenance of Gauges

- A. Are manufacturers' or distributors' procedures followed for routine cleaning and lubrication of gauges?
- B. Was each on-off mechanism tested for proper operation every 6 months or at other approved intervals?
- C. Are repair and maintenance of components related to the radiological safety of the gauge performed by the manufacturer, distributor, or person specifically authorized by the NRC or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with 10 CFR 20.1301 limits)?
- D. Are labels, signs, and postings identifying gauges containing radioactive material, radiation areas, and lock-out procedures and warnings clean and legible?

## 11. Transportation

**Note:** This section will not apply if you have not transported gauges during the period covered by this audit.

- A. Were DOT-7A or other authorized packages used? (49 CFR 173.415, "Authorized Type A Packages"; 49 CFR 173.416, "Authorized Type B Packages")
- B. Are package performance test records on file?
- C. For any special form source, is the International Atomic Energy Agency Certificate of Competent Authority or other safety analysis documentation maintained on file? (49 CFR 173.476(a))
- D. Were packages properly labeled? (49 CFR 172.403, "Class 7 (radioactive) material")
- E. Were packages properly marked? (49 CFR 172.301, "General marking requirements for non-bulk packagings"; 49 CFR 172.304, "Marking requirements"; 49 CFR 172.310, "Class 7 (radioactive) materials"; 49 CFR 172.324, "Hazardous substances in non-bulk packagings")
- F. Were packages closed and sealed before transport? (49 CFR 173.475(f))
- G. Were shipping papers prepared and used? (49 CFR 172.200(a))
- H. Did shipping papers contain proper entries (i.e., identification number (United Nations (UN) number), shipping name, hazard class, total quantity, package type, nuclide, reportable quantity (RQ), if applicable, physical and chemical form, activity (International System of Units required), category of label, Transportation Index (TI), shipper's name, certification and signature, emergency response phone number, cargo aircraft only (if applicable)? (49 CFR 172.200, "Applicability"; 49 CFR 172.201, "Preparation and retention of shipping papers"; 49 CFR 172.202, "Description of hazardous material on shipping papers";

49 CFR 172.203, "Additional description requirements"; 49 CFR 172.204, "Shipper's certification"; 49 CFR 172.604, "Emergency response telephone number")

- I. Were shipping papers within the driver's reach and readily accessible during transport? (49 CFR 177.817(e))
- J. Were packages secured against movement? (49 CFR 177.834, "General requirements")
- K. Were placards on the vehicle, if needed? (49 CFR 172.504, "General placarding requirements")
- L. If applicable, were proper overpacks used? (49 CFR 173.25, "Authorized packagings and overpacks")
- M. Were any incidents reported to DOT? (49 CFR 171.15, "Immediate notice of certain hazardous materials incidents"; 49 CFR 171.16, "Detailed hazardous materials incident reports")

## **12. Auditor's Independent Survey Measurements (If Made)**

Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits? (10 CFR 20.1501(a), 10 CFR 20.1502(a))

## **13. Notifications and Reports**

- A. Was any radioactive material lost or stolen? Were reports made? (10 CFR 20.2201)
- B. Did any reportable incidents occur? Were reports made? (10 CFR 20.2202, "Notification of incidents"; 10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation"; 10 CFR 30.34, "Terms and conditions of licenses"; 10 CFR 30.36, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas"; 10 CFR 30.50, "Reporting requirements")
- C. Did any overexposures or high radiation levels occur? Were reports made? (10 CFR 20.2203)
- D. If any events (as described in items a through c above) did occur, what was the root cause? Were corrective actions appropriate?
- E. Is the licensee aware of the telephone number for the NRC Emergency Operations Center, which is 301-816-5100?

## **14. Posting and Labeling**

- A. Is NRC Form 3, "Notice to Workers," posted? (10 CFR 19.11)
- B. Are NRC regulations and license documents posted, or is a notice posted stating



where these documents are located? (10 CFR 19.11, 10 CFR 21.6)

- C. Is there any other posting and labeling? (10 CFR 20.1902, "Posting requirements"; 10 CFR 20.1904, "Labeling containers")

**15. Record Keeping for Decommissioning**

- A. Are records kept of information important to decommissioning? (10 CFR 30.35(g))
- B. Do records include all information outlined in 10 CFR 30.35(g)?

**16. Bulletins and Information Notices**

- A. Are NRC Bulletins, NRC Information Notices (INs), and FSME Newsletters received?
- B. Is appropriate training and action taken in response to these?

**17. Special License Conditions or Issues**

Did the auditor review special license conditions or other issues (e.g., nonroutine maintenance)?

**18. Evaluation of Other Factors**

- A. Is senior licensee management appropriately involved with the radiation protection program and/or RSO oversight?
- B. Does the RSO have sufficient time to perform his or her radiation safety duties?
- C. Does the licensee have sufficient staff to support the radiation protection program?

**19. Deficiencies Identified in Audit and Corrective Actions**

- A. Summarize problems/deficiencies identified during the audit.
- B. If problems/deficiencies are identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at all licensed locations (not just the location audited)? Include date(s) when corrective actions are implemented.
- C. Provide any other recommendations for improvement.



**APPENDIX F**

**MODEL SURVEY INSTRUMENT CALIBRATION PROGRAM**



## **Training**

Before independently calibrating survey instruments, an individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
  - principles and practices of radiation protection;
  - radioactivity measurements, monitoring techniques, and the use of radiation detection instruments;
  - mathematics related to the use and measurement of radioactivity; and
  - biological effects of radiation.
- On-the-job training will be considered complete if the individual has completed both of the following:
  - observed authorized personnel performing survey instrument calibration; and
  - conducted survey meter calibrations under the supervision and in the physical presence of an individual already authorized to perform calibrations.

## **Facilities and Equipment**

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

## **Model Procedure for Calibrating Survey Instruments**

- A radioactive sealed source(s) will be used for calibrating survey instruments, and this source will incorporate the following:
  - approximate a point source;
  - have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within  $\pm 5$  percent accuracy by the National Institutes of Standards and Technology (NIST);
  - contain a radionuclide that emits radiation of identical or similar type and energy as the sealed sources that the instrument will normally measure; and

- be strong enough to emit a radiation field that is representative of the field being emitted by the gauge. For calibration of instruments intended to measure gamma radiation, the exposure rate should be at least 7.7 microcoulomb per kilogram per hour (30 milliroentgen per hour) at 100 centimeters (e.g., 3.1 gigabecquerels (85 millicuries) of cesium-137 or 780 megabecquerels (21 millicuries) of cobalt-60).
- Inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration.
- A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than  $\pm 20$  percent.
- There are three kinds of scales frequently used on radiation survey meters. They are calibrated either as described in American National Standards Institute (ANSI) N323A-1997, "American National Standard Radiation Protection Instrumentation Test and Calibration – Portable Survey Instruments," or as follows:
  - Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately 1/3 and 2/3 of the decade.
  - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade.
  - Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.
- Readings above 50 microcoulomb per kilogram per hour (200 milliroentgen per hour) need not be calibrated; however, higher scales should be checked for operation and approximately correct response.
- Survey meter calibration reports will indicate the procedure used and the results of the calibration. The reports will include the following:
  - the owner or user of the instrument;
  - a description of the instrument that includes the manufacturer's name, model number, serial number, and type of detector;
  - a description of the calibration source, including the exposure rate at a specified distance on a specified date, and the calibration procedure;

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

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

- the source used to calibrate the instrument;
- the proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
- for each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated;
- the date of calibration and the next calibration due date; and
- the apparent exposure rate from the check source, if used.

**References:** Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1997, “American National Standard Radiation Protection Instrumentation Test and Calibration – Portable Survey Instruments.” Copies may be ordered online at <http://www.ansi.org>.





**APPENDIX G**  
**DOSIMETRY-RELATED GUIDANCE**



## **Part 1: Guidance for Demonstrating that Unmonitored Individuals Are Not Likely To Exceed 10 Percent of the Allowable Limits**

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the applicable regulatory limits in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201, "Occupational dose limits for adults." Therefore, a licensee should evaluate the doses its workers receive in performing their duties to assess whether dosimetry is required.

### **Example**

**Note:** The examples in this appendix use conventional units. The conversions to International System of Units are as follows: 1 foot = 0.305 meter; 0.01 mSv = 1 mrem.

A gauge manufacturer has estimated the doses to the extremities and whole body of a person replacing the assay plate on one of its series of gauges. Each gauge in the series is authorized to contain up to 7.4 gigabecquerels (200 millicuries) of Cs-137. The manufacturer based its estimate on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer had the following information:

- time needed to perform the entire procedure (e.g., 15 minutes)
- expected dose rate received by the whole body of the individual, associated with the shielded source and determined using measured or manufacturer-determined data (e.g., 0.02 mSv per hour (2 mrem per hour) at 46 centimeters (18.1 inches) from the shield)
- time the hands were exposed to the shielded source (e.g., 6 minutes)
- expected dose rate received by the extremities of the individual, associated with the shielded source and determined using measured or manufacturer-determined data on contact with the shield (e.g., 0.15 mSv per hour (15 mrem per hour)).

From this information, the manufacturer estimated that the individual performing each routine cleaning and lubrication could receive the following:

- less than 0.005 mSv (0.5 mrem) to the whole body and
- 0.015 mSv (1.5 mrem) to the hands.

The applicable whole body dose limit is 50 mSv (5 rem) per year and 10 percent of that value is 5 mSv (500 mrem) per year. If one of these procedures delivers 0.005 mSv (0.5 mrem), then an individual could perform 1,000 of these procedures each year and remain within 10 percent of the applicable limit.

The applicable extremity dose limit is 500 mSv (50 rem) per year and 10 percent of that value is 50 mSv (5 rem or 5,000 mrem) per year. If one of these procedures delivers 0.015 mSv (1.5 mrem), then an individual could perform 3,333 of these procedures each year and remain within 10 percent of the applicable limit.

Based on the above specific situation, no dosimetry is required if a worker performs fewer than 1,000 routine maintenance procedures per year.

## Guidance to Licensees

Licensees who wish to demonstrate that they are *not* required to provide dosimetry to their workers must prepare a written evaluation similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may *not* be appropriate to individual licensee situations. In their evaluations, licensees must use information appropriate to the various types of gauges on which they will perform routine cleaning and lubrication. This information is generally available from gauge manufacturers or the SSD registration certificate maintained by the NRC or Agreement State.

Table G.1 may be helpful in documenting a licensee's evaluation.

Licensees should review evaluations periodically and revise them as needed. They should check assumptions used in their evaluations to ensure that the assumptions are up-to-date and accurate. For example, if workers became lax in following good radiation safety practices in the example used above, the extremities could be closer to the unshielded source, and the workers would receive more exposure than 0.15 mSv (15 mrem) per minute. Alternatively, workers could perform the task more slowly than the estimated 10 minutes total and 3 minutes with their hands near the unshielded source. Also, using new gauges containing sources of different activities, different radionuclides, or different cleaning and lubrication procedures requires a new evaluation.

**Table G.1 Dosimetry Evaluation**

Dosimetry Evaluation for _____		Model _____	Fixed Gauge _____
A.	Time needed to perform the entire routine cleaning and lubrication procedure on the gauge	_____ minutes	_____ hour (divide # of minutes by 60)
B.	Expected whole-body dose rate that the individual will encounter, determined using measured or manufacturer-provided data	_____ mrem/hour	
C.	Time the <i>hands</i> were exposed to the unshielded source	_____ minutes	_____ hour
D.	Expected extremity dose rate that the individual will encounter, determined using measured or manufacturer-provided data for the unshielded source at the typical distance from the hands to the unshielded source	_____ mrem/hour	
Estimated Whole Body Dose Equivalent*			
Formula: (_____ hours in Row A) x (_____ mrem/hour in Row B) = (_____ estimated mrem) x (_____ # of cleaning and lubrications conducted each year) = _____ Whole Body Dose mrem			
Estimated Extremity Dose Equivalent**			
Formula: (_____ hours in Row C) x (_____ mrem/hour in Row D) = (_____ estimated mrem) x (_____ # of cleaning and lubrications conducted each year) = _____ Extremity Dose mrem			

\* An expected Whole Body Dose Equivalent *less than* 500 mrem requires no dosimetry.

\*\* An expected Extremity Dose Equivalent *less than* 5000 mrem requires no dosimetry.

## **Part 2: Guidance for Demonstrating that Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits**

Licensees must ensure the following:

The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in 1 calendar year resulting from the licensee's possession and/or use of licensed materials.

**Members of the public include persons who live, work, or may be near locations where fixed gauges are used or stored. Employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where gauges are used or stored are also considered members of the public.**

The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any 1 hour.

**Typical unrestricted areas may include offices, shops, laboratories, a nearby walkway, areas outside buildings, and non-radioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons, such as security.**

Licensees must show compliance with both of these portions of the regulations. Calculations and measurements (e.g., using a dosimeter to monitor an area) are often used to prove compliance.

### **Calculational Method**

The calculational method takes a tiered approach, using a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each gauge is a point source, (2) typical radiation levels encountered when the source is in the shielded position are taken from either the SSD registration certificate or the manufacturer's literature, and (3) no credit is taken for any shielding found between the gauges and the unrestricted areas.

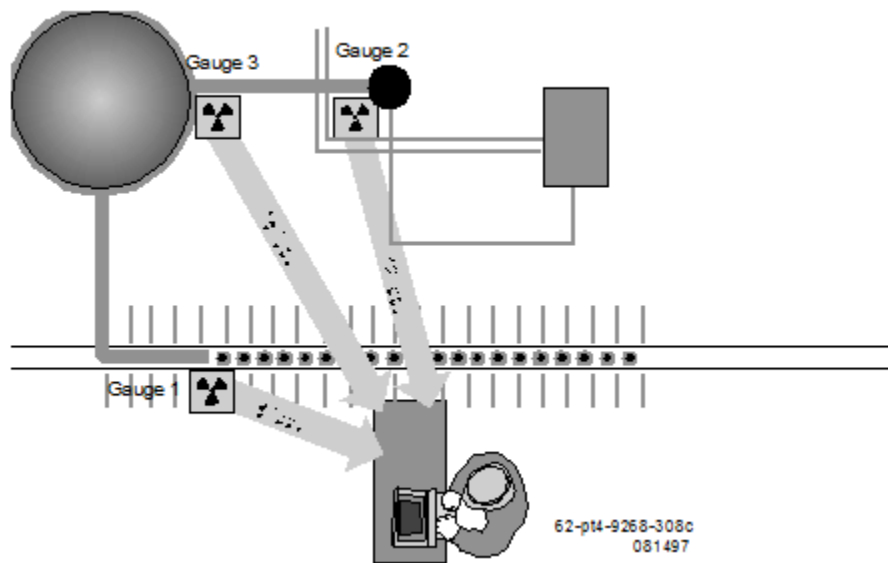
Part 1 of the calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the "inverse square law" to determine if the distance between the gauge and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers distance and the amount of time that both the gauge and the affected member of the public are present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases, licensees will need to use the calculational method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities but provide a method for estimating conservative doses that could be received.

**Note:** If calculated potential doses are not within regulatory limits initially, the licensee should take into account any shielding from the radiation beam provided by equipment or structures between the beam and workers or consider adding other shielding materials to reduce potential doses. In order to calculate the effects of any shielding, the licensee should seek the assistance of an individual knowledgeable in health physics.

*Example 1*

To better understand the calculational method, we will look at ABC Bottling, Inc., a fixed gauge licensee. Yesterday, the company's president noted that three new gauges will be very close to a bottling control panel where a quality control supervisor—a worker who does not work with fixed gauges—works. The company's president asked Joe, the RSO, to determine if the company is complying with the NRC's regulations.

Joe measures the distances from each gauge to the bottling control panel and looks up in the manufacturer's literature the radiation levels that individuals would encounter for each gauge. Figure G.1 is Joe's sketch of the areas in question, and Table G.2 summarizes the information Joe has on each gauge.



**Figure G.1 Diagram of bottling line and fixed gauges**

*This sketch shows the areas described in Examples 1 and 2.*

**Table G.2 Information Known about Each Gauge**

DESCRIPTION OF KNOWN INFORMATION	GAUGE 1	GAUGE 2	GAUGE 3
Where gauge is located	Gauge on bottling line	Gauge on main feed line	Gauge on tank
Dose rate in mrem/hour encountered at specified distance from the gauge (from manufacturer's literature)	2 mrem/hour at 1 ft	8 mrem/hour at 1 ft	2 mrem/hour at 3 ft
Distance in feet to bottling control panel	8 ft	12 ft	15 ft

*Example 1: Part 1*

Joe's first thought is that the distance between the gauges and the bottling control panel may be sufficient to show compliance with the regulation in 10 CFR 20.1301. So, taking a "worst case" approach, he assumes that: (1) the gauges are constantly present (i.e., 24 hours per day), (2) all three gauges are on (i.e., shutters are open), and (3) a quality control (QC) supervisor—a worker who does not work with the fixed gauges—is constantly sitting at the control panel (i.e., 24 hours per day). Joe proceeds to calculate the dose the QC supervisor might receive hourly and yearly from each gauge as shown in Tables G.3, G.4, and G.5 below.

**Table G.3 Calculational Method, Part 1 –  
Hourly and Annual Dose Received from Gauge 1**

Step No.	Description	Gauge 1	
		Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem per hour	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft <sup>2</sup>	(1) <sup>2</sup>	1
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in ft <sup>2</sup>	(8) <sup>2</sup>	64
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 1 = 2	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received by the worker at the bottling control panel = HOURLY DOSE RECEIVED FROM GAUGE 1, in mrem per hour	2/64 = 0.031	
6	Multiply the result of Step 5 by 24 hours per day x 365 days per year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 1, in mrem per year	0.031 x 24 x 365 = 0.031 x 8760 = 272	

**Table G.4 Calculational Method, Part 1 –  
Hourly and Annual Dose Received from Gauge 2**

<b>Gauge 2</b>			
<b>Step No.</b>	<b>Description</b>	<b>Input Data</b>	<b>Results</b>
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem per hour	8	8
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft <sup>2</sup>	(1) <sup>2</sup>	1
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in ft <sup>2</sup>	(12) <sup>2</sup>	144
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	8 x 1 = 8	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received in an hour by the worker at the bottling control panel = HOURLY DOSE RECEIVED FROM GAUGE 2, in mrem per hour	8/144 = .056	
6	Multiply the result of Step 5 by 24 hour per day x 365 days per year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 2, in mrem per year	0.056 x 24 x 365 = 0.056 x 8760 = 491	

**Table G.5 Calculational Method, Part 1 –  
Hourly and Annual Dose Received from Gauge 3**

<b>Gauge 3</b>			
<b>Step No.</b>	<b>Description</b>	<b>Input Data</b>	<b>Results</b>
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem per hour	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft <sup>2</sup>	(3) <sup>2</sup>	9
3	Square of the distance (ft) from the gauge to bottling control panel in an unrestricted area, in ft <sup>2</sup>	(15) <sup>2</sup>	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 9 = 18	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received by the worker at the bottling control panel = HOURLY DOSE RECEIVED FROM GAUGE 3, in mrem per hour	18/225 = 0.08	
6	Multiply the result of Step 5 by 24 hour per day x 365 days per year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 3, in mrem per year	0.08 x 24 x 365 = 0.08 x 8760 = 701	

To determine the total hourly and total annual dose received, Joe adds the pertinent data from the preceding tables (see Table G.6).

**Table G.6 Calculational Method, Part 1 –  
Total Hourly and Annual Dose Received from Gauges 1, 2, and 3**

<b>Step No.</b>	<b>Description</b>	<b>Gauge 1</b>	<b>Gauge 2</b>	<b>Gauge 3</b>	<b>Sum</b>
7	TOTAL HOURLY DOSE RECEIVED from Step 5 of Tables G.3, G.4, and G.5, in mrem per hour	0.031	0.056	0.08	0.031 + 0.056 + 0.08 = 0.167
8	TOTAL ANNUAL DOSE RECEIVED from Step 6 of Tables G.3, G.4, and G.5, in mrem per year	272	491	701	272 + 491 + 701 = 1,464



**Note:** The sum in Step 7 demonstrates compliance with the 2-mrem-in-any-one-hour limit. Reevaluate if assumptions change. If the sum in Step 8 exceeds 100 mrem per year, proceed to Part 2 of the calculational method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.167 mrem, but he notes that an individual could receive a dose of 1,464 mrem in a year, much higher than the 100-mrem regulatory limit.

*Example 1: Part 2*

Joe reviews his assumptions and recognizes that the QC supervisor is not at the bottling control panel 24 hours per day. He decides to make a realistic estimate of the number of hours the QC supervisor would be present at the bottling control panel, keeping his other assumptions constant (i.e., the gauges are constantly present 24 hours per day and all three gauges remain on (i.e., shutter is open)). He then recalculates the annual dose received (see Table G.7).

**Table G.7 Calculational Method, Part 2 – Annual Dose Received from Gauges 1, 2, and 3**

Step No.	Description	Results
9	A. Average number of hours per day that individual spends in area of concern (e.g., worker present at bottling control panel 5 hours per day; the rest of the day the worker is away from the area performing other duties not in the vicinity of gauges)	5
	B. Average number of days per week in area (e.g., worker is part time and works 3 days a week)	3
	C. Average number of weeks per year in area (e.g., worker works all year)	52
10	Multiply the results of Step 9A by the results of Step 9B by the results of Step 9C = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5 \times 3 \times 52 = 780$
11	Multiply the sum in Step 7 by the results of Step 10 = ANNUAL DOSE RECEIVED FROM GAUGES CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem per year	$0.167 \times 780 = 130$

**Note:** If Step 11 exceeds 100 mrem in a year, proceed to Part 3 of the calculational method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

*Example 1, Part 3*

Again Joe reviews his assumptions and recognizes that Gauge 3 will only be used on the process line during product changeovers and Gauge 2 has different radiation levels depending on whether the gauge is in the on or off position (i.e., shutter is open or closed). As he examines the situation, he realizes he must consider each gauge individually.

**Table G.8 Calculational Method, Part 3— Summary of Information**

<p>INFORMATION ON GAUGES:</p> <ul style="list-style-type: none"> <li>GAUGE 1: operates continuously (24 hours per day) on the bottling line.</li> <li>GAUGE 2: operates (in the “on” position) while the tank is being filled, approximately 1 hour during the time the worker is present. When the pipe is not filling the tank, the gauge is in the “off” position. While in the “off” position, the radiation level around the gauge drops to 2 mrem per hour at 1 foot, 1/4 of the radiation level when the gauge is in the “on” position.</li> <li>GAUGE 3: is only used on the process line during product changeovers, 4 weeks per year. While affixed, it operates continuously (24 hours per day).</li> </ul>	
<p>INFORMATION FROM EXAMPLE 1, PART 2, ON WHEN THE WORKER IS PRESENT AT THE BOTTLING CONTROL PANEL:</p> <ul style="list-style-type: none"> <li>5 hours per day</li> <li>3 days per week</li> <li>52 weeks per year</li> </ul>	

**Table G.9 Calculational Method, Part 3 – Annual Dose Received from Gauges 1, 2, and 3**

Step No.	Description	Gauge 1	Gauge 2 “On”	Gauge 2 “Off”	Gauge 3
12	Average number of <i>hours per day</i> gauge operates when worker is present at the bottling control panel	5	1	4	5
13	Average number of <i>days per week</i> gauge operates when worker is present at the bottling control panel	3	3	3	3
14	Average number of <i>weeks per year</i> gauge operates when worker is present at the bottling control panel	52	52	52	4
15	Multiply the results of Step 12 by the results of Step 13 by the results of Step 14 = TOTAL HOURS EACH GAUGE OPERATED PER YEAR WHILE WORKER IS PRESENT AT BOTTLING CONTROL PANEL	$5 \times 3 \times 52 = 780$	$1 \times 3 \times 52 = 156$	$4 \times 3 \times 52 = 624$	$5 \times 3 \times 4 = 60$
16	Multiply the results of Step 15 by the results of Step 7 (for Gauge 2 in the “off” position, the radiation level drops to 1/4th, so divide the results of Step 7 by 4) = ANNUAL DOSE RECEIVED FROM EACH GAUGE, in mrem in a year	$780 \times 0.031 = 24$	$156 \times 0.056 = 8.7$	$624 \times (0.056/4) = 8.7$	$60 \times 0.08 = 4.8$ in mrem in a year

Step No.	Description	Gauge 1	Gauge 2 "On"	Gauge 2 "Off"	Gauge 3
17	Sum the results of Step 16 for each gauge = TOTAL ANNUAL DOSE RECEIVED CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN AND TIME GAUGE OPERATES, in mrem per year				
		$24 + 8.7 + 8.7 + 4.8 = 46.2$			

**Note:** If the result in Step 17 is greater than 100 mrem per year, the licensee must take corrective actions.

Joe is pleased that the result in Step 17 shows compliance with the 100-mrem-per-year limit. Had the result in Step 17 been higher than 100 mrem per year, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy and the time each gauge operates are accurate, revise the assumptions as needed, and recalculate using the new assumptions.
- Calculate the effect of any shielding located between the gauges and the bottling control panel (such calculation is beyond the scope of this appendix).
- Take corrective action (e.g., add shielding, move the bottling control panel) and perform new calculations to demonstrate compliance.
- Designate the area outside the storage area as a restricted area and the QC supervisor as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training of the QC supervisor as required by 10 CFR 19.12, "Instruction to workers."

Note that in the example, Joe evaluated the unrestricted area at the bottling control panel. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the "as low as is reasonably achievable" (ALARA) principle, taking reasonable steps to keep radiation dose received below regulatory limits. In addition, licensees need to be alert to changes in situations (e.g., adding a gauge to the process line, changing the QC supervisor's schedule, or changing the estimate of the portion of time spent at the bottling control panel) and to perform additional evaluations, as needed.

**RECORDKEEPING:** 10 CFR 20.2107 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

### Combination Measurement – Calculational Method

This method, which allows the licensee to take credit for shielding between the gauge and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from each gauge. These measurements

must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2,080 hours (i.e., a work year of 40 hours per week for 52 weeks per year) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available survey instruments (i.e., Geiger-Mueller or G-M). Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., a micro-Roentgen or micro-R meter) should be adequate.

Licensees may also choose to use dosimeters specifically engineered for measuring environmental dose rates. Dosimeters used for personnel monitoring may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received by a personnel dosimeter is 0.1 mSv (10 mrem). Suppose a personnel dosimeter monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 100-millirem-per-year limit. If licensees use dosimeters to evaluate compliance with the public dose limits, they should consult with their dosimetry supplier and choose more sensitive dosimeters.

This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 100-mrem-per-year limit.

*Example 2*

As in Example 1, Joe is the RSO for ABC Bottling, Inc., a fixed gauge licensee. The company has three gauges located near a bottling control panel that is operated by a worker who does not work with the fixed gauges. See Figure G.1 and Table G.2 for information. Joe wants to see if the company complies with the public dose limits at the bottling control panel. Joe placed an environmental dosimeter at the bottling control panel for 30 days. The dosimetry processor sent Joe a report indicating the environmental dosimeter received 100 mrem in those 30 days.

**Table G.10 Combination Measurement – Calculational Method**

Step No.	Description	Input Data and Results
<b>Part 1</b>		
1	Dose received by dosimeter, in mrem	100
2	Total hours that dosimeter was exposed	24 hours per day x 30 days = 720
3	Divide the results of Step 1 by the results of Step 2 to determine HOURLY DOSE RECEIVED, in mrem per hour	0.14
4	Multiply the results of Step 3 by 8,760 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGES, in mrem per year	0.14 x 8,760 = 1,226

**Note:** For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2-mrem-in-any-one-hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses that could be received in any one hour.

Step 4 indicates that the annual dose received would be much greater than the 100 mrem per year allowed by the regulations.

<b>Part 2</b>
At this point Joe can adjust for a realistic estimate of the time the worker spends at the bottling control panel, as he did in Part 2 of Example 1.
<b>Part 3</b>
If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he can make adjustments for realistic estimates of the time of exposure in the area of concern, as in Part 3 of Example 1. Recall that the dosimeter measurement was made while all the gauges were operating (i.e., 24 hours a day for the 30 days that the dosimeter was in place).



**APPENDIX H**  
**OPERATING AND EMERGENCY PROCEDURES**





## **Operating Procedures**

- If personnel dosimetry is provided, do the following:
  - Always wear your assigned dosimeter when using the gauge.
  - Never wear another person's dosimeter.
  - Never store your dosimeter near a gauge.
- Use the gauge according to the manufacturer's or distributor's instructions and recommendations. Perform routine cleaning and maintenance according to the manufacturer's or distributor's instructions and recommendations.
- Test each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the SSD registration certificate.
- Do not touch the unshielded source with your fingers, hands, or any part of your body.
- Do not place hands, fingers, feet, or other body parts in the radiation field from an unshielded source.
- Post a radiation warning sign at each entryway to an area where it is possible to be exposed to the radiation beam.
- Prevent employees from entering the radiation beam during maintenance, repairs, or work in, on, or around the equipment on which the device is mounted by developing lock-out procedures. These procedures should specify who will be responsible for ensuring that the lock-out procedures are followed.
- Prevent unauthorized access, removal, or use of the gauge.
- After making changes affecting the gauge (e.g., changing the location of gauges, removing shielding, adding gauges, changing the occupancy of adjacent areas, etc.) reevaluate compliance with public dose limits and ensure proper security of gauges.
- Conduct a physical inventory every 6 months to account for all devices.
- Provide instructions to prevent unauthorized access, removal, or use of fixed gauges, including at temporary job sites if authorized on the license.
- Require timely reporting to the NRC pursuant to 10 CFR 20.2201 and 10 CFR 20.2207, as appropriate.
- Address guidelines to meet the security requirements of 10 CFR 20.1801, 10 CFR 20.1802, and any other applicable security requirements.

## **Emergency Procedures**

- If a gauge becomes damaged, a source becomes dislodged, a source is leaking, the device fails to function properly, or if any other non-radiological emergency (e.g., fire or medical emergency) or unusual situation arises:
  - Stop use of the gauge.
  - Immediately secure the area and keep people away from the gauge until the situation is assessed and radiation levels are known. Perform first aid for any injured individuals and remove them from the area when it is medically safe to do so.
  - If any equipment is involved, isolate the equipment until it is determined there is no contamination present.
  - Gauge users and other potentially contaminated individuals should not leave the scene until emergency assistance arrives.
  - Notify the persons, in the order listed below, of the situation:

<b>NAME<sup>1</sup></b>	<b>WORK PHONE NUMBER<sup>1</sup></b>	<b>HOME PHONE NUMBER<sup>1</sup></b>
_____	_____	_____
_____	_____	_____
_____	_____	_____

- Follow the directions provided by the person contacted above.

## **Radiation Safety Officer and Licensee Management**

- Arrange for a radiation survey to be conducted as soon as possible by a knowledgeable person using appropriate radiation detection instrumentation. This person could be a licensee employee using a survey meter, a local emergency responder, or a consultant. To accurately assess the radiation danger, it is essential that the person performing the survey be competent in the use of the survey meter.

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<sup>1</sup> Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the RSO, AUs, or other knowledgeable licensee staff, licensee's consultant, gauge manufacturer, distributor, or representative, fire department, or other emergency response organization, as appropriate, and the NRC) to be contacted in case of emergency.

- Make necessary notifications to local authorities as well as the NRC as required. Appendix L contains typical NRC incident notifications required for fixed gauge licensees.

(Even if not required to do so, you may report ANY incident to the NRC by calling the NRC's Operations Center at (301) 816-5100, which is staffed 24 hours a day and accepts collect calls.) NRC notification is required when gauges containing licensed material are lost or stolen and when gauges are damaged or involved in incidents that result in doses in excess of 10 CFR 20.2203 limits. Reporting requirements are found in 10 CFR 20.2201-2203 and in 10 CFR 30.50.



**APPENDIX I**  
**MODEL LEAK TEST PROGRAM**



## Training

Before allowing an individual to perform leak testing, the RSO will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

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

- principles and practices of radiation protection;
- radioactivity measurements, monitoring techniques, and the use of instruments;
- mathematics and calculations used for measuring radioactivity; and
- biological effects of radiation.

Appropriate on-the-job training consists of:

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

## Facilities and Equipment

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

$$MDA = \frac{2.71 + 4.65 \sqrt{(bkg \times t)}}{t \times E}$$

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

*Example*

Assume:  $bkg = 200$  counts per minute (cpm)  
 $E = 0.1$  counts per disintegration (10 percent efficient)  
 $T = 2$  minutes

$$\begin{aligned} MDA &= \frac{2.71 + 4.65 \sqrt{(200 \text{ cpm} \times 2 \text{ minutes})}}{2 \times 0.1} = \frac{2.71 + 4.65 \sqrt{(400)}}{0.2} \\ &= \frac{2.71 + 4.65 (20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2} \\ &= \frac{478.55 \text{ disintegrations}}{\text{minute}} \end{aligned}$$

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

$$MDA = \frac{478.55 \text{ disintegration}}{\text{minutes}} \times \frac{1 \text{ minute}}{60 \text{ seconds}} = 7.976 \text{ Bq}$$

**Frequency for Conducting Leak Tests of Sealed Sources**

Leak tests will be conducted at the frequency specified in the respective Sealed Source and Device (SSD) registration certificate.

**Procedure for Performing Leak Testing and Analysis**

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



- Calculate the counting efficiency of the detector. The counting efficiency may be determined using the following formula:

$$\text{Efficiency in cpm/Bq} = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of standard source in Bq}}$$

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

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries). The activity of the sample in becquerels may be calculated using the following formula:

$$\text{Activity of sample} = \frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}}$$

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



**APPENDIX J**

**INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST TO  
PERFORM NONROUTINE OPERATIONS**



Applicants should review Section 8.10.8, "Maintenance," which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Nonroutine operations include installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources. See Figure 8.6 in Section 8.10.8.

Any replacement components, parts, or other materials (e.g., lubricants) other than those supplied, specified, or recommended by the manufacturer or distributor need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device's SSD registration certificate. Licensees also need to ensure that, after maintenance or repair is completed, the gauge is tested and functions as designed before the unit is returned to routine use.

If nonroutine operations are not performed properly with attention to good radiation safety principles, the gauge may not operate as designed, and personnel performing these tasks could receive radiation doses that exceed the NRC's regulatory limits. Radionuclides and activities in fixed gauges vary widely. For illustrative purposes, in less than one minute, an unshielded cesium-137 source with an activity of 3.7 gigabecquerels (100 millicuries) can deliver 0.05 Sv (5 rem) to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. This dose corresponds to the threshold for extremity monitoring. Some gauges may contain sources of even higher activities with correspondingly higher dose rates.

Thus, applicants wishing to perform nonroutine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's or distributor's instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, and personnel dosimetry (if required)).

Accordingly, applicants wishing to perform nonroutine operations must provide the following information with their license application:

- Describe the types of work, maintenance, cleaning, and/or repair that involve any of the following:
  - installation, relocation, or alignment of the gauge;
  - components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding);
  - replacement and disposal of sealed sources;
  - removal of a gauge from service;
  - a potential for any portion of the body to come into contact with the primary radiation beam; or
  - any other activity during which personnel could receive radiation doses exceeding NRC limits.

- Identify who will perform nonroutine operations and describe their training and experience. Acceptable training includes manufacturers' or distributors' courses for nonroutine operations or an equivalent.
- Submit procedures for nonroutine operations. These procedures should ensure the following:
  - Doses to personnel and members of the public are within regulatory limits and are kept as low as is reasonably achievable (ALARA) (e.g., use of shielded containers or shielding).
  - The source is secured against unauthorized removal or access or is under constant surveillance.
  - Appropriate labels and signs are used.
  - Lock-out procedures are adequate to ensure that no individual or portion of an individual's body can enter the radiation beam.
  - Manufacturer's or distributor's instructions and recommendations are followed.
  - Replacement components, parts, or other materials (e.g., lubricants) other than those supplied, specified, or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the SSD registration certificate.
  - The gauge, before being returned to routine use, is tested to verify that it functions as designed and source integrity is not compromised.
- Confirm that individuals performing nonroutine operations on gauges will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing nonroutine operations are not likely to receive, in one year, a radiation dose in excess of 10 percent of the NRC's regulatory limits.
- Confirm possession of at least one survey instrument that is appropriate for measuring the types of radiation and expected dose rates from the fixed gauge(s).
- Describe steps to be taken to ensure that radiation levels in areas where nonroutine operations will take place do not exceed limits set in 10 CFR 20.1301(e.g., surveys, calculations, etc.).

**APPENDIX K**

**APPLICABLE U.S. DEPARTMENT OF TRANSPORTATION  
REGULATIONS**





**Note:** The reference guides included at the end of this appendix are for reference only and are not a substitute for transportation regulations.

In 10 CFR 71.5, "Transportation of licensed material," the U.S. Nuclear Regulatory Commission (NRC) requires compliance with U.S. Department of Transportation (DOT) regulations in 49 CFR, "Transportation." The major areas in the DOT regulations that are most relevant for transportation of typical fixed gauges shipped as Type A quantities are as follows:

- 49 CFR Part 172, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans"
  - (1) Table of Hazardous Materials and Special Provisions (Subpart B)
    - Purpose and use of hazardous materials table (49 CFR 172.101)
    - List of Hazardous Substances and Reportable Quantities (49 CFR 172.101, Appendix A, Table 2)
  - (2) Shipping Papers (Subpart C)
    - Preparation and retention of shipping papers (49 CFR 172.201)
    - Description of hazardous material on shipping papers (49 CFR 172.202)
    - Additional description requirements (49 CFR 172.203)
    - Shipper's certification (49 CFR 172.204)
  - (3) Marking (Subpart D)
    - General marking requirements for non-bulk packagings (49 CFR 172.301)
    - Prohibited marking (49 CFR 172.303)
    - Marking requirements (49 CFR 172.304)
    - Class 7 (radioactive) materials (49 CFR 172.310)
    - Hazardous substances in non-bulk packagings (49 CFR 172.324)
  - (4) Labeling (Subpart E)
    - General labeling requirements (49 CFR 172.400)
    - Prohibited labeling (49 CFR 172.401)
    - Class 7 (radioactive) material (49 CFR 172.403)
    - Placement of labels (49 CFR 172.406)
    - Label specifications (49 CFR 172.407)
    - RADIOACTIVE WHITE-I label (49 CFR 172.436)
    - RADIOACTIVE YELLOW-II label (49 CFR 172.438)
    - RADIOACTIVE YELLOW-III label (49 CFR 172.440)
  - (5) Placarding (Subpart F)
    - Applicability of placarding requirements (49 CFR 172.500)
    - Prohibited and permissive placarding (49 CFR 172.502)
    - General placarding requirements (49 CFR 172.504)
    - Providing and affixing placards: highway (49 CFR 172.506)
    - Visibility and display of placards (49 CFR 172.516)
    - General specifications for placards (49 CFR 172.519)
    - RADIOACTIVE placard (49 CFR 172.556)
  - (6) Emergency Response Information (Subpart G)
    - Applicability and general requirements (49 CFR 172.600)

- Emergency response information (49 CFR 172.602)
  - Emergency response telephone number (49 CFR 172.604)
- (7) Training (Subpart H)
  - Applicability and responsibility for training and testing (49 CFR 172.702)
  - Training requirements (49 CFR 172.704)
- 49 CFR Part 173, “Shippers – General Requirements for Shipments and Packagings,” Class 7 (Radioactive) Materials (Subpart I)
  - Definitions (49 CFR 173.403)
  - General design requirements (49 CFR 173.410)
  - Additional design requirements for Type A packages (49 CFR 173.412)
  - Authorized Type A packages (49 CFR 173.415)
  - Requirements for determining basic radionuclide values, and for the listing of radionuclides on shipping papers and labels (49 CFR 173.433)
  - Table of  $A_1$  and  $A_2$  values for radionuclides (49 CFR 173.435)
  - Radiation level limitations and exclusive use provisions (49 CFR 173.441)
  - Quality control requirements prior to each shipment of Class 7 (radioactive) materials (49 CFR 173.475)
  - Approval of special form Class 7 (radioactive) materials (49 CFR 173.476)
- 49 CFR Part 177, “Carriage by Public Highway”
  - (1) General Information and Regulations (Subpart A)
    - Driver training (49 CFR 177.816)
    - Shipping papers (49 CFR 177.817)
  - (2) Loading and Unloading (Subpart B)
    - General requirements (packages secured in a motor vehicle against movement) (49 CFR 177.834(a))
    - Class 7 (radioactive) material (49 CFR 177.842)

**1. Minimum Required Packaging for Class 7 (Radioactive) Material<sup>[1]</sup> (49 CFR 173 and 10 CFR 71)<sup>[4]</sup>**  
 These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

**Minimum Packaging Required for Radioactive Materials other than Low Specific Activity (LSA) Material and Surface Contaminated Objects (SCO) based on Activity of Package Contents**

Radioactive Material Quantity <sup>[3]</sup>		Excepted Quantities and Articles	Type A <sup>[4]</sup>	Type B
Activity Restrictions		≤ the limits specified in Table 4 of §173.425	≤ A <sub>1</sub> for special form ≤ A <sub>2</sub> for normal form	> A <sub>1</sub> for special form > A <sub>2</sub> for normal form
Contents of Package	Non-fissile and Fissile Excepted	Excepted Package	Type A Package	Type B(U) or Type B(M) package
	Fissile	N/A	Type AF package	Type B(U)F or Type B(M)F package

**Minimum Packaging Required for LSA Material and SCO<sup>[5,6]</sup>**

Type(s) of LSA and/or SCO	LSA-I	LSA-II	LSA-III	SCO-I	SCO-II
Category of Package for Domestic or International Transport <sup>[7,8]</sup>	Unpackaged <sup>[9]</sup> IP-1: solids, or liquids/exclusive use IP-2: liquids/non-exclusive use Specification tank cars or cargo tank motor vehicles: liquids/exclusive use	- IP-2: exclusive use IP-3: liquids or gases/non-exclusive use	- IP-2: exclusive use IP-3: non-exclusive use	Unpackaged <sup>[9]</sup> IP-1 - -	- IP-2 -

Alternative Provisions for Domestic only Transport<sup>[9]</sup>  
 Packaging shall meet the requirements of §§173.24, 24a, and 410  
 Transportation shall be an exclusive use shipment  
 Activity per shipment must be less than an A<sub>2</sub> quantity

[1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.  
 [2] Each NRC licensee shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397 (see §71.5).  
 [3] Materials that contain radionuclides, where both the activity concentration and the total activity in the consignment exceed either the values specified in the table in §173.436 or the values derived according to the instructions in §173.433, must be regulated in transport as Class 7 (radioactive) material.  
 [4] Except for LSA material and SCO, a Type A package may not contain a quantity of Class 7 (radioactive) materials greater than A<sub>1</sub> or A<sub>2</sub>.  
 [5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 m from the unshielded material or objects (see §173.427(a)(1)).  
 [6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriate Type AF or Type BF packages. For alternate domestic transport provisions, see §173.427(b)(4). For comprehensive guidance on packaging and transportation of LSA material and SCO, see NUREG-1608.  
 [7] For LSA material and SCO, transport of combustible solids, all liquids and all gases classified as LSA-II and LSA-III material, and transport of all SCO-I and SCO-II is limited to a maximum activity of 100 A<sub>2</sub> in a conveyance (see §173.427(a)(2)).  
 [8] Unless excepted by §§173.427(c) or (d), the material or object(s) shall be appropriately packaged in a Type IP, DOT-7A Type A or Type B package.  
 [9] Certain LSA-I and SCO-I may be transported unpackaged under the conditions specified in §173.427(c).

**2. Radiation Level, TI and CSI Limits for Transportation by Road, Rail and Air<sup>[1]</sup> (49 CFR 172 - 177, and 10 CFR 71)**

Type of Transport	Non-exclusive use		Exclusive use		
Mode of Transport	Road, Rail, Vessel and Air		Road and Rail	Vessel	Air (cargo only)
<b>Radiation Level Limits<sup>[4]</sup></b>					
Package Surface <sup>[1]</sup>	2 mSv/h (200 mrem/h)		2 mSv/h (200 mrem/h): other than closed vehicles 10 mSv/h (1000 mrem/h): closed vehicles	None specified	2 mSv/h (200 mrem/h) <sup>[5]</sup>
Conveyance <sup>[4]</sup>	N/A		2 mSv/h (200 mrem/h): outer surfaces (sides, top and underside) of vehicle <sup>[5]</sup> 0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle <sup>[5]</sup>	N/A	N/A
Occupied position	N/A		0.02 mSv/h (2 mrem/h): at any normally occupied area <sup>[6]</sup>	Requirement of §176.708 applies	N/A
<b>Transport Index (TI) Limits<sup>[2]</sup></b>					
Package <sup>[1,7]</sup>	3: passenger aircraft 10: road, rail, vessels and cargo aircraft		No limit		10
Conveyance <sup>[4]</sup>	50: road, rail and passenger aircraft 50 to No limit: vessels <sup>[3]</sup> 200: cargo aircraft		No limit		200
Overpack	N/A: for road, rail 50 to 200: vessels <sup>[3]</sup> 3: passenger aircraft; 10: cargo aircraft		N/A	No limit <sup>[8]</sup>	N/A
<b>Criticality Safety Index (CSI) Limit for fissile material<sup>[4]</sup></b>					
Package <sup>[1,7]</sup>	50		100	100	100
Conveyance <sup>[4]</sup>	50: for holds, compartments or defined deck areas of vessels <sup>[3]</sup> 200 to No limit: for a total vessel <sup>[3]</sup>		100	200 to No limit: for a total vessel <sup>[3]</sup>	100
Overpack	50: road, rail, vessels <sup>[3]</sup> and air		N/A		

[1] The limits in this table do not apply to excepted packages.  
 [2] In addition to any applicable radiation level, TI and CSI limits, separation distance requirements apply to packages, conveyances, freight containers and overpacks; to occupied positions; and to materials stored in transit. Separation distances are based on the sum of the TIs and, for fissile materials, also the sum of the CSIs.  
 [3] Higher package surface radiation levels may be allowed through an approved special arrangement.  
 [4] Conveyance is, for transport by public highway or rail, any transport vehicle or large freight container; and for transport by air, any aircraft.  
 [5] The outer surfaces (sides, top and underside) of vehicles are defined for road and rail vehicles in §173.441.  
 [6] For rail, normally occupied areas include the transport vehicle and adjacent rail cars. The 0.02 mSv/h (2 mrem/h) limit does not apply to carriers operating under a State or federally regulated radiation protection program where personnel wear radiation dosimetry devices.  
 [7] Additional TI and CSI limits apply for individual packages when non-fissile radioactive material packages are mixed with fissile material packages. Also, see CSI limits established by §71.59.  
 [8] For details on TI and CSI limits for transport by vessel, see §176.708.

**3. Contamination Limits and Quality Control for Class 7 (Radioactive) Materials:  
(49 CFR 173.443 and 173.475, and 10 CFR 71)**

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

**Maximum Permissible Limits for Non-fixed Radioactive Contamination on Packages When Offered for Transport**

The level of non-fixed (removable) radioactive contamination on external surfaces of packages offered for transport must be kept as low as reasonable achievable, and shall not exceed the values shown in the following table:

Contaminant	Maximum permissible limits (§173.443(a), Table 9)		
	Bq/cm <sup>2</sup>	µCi/cm <sup>2</sup>	dpm/cm <sup>2</sup>
Beta, gamma and low toxicity alpha emitters	4	10 <sup>-4</sup>	220
All other alpha emitting radionuclides	0.4	10 <sup>-5</sup>	22

The non-fixed contamination shall be determined by:

- wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
- ensuring each wipe area is 300 cm<sup>2</sup> in size;
- measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

Alternatively, the contamination level may be determined using alternative methods of equal or greater efficiency.

**Provisions for Control of Contamination on Radioactive Material Packages Prior to Shipment**

Prior to shipment, the non-fixed contamination on each package of radioactive material:

- must be kept as low as reasonable achievable; and
- may not exceed the limits set forth in §173.443(a), Table 9 (as shown above).

**Provisions for Non-fixed (Removable) Contamination on Excepted and Empty Radioactive Material Packages**

- The non-fixed radioactive surface contamination on the external surface of excepted and empty packages shall not exceed the limits specified in §173.443(a), Table 9 (as shown above).
- The internal contamination of an empty package must not exceed 100 times the limits in §173.443(a), Table 9 (as shown above).

**Provisions for Non-fixed (Removable) Contamination on Packages and in Rail and Road Vehicles used for Exclusive Use Shipments of Radioactive Material**

- The levels of non-fixed radioactive contamination on the packages (a) at the beginning of transport, may not exceed the levels prescribed in the above table, and (b) at any time during transport, may not exceed ten times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each transport vehicle used for transporting the radioactive material packages must be surveyed with appropriate radiation detection instruments after each use. If contamination values exceed acceptable levels, the transport vehicle may not be returned to service until the radiation dose rate at each accessible surface is demonstrated to be 0.005 mSv/h (0.5 mrem/h) or less, and that there is no significant non-fixed radioactive surface contamination specified in §173.443(a), Table 9 (as shown above).

**Provisions for Non-fixed (Removable) Contamination in Closed Rail and Road Vehicles that are used Solely for the Transportation of Radioactive Material**

- The contamination levels must not exceed 10 times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each vehicle shall be stenciled with the words "For Radioactive Materials Use Only" in letters at least 76 mm (3 in) high in a conspicuous place on both sides of the exterior of the vehicle.
- A survey of the interior surfaces of the empty closed vehicle must show that the radiation dose rate at any point does not exceed 0.1 mSv/h (10 mrem/h) at the surface or 0.02 mSv/h (2 mrem/h) at 1 m (3.3 feet) from the surfaces.
- Each vehicle shall be kept closed except for loading or unloading.

**Provisions for Quality Control Prior to Each Shipment of Radioactive Material (§173.475)**

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
  - the packaging is proper for the contents to be shipped;
  - the packaging is in unimpaired physical condition, except for superficial marks;
  - each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
  - for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
  - each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
  - each closure, valve, or other opening of the containment system is properly closed and sealed;
  - each packaging containing liquid in excess of an A<sub>2</sub> quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
  - the internal pressure of the containment system will not exceed the design pressure during transportation; and
  - the external radiation and contamination levels are within the allowable limits specified in §173.441 and 443.



#### 4. Hazard Communications for Class 7 (Radioactive) Materials: Shipping Papers (49 CFR 172, Subpart C)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Shipping Paper Entries		
Always Required	Sometimes Required	Optional Entries
<p><u>Basic description (in sequence):</u></p> <ul style="list-style-type: none"> <li>• <b>UN Identification number</b></li> <li>• <b>Proper Shipping Name</b></li> <li>• <b>Hazard Class (7)</b></li> <li>• <b>Total activity contained in each package in SI units</b> (e.g. Bq, TBq, etc.), or in both SI and customary units (e.g. Ci, mCi, etc.) with customary units in parentheses following the SI units</li> <li>• <b>Number and type of packages</b></li> </ul> <p><u>Additional description:</u></p> <ul style="list-style-type: none"> <li>• <b>Name of each radionuclide</b><sup>[1]</sup></li> <li>• <b>Description of physical and chemical form</b> (unless special form)</li> <li>• <b>Category of label used</b></li> <li>• <b>Transport index (TI)</b> of each package bearing a Yellow-II or Yellow-III label</li> </ul> <p><u>Additional entry requirements:</u></p> <ul style="list-style-type: none"> <li>• <b>24 hour emergency telephone number</b></li> <li>• <b>Shipper's Certification</b> shall be provided by each person offering radioactive material for transportation<sup>[2]</sup></li> <li>• Proper page numbering (e.g. Page 1 of 4)</li> </ul>	<p><u>Materials-based Requirements:</u></p> <ul style="list-style-type: none"> <li>• The criticality safety index (CSI) or "Fissile Excepted" for fissile material</li> <li>• The words "Highway route controlled quantity" or the term "HRCQ" entered in the basic description for highway route controlled quantities</li> <li>• The letters "RQ" entered on the shipping paper either before or after the basic description for each hazardous substance (see §171.8)</li> <li>• Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required</li> <li>• A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste</li> </ul> <p><u>Package-based Requirements:</u></p> <ul style="list-style-type: none"> <li>• The applicable DOE or NRC package approval identification marking for certified Type AF and Type B packages</li> <li>• The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package</li> </ul> <p><u>Shipment- and Administrative-based Requirements:</u></p> <ul style="list-style-type: none"> <li>• Specify "exclusive use shipment" as required</li> <li>• Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use</li> <li>• Specify the notation "DOT-SP" followed by the special permit number<sup>[3]</sup> for a special permit shipment</li> </ul>	<ul style="list-style-type: none"> <li>• The weight in grams or kilograms of radionuclides may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241</li> <li>• The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units</li> <li>• The words "RESIDUE: Last Contained * * *" may be included in association with the basic description of the hazardous material last contained in the packaging</li> <li>• Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information</li> </ul>
Special Considerations/Exceptions for Shipping Papers		
<ul style="list-style-type: none"> <li>• For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, <u>or</u> be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, <u>or</u> be designated by an "X" (or "RQ" if appropriate).</li> <li>• Emergency response information consistent with §§172.600-606 shall be readily available on the transport vehicle.</li> <li>• Shipments of limited quantities of radioactive material in excepted packages, under UN2908, 2909, 2910 and 2911, are excepted from shipping paper requirements if (a) the package does not contain fissile material unless excepted by §173.453, and (b) the limited quantity of radioactive material is not a hazardous substance or hazardous waste.</li> <li>• For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver's immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat.</li> </ul>		



[1] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with §173.433(g), which is commonly known as the 95% rule; abbreviations (symbols) are authorized.

[2] The shipper's certification shall satisfy the requirements of either §§172.204(a)(1) or 204(a)(2); or if transported by air of §172.204(c); but is not required if the shipper is a private carrier and the shipment is not reshipped or transferred from one carrier to another.

[3] Shipments made under an exemption or special permit issued prior to October 1, 2007 may bear the notation "DOT-E" followed by the number assigned.

**5. Hazard Communication for Class 7 (Radioactive) Materials: Marking of Packagings:  
(49 CFR 172, Subpart D; and 49 CFR 178.3 and 178.350)**

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.  
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Markings on Packages		
Markings Always Required Unless Excepted <sup>[1]</sup>	Additional Markings Sometimes Required	Optional Markings
<p><b>Markings for Non-bulk Packagings:</b></p> <ul style="list-style-type: none"> <li>• Proper shipping name</li> <li>• Identification number (preceded by "UN" or "NA," as appropriate)</li> <li>• Name and address of consignor or consignee, unless the package is: <ul style="list-style-type: none"> <li>▪ highway only and no motor carrier transfers; or</li> <li>▪ part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee</li> </ul> </li> </ul> <p><b>Markings for Bulk Packages:</b></p> <ul style="list-style-type: none"> <li>• Identification number on orange rectangular panel: <ul style="list-style-type: none"> <li>▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more, or</li> <li>▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons), or</li> <li>▪ on each side and end of motor vehicle carrying cylinders permanently installed on a tube trailer</li> </ul> </li> </ul>	<p><b>Package-based marking requirements:</b></p> <ul style="list-style-type: none"> <li>• Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb)</li> <li>• Package type as appropriate, i.e., "TYPE IP-1," "TYPE IP-2," "TYPE IP-3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"<sup>[1]</sup></li> <li>• Marked with international vehicle registration code of country of origin for IP-1, IP-2, IP-3 or Type A package design<sup>[2]</sup></li> <li>• Radiation (trefoil) symbol<sup>[3]</sup> on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design </li> <li>• For NRC or DOE packaging, model number, serial number, gross weight, and package identification number for each certified package (Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F)</li> <li>• For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A", and the name and address or symbol of the manufacturer satisfying §178.3 and §178.350.</li> </ul> <p><b>Materials-based requirements:</b></p> <ul style="list-style-type: none"> <li>• For non-bulk IP-1 package containing a liquid, use underlined double arrow symbol indicating upright orientation<sup>[4]</sup>, where the symbol is placed on two opposite sides of the packaging </li> <li>• If a hazardous substance in non-bulk package, mark outside of each package with the letters "RQ" in association with the proper shipping name</li> </ul> <p><b>Administrative-based requirements:</b></p> <ul style="list-style-type: none"> <li>• For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in U.S. Competent Authority Certificate</li> <li>• Mark "DOT-SP" followed by the special permit number assigned for each package authorized by special permit</li> <li>• Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type C, Type CF, Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required</li> </ul>	<ul style="list-style-type: none"> <li>• Both the name and address of consignor and consignee is recommended.</li> <li>• Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling.</li> </ul>
Special Considerations for Marking Requirements		
<ul style="list-style-type: none"> <li>• All markings are to be (a) on the outside of each packaging, (b) durable and legible, (c) in English, (d) printed on or affixed to the surface of a package or on a label, tag, or sign, (e) displayed on a background of sharply contrasting color, and (f) unobscured by labels or attachments.</li> </ul>		

[1] Some exceptions exist as specified in §§172.301(a) and 302(a); and in §§173.421(a), 422(a).

[2] The international vehicle registration code for packages designed by a U.S. company or agency is the symbol "USA."

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water that conform to the requirements of Appendix B to Part 172.

[4] The arrows must be either black or red on white or other suitable contrasting background and commensurate with the size of the package; depicting a rectangular border around the arrows is optional.

**6. Hazard Communications for Class 7 (Radioactive) Materials:  
Labeling of Packages (49 CFR 172.400-450)**




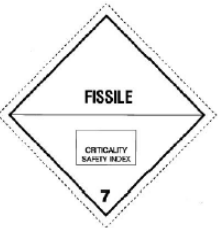
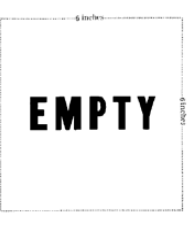
These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.  
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

**Requirements for Labels <sup>[1]</sup>**

- Label each package except for (a) excepted packages containing a limited quantity of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported domestically and when material or object contains less than an A<sub>2</sub> quantity.
- Labeling is required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) un-obscured by markings or other attachments, and (f) representative of hazardous material content.
- Display duplicate labels on at least two opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material except as noted above for excepted packages, and packaged or unpackaged LSA material and SCO.

**Radioactive Category Labels <sup>[3]</sup>**

**Other Labels <sup>[2]</sup>**

					
White-I	Yellow-II	Yellow-III	Fissile	Empty	
<b>Radiation Surface Level (RSL):</b>			Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.	Empty labels required for shipments of empty Class 7 (radioactive) packages satisfying §173.428; and any previously-used labels cannot be visible	
mSv/h:	RSL ≤ 0.005	0.005 < RSL ≤ 0.5			0.5 < RSL ≤ 2 <sup>[4]</sup>
mrem/h:	RSL ≤ 0.5	0.5 < RSL ≤ 50			50 < RSL ≤ 200 <sup>[4]</sup>
<b>Transport Index (TI):<sup>[4]</sup></b>					
	TI = 0 <sup>[4]</sup>	0 <sup>[4]</sup> < TI ≤ 1	1 < TI ≤ 10 <sup>[4, 5]</sup>		

**Contents on Labels**

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in §172.433(g); and, for LSA-I material, the term "LSA-I"; (b) activity in appropriate SI units (e.g. Bq, TBq), or appropriate customary units (e.g. Ci, mCi) in parentheses following SI units; and (c) for Yellow-II or Yellow-III labels the Transport Index (TI). Abbreviations and symbols may be used. Except for Pu-239 and Pu-241, the weight in g or kg of fissile radionuclides may be inserted instead of activity units; for Pu-239 and Pu-241, the weight in g of fissile radionuclides may be inserted in addition to the activity units.
- Each fissile label must contain the relevant Criticality Safety Index (CSI).

- [1] Additional labeling may be required if the radioactive material also meets the definition of one or more other hazard classes. See §§172.402 and 403 for details on label requirements. See §§172.403, 421 and 427 for details when labels are not required, and see §172.407 for details on label design, size, color, form identification, exceptions, etc.
- [2] An additional "Cargo Aircraft Only" label is required for each package containing a hazardous material which is authorized for cargo aircraft only.
- [3] The category of the label must be the higher of the two values specified for RSL and TI; see §172.403(b).
- [4] The TI is determined from radiation level 1 m from package surface; see definition for TI in §173.403 for details. If the measured TI is not greater than 0.05, the value may be considered to be zero.
- [5] RSLs less than or equal to 10 mSv/h (1000 mrem/h), and TIs more than 10 are allowed for shipments under exclusive-use; see §§172.403(a) – 403(c). In addition; any package containing a Highway Route Controlled Quantity (HRCQ) must bear a YELLOW-III label.



## 7. Hazard Communications for Class 7 (Radioactive) Materials: Placarding (49 CFR 172, Subpart F)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

### Conditions when Display of Radioactive Placards is Required [§§172.504, 507(a), 508 and 512(b)(2)]

- On bulk packages, road transport vehicles, rail cars, and freight containers, and on aircraft unit load devices having a capacity of 640 cubic feet or more<sup>[1]</sup>, on each side and each end when they contain either a package with a Radioactive Yellow-III label, or low specific activity (LSA) material or surface contaminated objects (SCO) being transported under exclusive use.
- On a square background on any motor vehicle used to transport a package containing Highway Route Controlled Quantity (HRCQ) Class 7 (radioactive) materials<sup>[2]</sup>.

### Visibility and Display of Radioactive Placards [§172.516]

- Placards are required to:
  - be clearly visible, on a motor vehicle and rail car, from the direction they face, except from the direction of another transport vehicle or rail car to which the motor vehicle or rail car is coupled<sup>[3]</sup>;
  - be securely attached or affixed thereto or placed in a holder thereon;
  - be located clear of appurtenances and devices such as ladders, pipes, doors, and tarpaulins;
  - be located, so far as practical, so dirt or water is not directed to it from transport vehicle wheels;
  - be located at least 3 inches (76.0 mm) away from any marking (e.g. advertising) that could reduce its effectiveness;
  - have authorized words or identification number printed on it displayed horizontally, reading from left to right;
  - be maintained by the carrier so format, legibility, color, and visibility of the placard will not be substantially reduced due to damage, deterioration, or obscurement by dirt or other matter;
  - be affixed to background of contrasting color, or dotted or solid line outer border which contrasts with the background color.

### Radioactive Placards

#### PLACARD (FOR OTHER THAN HRCQ)



White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black.  
[see §172.556 for detailed requirements]

#### PLACARD FOR HRCQ



Square background must consist of a white square surrounded by black border. The placard inside the square is identical to that for other than HRCQ.  
[see §172.527 for detailed requirements]

### Special Considerations/Exceptions for Placarding

- Placards must conform to the specifications set forth in §172.519.
- A corrosive placard is required for more than 454 kg (1001 pounds) or more gross weight of fissile or low specific activity uranium hexafluoride.

[1] See §172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.

[2] See §173.403 for definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels; see §172.507(a).

[3] Required placarding of the front of a motor vehicle may be on the front of a truck tractor instead of or in addition to the placarding on the front of the cargo body to which a truck tractor is attached; §172.516(b).



## 8. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49 CFR 107, Subpart G, 49 CFR 171.15 and 49 CFR 172, Subparts G and H)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

### Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR 107, Subpart G)

- Any person, other than those excepted by §107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
  - a highway route-controlled quantity of radioactive material;
  - a shipment in a bulk packaging with a capacity  $\geq$  13,248 L (3,500 gallons) for liquids or gases, or  $>$  13.24 cubic meters (468 cubic feet) for solids; or
  - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with §107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§107.612 and 616.

### Provisions for Providing and Maintaining Emergency Response Information (49 CFR 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required (see Part 172, Subpart C), emergency response information shall
  - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
  - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
  - be immediately available for use at all times the hazardous material is present; and
  - include and make available the emergency response telephone number (see §172.604) to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§172.602 and 604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of §172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

### Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

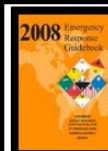
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material, if radioactive material has been released in a road, rail, or air transport conveyance, the conveyance must be taken out of and remain out of service until the radiation dose rate at every accessible surface is less than 0.005 mSv/h (0.5 mrem/h) and the non-fixed radioactive surface contamination levels are below the values the limits in §173.443(a), Table 9 [see Chart 3].
- Each aircraft used routinely, and each motor vehicle used, for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §173.443(a), Table 9 [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use. [see §§174.750(a) and 750(e), and §177.843(b)]

### Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§171.15 and 16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see §171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center (NRC) by telephone at 800-424-8802 (toll free) or 202-267-2675 (toll call) or online at <http://www.nrc.uscg.mil>.
  - Each notice must include the information specified in §171.15(a)(1) – (a)(7).
- A detailed incident report must also be submitted as required by §171.16.

### Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the specific or generic hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The **Emergency Response Guidebook 2008 (ERG2008)** is available at the following URL:  
[http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/erg2008\\_eng.pdf](http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/erg2008_eng.pdf)



**9. Requirements for Training and Security for Class 7 (Radioactive) Materials:  
(49 CFR 172, Subparts H and I, and 49 CFR 173)**

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

**Provisions for Training (49 CFR 172, Subpart H)**

- For any person who is employed by an employer or is self-employed, and who directly affects radioactive materials transportation safety, a systematic program shall be established to ensure that the person:
  - has familiarity with the general provisions of [Part 172, Subpart H](#);
  - is able to recognize and identify radioactive materials;
  - has knowledge of specific requirements of [Part 172](#) that are applicable to functions performed by the employee;
  - has knowledge of emergency response information, self protection measures and accident prevention methods and procedures; and
  - does not perform any function related to the requirements of [Part 172](#) unless instructed in the requirements that apply to that function.
- The person shall be trained pursuant to the requirements of [§§172.704\(a\) and \(b\)](#), may be trained by the employer or by other public or private sources, and shall be tested by appropriate means. The training must include the following:
  - (a) general awareness training providing familiarity with applicable regulatory requirements;
  - (b) function-specific training applicable to functions the employee performs;
  - (c) safety training concerning emergency response information, measures to protect the employee from hazards, and methods and procedures for avoiding accidents;
  - (d) security awareness training providing awareness of security risks and methods designed to enhance transportation security; and
  - (e) in-depth security training if a security plan is required for the shipment(s) involved.
- Initial and recurrent training shall comply with the requirements of [§172.704\(c\)](#)
- Records of training shall be created and retained in compliance with the requirements of [§172.704\(d\)](#).

**Provisions for Security (49 CFR 172, Subpart I and 49 CFR 173)**

- A security plan for hazardous materials that conforms to the requirements of [Part 172, Subpart I](#) must be developed and adhered to by each person who offers for transportation in commerce or transports in commerce in a motor vehicle, rail car, or freight container any of the following radioactive materials:
  - (a) IAEA Code of Conduct Category 1 and 2 materials (see [§172.800\(b\)\(15\)](#));
  - (b) a highway route controlled quantity (HRCQ) of radioactive material as defined in [§173.403](#) (see [§172.800\(b\)\(15\)](#));
  - (c) known radionuclides in forms listed as radioactive material quantities of concern (RAM-QC) by the NRC (see [§172.800\(b\)\(15\)](#)); or
  - (d) a quantity of uranium hexafluoride requiring placarding under [§172.505\(b\)](#) (see [§172.800\(b\)\(14\)](#)).
- The security plan must include an assessment of possible transportation security risks and appropriate measures to address the assessed risks.
- Specific measures put into place by the plan may vary commensurate with the level of threat at a particular time.
- At a minimum, a security plan must address personnel security, unauthorized access, and en route security.
- The security plan must be
  - (a) in writing;
  - (b) retained for as long as it remains in effect;
  - (c) available as copies or portions thereof to the employees who are responsible for implementing it, consistent with personnel security clearance or background investigation restrictions and a demonstrated need to know;
  - (d) revised and updated as necessary to reflect changing circumstances; and
  - (e) maintained (all copies) as of the date of the most recent revision, when it is updated or revised.
- Security plans that conform to regulations, standards, protocols, or guidelines issued by other Federal agencies, international organizations, or industry organizations may be used to satisfy the requirements in [Part 172, Subpart I](#), provided such security plans address the requirements specified in [Part 172, Subpart I](#).
- Additional security planning requirements may apply for rail transport of a highway route controlled quantity of radioactive material (see [§§172.820 and 173.403](#)).

**APPENDIX L**  
**NRC INCIDENT NOTIFICATIONS**



**Table L.1 Typical NRC Incident Notifications Required for Fixed Gauge 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 of 0.25 Sv (25 rem) or more	Immediate	30 days	10 CFR 20.2202(a)(1)(i)
Extremity dose of 2.5 Gy (250 rads) or more	Immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rem) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i)
Extremity dose greater than 0.5 Sv (50 rem) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rem)	None	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv (100 mrem)	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 any chapter of title 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 <i>entire site</i>	None	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities in any <i>separate building or outdoor area</i> that is unsuitable for release for unrestricted use	None	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months <i>at the entire site</i>	None	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months <i>in any separate building or outdoor area</i> 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 exposures 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.



**APPENDIX M**

**INTERIM STAFF GUIDANCE ON CONSTRUCTION**





**INTERIM STAFF GUIDANCE TO NUREG-1556 AND NUREG-1520:  
COMMENCEMENT OF CONSTRUCTION AT EXISTING AND PROPOSED SOURCE,  
BYPRODUCT, AND SPECIAL NUCLEAR MATERIAL FACILITIES AND IRRADIATORS WITH  
SIGNIFICANT ENVIRONMENTAL IMPACTS**

**PURPOSE AND SCOPE**

This Interim Staff Guidance (ISG) provides guidance to U.S. Nuclear Regulatory Commission (NRC) staff on the new definition of construction and the consideration of activities that can be performed by materials license applicants and potential applicants (hereinafter collectively referred to as “applicants”), and licensees before the NRC staff has concluded its environmental review of the proposed licensing action.

This ISG applies to the review of licensing actions related to the receipt and possession of licensable source, byproduct, and special nuclear material (SNM) for the conduct of any activity which the NRC determines will significantly affect the quality of the environment. This ISG is intended to provide guidance to NRC staff but may also be instructive to all holders of operating licenses for source, byproduct, and SNM facilities and irradiators, and all persons that have submitted applications to construct source, byproduct, and SNM facilities or irradiators, or have submitted letters of intent to submit such applications under Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 36, 40, and 70.

This ISG applies to all Part 30, 36, 40 and 70 materials facilities other than uranium recovery facilities. Site preparation activities at uranium recovery facilities are addressed in Regulatory Issue Summary 2009-12, Uranium Recovery Policy Regarding Site Preparation Activities at Proposed, Unlicensed Uranium Recovery Facilities, September 23, 2009, ML092090353.

If a licensing action initiated pursuant to 10 CFR Parts 30, 40, or 70 meets any of the criteria in 10 CFR 51.20 or 51.21, then commencement of construction of a facility before the NRC staff has completed its environmental review process is grounds for denial of the license application, in accordance with 10 CFR 30.33(a)(5), 40.32(e), and 70.23(a)(7). However, if the licensing action meets the criteria in 10 CFR 51.22(c) for a categorical exclusion, and the NRC has not determined that an environmental assessment or an environmental impact statement is required in accordance with 10 CFR 51.22(b), then commencement of construction before the NRC staff concludes the environmental process should not be the sole basis for denial of the license application, as the NRC has already determined that this category of actions does not have a significant impact on the environment. In accordance with 10 CFR 36.15, commencement of construction of an irradiator will only be grounds for denial if the licensee or applicant has not submitted both an application and the requisite licensing fee.

**BACKGROUND**

The NRC amended its regulations in September 2011, by revising certain provisions applicable to the licensing and approval processes for byproduct, source and SNMs licenses, and irradiators in the final rule, “Licenses, Certifications, and Approvals for Materials Licensees” (76 FR 56951; September 15, 2011) (Material Licenses Construction Rule). The revisions contained in the Material Licenses Construction Rule revised the definitions of “construction” and “commencement of construction” with respect to materials licensing actions conducted under the NRC’s regulations. The NRC adopted these changes to further improve the effectiveness and efficiency of the licensing and approval processes for future materials license

applications, as well as to eliminate certain inconsistencies that existed within the NRC's regulations with respect to the use and definition of the terms "construction" or "commencement of construction" for certain materials licensees for purposes of its environmental reviews.

The new definitions of "commencement of construction" in 10 CFR 30.4, 36.2, 40.4, and 70.4 are identical.

*Commencement of construction* means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this part that has a reasonable nexus to:

1. Radiological health and safety; or
2. Common defense and security.

In 10 CFR 150.31, *commencement of construction* means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this part that has a reasonable nexus to radiological health and safety. The regulations in 10 CFR 150.31 address the requirement for Agreement State regulation of byproduct material. Although Agreement State licensees may find this ISG informative, they should also communicate with the pertinent Agreement State agency for that agency's applicable requirements and guidance.

The new definitions of "construction" in 10 CFR 30.4, 36.2, and 70.4 are also identical.

*Construction* means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:

- (1) Changes for temporary use of the land for public recreational purposes;
- (2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;
- (5) Excavation;
- (6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (9) Taking any other action that has no reasonable nexus to:
  - (i) Radiological health and safety, or
  - (ii) Common defense and security.

“Construction,” as defined in 10 CFR 40.4, also includes the installation of wells associated with radiological operations (e.g., production, injection, or monitoring well networks associated with in-situ recovery or other facilities).

The Atomic Energy Act of 1954, as amended, expressly limits the NRC’s regulatory authority to matters concerning the radiological public health and safety or common defense and security and non-radiological hazards to the extent such hazards result from the actual processing of by-product material. The NRC has determined that this authority does not extend to site preparation activities that do not have a nexus to radiological health and safety or common defense and security.

This guidance provides criteria for NRC staff to use in evaluating whether a particular construction activity has a nexus to radiological health and safety, and thus falls under the jurisdiction of the NRC for licensing purposes. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a materials facility is operating, or will operate, in accordance with the NRC’s regulations and in a manner that protects the public health and safety or the common defense and security from radiological hazards. The revised definition of construction in 10 CFR 30.4, 36.2, 40.4, 70.4, and 150.31 list activities that are not considered “construction.” This guidance provides examples of activities that fall under each of the excepted activities that do not constitute construction. This guidance addresses some important considerations for materials licensees and applicants that were emphasized in the response to comments on the proposed Material Licenses Construction Rule. For example, site preparation activities that are not considered “construction,” while not under NRC jurisdiction may be subject to the regulatory authority of another Federal, State, or local agency which may require National Environmental Policy Act or state environmental review. NRC’s responsibilities under the National Historic Preservation Act of 1966, as amended (NHPA), must also be satisfied before a license is issued. Specifically, as noted in the SOC to the final Material Licenses Construction Rule, under certain circumstances the NRC may be required to deny a license application if the NRC determines that the applicant intentionally significantly adversely affected, or allowed to be affected, a historic property with intent to avoid the requirements of §106 of the NHPA.

## **DISCUSSION OF EXAMPLES**

In addition to the background discussion provided above, the following examples clarify the delineation of site preparation activities and construction activities. It is important to recognize that the NRC may have regulatory authority over activities that can occur before construction begins, such as procurement of basic components as defined in 10 CFR Part 21, the process of dedicating commercial grade items or basic components, or procurement of items relied on for safety (IROFS) as defined in 10 CFR Part 70. It should also be noted that, while site preparation activities may not require prior NRC approval, various local, State, or other Federal permits may be required.

### **BYPRODUCT MATERIAL (10 CFR PART 30)**

Prior to the conclusion of the environmental review process, applicants for byproduct material licenses or license amendments should not perform construction activities that have a nexus to radiological health and safety or the common defense and security. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC’s regulations and in a manner that

protects the public health and safety or the common defense and security from radiological hazards.

Installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 10 CFR Part 30 that are related to radiological health and safety or common defense and security should not be performed prior to the conclusion of the environmental review of a license application or amendment. Byproduct material license applicants subject to 10 CFR Part 30 may perform those site preparation activities identified in revised 10 CFR 30.4 before the NRC has completed its environmental review of the license application.

Excavation and other site preparation activities that do not have a reasonable nexus to radiological public health and safety or common defense and security, whether permanent or temporary, are not “construction” activities. For example, piles driven to support the erection of a bridge for a temporary or permanent access road to a new facility would not be considered as construction and may be performed prior to the NRC staff concluding its environmental review of a proposed action.

The installation of a temporary feature within an excavation for a building in which materials license activities will be conducted and that will be removed during construction is a site preparation activity. Such features include retaining walls, dewatering systems, ramps, and other structures that will have no physical presence following construction.

Construction includes installation of the foundation, including soil compaction; the installation of permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats), or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; the installation of reinforcing bars to be incorporated into the foundation of the structure; the erection of concrete forms for the foundations that will remain in place permanently (even if nonstructural); and the placement of concrete or other material constituting the foundation of any safety-related feature.

The term “permanent” in this context includes anything that will exist in its final, in-place facility location after commencement of operations with licensed material. Construction also includes the “onsite, in-place” fabrication, erection, integration, or testing activities for any in-scope safety-related equipment. The terms “onsite, in place, fabrication, erection, integration, or testing” describe the process of constructing a facility in its final, onsite plant location, where components or modules are integrated into the final, in-plant location. The fabrication, assembly, and testing of components and modules in a shop building, warehouse, or laydown area, even if located onsite, is not construction. However, the installation or integration of the safety-related equipment into its final plant location is construction.

Construction also includes driving piles for safety-related equipment. Hence, an applicant must obtain a license before driving piles for safety-related equipment. However, driving piles that do not ensure the structural stability or integrity of a safety-related structure (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road) is not construction; therefore, those piles may be driven prior to the NRC staff concluding its environmental review of a proposed action.

## IRRADIATORS (10 CFR 36)

An applicant for a new irradiator license under 10 CFR Part 36 may perform the non-construction activities identified in revised 10 CFR 36.2 at any time. However, installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 10 CFR Part 36 that have a reasonable nexus to radiological safety or security should not be performed prior to the submission of an application for a license and the fee required by 10 CFR 170.31. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC's regulations and in a manner that protects the public health and safety or the common defense and security from radiological hazards. Activities that have a reasonable nexus to radiological health and safety or common defense and security include, but are not limited to, construction of systems subject to 10 CFR Part 36, Subpart C, and the following:

- Earthwork
- Pool excavation
- Footings and foundation for pool
- Irradiator foundations and walls
- Backfill pool
- Install pool liner
- Mechanical rough-in
- Electrical rough-in
- Shoring for roof
- Form and place roof
- Slab on grade

Subpart C of 10 CFR Part 36 currently lists the systems that have a nexus to radiological health and safety and defines the related engineering and safety concerns associated with each system:

- Access Control: Adequacy of access control systems using interlocks and radiation monitors to prevent inadvertent entry to areas where radiation sources are unshielded; to provide emergency exits; and to ensure compliance with all the requirements of 10 CFR 36.23. For computer-controlled access-control systems, licensing staff should consider expert evaluation of the software/system logic before operational testing.
- Site: Potential need for protection against flooding and earth slides.
- Base (soil, rock) for the Pool and Shielding Structures: Strength, settlement, liquefaction, ground water, soil compaction.
- Footers and Foundations for the Pool and Shielding Structures: Strength and reinforcement, alignment with pool and shielding structures.
- Pool and Shielding Structures: Strength and reinforcement, proper density of shielding materials, correct dimensions, minimization of voids in concrete or other shielding.
- Pool Liner: Contact with pool structure, penetrations in the liner, leak-tight welds.
- Pool Plumbing: Makeup water system; water cleanup system; effect of construction materials on pool-water chemistry; drainage system (potentially contaminated spilled water should flow into the pool); siphon breakers; radiation detection and alarm systems.
- Penetrations Through Shielding: Any significant effect on structural strength, shielding, or both.

- Source Rack Protection: If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.
- Source-Rack Mechanical Positioning System: Strength and stiffness of the rack and positioning cables or chains, source shroud will not interfere with source positioning, adequacy of motive power, potential for jamming.
- Source-Rack Movement and Position-Sensing System: Structural attachments for electrical and mechanical transducers, adequacy of transducers for interacting with the source-rack control system.
- Source-Rack Electrical Control System: Adequacy of the design of logistical and operational electrical circuitry and electromechanical components, to ensure unambiguous response of the system, which includes programmable controllers or computers and their interaction with operations, interlocks, doors, signals, and alarms.
- Source-Leak Detection: Adequacy of systems for detecting and isolating leaking sources.
- Hard Wiring: Adequacy of wire gauge and insulation to safely carry design currents and to withstand radiation and ozone damage if exposed; locating and attaching wiring to prevent fretting, wear, and exposure to potential fire hazards; accessibility to wiring for inspection and repair.
- Uninterruptable Electrical Power Supply: Adequate and reliable power capability to operate all electrical systems that are important to safety (including backup power sources); compatibility of the power supply with the electrical system.
- Fire Protection System: Adequacy to detect fire and smoke and to be manually as well as automatically initiated; must ensure that raised sources are immediately lowered into the pool.
- Emergency Systems for Returning an Up-stuck Source Rack to the Pool: Capability of the electrical control system to sense and signal the occurrence of an up-stuck source-rack; adequacy of mechanical or electrical means for personnel to safely release and lower the rack; need for, and adequacy of, a system to cool the source-rack until it can be released and lowered.
- Ozone Ventilation System: Capability of the system to be properly initiated and to provide adequate volume flow rate of air to protect personnel and components.
- System for Transferring Sources from and to Transport Vehicles: Adequately sized openings in the shield-structure roof if sources are roof-loaded; structural adequacy of the roof-shield plug and its supports for its removal and replacement; structural and mechanical adequacy of systems for moving shipping containers into and out of the pool area.

URANIUM CONVERSION FACILITIES, ENRICHMENT FACILITIES, FUEL FABRICATION FACILITIES, AND URANIUM HEXAFLUORIDE (UF<sub>6</sub>) DECONVERSION FACILITIES (10 CFR PART 40 and 10 CFR PART 70)

If any of the following actions are performed before the NRC staff has completed its environmental review process, then the NRC has grounds for denial of a license application, in accordance with 10 CFR 40.32(e), and 70.23(a)(7):

1. Procurement or construction of engineered items that are items relied on for safety (IROFS) required to meet the performance requirements of 10 CFR 70.61.

2. Construction of guard stations, fences, vehicle barriers, or other features that are, or will become, components of physical security systems required by regulations or orders.
3. Construction or installation of equipment whose purpose is the detection of radioactive material accidents or mitigation of the consequences of radioactive material accidents.
4. Installation of storage tanks that contain chemicals that could affect the safety of licensed material.
5. Construction of facilities or warehouses that will be used for operations involving licensed material.
6. Driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for IROFS and on-site emergency facilities.
7. Erection of buildings, offices, construction trailers and warehouses that will become part of a Standard Practice Procedures Plan for Protection of Classified Information.

Construction includes the onsite, in-place fabrication, erection, integration, or testing activities for any safety related item. The terms “onsite, in place, fabrication, erection, integration, or testing” describe the process of constructing a fuel cycle facility in its final, onsite plant location, where components or modules are integrated into the final, in-plant location. Under the definition of “construction” applicants and existing licensees may be able to fabricate, assemble, and test components and modules in a shop building, warehouse, or laydown area, even if these facilities are located onsite. However, the installation or integration of that safety related equipment into its final plant location is a construction activity and should not be performed until after the NRC staff concludes its environmental review of the license application.

Excavation includes the removal of any soil, rock, gravel, or other material below the final ground elevation to the final parent material, and may be conducted prior to the conclusion of the NRC staff’s environmental review. However, placing permanent, nonstructural dewatering materials, mudmats, or engineered backfill in advance of placing the foundation and associated permanent retaining walls for buildings or structures that will contain licensed materials are construction activities and should not be performed prior to the conclusion of the NRC staff’s environmental review.

Construction includes driving piles for buildings or structures that will contain licensed materials. Hence the driving of piles for such buildings or structures should not be performed before the NRC staff concludes its environmental review. Driving piles that do not ensure the structural stability or integrity of buildings or structures within the scope of the definition of “construction” (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road) is not “construction”; therefore, those piles may be driven prior to the conclusion of the NRC staff’s environmental review.

In addition to 10 CFR 40.4, 51.4, and 70.4 criteria that are used to determine the scope of activities that fall within the definition of construction, construction includes the necessary excavation for safety related items. A necessary excavation is the portion of an excavation that provides sufficient construction access to the structures that are within the definition of construction. Applicants should ensure, and NRC staff will confirm, that these construction activities are separate from, and do not result in, adverse interactions with construction-related safety related item including influence on the stability (static and dynamic) analyses.

Construction includes any change made to the parent material in which the excavation occurs (e.g., soil compaction, rock grouting); the driving of piles; the installation of foundations; the installation of permanent drainage systems and geofabric; the placement of backfill, concrete

(e.g., mudmats) or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; and the installation of reinforcing bars to be incorporated into the foundation of any safety related items that fall within the definition of construction. The foregoing items fall within the definition of construction because they have a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC's regulations and in a manner that protects the public health and safety from radiological hazards.

### ACTIVITIES WHICH HAVE NO REASONABLE NEXUS TO RADIOLOGICAL SAFETY OR SECURITY

The NRC has determined that, in general, the following activities at source, byproduct, and SNM facilities and irradiators listed in 10 CFR 30.4, 36.2, 40.4, and 70.4, do not have a reasonable nexus to radiological health and safety and the common defense and security may be performed by a licensee or applicant at any time. Note that in some circumstances, based on the specific licensing proposal, any of these activities could be determined to have a reasonable nexus to radiological health and safety or common defense and security and, based on that determination, these activities would be construction:

- (1) Changes for temporary use of the land for public recreational purposes;
- (2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to 10 CFR Parts 30, 36, 40, or 70;
- (5) Excavation;
- (6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (9) Taking any other action that has no reasonable nexus to:
  - (i) Radiological health and safety, or
  - (ii) Common defense and security.

While the above site preparation activities may not require prior NRC approval, other Federal, State, or Local permits may be required.

### **FINAL RESOLUTION**

This interim staff guidance will be incorporated into the next revisions of NUREG-1556, and NUREG-1520.



## APPLICABILITY

This ISG is applicable to all 10 CFR Parts 30, 36, 40, and 70 license applicants and existing licensees considering site preparation activities or construction activities at a facility that is subject to, or will be subject to, the licensing requirements of these parts.

## REFERENCES

- 1) NUREG-1556, Volume 6, "Consolidated Guidance About Material Facilities: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses," January 1999.
- 2) NUREG-1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Possession Licenses for Manufacturing and Distribution," December 2000.
- 3) NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 2010.
- 4) Regulatory Issue Summary 2009-12, Uranium Recovery Policy Regarding Site Preparation Activities at Proposed, Unlicensed Uranium Recovery Facilities, September 23, 2009, ML092090353.
- 5) NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with Materials Facilities," August 2003.
- 6) DC/COL-ISG-4, "Interim Staff Guidance on the Definition of Construction and on Limited Work Authorizations," February 9, 2009, ML082970729.
- 7) Inspection Manual Chapter 2815, "Construction and Preoperational Inspection of Panoramic Wet-Source-Storage Gamma Irradiators," March 27, 2001, ML010990225.
- 8) Docket No. 030-36974, Final Environmental Assessment Related to the Proposed Pa'ina Hawaii, LLC, Underwater Irradiator in Honolulu, Hawaii; August 10, 2007; ML071150121.
- 9) Docket No. 70-7015, Environmental Assessment for an Exemption to 10 CFR Parts 30, 40, and 70, Commencement of Construction Requirements, Areva Enrichment Services, Eagle Rock Enrichment Facility, Bonneville County, Idaho, February 28, 2010, ML093220528.
- 10) NUREG-1811, "Environmental Impact Statement for an Early Site Permit at the North Anna ESP Site," December 2006.
- 11) NUREG-1947, "Final Supplemental Environmental Impact Statement for Combined License (COLs) for Vogtle Electric Generating Plant Unit 3 and 4," March 2011.

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**APPENDIX N**

**SAFETY CULTURE STATEMENT OF POLICY**



## **Safety Culture**

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011, and can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf>. It is also posted in the NRC's Agencywide Documents Access and Management System (ADAMS) and can be found using Accession Number ML11146A047.

### **Safety Culture Policy Statement**

The purpose of this Statement of Policy is to set forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The Commission encourages the Agreement States, Agreement State licensees and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy.

Nuclear Safety Culture is defined as *the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment*. Individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The performance of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The NRC will not monitor or trend values. These will be the organization's responsibility as part of its safety culture program.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, e.g., production, schedule, and the cost of the effort versus safety. It should be noted that although the term "security" is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

The following are traits of a positive safety culture:

- (1) *Leadership Safety Values and Actions* – Leaders demonstrate a commitment to safety in their decisions and behaviors;
- (2) *Problem Identification and Resolution* – Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance;
- (3) *Personal Accountability* – All individuals take personal responsibility for safety;
- (4) *Work Processes* – The process of planning and controlling work activities is implemented so that safety is maintained;
- (5) *Continuous Learning* – Opportunities to learn about ways to ensure safety are sought out and implemented;
- (6) *Environment for Raising Concerns* – A safety-conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;
- (7) *Effective Safety Communication* – Communications maintain a focus on safety;
- (8) *Respectful Work Environment* – Trust and respect permeate the organization; and
- (9) *Questioning Attitude* – Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

There may be traits not included in this Statement of Policy that are also important in a positive safety culture. It should be noted that these traits were not developed to be used for inspection purposes.

It is the Commission's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials, should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments. The Commission recognizes the diversity of these organizations and acknowledges that some organizations have already spent significant time and resources in the development of a positive safety culture. The Commission will take this into consideration as the regulated community addresses the Statement of Policy.

<b>NRC FORM 335</b> (12-2010) NRCMD 3.7	<b>U.S. NUCLEAR REGULATORY COMMISSION</b>  <b>BIBLIOGRAPHIC DATA SHEET</b> <i>(See instructions on the reverse)</i>	<b>1. REPORT NUMBER</b> (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.) NUREG-1556, Volume 4, Revision 1 DRAFT			
<b>2. TITLE AND SUBTITLE</b> Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauge Licenses - Draft Report for Comment	<b>3. DATE REPORT PUBLISHED</b> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">MONTH</td> <td style="width: 50%;">YEAR</td> </tr> <tr> <td>March</td> <td>2013</td> </tr> </table>	MONTH	YEAR	March	2013
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March	2013				
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<b>5. AUTHOR(S)</b> Jackie Cook, Brandon Juran, Aaron McCraw, Michael Reichard, and Gretchen Rivera-Capella	<b>6. TYPE OF REPORT</b> <p style="text-align: center;">Technical</p>				
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<b>11. ABSTRACT (200 words or less)</b> This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for fixed gauges. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.					
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