

Consolidated Guidance About Materials Licenses

Program-Specific Guidance
About Fixed Gauge Licenses

Final Report

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Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Fixed Gauge Licenses

Final Report

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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 whether the proposed activities are acceptable for licensing purposes.

Paperwork Reduction Act Statement

This NUREG references information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0001, 3150-0008, 3150-0011, 3150-0014, 3150-0016, 3150-0017, 3150-0035, 3150-0044, 3150-0120, 3150-0151, and 3150-0214.

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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.

Volume No.	Volume Title
1	Program-Specific Guidance About Portable Gauge Licenses
2	Program-Specific Guidance About Industrial Radiography Licenses
3	Applications for Sealed Source and Device Evaluation and Registration
4	Program-Specific Guidance About Fixed Gauge Licenses
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers
8	Program-Specific Guidance About Exempt Distribution Licenses
9	Program-Specific Guidance About Medical Use Licenses
10	Program-Specific Guidance About Master Materials Licenses
11	Program-Specific Guidance About Licenses of Broad Scope
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses
18	Program-Specific Guidance About Service Provider Licenses
19	Guidance for Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
20	Guidance About Administrative Licensing Procedures
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

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, to incorporate certain security requirements and other regulatory and policy changes that have been implemented since the original version was published.

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 or Agreement State 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 renew a license.

The comments received during the public comment period for NUREG–1556, Volume 4, Revision 1, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents Access and Management System (ADAMS) under ML15055A205. Access to ADAMS is available on the public Web site at: <http://www.nrc.gov/reading-rm/adams.html>. The comments received by NRC included general corrections, comments on training, and comments on safety culture.

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ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
ANSI	American National Standards Institute
AU	authorized user
bkg	background
Bq	becquerel
CFR	<i>Code of Federal Regulations</i>
cpm	counts per minute
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
G-M	Geiger-Mueller
Gy	Gray
HAZMAT	hazardous material
IN	Information Notice
L/C	License Condition
MDA	minimum detectable activity
mrem	millirem
mSv	millisievert
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NSTS	National Source Tracking System
NSTTR	National Source Tracking Transaction Report
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
PII	personally identifiable information
Q	quality factor
R	Roentgen
Rev.	revision
RIS	Regulatory Issue Summary
RQ	reportable quantity
RSO	radiation safety officer
SSD	Sealed Source and Device [registration certificate]
std	standard
Sv	sievert
TEDE	total effective dose equivalent
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 also provides the U.S. Nuclear Regulatory Commission (NRC) staff with the criteria for evaluating such applications. It is not intended to address the research and development of fixed gauges or the commercial aspects of manufacturing, distributing, and nonroutine 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 considerations. Applicants should obtain this information from the manufacturers or suppliers if such information is not provided with the gauge.

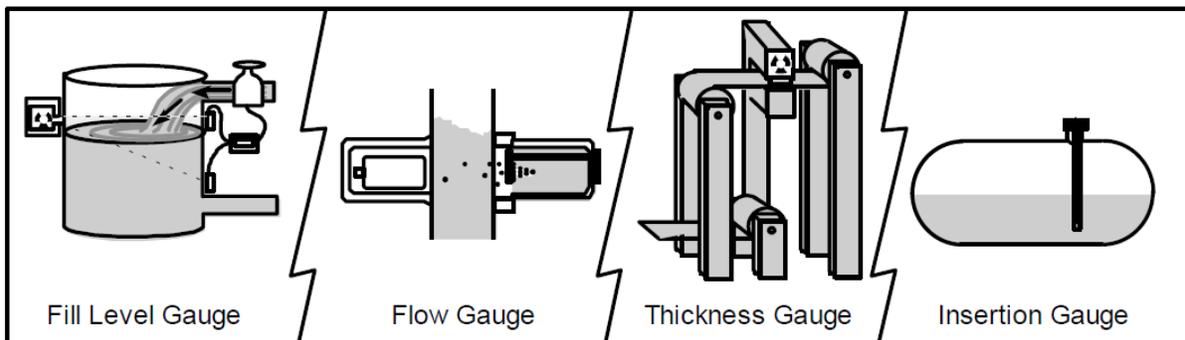


Figure 1-1. Examples of Several Different Types of Fixed Gauges

Chapter 8, “Contents of an Application,” of this report identifies the information needed to complete NRC Form 313, “Application for Materials License” (see Appendix A of this NUREG), 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 of this NUREG, "Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313," may be used to provide supporting information.

In this document, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE), as defined in 10 CFR Part 20, "Standards for Protection Against Radiation." To describe units of radiation exposure or dose, rem and its International System of Units equivalent, sievert (Sv) (1 rem = 0.01 Sv), are used. This is done because 10 CFR Part 20 sets dose limits in terms of rem (Sv), rather than rad or roentgen. When the radioactive material emits beta and gamma rays, 1 roentgen is assumed to equal 1 rad, which is assumed to equal 1 rem. For alpha- and neutron-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles and neutrons requires the use of an appropriate quality factor (Q) value. These Q values are used to convert absorbed dose (rad) to dose equivalent (rem). Tables 1004(b).1 and .2 in 10 CFR 20.1004, "Units of radiation dose," address the Q values for alpha particles and neutrons.

The NRC has regulatory authority over land determined to be “exclusive Federal jurisdiction,” while the Agreement State may have jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for determining, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS) procedures in the State Agreement series, SA-500, “Jurisdiction Determination,” which is available at <https://scp.nrc.gov>. Once on the Web site, use the link for “NMSS Procedures” in the left-hand column under “Resources & Tools.”

Table 2-1 provides a quick way to evaluate whether the NRC or an Agreement State has regulatory authority.

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that 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 ³
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State.	Agreement State
Non-Federal entity in Agreement State	Agreement State ⁴
Non-Federal entity in Agreement State at federally controlled site not subject to exclusive Federal jurisdiction	Agreement State ⁴

³The 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 may be 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.

⁴Section 274m. of the Atomic Energy Act (AEA) withholds to the NRC regulatory authority over radioactive materials covered under the Section 274b. agreements 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. (This is an uncommon situation that NRC usually evaluates on a case-by-case basis.) Individuals or companies wishing to possess or use licensed material should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use.

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 10 CFR 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 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State ⁴

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available at the NMSS public Web site, <https://scp.nrc.gov>. A request for the list can also be made to an NRC regional office.

2.2 Reciprocal Recognition of Specific Licenses

Performing licensed activities in other jurisdictions is possible through reciprocal recognition of specific licenses (i.e., reciprocity). Agreement States have reciprocity provisions that permit NRC licensees to perform licensed activities under circumstances when an Agreement State is the regulatory authority (See Section 2.1). NRC licensees and Agreement State licensees are subject to the regulations of the regulatory authority as indicated in Section 2.1. To ensure compliance with an Agreement State’s reciprocity requirements, licensees are advised to request authorization from the appropriate Agreement State radiation control program office well in advance of the scheduled use of licensed material.

Agreement State licensees that wish to conduct licensed activities in areas under NRC jurisdiction must either obtain a specific NRC license or file for reciprocity with the appropriate NRC regional office for the Agreement State that issued their license. Failure to file for reciprocity or obtain a specific NRC license before working in areas under NRC jurisdiction can result in NRC enforcement action, which may include civil penalties. The reciprocity filing must be renewed annually.

Specific guidance regarding NRC licensees filing for reciprocity in Agreement States and Agreement State licensees filing for reciprocity with the NRC or another Agreement State are provided in NUREG–1556, Volume 19, “Consolidated Guidance About Materials Licenses: 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).”

3 MANAGEMENT RESPONSIBILITY

The U.S. Nuclear Regulatory Commission (NRC) recognizes that effective management of radiation safety programs 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 Title 10 of the *Code of Federal Regulations* (10 CFR) 30.32(c), each application must be signed by the applicant or licensee or a person duly authorized to act for and on 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 behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on 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, the licensee’s operating, emergency, and security procedures, and NRC license commitments
- 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
- commitment to report defects, noncompliances, or reportable events in accordance with regulations
- 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, “Employee protection,” and 10 CFR 30.10, “Deliberate misconduct”
- 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)
- 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, under “Document Collections” 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 NRC’s safety culture policy statement (76 FR 34773; June 14, 2011) 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.

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.

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. 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 safety culture trait specified in Table 3-1 as "Problem Identification and Resolution" (issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance). However, licensees should be aware that this is just an example, and should consider reviewing their radiation safety programs in order to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

Refer to Appendix M of this NUREG 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/safety-culture.html>.

Table 3-1. Traits of a Positive Safety Culture		
Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
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
Work Processes	Continuous Learning	Environment for Raising Concerns
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

Table 3-1. Traits of a Positive Safety Culture

Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Communications maintain a focus on safety	Trust and respect permeate the organization	Individuals avoid complacency and continuously 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. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

The current versions of these parts can be found under the "Basic References" link at the U.S. Nuclear Regulatory Commission's (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](#), "Agency Rules of Practice and Procedure"
- [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 37](#), "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- [10 CFR Part 71](#), "Packaging and Transportation of Radioactive Material"
- [10 CFR Part 110](#), "Export and Import of Nuclear Equipment and Material"
- [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 these documents may be obtained by calling the Government Publishing Office Customer Contact Center toll-free at 866-512-1800, in Washington, DC; calling 202-512-1800; or ordering online at <http://bookstore.gpo.gov>.

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 can also be accessed from the "NRC Library" link on the NRC's public Web site at <http://www.nrc.gov>. Regulations are periodically amended, and the NRC (as well as all other Federal agencies) is required to publish notice of such amendments in the *Federal Register*.

5 HOW TO FILE

5.1 Application Preparation

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix B of this NUREG), Items 1 through 4, 12, and 13, on the form itself. A link to the form is available at <http://www.nrc.gov/reading-rm/doc-collections/forms/>.
- Complete NRC Form 313, Items 5 through 11, on supplementary pages or use Appendix C of this NUREG.
- Provide sufficient detail for the NRC to determine that the 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 C pages, as applicable, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Avoid submitting proprietary information and personally identifiable information. If submitted, proprietary, personal privacy, security-related, and other sensitive information should be clearly identified according to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public inspections, exemptions, requests for withholding" (see Chapter 6, "Identifying and Protecting Sensitive Information").

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 Paper Applications

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 all documents, typed, on 8½ × 11-inch or legal-sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura.
- Use 11-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).

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").

5.4 Electronic Applications

Applications may be submitted in electronic form via the NRC's Electronic Information Exchange, or CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of non-public information.

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

All licensing applications, except for portions containing sensitive information, will be made available for review in the U.S. Nuclear Regulatory Commission (NRC) Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit www.nrc.gov.

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information should be marked as indicated in the list that follows in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR 2.390) before the information is submitted to the NRC. Key examples are as follows:

- **Proprietary Information and 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. Appendix N of this NUREG provides a checklist for requests for withholding proprietary information from public disclosure.
- **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, and Information Notice (IN) 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" and "Information Notices," respectively: <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 the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. 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 Information—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 Web page 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>.

The regulations list various forms of information that can be protected from public disclosure. These include:

- trade secrets and commercial or financial information
- interagency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with NRC
- certain records or information compiled for law enforcement purposes
- geological and geophysical information and data, including maps, or information concerning wells
- personnel, medical, and other information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

In 10 CFR 2.390, NRC specifies the procedures and requirements for persons to submit sensitive information to NRC so that it may be properly protected from disclosure. This regulation is available electronically on the NRC Web site: <http://www.nrc.gov/reading-rm/doc-collections/cfr>.

Except for personal privacy information, which is not subject to the affidavit requirement, if NRC determines that the application or affidavit is deficient (i.e., does not contain the required information as outlined in 10 CFR 2.390), the applicant will be notified that additional information is needed and that the review will continue when the required information is received.

If the request is denied, in whole or in part, NRC will give the applicant the option of withdrawing the information or application, as permitted in 10 CFR 2.390. If the applicant decides not to withdraw the information or application, NRC will notify the applicant in writing that the request for withholding has been denied and that NRC will disregard any references concerning the proprietary status of the information.

Any part of a license application or information provided by a licensee or applicant that the NRC determines should be withheld from public disclosure will be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the licensee or applicant will be notified in writing that NRC plans to honor the request. Management Directive 12.6 is available electronically on the NRC Web site: <http://www.nrc.gov/reading-rm/doc-collections/management-directives/>.

Anyone submitting a request to withhold information from public disclosure should thoroughly review 10 CFR 2.390 and be familiar with its requirements and limitations.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, NRC may send copies of this information to NRC consultants working in that area. NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future, such that the information could then be made available for public inspection, the licensee or applicant should promptly notify the NRC. The licensee or applicant also should understand that NRC may have cause to review this determination in the future; for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if NRC makes a determination adverse to the above, the licensee or applicant will be notified in advance of any public disclosure. Anyone submitting commercial or financial information they believe to be privileged, confidential, or a trade secret must remember that the NRC's policy is to achieve an effective balance between legitimate concerns for the protection of competitive positions and the right of the public to be fully apprised of the basis for, and the effects of, licensing or rulemaking actions. It is within NRC's discretion to withhold such information from public disclosure.

7 APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to Title 10 of the *Code of Federal Regulations* (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 U.S. Nuclear Regulatory Commission (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 of an application 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." Note that in order to pay reduced fees, a licensee that qualifies as a "small entity" must provide proper certification of this status to the NRC each year along with its annual fee payment.

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.

8 CONTENTS OF AN APPLICATION

The following information applies to the indicated items on U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix A of this NUREG).

All items in the application should be completed in enough detail for the NRC to determine whether the proposed equipment, facilities, training and experience, and radiation safety and security programs satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. Consideration should 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.

Title 10 of the *Code of Federal Regulations* (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.

The application should include information on how the licensee will implement the security requirements in 10 CFR 20.1801, "Security of stored material," and 10 CFR 20.1802, "Control of material 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 precicensing visit may be conducted prior to 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. See "License Amendments and Renewals" 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 and the transfer approved before control of the license is transferred (see Section 9.1, "Timely Notification of Transfer of Control"). The NRC must also be notified 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.

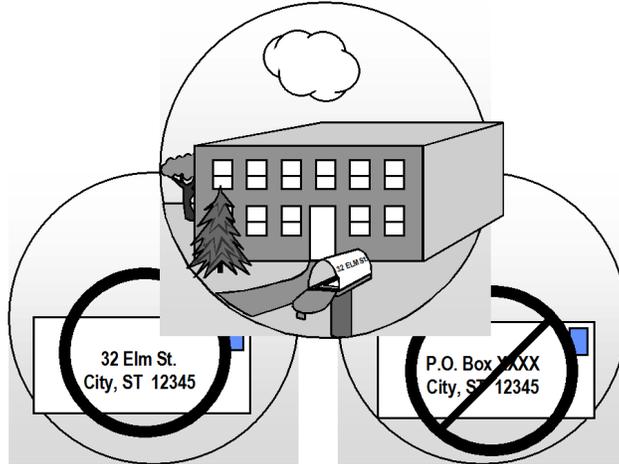
Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains subject to all applicable NRC regulatory requirements. The NRC must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled 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 and may request that the U.S. Department of Justice represent the NRC's interests in the bankruptcy proceeding.

Response from Applicant: None is required at the time of application for a new license. Licensees must immediately notify the NRC in writing following 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 acceptable location of use or possession specifies street address, city, State, and zip code and does not include a post office box number.

Figure 8-1. Location of Use or Possession

A license amendment is required before receiving, using, or storing licensed material at an address or location not 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).

To conduct operations at temporary jobsites (i.e., locations where work is conducted for limited periods of time), the address may be stated as “temporary jobsites anywhere in the U.S. where the NRC maintains jurisdiction.” For more information, see Section 8.10.10, “Fixed Gauges Used at Temporary Job Sites,” of this NUREG. That section offers examples of operations where fixed gauges might be used at temporary jobsites and identifies information that should be provided to the NRC to support a request for these operations.

If an applicant submits documents that give the exact location of use and storage for any amount of radioactive material, the applicant should mark these documents as “Security-Related Information—Withhold under 10 CFR 2.390.” See Chapter 6, “Identifying and Protecting Sensitive Information,” for more details.

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 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 or room numbers where each gauge was used or

stored, and any information relevant to damaged devices or leaking radioactive sources or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

8.4 Item 4: Person To Be Contacted About This Application

Identify the individual who can answer questions about the application, and include a telephone number where the individual may be contacted as well as business cell phone numbers and e-mail addresses. This individual, usually the radiation safety officer (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 provided for informational purposes 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 of this NUREG), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix B of this NUREG 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 31.5, 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.210

Criteria: Applicants must provide the radionuclide and nominal activity for each requested sealed source, the manufacturer's or distributor's name, and model number for each device, and the number of gauges for each model. Licensees will be authorized to possess and use only those sealed source and devices specifically approved and registered by the NRC or an Agreement State. The applicant should also provide a description of the use of the gauges.

Discussion: The NRC or an Agreement State performs safety evaluations of fixed gauges before distribution of the devices to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) registration certificate issued to the manufacturer (or distributor).

Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates without obtaining the 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, particular conditions of use that would reduce the radiation safety of the device, or circumstances unique to the sealed source and device. For example, the working life of the device or the 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 from the manufacturer or distributor. If the manufacturer and distributor are no longer in service, a copy of the SSD registration certificate may be requested from the NRC or the issuing Agreement State. The applicant should review the provisions of the SSD registration certificate with the manufacturer or distributor, the NRC, or the issuing Agreement State.

The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material, as specified in Appendix A to 10 CFR Part 37. The requirements in 10 CFR 20.2207 for submitting National Source Tracking Transaction Reports (NSTTR) are applicable to those licensees that manufacture, transfer, receive, disassemble, or dispose of sealed sources containing a quantity equal to or greater than the Category 1 or Category 2 levels of radioactive material listed in Appendix E to 10 CFR Part 20. See section 8.10.11, “Security Program for Category 1 and Category 2 Radioactive Material,” of this NUREG for further information.

This NUREG addresses fixed gauges that are authorized under a specific license. Note that some fixed gauges may be authorized under a general license in accordance with 10 CFR 31.5. A specific license is not necessary to possess generally licensed gauges, and an application for a specific license does not have to include such gauges. However, licensees may choose to list generally licensed gauges on their specific licenses, which would require such licensees to possess and use these gauges in accordance with their specific license.

Response from Applicant: Provide all of the following:

- Identify each radionuclide and nominal activity in each fixed gauge.
- Identify the manufacturer (or distributor) and model number of each type of fixed gauge.
- State the number of each type of fixed gauge requested.
- Provide a description of the use of the gauges.
- Confirm that the activity per source and maximum activity per gauge being requested will not exceed the maximum activity listed in the approved certificate of registration issued by the NRC or by an Agreement State.

For existing licensees with Category 1 or Category 2 quantities of materials, mark the section related to the possession of sealed source 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 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, 10 CFR 30.51(f)

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. Pursuant to 10 CFR 30.35(g), licensees must transfer these records important to decommissioning to the new proposed licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, each licensee must forward the records required by 10 CFR 30.35(g) to the appropriate NRC regional office.

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 possession limits do 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.

Radionuclide (Sealed Sources)	Activity in Gigabecquerels	Activity in Curies
Cobalt-60	3.7×10^5	10,000
Krypton-85	3.7×10^7	1,000,000
Strontium-90	3.7×10^4	1,000
Cesium-137	3.7×10^6	100,000
Americium-241	3.7×10^3	100
Californium-252	3.7×10^3	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 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 regulations in 10 CFR 30.35(g) also require 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 (not blueprints) with modifications of structures and equipment shown, as appropriate, fulfill this requirement. If drawings are not available, licensees must substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning these areas and locations. If no records exist regarding structures and equipment where gauges were used or stored, licensees must 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 and other incidents that involve the spread of contamination) they also need to maintain records about possible 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, copies of a current leak test for each gauge, and records of transfer or disposal.

Response from Applicant: No response is needed from most applicants. If financial assurance is required, submit the documentation required under 10 CFR 30.35 and follow the guidance of NUREG-1757.

Reference: NUREG-1757, Volume 3, “Consolidated 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. 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.
- 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 of this NUREG

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 is key to overseeing and ensuring safe operation of the licensee's radiation protection program. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations that he or she considers unsafe. He or she should have sufficient time and commitment from management to fulfill his or her duties and responsibilities to ensure that radioactive materials are used in a safe manner, approved radiation safety procedures are being implemented, and the required records of licensed activities are maintained. Typical RSO duties are illustrated in Figure 8-2 and described in Appendix C of this NUREG. 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 identified and that the named individual knows of his or her designation as RSO. Appendix C of this NREG also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO.

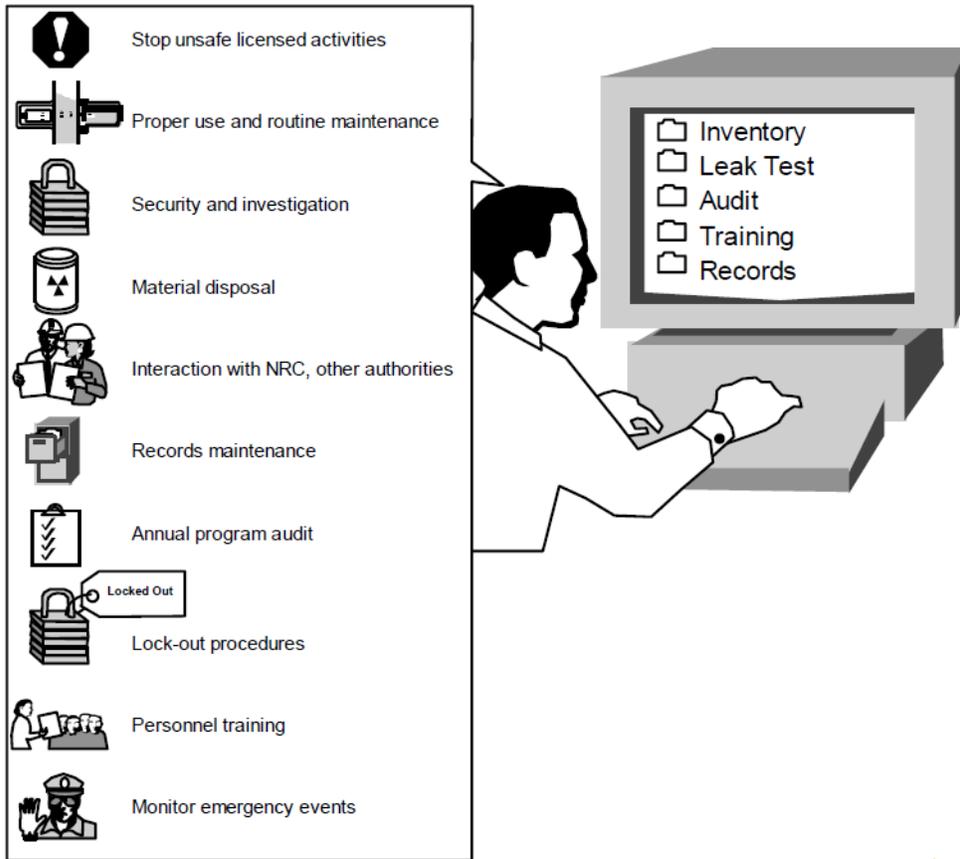


Figure 8-2. Typical Duties and Responsibilities of RSOs

The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals, sometimes referred to as “alternate RSOs” or “site RSOs.” For example, a licensee with multiple permanent locations of use or use at temporary jobsites may appoint “site RSOs,” who assist the RSO and are responsible for the day-to-day activities at these locations. Licensees may also appoint “alternate RSOs” who may “step in” as an emergency contact when the RSO is unavailable. Such “alternate RSOs” or “site RSOs” do not need to meet all RSO qualifications; however, they should be qualified, experienced authorized users who have adequate knowledge of the activities to which they are assigned. These individuals should have the same management support and decision-making authority as the RSO that is necessary to accomplish the tasks to which they have been assigned. Please note that only the primary RSO is named on an NRC license.

Response from Applicant: Provide the following:

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

Note: Licensees must notify the NRC and obtain a license amendment before making changes in the designation of the RSO responsible for the radiation safety program.

8.7.2 Authorized Users

Regulation: 10 CFR 30.33(a)(3)

Criteria: The individuals using the gauges are usually referred to as “authorized users.” 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 of this NUREG

Applicants requesting to perform nonroutine operations, such as gauge 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; gauge 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 titled, ‘Authorized Users’ in NUREG–1556, Volume 4, Revision 1, ‘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 3 years following the last use of licensed material by the AU.

8.8 Item 8: Training for Individuals Working In or Frequenting Restricted Areas

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

Criteria: Individuals 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, 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 titled, "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:

- the statement: “We will ensure that the location of each fixed gauge meets the criteria in Section 8.9, ‘Facilities and Equipment,’ in NUREG–1556, Volume 4, Revision 1, ‘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, 10 CFR 20.2102, 10 CFR 20.2103(a)

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 U.S. Department of Transportation (DOT) regulations (as applicable) and the terms and conditions of the license.
- Occupational doses and doses to members of the public are ALARA.

Records of audits and other reviews of program content are maintained for 3 years after the record is made.

Discussion: Appendix E of this NUREG contains a suggested annual audit program that is specific to the use of fixed gauges and is acceptable to the NRC. Since all areas indicated in Appendix E may not be applicable to every licensee and all items may not need to be addressed during each audit, licensees may wish to develop a program-specific audit checklist.

The NRC encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff, and spot-checking required records. As part of the audit program, licensees should consider including unannounced audits of fixed gauge users to observe whether radiation safety procedures are being followed.

It is essential that once problems are identified, comprehensive corrective actions 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 routinely reviews licensee's records to verify whether appropriate corrective actions were implemented in a timely manner to address recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. The NRC can opt to exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented. The NRC's Enforcement Policy may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>, and the Enforcement Manual may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>. For examples of the NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's enforcement documents at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

With regard to audit records, 10 CFR 20.2102 requires, in part, that licensees maintain records of "audits and other reviews of program content and implementation" for 3 years after the record is made. 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 should not submit its audit program to the NRC for review during the licensing phase. The audit program will be reviewed during NRC inspections.

Reference: Inspection Procedure 87124, "Fixed and Portable Gauge Programs"

8.10.2 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 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 that only engage in routine operations do not possess their own radiation survey meters, because these licensees contract with service providers that perform the surveys required by 10 CFR 20.1501. However, an applicant that plans to conduct nonroutine operations will also need to perform surveys in accordance with 10 CFR 20.1501 that are related to these activities and such licensees usually possess radiation survey meters that are used for this purpose. 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 of this NUREG 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 whether 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:

- the statement: “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

- the statement: “We will use radiation survey instruments that meet the criteria in Section 8.10.2, ‘Radiation Monitoring Instruments,’ in NUREG–1556, Volume 4, Revision 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses,’ and one of the following three choices:
 - “Each radiation survey meter will be calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform radiation survey meter calibrations.”

OR

- “We will implement the model radiation survey instrument calibration program in Appendix F, ‘Model Radiation Survey Instrument Calibration Program,’ in NUREG–1556, Volume 4, Revision 1, ‘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 PREVIOUS STATEMENTS

- submit a description of an alternative method to perform radiation surveys according to 10 CFR 20.1501

Notes:

- Alternative responses will be reviewed against the previously criteria listed.
- Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized firm to perform calibrations, the licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made, 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 every 6 months (or at some other intervals justified by the applicant and approved by the NRC) to account for all sealed sources
- update transactions in the National Source Tracking System (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 sealed sources/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 fixed 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:

- radionuclide and the activity (in units of becquerels or curies) of byproduct material in each sealed source
- manufacturer’s or distributor’s name, model number, and serial number (if appropriate) of each device containing byproduct material
- location of each sealed source and device
- for inventories, the date of the inventory, and name 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)

Type of Record	How Long Record Must Be Maintained
Receipt	For as long as the material is possessed and for 3 years following the transfer or disposal of the material
Inventory	For 5 years from the date of the inventory in accordance with license conditions
Transfer	For 3 years after each transfer unless a specific requirement dictates otherwise
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 either of the following:

- the statement: “Physical inventories will be conducted 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.”

OR

- a description and justification of an alternate frequency and/or procedure to account for all sealed sources and devices received and possessed under the license

AND

- the statement: “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 Web site 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, 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 a radiation dose in excess of the limits in 10 CFR 20.1502(a), and maintain a record of this evaluation for inspection by the NRC

OR

- provide and require the use of individual monitoring devices (dosimetry) (All personnel dosimeters that require processing to determine the radiation dose must be processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved processor.)

Discussion: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. When personnel monitoring is required, for all personnel dosimeters that require processing to determine the radiation dose, licensees must 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.

The annual dose limits for adult radiation workers are shown in Figure 8-3. Note that in accordance with 10 CFR 20.1207, the annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers. Also, 10 CFR 20.1208 requires the licensee to ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupation exposure of a declared pregnant woman, does not exceed 0.5 rem [5 mSv].

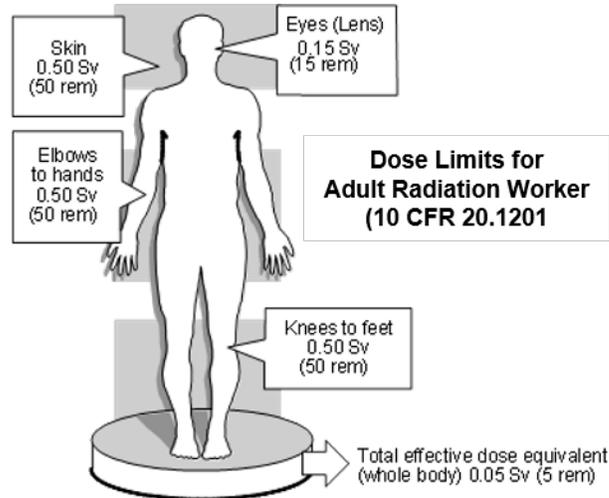


Figure 8-3. Annual Dose Limits for Adult Radiation Workers

Total effective dose equivalent (TEDE) equals the effective dose equivalent (for external exposures) plus the committed effective dose equivalent (for internal exposures).

The use of individual monitoring devices for external dose is required, pursuant to 10 CFR 20.1502(a), for

- adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately)
 - 5 mSv [0.5 rem] deep-dose equivalent
 - 15 mSv [1.5 rems] lens (of the eye) dose equivalent
 - 50 mSv [5 rems] shallow-dose equivalent to the skin
 - 50 mSv [5 rems] shallow-dose equivalent to any extremity
- minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately)
 - 1.0 mSv [0.1 rem] deep-dose equivalent
 - 1.5 mSv [0.15 rem] lens (of the eye) dose equivalent
 - 5 mSv [0.5 rem] shallow-dose equivalent to the skin
 - 5 mSv [0.5 rem] shallow-dose equivalent to any extremity
- declared pregnant women who are likely to receive a dose from radiation sources external to the body during the entire pregnancy in excess of 1.0 mSv [0.1 rem] deep-dose equivalent

- individuals entering a high or very high radiation area

Under conditions of routine use, typically a worker does not require an individual monitoring device (dosimetry). A worker also may not require dosimetry when proper emergency procedures are followed. Appendix G of this NUREG provides guidance on performing a prospective evaluation demonstrating that workers are not likely to exceed the limits in 10 CFR 20.1502(a) and thus are not required to have personnel dosimetry.

Workers who perform nonroutine operations, such as gauge 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; gauge alignment; or removal of a gauge from service, are more likely than workers who only engage in routine activities to exceed the limits in 10 CFR 20.1502(a). Applicants must provide dosimetry (whole body and perhaps extremity monitors) to workers who perform nonroutine operations or must perform a prospective evaluation demonstrating that unmonitored workers who perform nonroutine operations are not likely to receive radiation doses in excess of the limits in 10 CFR 20.1502(a).

Response from Applicant: Provide one of the following:

- the statement: “We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a).”

OR

- the statement: “We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed and evaluated by a NVLAP-approved processor.”

Notes:

- Alternative methods for demonstrating compliance with the referenced regulations will be evaluated against the previously listed criteria.
- 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 maintains a directory of laboratories that are NVLAP-approved at <http://ts.nist.gov/standards/scopes/dosim.htm>.

8.10.5 Public Dose

Regulations: 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107

Criteria: Licensees must do the following:

- ensure that 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 a year, and the

dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour, from licensed operations

- prevent unauthorized access, removal, or use of 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. Because a fixed gauge presents a radiation field, the applicant must use methods to limit the public dose such that it 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), 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. 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 8-4).

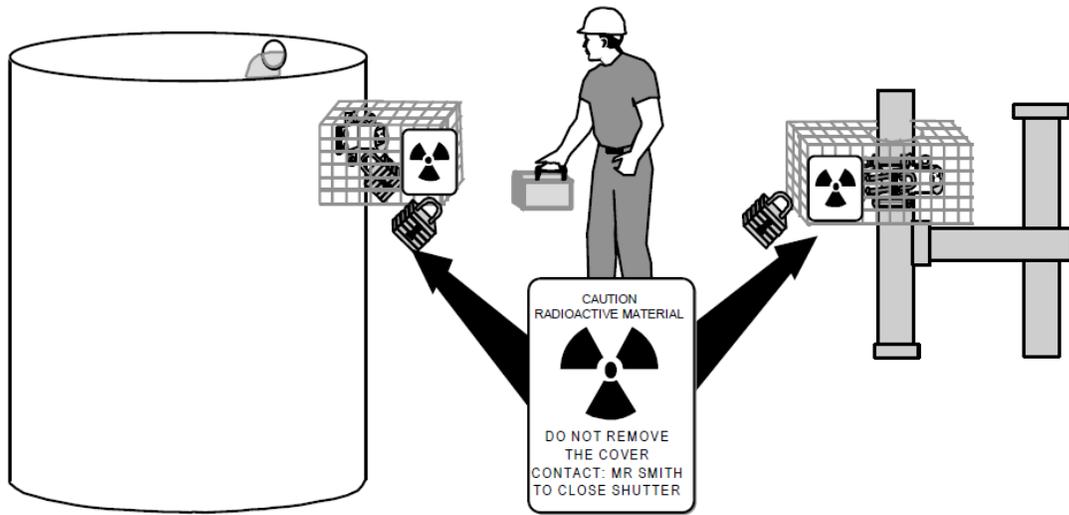


Figure 8-4. Limiting Public Dose. *When dose rates in an area are high enough that a member of the public could receive a dose in excess of 0.02 mSv [2 mrem] in any one hour or 1 mSv [100 mrem] in a year, licensees must take additional measures to prevent public access to these higher dose rates, such 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 of this NUREG 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 of this NUREG for examples of methods to demonstrate compliance).

Response from Applicant: No response is required from the applicant in a license application, but the NRC will examine this matter during inspections.

8.10.6 Operating, Emergency, and Security 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 30.50

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 jobsites 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 jobsites)
 - 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 Sealed Source and Device (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 gauge 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; gauge 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 jobsites
- 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 jobsites
- 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 jobsites 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
 - if a licensee possesses or uses an aggregated Category 1 or Category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37 at any site, procedures should be developed that ensure the physical protection of the radioactive material (See Section 8.10.11, "Security Program for Category 1 and Category 2 Radioactive Materials").
- provide copies of operating, emergency, and security procedures to all gauge users and have them available 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 that will be reviewed by the NRC during inspections. 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-centimeter [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 outlined previously, 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 of this NUREG. Figure 8-5 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).

1. Move Away from Source at Once



2. Sound the Alarm



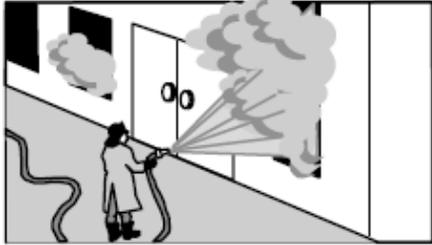
3. Secure the Area



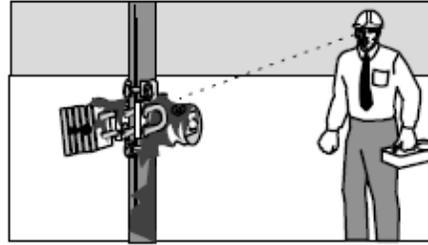
4. Notify RSO



5. Emergency Responders Stabilize Conditions



6. RSO Identifies Damaged Gauge



7. RSO Notifies NRC within 24 hours, Pursuant to 10 CFR 30.50(b)(4)



8. Trained Radiological Professionals Handle Gauge Recovery and Clean-up

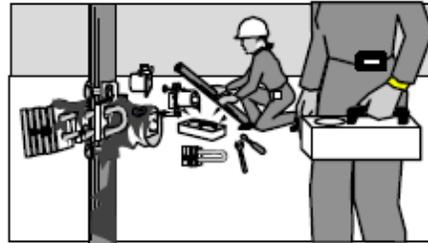


Figure 8-5. Proper Handling of Incident. Licensee personnel implement emergency procedures when a fire melts the lead shielding of a gauge, producing the potential for elevated exposure levels.

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 and the relevant 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.

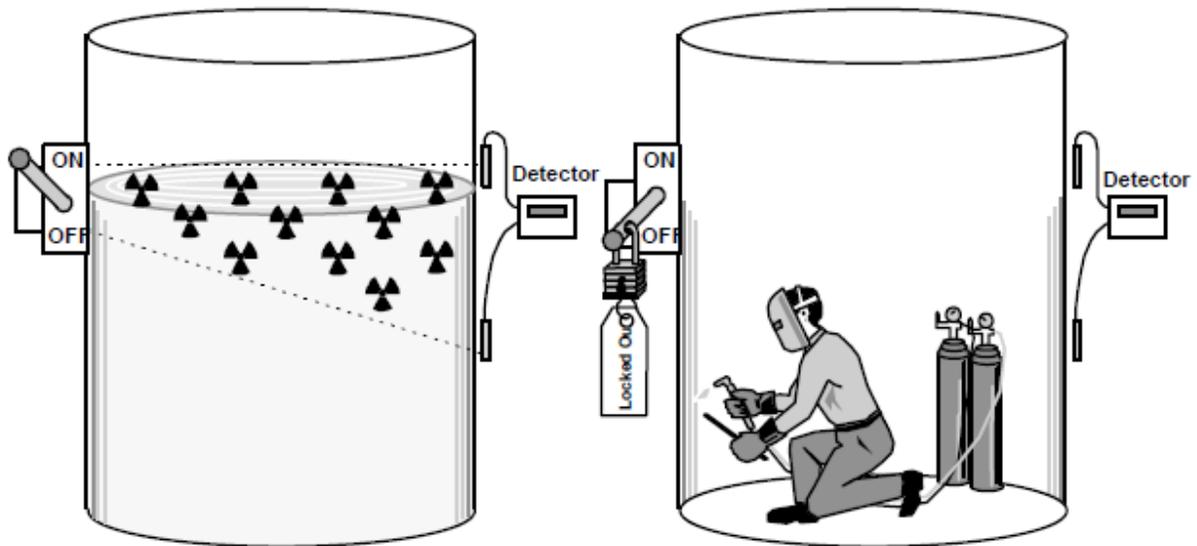


Figure 8-6. Lock-Out Procedures. Typical lock-out procedures include locking the shutter into the “off” position and tagging the shutter control mechanism to indicate the gauge is locked out.

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 (See Figure 8-6). 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 statement: “Operating, emergency, and security procedures will be developed, implemented, maintained, and distributed, and will meet the criteria in Section 8.10.6, ‘Operating, Emergency, and Security Procedures’ in NUREG–1556,

Volume 4, Revision 1, '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.

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
- IN 2009-05, "Contamination Events Resulting From Damage to Sealed Radioactive Sources During Gauge Dismantlement and Non-Routine Maintenance Operations," dated February 3, 2009
- IN 2011-09, "Fixed Gauge Shutter Failures Due to Operating in Harsh Working Environments," dated May 18, 2011

8.10.7 Leak Tests

Regulations: 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 30.50(c)(2), 10 CFR 30.53

Criteria: The NRC requires testing to determine whether there is any radioactive leakage from the source in the fixed gauge. The NRC finds leak testing to be acceptable if it is conducted by an organization licensed by the NRC or an Agreement State. Licensees must maintain records of leak test results in accordance with license requirements and NRC regulations.

Discussion: When issued, a license will require the performance of leak tests at intervals approved by the NRC or an Agreement State, as specified 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. If the test reveals the presence of 185 Bq [0.005 microcurie] or more of removable contamination, a report should be filed with the NRC in accordance with 10 CFR 30.50(c)(2).

Manufacturers, distributors, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test process for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the gauge manufacturer's and the kit supplier's instructions and return it to the kit supplier for analysis and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The NRC or an Agreement State may, in a license condition, specifically authorize portable gauge licensees to conduct the entire leak test sequence themselves. Appendix I of this NUREG provides information to support a request to perform leak testing and sample analysis.

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

- the statement: "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 licensed by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits and/or sample analysis services to other licensees and according to the kit supplier's instructions. Records of leak test results will be maintained."

OR

- the statement: "We will implement the model leak test program in Appendix I of NUREG-1556, Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses.' Records of leak tests will be maintained."

OR

- a description of alternative equipment and/or procedures for determining whether there is any radioactive leakage from sources contained in gauges and the statement: "Records of leak tests will be maintained."

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

8.10.8 Maintenance

Regulations: 10 CFR 20.1101, 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.

Specific authorization by the NRC or an Agreement State is required to perform nonroutine maintenance and repair of fixed gauges. Typically, fixed gauge manufacturers, distributors, and other service providers are specifically authorized to perform such operations. Fixed gauge licensees that have received specific authorization from the NRC or an Agreement State may perform nonroutine activities. Appendix J of this NUREG presents information to support requests for specific authorization to perform nonroutine maintenance or repair.

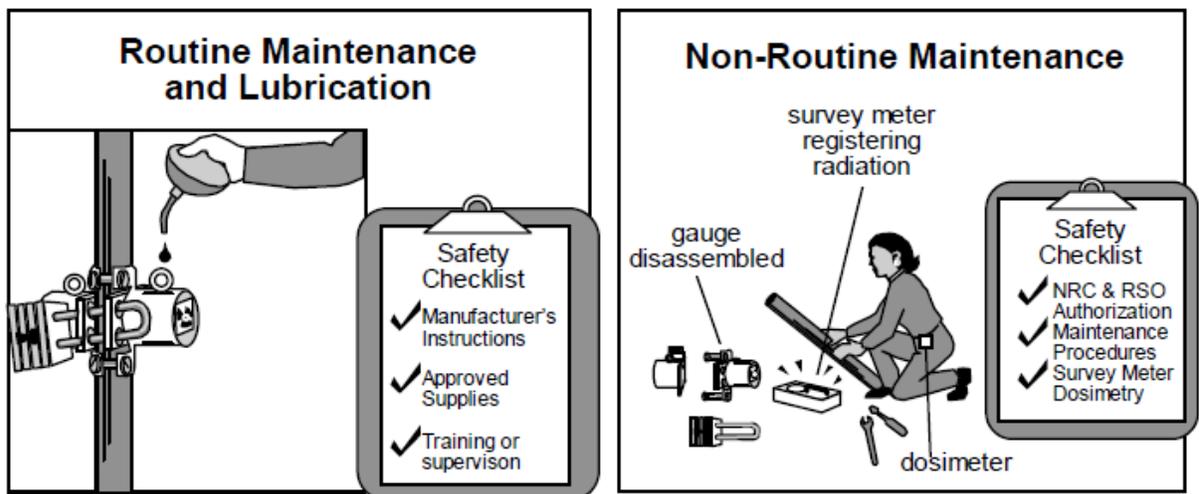


Figure 8-7. Maintenance. Licensees need to perform routine maintenance to ensure proper operation of the fixed gauge. For nonroutine maintenance, most licensees use or contract the services of the gauge manufacturer, distributor, or a service company.

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, and other materials to be used in the gauge
- 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 INs discuss the importance of performing shutter checks: (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.

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
- 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 in 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 in 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 gauge 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; gauge alignment; or removal of a gauge from service, may 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 of this NUREG for more information.

Response from Applicant:

For routine maintenance: Submit either of the following:

- the statement: “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 NRC review

For nonroutine operations: Submit either of the following:

- the statement: “The gauge manufacturer, distributor, or other person licensed 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

- a request to perform this work “in-house,” using the information in Appendix J of this NUREG to support the request

Notes:

- Alternative procedures for performing routine maintenance will be evaluated using the criteria listed previously.
- Information requested in Appendix J of this NUREG will be reviewed on a case-by-case basis; if the request is approved, the license will contain a specific condition authorizing the licensee to perform nonroutine operations.

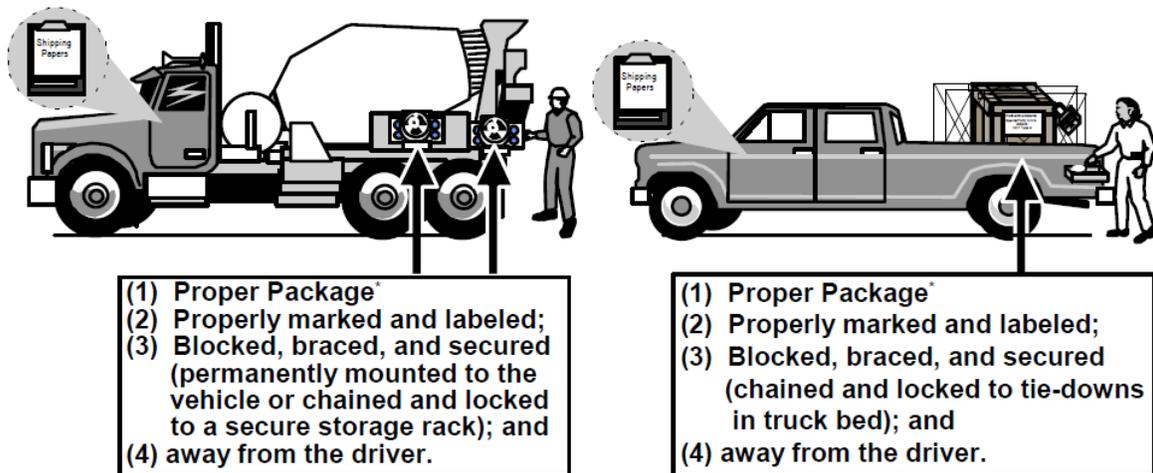
8.10.9 Transportation

Regulations: 10 CFR 20.1101, 10 CFR 71.5, 49 CFR Parts 171–178, 390–397

Criteria: Applicants must follow DOT regulations for the offsite transport of radioactive material.

Discussion: Some fixed gauge licensees have the manufacturer, distributor, or another licensee 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 material (HAZMAT) employee training.

Figure 8-8 illustrates some important DOT requirements for gauge licensees. The NRC uses the provisions of 10 CFR 71.5, "Transportation of licensed material," to examine and enforce transportation requirements found in 49 CFR, "Transportation." Appendix K of this NUREG 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.

Figure 8-8. DOT Transportation Requirements

Response from Applicant: No response is needed; the NRC will review this issue during inspection.

Reference: "Radioactive Material Regulations Review," published by DOT, 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), 10 CFR 30.50

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

Discussion: A temporary jobsite is a location where work with licensed materials is conducted for a limited period of time. Temporary jobsites are not specifically listed on a license. A gauge user may be dispatched to work at several temporary jobsites in one day. A location is not considered a temporary jobsite 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 jobsites: (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 8-9). 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 jobsites.

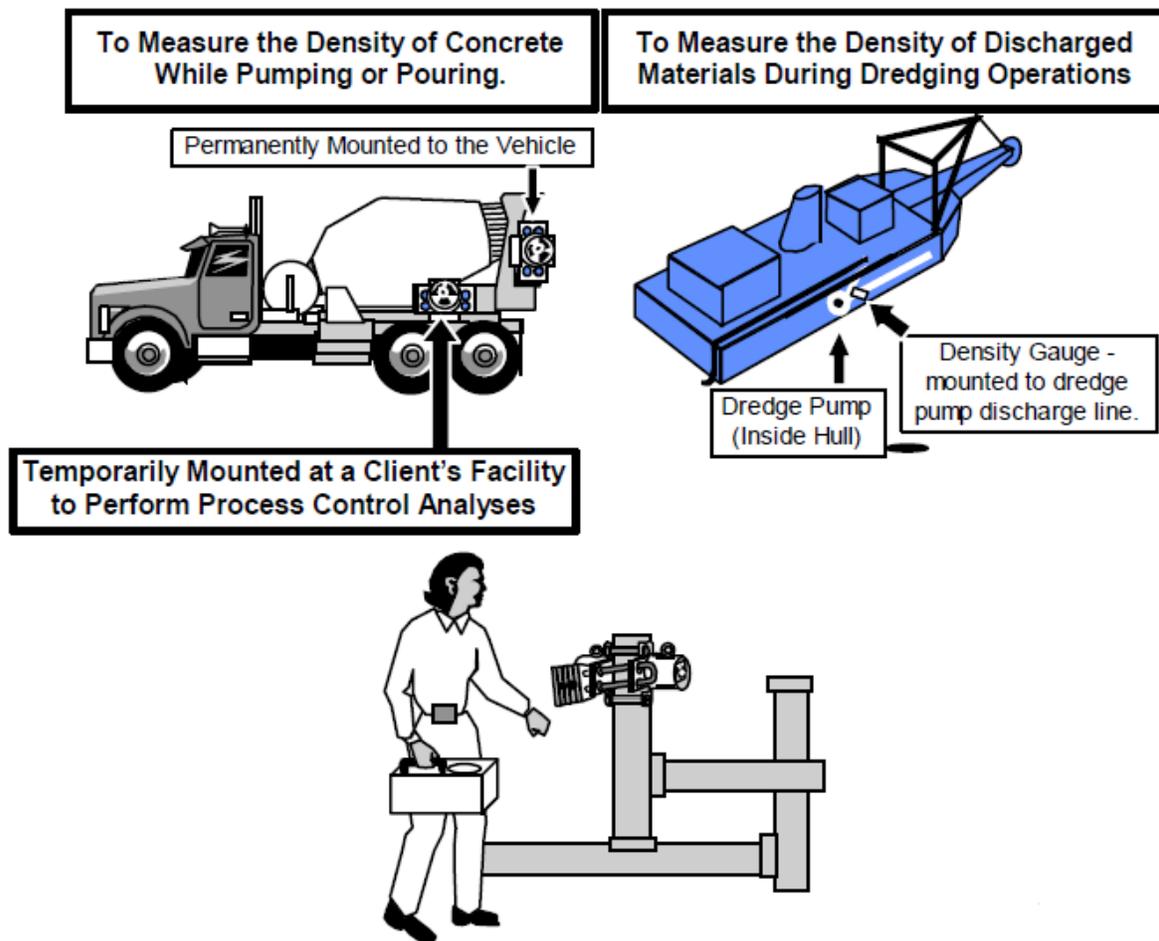


Figure 8-9. Examples of Uses for Fixed Gauges at Temporary Job Sites

When working at a temporary jobsite, 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, nonlicensee 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 8-10).

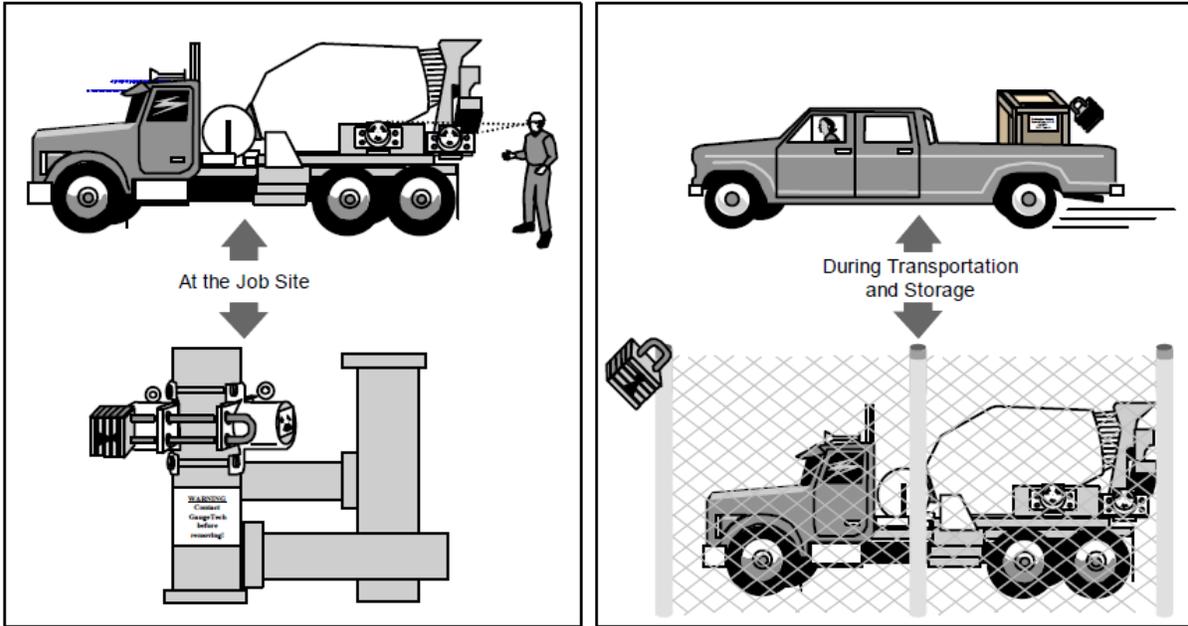


Figure 8-10. Security. *Examples of Methods Used To Secure and Control Fixed Gauges at Temporary Job Sites.*

While installing gauges at a temporary jobsite, 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 must use a survey meter to monitor radiological conditions (see Figure 8-11).

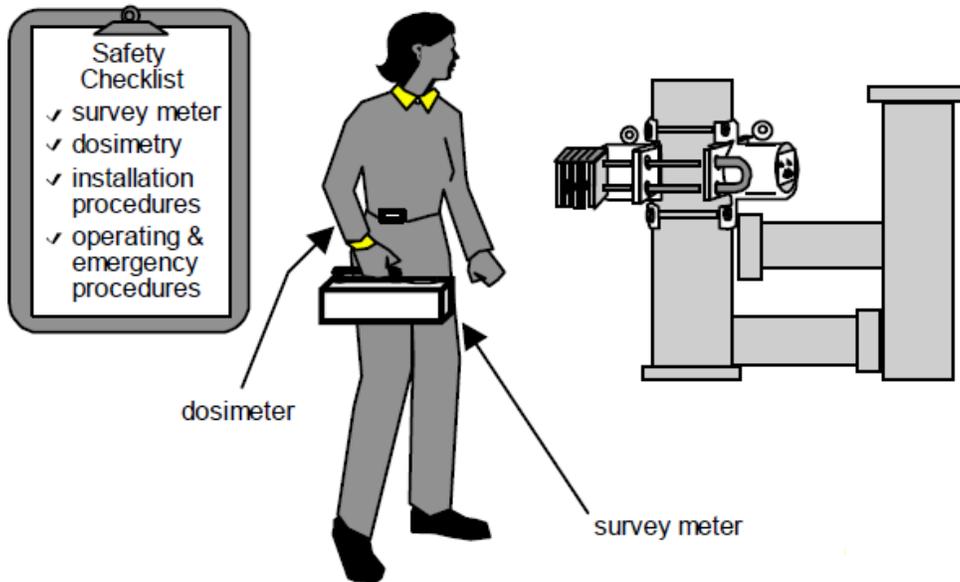


Figure 8-11. Installation of Fixed Gauges at Temporary Job Sites. *Examples of the Additional Precautions Needed When Installing Fixed Gauges at Temporary Job Sites.*

After installing a gauge at a temporary jobsite, a radiation survey must be conducted to ensure that doses 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 implement additional measures to prevent public access, such as maintaining constant surveillance or erecting physical barriers.

Response from Applicant: Submit one of the following:

- the statement: “We will not use fixed gauges at temporary jobsites.”

OR

- the statement: “We will address the use of fixed gauges at temporary jobsites in our operating, emergency, and security procedures developed in accordance with the Criteria in Section 8.10.6 ‘Operating, Emergency, and Security Procedures,’ of NUREG–1556, Volume 4, Revision 1, ‘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 jobsites.”

8.10.11 Security Program for Category 1 and Category 2 Radioactive Material

Regulations: 10 CFR Part 37, 10 CFR 20.2207

Criteria: Licensees must ensure the security of Category 1 and Category 2 radioactive material.

Note: The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material, as specified in Appendix A to 10 CFR Part 37. The requirements in 10 CFR 20.2207 for submitting National Source Tracking Transaction Reports (NSTTR) are applicable to those licensees that manufacture, transfer, receive, disassemble, or dispose of sealed sources containing a quantity equal to or greater than the Category 1 or Category 2 levels of radioactive material listed in Appendix E to 10 CFR Part 20.

Discussion:

Requirements in 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material”

In accordance with 10 CFR Part 37, licensees authorized to possess Category 1 or Category 2 quantities of radioactive material must establish, implement, and maintain a security program to ensure physical protection of the radioactive material.

Table 1 of Appendix A, “Category 1 and Category 2 Radioactive Materials,” to 10 CFR Part 37, lists Category 1 and Category 2 threshold quantities of radioactive material. The applicant should refer to this table to determine whether its proposed activities would be subject to the 10 CFR Part 37 requirements.

Licenses authorized to hold Category 1 or Category 2 quantities of radioactive material must establish access authorization programs in accordance with 10 CFR Part 37, Subpart B. Before giving individuals unescorted access to such quantities of radioactive material, licensees must conduct prior background investigations of these individuals in accordance with 10 CFR 37.25.

In accordance with 10 CFR 37.41(b), licensees must establish a security program designed to monitor and, without delay, detect, assess, and respond to any actual or attempted efforts to gain unauthorized access to Category 1 or Category 2 quantities of radioactive material.

Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or Category 2 quantities of radioactive materials in transit. These requirements apply to licensees delivering such material to a carrier for transport, as well as cases in which licensees are transporting such material. Please note that the Subpart D requirements applicable to the transport of Category 1 quantities of radioactive material are more stringent than those applicable to Category 2 quantities.

Applicants and licensees are required to implement the 10 CFR Part 37 security requirements before they take possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

In accordance with 10 CFR 37.41(a)(3), any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been made subject to the provisions of 10 CFR Part 37, Subpart C shall notify the NRC regional office specified in 10 CFR 30.6 in writing at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, “Implementation Guidance for 10 CFR Part 37, ‘Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material’.” Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, “Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material.”

Requirements in 10 CFR 20.2207, “Reports of transactions involving nationally tracked sources”

The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit an NSTTR to the NRC. The NSTTRs are maintained in the National Source Tracking System (NSTS), a secure 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 the source activity decays enough to no longer be of concern.

Response from Applicant: No response is required from an applicant or licensee.

Note: In relation to security events involving a Category 1 or Category 2 quantity of radioactive material, notifications to the local law enforcement agency and the NRC, as well as subsequent reports to the NRC, must be made in accordance with 10 CFR 37.57 and 10 CFR 37.81, as appropriate.

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, 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: Significant problems can arise from improper gauge transfer or failure to dispose of gauges in a proper and timely manner. Such problems include the possession of radioactive materials by unauthorized individuals, which could result in exposures to members of the general public. 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., their license specifically authorizes the same manufacturer, model, isotope(s), and quantity of byproduct material).

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. The licensee must maintain records of the transfer, 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 gauge transfer and 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>.

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.

8.13 Item 13: Certification

A representative of the corporation or legal entity filing the application must sign and date NRC Form 313. 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 knowingly and willfully make a false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items will be incorporated into the license and therefore will become binding regulatory requirements.

9 LICENSE AMENDMENTS AND RENEWALS

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 (Title 10 of the *Code of Federal Regulations* (10 CFR) [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 a U.S. Nuclear Regulatory Commission (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, including all required program elements outlined in Appendix B of this NUREG. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b)

Criteria: Licensees must provide all supporting information and obtain the NRC's *prior, written consent* before transferring control of the license, also referred to as a "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 capable, 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, "Consolidated Guidance

About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses,” for more information about transfer of control (i.e., ownership).

Reference: For further information, see Regulatory Issue Summary (RIS) 2014-08, Revision 1, “Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses,” dated May 5, 2016, which can be found on the NRC’s Generic Communications Web page under “Regulatory Issue Summaries”: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>

10 APPLICATIONS FOR EXEMPTIONS

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

Criteria: Licensees may request exemptions from U.S. Nuclear Regulatory Commission (NRC) 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. Requests for exemptions submitted to the NRC must identify the regulation for which the exemption is being requested and include a justification for the requested exemption.

Unless the NRC has granted an exemption in writing, licensees must comply with all applicable regulations.
--

11 TERMINATION OF ACTIVITIES

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

Criteria: The licensee must do the following:

- Notify the U.S. Nuclear Regulatory Commission (NRC), in writing, within 60 days of the occurrence of any of the following:
 - expiration of its license
 - a decision to permanently cease principal activities¹ at the entire site
 - a decision to permanently cease principal activities¹ 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 activities¹ under the license have been conducted for a period of 24 months
 - no principal activities¹ 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
- Conduct decommissioning, as required by Title 10 of the Code of Federal Regulations (10 CFR) 30.36(h).
- Submit, to the appropriate NRC regional office, a completed NRC Form 314, “Certificate of Disposition of Materials” (or equivalent information), and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final leak tests of sealed sources).
- Before a license is terminated, send records important to decommissioning that are required by 10 CFR 30.35(g) to the appropriate NRC regional office in accordance with 10 CFR 30.51(f).

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

- The licensee must 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.”
- The licensee must copy applicable decommissioning records as described in Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning.” Typically, this includes transfer of records and final leak test records to the appropriate NRC regional

¹ ‘Principal activities’ are activities which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

office. See Section 8.5.2 for additional recordkeeping requirements if leaking sealed sources or other incidents that involve the spreading of contamination have occurred.

- The licensee must 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 the previously listed "Criteria."

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

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

Please use the most current version of this form, which may be found at:
<http://www.nrc.gov/reading-rm/doc-collections/forms/>

<p>NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION (06-2016) 10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40</p> <p style="text-align: center;">APPLICATION FOR MATERIALS LICENSE</p>	<p>APPROVED BY OMB: NO. 3150-0120 EXPIRES: 06/30/2019</p> <p><small>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 FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.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.</small></p>												
<p>INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.</p>													
<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p style="font-size: small;">MATERIALS SAFETY LICENSING BRANCH DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN:</p> <p style="font-size: small;">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,</p> <p>SEND APPLICATIONS TO:</p> <p style="font-size: small;">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</p>	<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p style="font-size: small;">MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352</p> <p>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,</p> <p>SEND APPLICATIONS TO:</p> <p style="font-size: small;">NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1800 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511</p>												
<p>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.</p>													
<p>1. THIS IS AN APPLICATION FOR <i>(Check appropriate item)</i></p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT <i>(Include ZIP code)</i></p>												
<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; font-size: small;">BUSINESS TELEPHONE NUMBER</td> <td style="width: 50%; font-size: small;">BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td colspan="2" style="font-size: small;">BUSINESS EMAIL ADDRESS</td> </tr> </table>	BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER	BUSINESS EMAIL ADDRESS									
BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER												
BUSINESS EMAIL ADDRESS													
<p>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.</p>													
<p>5. RADIOACTIVE MATERIAL</p> <p style="font-size: x-small;">a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>												
<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>	<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.</p>												
<p>10. RADIATION SAFETY PROGRAM.</p>	<p>9. FACILITIES AND EQUIPMENT.</p>												
<p>12. LICENSE FEES <i>(Fees required only for new applications, with few exceptions*)</i> <i>(See 10 CFR 170 and Section 170.31)</i> *Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.</p> <table style="width: 100%; border: none;"> <tr> <td style="text-align: right; font-size: x-small;">FEE CATEGORY</td> <td style="border: 1px solid black; width: 50px; height: 20px;"></td> <td style="text-align: right; font-size: x-small;">AMOUNT ENCLOSED</td> <td style="border: 1px solid black; width: 50px; height: 20px;"></td> </tr> </table>	FEE CATEGORY		AMOUNT ENCLOSED		<p>11. WASTE MANAGEMENT.</p>								
FEE CATEGORY		AMOUNT ENCLOSED											
<p>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.</p> <p>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, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.</p> <p>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.</p>													
<p>CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">SIGNATURE</td> <td style="width: 30%;">DATE</td> </tr> </table>	SIGNATURE	DATE										
SIGNATURE	DATE												
FOR NRC USE ONLY													
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 15%;">TYPE OF FEE</th> <th style="width: 15%;">FEE LOG</th> <th style="width: 15%;">FEE CATEGORY</th> <th style="width: 15%;">AMOUNT RECEIVED</th> <th style="width: 15%;">CHECK NUMBER</th> <th style="width: 30%;">COMMENTS</th> </tr> <tr> <td style="font-size: x-small;">APPROVED BY</td> <td></td> <td></td> <td style="font-size: x-small;">\$</td> <td style="font-size: x-small;">DATE</td> <td></td> </tr> </table>	TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS	APPROVED BY			\$	DATE		
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**

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

Items 5 and 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
		Isotope (Specify):	Device manufacturer (or distributor) and model number: _____	Specify activity per source and number of gauges requested.	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)
		Isotope (Specify):	Device manufacturer (or distributor) and model number: _____	Specify activity per source and number of gauges requested.	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)
		Isotope (Specify):	Device manufacturer (or distributor) and model number: _____	Specify activity per source and number of gauges requested.	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.						

NOTE: Copy and attach additional pages as needed.

**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: _____	Documentation demonstrating the proposed radiation safety officer's training and experience (e.g., certificate of completion of the RSO's course and/or the authorized user's course).	<input type="checkbox"/>	<input type="checkbox"/>
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 titled, "Authorized Users" in NUREG-1556, Volume 4, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses."	<input type="checkbox"/>	<input type="checkbox"/>
8. Training for Individuals Working In or Frequenting Restricted Areas	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.	<input type="checkbox"/>	Need not be submitted with application.

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10.3 Radiation Safety Program – Material Receipt and Accountability	<p>Physical inventories will be conducted 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.</p> <p style="text-align: center;">AND</p> <p>We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.</p>	<input type="checkbox"/>	<input type="checkbox"/>
10.4 Radiation Safety Program – Occupational Dose	<p>We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a).</p> <p style="text-align: center;">OR</p> <p>We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed and evaluated by a NVLAP-approved processor.</p>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
10.5 Radiation Safety Program – Public Dose	<p>The applicant is <i>not</i> required to submit a response to the public dose section in a license application. This matter will be examined during NRC inspections.</p>	Need not be submitted with application.	
10.6 Radiation Safety Program – Operating, Emergency, and Security Procedures	<p>If the gauge meets one or more of the safety conditions specified in the “Discussion” part of Section 8.10.6, “Operating, Emergency, and Security Procedures,” in NUREG-1556, Volume 4, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses,” state the following: Operating, emergency, and security procedures will be developed, implemented, maintained, and distributed and will meet the criteria in Section 8.10.6, “Operating, Emergency, and Security Procedures,” in NUREG-1556, Volume 4, Revision 1.</p> <p style="text-align: center;">OR</p> <p>If each gauge requested does not meet any of the safety conditions specified in the “Discussion” part of Section 8.10.6, “Operating, Emergency, and Security Procedures,” in NUREG-1556, Volume 4, Revision 1, provide your operating, emergency, security, and lock-out (if applicable) procedures.</p>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Procedures Attached

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10.10 Radiation Safety Program – Fixed Gauges Used at Temporary Job Sites	<p>We will not use fixed gauges at temporary jobsites.</p> <p style="text-align: center;">OR</p> <p>We will address the use of fixed gauges at temporary jobsites in our operating, emergency, and security procedures developed in accordance with the Criteria in Section 8.10.6, “Operating, Emergency, and Security Procedures,” of NUREG-1556, Volume 4, Revision 1, “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 jobsites.</p>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
10.11 Radiation Safety Program – Security Program for Category 1 and Category 2 Radioactive Material	The applicant is <i>not</i> required to submit a response to the security program section in a license application. This matter will be examined during NRC inspections.	Need not be submitted with application.	
11. Waste Management – Gauge Disposal & Transfer	The applicant is <i>not</i> required to submit a response about waste management during the licensing process; however, the licensee should establish and include gauge transfer and waste disposal procedures in its radiation protection program.	Need not be submitted with application.	

APPENDIX C

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

TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

The radiation safety officer's (RSO's) duties and responsibilities (illustrated in Figure 8-2) typically include ensuring the following:

- Licensed activities that the RSO considers unsafe are stopped.
- 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.
- Individuals who use fixed gauges are properly trained.
- Radiation exposures are kept as low as is reasonably achievable (ALARA).
- Prospective evaluations are performed to demonstrate that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a) 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.
- Up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed.
- 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 U.S. Nuclear Regulatory Commission (NRC) or an Agreement State.
- 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 *Code of Federal Regulations* 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, accident, damage, theft) are investigated, cause(s) are determined, and appropriate corrective action(s) are identified, and corrective action taken.
- Audits are performed at least annually and documented, 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 U.S. Department of Transportation 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.
- Documents are posted as required by 10 CFR 19.11, "Posting of notices to workers," (10 CFR Part 19, license documents, operating procedures, NRC Form 3, "Notice to Employees,"), and 10 CFR 21.6, "Posting Requirements," (10 CFR Part 21 Section 206 of the Energy Reorganization Act of 1974, procedures adopted under Part 21), or a note is posted indicating where these documents can be examined.

Model Delegation of Authority to Radiation Safety Officer

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**

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 the following:

Radiation Safety:

- radiation versus contamination
- internal versus external exposure
- biological effects of radiation
- types and relative hazards of radioactive material possessed
- as low as is reasonably achievable (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, emergency, and security 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 authorized user (AU) or radiation safety officer (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 RSO training course
- documentation of 8 hours of hands-on experience with fixed gauges

Note: Additional training is required for those applicants intending to perform nonroutine operations, such as gauge 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; gauge alignment; or removal of a gauge from service. See Appendix J of this NUREG, "Information Needed to Support Applicant's Request to Perform Nonroutine Operations."

APPENDIX E
FIXED GAUGE AUDIT CHECKLIST

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 _____

Auditor Signature Auditor Printed Name Date

Management Signature Management Printed Name Date

1. **Audit History**

- A. Were previous audits conducted periodically (at least annually)? (10 CFR 20.1101)
- B. Were records of previous audits maintained? (10 CFR 20.2102)
- C. Were any deficiencies identified during the last two audits or 2 years, whichever is longer?
- D. 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? [License Condition (L/C)]
- B. If ownership changed or bankruptcy was filed, did the licensee obtain prior U.S. Nuclear Regulatory Commission (NRC) consent or notify the NRC? [10 CFR 30.34(b)]
- C. If the licensee changed the radiation safety officer (RSO), was the license amended? (L/C)
- D. Sealed Sources and Devices
 - 1. Does the license authorize all of the NRC-regulated radionuclides contained in the gauges possessed? (L/C)
 - 2. Are the gauges as described in the Sealed Source and Device (SSD) registration certificate? (L/C)

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? (L/C)
 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? (L/C)
- E. Is the current inventory of material below the possession limits listed on the license? (L/C)

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 authorized user (AU) receive training and instruction given at the time of gauge installation or equivalent training and instruction before using gauges? (L/C)
- C. Are training records maintained for each AU? (L/C)
- D. Did individuals who perform nonroutine operations receive training before performing these operations? (L/C)
- 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 U.S. Department of Transportation (DOT) hazardous material (HAZMAT) training provided, if required? (49 CFR 172.700, 172.701, 172.702, 172.704)

4. Radiation Survey Instruments

- A. If a survey is performed, did the survey meter meet the NRC requirements? [10 CFR 20.1501(c)]
- 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 in the event of an emergency?

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 or at other intervals approved by the NRC? (L/C)
- C. Are records of inventory results with appropriate information maintained? (L/C)

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 less than the limits in 10 CFR 20.1502(a)? Did these evaluations consider doses to minors [10 CFR 20.1502(a)(2)] and declared pregnant women [10 CFR 20.1502(a)(3)]?
- C. Did unmonitored individuals' activities change during the year in a way that could put them over the limits in 10 CFR 20.1502(a)? If yes, was a new evaluation performed?
- D. If external dosimetry is required [i.e., when individuals are likely to receive greater than the limits in 10 CFR 20.1502(a)], 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), 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?
- E. Are there any declared pregnant workers?
 - 1. If a worker declared her pregnancy, did the licensee comply with 10 CFR 20.1208, "Dose equivalent to an embryo/fetus"?
 - 2. Were records kept of doses to an embryo/fetus per 10 CFR 20.2106(e)?

- F. Are records of exposures, surveys, monitoring, and evaluations maintained? (10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2106)

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, Emergency, and Security Procedures

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

- A. Have operating, emergency, and security procedures been developed and updated to incorporate any new elements, practices, or requirements?
- B. Does each individual working with the gauges have current copies of the operating, emergency, and security 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?
- E. Were gauges properly controlled or secured during use or storage? (10 CFR 20.1801, 10 CFR 20.1802)

9. Leak Tests

- A. Were sealed source leak tests performed every 6 months or at other authorized intervals? (L/C)
- B. Were leak tests performed in accordance with license requirements? (L/C)

- C. Are records of leak test results retained with all of the required information included? (L/C)
- D. Were any sources found to be leaking, and if yes, was the NRC notified? (L/C)

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? (L/C)
- 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)? (L/C)
- 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 U.S. Department of Transportation (DOT)-7A or other authorized packages used? (49 CFR 173.415, 49 CFR 173.416)
- B. Are Type A package, engineering drawings, and performance test records on file? [49 CFR 171.2 (a, b, e), 49 CFR 173.415(a)]
- 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 172.400, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407)
- E. Were packages properly marked? (49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324)
- 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., proper shipping name, hazard class, identification number [United Nations (UN) number], 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, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604)

- 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)
- K. Were placards on the vehicle, if needed? (49 CFR 172.504)
- L. Were overpacks, if needed, used properly? (49 CFR 173.25)
- M. Were any incidents reported to the DOT? (49 CFR 171.15, 49 CFR 171.16)

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

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

13. Notifications and Reports

- A. Did any reportable incidents occur? Were the appropriate notifications made to the NRC Emergency Operations Center (301-816-5100)? Examples of incidents with notification requirements are as follows:
 - 1. Lost or stolen radioactive material (10 CFR 20.2201)
 - 2. Overexposures or high radiation levels (10 CFR 20.2202)
 - 3. Inoperable or "stuck" shutter [10 CFR 30.50(b)(2)]
 - 4. Generic equipment issues identified by the licensee (10 CFR 21.21)
- B. Were the required written reports made as followups to the events?

14. Posting and Labeling

- A. Is NRC Form 3, "Notice to Employees," 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. Are any other posting and labeling requirements met? (10 CFR 20.1902, 10 CFR 20.1904)

15. Decommissioning

- A. Were any locations of use or separate buildings decommissioned since the last audit? Were appropriate notifications made or license amendments requested? (10 CFR 30.36)

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

16. Generic Communications and Newsletter

- A. Are NRC Regulatory Issue Summaries, NRC Information Notices, and Office of Nuclear Material Safety and Safeguards quarterly 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)? (L/C)

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 and/or deficiencies identified during the audit.
- B. If problems and/or deficiencies were 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.
- D. Describe communication with management about deficiencies.

APPENDIX F

MODEL RADIATION SURVEY INSTRUMENT CALIBRATION PROGRAM

MODEL RADIATION SURVEY INSTRUMENT CALIBRATION PROGRAM

Training

Before independently calibrating radiation 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
 - biological effects of radiation
- On-the-job training will consist of the following:
 - observed authorized personnel performing radiation survey instrument calibration
 - conducted radiation 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 radiation survey instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- The calibration source should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.
- The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use.
- Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR 20.
- Individuals conducting calibrations of radiation survey instruments will wear assigned dosimetry.
- Individuals conducting calibrations will use a calibrated and operable radiation survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Frequency of Calibration of Radiation Measurement Instruments and Equipment

A licensee committed to a routine or emergency radiation survey program should perform an acceptable calibration of all radiation measurement instruments and equipment at the frequency specified in NRC regulations, annually, or at the frequency recommended by the manufacturer, whichever period is shorter.

Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a radiation measurement instrument have changed, by repair or alteration, or whenever system performance is observed to change significantly.

Routine maintenance of radiation measurement instruments should be performed as recommended by the manufacturer.

Primary or secondary standard instruments used to calibrate radiation measurement instruments should be inspected frequently for consistency of performance.

Calibration Sources for Dose and Dose Rate Measuring Instruments

A radioactive sealed source(s) will be used for calibrating dose and dose rate measuring radiation survey instruments, and this source will have the following characteristics:

- The source should approximate a point source.
- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 $\mu\text{Gy/h}$ (0.1 mrad/h) and 10 percent for dose rates less than 1.0 $\mu\text{Gy/h}$ (0.1 mrad/h).
- The source should contain a radionuclide that emits radiation of identical or similar type and energy as environment in which the calibrated device will be used.
- The source should be strong enough to give an exposure rate of 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).

Note: Inverse square and radioactive decay laws should be used to correct changes in exposure rate due to changes in distance or source decay.

Calibration of Dose or Dose Rate Measuring Instruments

There are three kinds of scales frequently used on dose and dose-rate survey meters. These are calibrated as follows:

- **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, check the response of the instrument at approximately 20 percent and 80 percent of full scale. Instrument readings should be within $\pm x$ of the conventionally true value for the following ranges:
 - Background to 10 $\mu\text{Gy/h}$ (1.0 mrad/h); $\pm x = \pm 30\%$
 - 10 $\mu\text{Gy/h}$ (1.0 mrad/h) to 1.0 mGy/h (100 mrad/h); $\pm x = \pm 20\%$
 - 1.0 mGy/h (100 mrad/h) to 10 Gy/h (1,000 Rad/h); $\pm x = \pm 10\%$
- **Logarithmic readout instruments**, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for linear readout instruments.
- **Digital readout instruments** should be calibrated the same as linear readout instruments.

Note: Readings above 50 microcoulomb per kilogram per hour (200 milliroentgen per hour) need not be calibrated, unless the licensee expects to make measurements at higher dose rates; regardless, such scales should be checked for operation and response to radiation.

Calibration Records

Calibration records for all radiation survey instruments should indicate the procedure used and the results of the calibration. The records should include the following:

- the owner or user of the radiation survey instrument
- a description of the radiation survey 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 or activity on a specified date
- 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 radiation survey instrument
- the exposure reading indicated with the radiation survey instrument in the "battery check" mode (if available on the instrument)

- for radiation survey instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- for radiation survey instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument
- for radiation 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
- the name and 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 radiation survey instrument as a calibration sticker or tag:

- the source radionuclide used to calibrate the radiation survey 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
- the apparent exposure rate from the check source, if used

Reference: Detailed information about portable radiation survey instrument calibration may be obtained by referring to American National Standards Institute (ANSI)-N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments."

APPENDIX G
DOSIMETRY-RELATED GUIDANCE

DOSIMETRY-RELATED GUIDANCE

Part 1: Guidance for Demonstrating that Unmonitored Workers Are Not Likely To Exceed the Limits in 10 CFR 20.1502(a)

Dosimetry is required for individuals likely to receive, from sources external to the body, a dose in excess of the limits in Title 10 of the *Code of Federal Regulations* [(10 CFR) 20.1502(a)]. 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 cesium-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
- 0.015 mSv [1.5 mrem] to the hands

The applicable whole body dose limit for adult workers is 50 mSv [5 rem] per year, with individual monitoring devices required when it is likely that an individual will receive 10 percent of that value [i.e., 5 mSv (500 mrem) per year]. If one of these procedures delivers 0.005 mSv [0.5 mrem], then an adult worker could perform 1,000 of these procedures each year and remain within 10 percent of the applicable limit.

The applicable whole body dose limit for minors is 10 percent of the annual dose limits specified for adult workers [i.e., 5 mSv (0.5 rem) per year], with individual monitoring devices required when it is likely that a minor will receive a deep dose equivalent in excess of 1 mSv [0.1 rem]. If one of these procedures delivers 0.005 mSv [0.5 mrem], then a minor could perform 200 such procedures each year without exceeding the individual monitoring device threshold.

For declared pregnant women, individual monitoring devices are required when these individuals are likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem). If one of these procedures delivers 0.005 mSv [0.5 mrem], then a declared pregnant women could perform 200 of these procedures during her entire pregnancy without exceeding the individual monitoring device threshold.

The applicable extremity dose limit for adult workers is 500 mSv [50 rem] per year with individual monitoring devices required when it is likely than an individual will receive 10 percent of that value [i.e., 50 mSv (5 rem or 5,000 mrem) per year]. If one of these procedures delivers 0.015 mSv [1.5 mrem], then an adult worker could perform 3,333 of these procedures each year and remain within 10 percent of the applicable limit.

The applicable extremity dose limit for minors is 10 percent of the annual dose limits specified for adult workers [i.e., 50 mSv (5 rem) per year], with individual monitoring devices required when it is likely that a minor will receive a dose to the extremities in excess of 5 mSv [0.5 rem]. If one of these procedures delivers 0.015 mSv [1.5 mrem], then a minor could perform 333 of these procedures each year and remain within 10 percent of the applicable limit.

Declared pregnant women have no requirements concerning dose the extremities or the monitoring thereof.

Based on the specific situation described previously, no dosimetry is required if an adult worker performs fewer than 1,000 routine maintenance procedures per year; a minor performs fewer than 200 routine maintenance procedures per year; or a declared pregnant woman performs fewer than 200 procedures during the entire pregnancy.

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 previous example. 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 U.S. Nuclear Regulatory Commission (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 previously, the extremities could be closer to the unshielded source, and the workers would receive more exposure than 0.15 mSv [15 mrem] per hour. Alternatively, workers could perform the task more slowly than the estimated 15 minutes total, and 6 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 for adult workers *less than* 500 mrem requires no dosimetry. The corresponding value for minors is 100 mrem. The corresponding value for declared pregnant women during the entire pregnancy is 100 mrem.

†An expected extremity dose equivalent for adult workers *less than* 5,000 mrem requires no dosimetry. The corresponding value for minors is 500 mrem. There is no corresponding value for declared pregnant women.

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 one 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 whether 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 radiation safety officer (RSO), to determine whether 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.

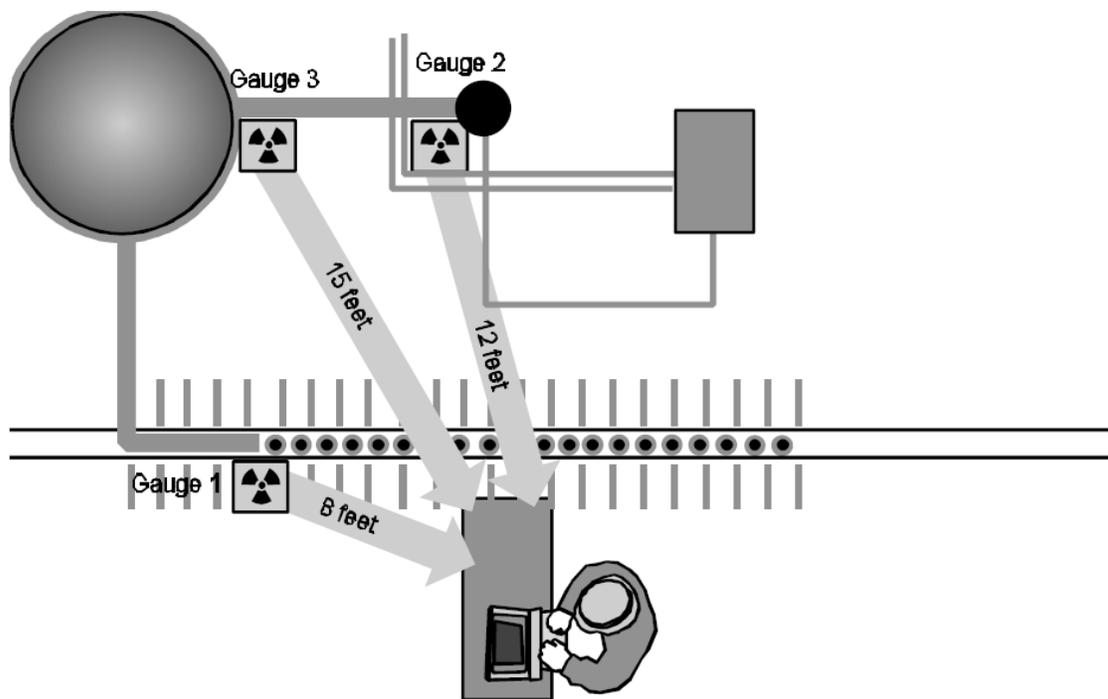


Figure G-1. Diagram of Bottling Line and Fixed Gauges. *This sketch shows the areas described in Examples 1 and 2.*

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 next.

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 ²	(1) ²	1
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in ft ²	(8) ²	64
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 × 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 × 365 days per year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 1, in mrem per year	0.031 × 24 × 365 = 0.031 × 8,760 = 272	

Table G-4. Calculational Method, Part 1—Hourly and Annual Dose Received From Gauge 2

Gauge 2			
Step No.	Description	Input Data	Results
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 ²	(1) ²	1
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in ft ²	(12) ²	144
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	8 × 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 × 365 days per year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 2, in mrem per year	0.056 × 24 × 365 = 0.056 × 8,760 = 491	

Table G-5. Calculational Method, Part 1—Hourly and Annual Dose Received From Gauge 3

Gauge 3			
Step No.	Description	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 ²	(3) ²	9
3	Square of the distance (ft) from the gauge to bottling control panel in an unrestricted area, in ft ²	(15) ²	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 × 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 × 365 days per year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 3, in mrem per year	0.08 × 24 × 365 = 0.08 × 8,760 = 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

Step No.	Description	Gauge 1	Gauge 2	Gauge 3	Sum
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

INFORMATION ON GAUGES:

- GAUGE 1 operates continuously (24 hours per day) on the bottling line.
- 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.
- 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).

INFORMATION FROM EXAMPLE 1, PART 2, ON WHEN THE WORKER IS PRESENT AT THE BOTTLING CONTROL PANEL:

- 5 hours per day
- 3 days per week
- 52 weeks per year

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
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.
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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 NaI (TI) or 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 whether 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
Part 1		
1	Dose received by dosimeter, in mrem	100
2	Total hours that dosimeter was exposed	24 hours per day × 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 × 8,760 = 1,226

Note: For the conditions described in Table G-10, 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.

Part 2	
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.	
Part 3	
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, EMERGENCY, AND SECURITY PROCEDURES

OPERATING, EMERGENCY, AND SECURITY 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 Sealed Source and Device (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.
- Provide instructions to 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) reevaluate compliance with public dose limits and ensure proper security of gauges.
- Conduct a physical inventory every 6 months to account for all devices.
- Require timely reporting to the U.S. Nuclear Regulatory Commission (NRC) pursuant to 10 CFR 20.2201 and 10 CFR 20.2207, as appropriate.

Emergency Procedures

- If a gauge becomes damaged, a source becomes dislodged, a source is leaking, the device fails to function properly, or any other nonradiological emergency (e.g., fire or medical emergency) or unusual situation arises, do the following:
 - 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 next, of the situation:

NAME ¹	WORK PHONE NUMBER ¹	HOME PHONE NUMBER ¹
_____	_____	_____
_____	_____	_____
_____	_____	_____

- Follow the directions provided by the person contacted in the previous list.

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.
- Make necessary notifications to local authorities as well as the NRC as required. Appendix L of this NUREG contains typical NRC incident notifications and reporting 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 Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2203 limits. Reporting requirements are found in 10 CFR 20.2201-2203 and in 10 CFR 30.50.

Security Procedures

- Address guidelines to meet the security and control requirements of 10 CFR 20.1801, 10 CFR 20.1802, and any other applicable security and control requirements.
- Provide instructions to prevent unauthorized access, removal, or use of fixed gauges, including at temporary jobsites if authorized on the license.

¹ Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the radiation safety officer (RSO), authorized users (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.

APPENDIX I

MODEL LEAK TEST PROGRAM

MODEL LEAK TEST PROGRAM

Training

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

Classroom training may be in the form of lecture, online, video, hands-on, or self-study and should cover the following subject areas:

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

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

- observing authorized personnel collecting and analyzing leak test samples
- collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak testing and sample analysis

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., NaI(Tl) well-counter system for gamma emitters, liquid scintillation for beta emitters, and gas-flow proportional counter for alpha emitters).
- If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). 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

For example:

$$\begin{array}{lcl} \text{where:} & bkg & = 200 \text{ cpm} \\ & E & = 0.1 \text{ counts per disintegration (10 percent efficient)} \\ & t & = 2 \text{ minutes} \end{array}$$

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

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

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

Note: The MDA equation shown assumes that counting times for the background measurement and for the sample will be equal. MDA equations for non-equal counting times, as well as derivations of equations and discussions of limitations, can be found in “Decommissioning Health Physics—A Handbook for MARSSIM Users,” Eric W. Abelquist, published by Taylor & Francis Group, 2001.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective Sealed Source and Device registration certificate. If a sealed source is not registered, leak tests should be conducted at 6 month intervals, unless a different interval is established during the licensing process. Leak testing of sealed sources may be required by license condition.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as the sealed source serial number, manufacturer, model number, radionuclide, and activity.
- Use a radiation 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, but do not wipe the surface of a plated or foil source (see manufacturer's instructions).

- Select instrumentation that is sensitive enough to detect 185 becquerels (Bq) (0.005 microcurie) of the radionuclide contained in the gauge.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. The calibration source should be in the same configuration as the sample. Accuracy of standards should be within plus or minus 5 percent of the stated value and traceable to primary radiation standards such as those maintained by the National Institute of Standards and Technology.
- Calculate the counting efficiency of the detector.

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

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

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

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

- Sign and date the list of sources, data, and calculations. Retain records for 3 years [under Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2103(a)].
- If the wipe test activity is 185 becquerels (0.005 microcuries) or greater, notify the radiation safety officer so that the source can be withdrawn from use and disposed of properly. Also, notify the U.S. Nuclear Regulatory Commission.

APPENDIX J

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

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, which require specific authorization by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State, include gauge installation; initial radiation survey; repair and maintenance of radiological safety components; gauge relocation; replacement and disposal of sealed sources; gauge alignment; or removal of a gauge from service. See Figure 8-7 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 Sealed Source and Device (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 1 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 specialized training for the activities intended to be performed 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
- 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 a radiation dose in excess of the limits in 10 CFR 20.1502(a).
- 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).

APPENDIX K

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

Note: The following list of U.S. Department of Transportation (DOT) regulations is provided to inform licensees about typical requirements that apply to the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: <http://www.dot.gov/>.

- Table of Hazardous Materials and Special Provisions—49 CFR 172, Subpart B
 - 49 CFR 172.101—Hazardous Materials Table [proper shipping name, hazard class, identification number]
 - 49 CFR 172.101—List of Hazardous Substances and Reportable Quantities, Table 2 to Appendix A—Radionuclides
- Shipping Papers—49 CFR 172, Subpart C
 - 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
- Marking—49 CFR 172, Subpart D
 - 49 CFR 172.300—Applicability
 - 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 [designation of “reportable quantities” with the letters “RQ”]
- Labeling—49 CFR 172, Subpart E
 - 49 CFR 172.400—General labeling requirements
 - 49 CFR 172.400a—Exceptions from labeling
 - 49 CFR 172.401—Prohibited labeling
 - 49 CFR 172.403—Class 7 (radioactive) material
 - 49 CFR 172.406—Placement of labels
 - 49 CFR 172.436—RADIOACTIVE WHITE-I label
 - 49 CFR 172.438—RADIOACTIVE YELLOW-II label
 - 49 CFR 172.440—RADIOACTIVE YELLOW-III label
- Emergency Response Information—49 CFR 172, Subpart G
 - 49 CFR 172.600—Applicability and general requirements
 - 49 CFR 172.602—Emergency response information
 - 49 CFR 172.604—Emergency response telephone number

- Training—49 CFR 172, Subpart H
 - 49 CFR 172.702—Applicability and responsibility for training and testing
 - 49 CFR 172.704—Training requirements

- Shippers—General Requirements for Shipments and Packagings—49 CFR Part 173
 - 49 CFR 173.25—Authorized packagings and overpacks
 - 49 CFR 173.403—Definitions
 - 49 CFR 173.411—Industrial packages
 - 49 CFR 173.412—Additional design requirements for Type A packages
 - 49 CFR 173.415—Authorized Type A packages
 - 49 CFR 173.433—Requirements for determining basic radionuclide values, and for the listing of radionuclides on shipping papers and labels
 - 49 CFR 173.435—Table of A_1 and A_2 values for radionuclides
 - 49 CFR 173.441—Radiation level limitations and exclusive use provisions
 - 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved packages
 - 49 CFR 173.475—Quality control requirements prior to each shipment of Class 7 (radioactive) materials
 - 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials

- Carriage by Public Highway—49 CFR Part 177
 - 49 CFR 177.817—Shipping papers
 - 49 CFR 177.842—Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

Note: The following reference charts are for reference only and are not a substitute for DOT and U.S. Nuclear Regulatory Commission transportation regulations.

1. Minimum Required Packaging for Class 7 (Radioactive) Material ^[1] (49 CFR 173 and 10 CFR 71) ^[2]						
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 ^[3]		Excepted Quantities and Articles	Type A ^[4]	Type B		
Activity Restrictions		≤ the limits specified in Table 4 of §173.425	≤ A ₁ for special form ≤ A ₂ for normal form	> A ₁ for special form > A ₂ 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 ^[5,6]						
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 ^[7,8]	Unpackaged ^[9] 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 ^[9] IP-1 - -	- IP-2 -
Alternative Provisions for Domestic only Transport ^[9]	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 ₂ quantity					

[1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.
[2] Each NRC license 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 A₁ or A₂.
[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 A₂ 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 ^[1] (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)
Radiation Level Limits ^[2]					
Package Surface ^[1]	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) ^[3]
Conveyance ^[4]	N/A		2 mSv/h (200 mrem/h): outer surfaces (sides, top and underside) of vehicle ^[5] 0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle ^[5]	N/A	N/A
Occupied position	N/A		0.02 mSv/h (2 mrem/h): at any normally occupied area ^[6]	Requirement of §176.708 applies	N/A
Transport Index (TI) Limits ^[4]					
Package ^[1,7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft		No limit		10
Conveyance ^[4]	50: road, rail and passenger aircraft 50 to No limit: vessels ^[8] 200: cargo aircraft		No limit		200
Overpack	N/A: for road, rail 50 to 200: vessels ^[8] 3: passenger aircraft; 10: cargo aircraft		N/A	No limit ^[8]	N/A
Criticality Safety Index (CSI) Limit for fissile material ^[4]					
Package ^[1,7]	50		100	100	100
Conveyance ^[4]	50: road, rail and air 50: for holds, compartments or defined deck areas of vessels ^[8] 200 to No limit: for a total vessel ^[8]		100	200 to No limit: for a total vessel ^[8]	100
Overpack	50: road, rail, vessels ^[8] 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 §71.50.
[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 ²	µCi/cm ²	dpm/cm ²
Beta, gamma and low toxicity alpha emitters	4	10 ⁻⁴	220
All other alpha emitting radionuclides	0.4	10 ⁻⁵	22

The non-fixed contamination shall be determined by:

- (a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
- (b) ensuring each wipe area is 300 cm² in size;
- (c) 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:
 - (a) the packaging is proper for the contents to be shipped;
 - (b) the packaging is in unimpaired physical condition, except for superficial marks;
 - (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
 - (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
 - (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
 - (f) each closure, valve, or other opening of the containment system is properly closed and sealed;
 - (g) each packaging containing liquid in excess of an A₂ 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;
 - (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
 - (i) 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"> • UN Identification number • Proper Shipping Name • Hazard Class (7) • Total activity contained in each package in SI units (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 • Number and type of packages <p><u>Additional description:</u></p> <ul style="list-style-type: none"> • Name of each radionuclide^[1] • Description of physical and chemical form (unless special form) • Category of label used • Transport index (TI) of each package bearing a Yellow-II or Yellow-III label <p><u>Additional entry requirements:</u></p> <ul style="list-style-type: none"> • 24 hour emergency telephone number • Shipper's Certification shall be provided by each person offering radioactive material for transportation^[2] • Proper page numbering (e.g. Page 1 of 4) 	<p><u>Materials-based Requirements:</u></p> <ul style="list-style-type: none"> • The criticality safety index (CSI) or "Fissile Excepted" for fissile material • The words "Highway route controlled quantity" or the term "HRCQ" entered in the basic description for highway route controlled quantities • The letters "RQ" entered on the shipping paper either before or after the basic description for each hazardous substance (see §171.8) • Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required • A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste <p><u>Package-based Requirements:</u></p> <ul style="list-style-type: none"> • The applicable DOE or NRC package approval identification marking for certified Type AF and Type B packages • The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package <p><u>Shipment- and Administrative-based Requirements:</u></p> <ul style="list-style-type: none"> • Specify "exclusive use shipment" as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation "DOT-SP" followed by the special permit number^[3] for a special permit shipment 	<ul style="list-style-type: none"> • 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 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • The words "RESIDUE: Last Contained * * *" may be included in association with the basic description of the hazardous material last contained in the packaging • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information
Special Considerations/Exceptions for Shipping Papers		
<ul style="list-style-type: none"> • 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). • Emergency response information consistent with §§172.600-606 shall be readily available on the transport vehicle. • 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. • 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. 		

[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 ^[1]	Additional Markings Sometimes Required	Optional Markings
<p>Markings for Non-bulk Packagings:</p> <ul style="list-style-type: none"> • Proper shipping name • Identification number (preceded by "UN" or "NA," as appropriate) • Name and address of consignor or consignee, unless the package is: <ul style="list-style-type: none"> ▪ highway only and no motor carrier transfers; or ▪ 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 <p>Markings for Bulk Packages:</p> <ul style="list-style-type: none"> • Identification number on orange rectangular panel: <ul style="list-style-type: none"> ▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more, or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons), or ▪ on each side and end of motor vehicle carrying cylinders permanently installed on a tube trailer 	<p>Package-based marking requirements:</p> <ul style="list-style-type: none"> • Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb) • Package type as appropriate, i.e., "TYPE IP-1," "TYPE IP-2," "TYPE IP-3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"^[1] • Marked with international vehicle registration code of country of origin for IP-1, IP-2, IP-3 or Type A package design^[2] • Radiation (trefoil) symbol^[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design  • 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) • 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. <p>Materials-based requirements:</p> <ul style="list-style-type: none"> • For non-bulk IP-1 package containing a liquid, use underlined double arrow symbol indicating upright orientation^[4], where the symbol is placed on two opposite sides of the packaging  • If a hazardous substance in non-bulk package, mark outside of each package with the letters "RQ" in association with the proper shipping name <p>Administrative-based requirements:</p> <ul style="list-style-type: none"> • 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 • Mark "DOT-SP" followed by the special permit number assigned for each package authorized by special permit • 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 	<ul style="list-style-type: none"> • Both the name and address of consignor and consignee is recommended. • Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling.
Special Considerations for Marking Requirements		
<ul style="list-style-type: none"> • 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. 		

[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 ^[1]

- 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 A₂ 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 ^[3]

Other Labels ^[2]

				
White-I	Yellow-II	Yellow-III	Fissile	Empty
Radiation Surface Level (RSL):				
mSv/h:	RSL ≤ 0.005	0.005 < RSL ≤ 0.5	0.5 < RSL ≤ 2 ^[4]	
mrem/h:	RSL ≤ 0.5	0.5 < RSL ≤ 50	50 < RSL ≤ 200 ^[4]	
Transport Index (TI):^[4]				
TI = 0 ^[4]	0 ^[4] < TI ≤ 1	1 < TI ≤ 10 ^[4, 5]		

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

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^[1], 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^[2].

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^[3];
 - 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 2012 (ERG2012) is available at the following URL:
http://phmsa.dot.gov/pv_obj_cache/pv_obj_id_7410989F4294AE44A2EBF6A80ADB640BCA8E4200/filename/ERG2012.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](#), 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
INCIDENT NOTIFICATIONS AND REPORTING

INCIDENT NOTIFICATIONS AND REPORTING

Table L-1. Typical NRC Notification and Reporting Requirements for Incidents

Note: The following list of notification and reporting requirements is provided to inform licensees about typical notification and reporting requirements that apply to their licensed activities. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, notification and reporting requirements change; therefore, licensees should consult the regulations for definitive information about current requirements.

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of licensed material	immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gy (250 rads)	immediate	30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv (5 rems)	none	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv (0.1 rem)	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) & (ii)
Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a) & (c)(2)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2) & (c)(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) & (c)(2)

Note: Telephone notifications must be made to the U.S. Nuclear Regulatory Commission Operations Center at 301-816-5100.

APPENDIX M
SAFETY CULTURE POLICY STATEMENT

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.

APPENDIX N

**CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY
INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)**

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:

<input type="checkbox"/>	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
<input type="checkbox"/>	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.
<input type="checkbox"/>	An affidavit that:
<input type="checkbox"/>	Is signed under oath and affirmation (notarization may suffice).
<input type="checkbox"/>	Clearly identifies (such as by name or title and date) the document to be withheld.
<input type="checkbox"/>	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
<input type="checkbox"/>	States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
<input type="checkbox"/>	Provides a rational basis for holding the information in confidence.
<input type="checkbox"/>	Fully addresses the following issues:
<input type="checkbox"/>	Is the information submitted to, and received by, the NRC in confidence? Provide details.
<input type="checkbox"/>	To the best of the applicant's knowledge, is the information currently available in public sources?
<input type="checkbox"/>	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
<input type="checkbox"/>	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your organization, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

<p>NRC FORM 335 (12-2010) NRCMD 3.7</p> <p style="text-align: center;">U.S. NUCLEAR REGULATORY COMMISSION</p> <p style="text-align: center;">BIBLIOGRAPHIC DATA SHEET <i>(See instructions on the reverse)</i></p>	<p>1. REPORT NUMBER (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.) NUREG-1556, Volume 4, Revision 1 FINAL</p>	
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