

Wisconsin
Chapter DHS 157 - Radiation Protection
Regulatory Guide

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Guidance for Fixed Gauge Devices

Department of Health Services

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EXECUTIVE SUMMARY

Wisconsin Regulatory Guides (WISREGS) are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of **Wisconsin Administrative Code, Chapter DHS 157 ‘Radiation Protection’**, to delineate techniques used by DHS in evaluating past problems or postulated accidents, and to provide guidance to applicants, licensees, or registrants. WISREGS are not substitutes for **Chapter DHS 157 ‘Radiation Protection,’** therefore compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Department of Health Services (DHS), Radiation Protection Section to determine if a radiation protection program meets the current rule and protects health and safety.

Comments and suggestions for improvements in this WISREG are encouraged. This WISREG will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to **Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659.**

Requests for single copies of this guide (which may be reproduced) can be made in writing to **Department of Health Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659**

This WISREG “Guidance for Fixed Gauge Devices” has been developed to streamline the application process for a fixed gauge license. A copy of the application F-45009 ‘*Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices,*’ is located in **Appendix A** of this guide.

Appendix C through P provides examples, models and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **DHS 157.10** for a fixed gauge device.

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
Am-241	americium-241
ANSI	American National Standards Institute
AU	authorized user
bkg	Background
Bq	Becquerel
CaF ₂	calcium fluoride
Cf-252	californium-252
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulation
Ci	Curie
C/kg	coulomb per kilogram
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
d	Day
DHS	Department of Health Services
DOE	United States Department of Energy
DOT	United States Department of Transportation
ft	Foot
GBq	Gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
hr	Hour
DHS 157	Wisconsin Administrative Code Chapter DHS 157 'Radiation Protection'
IN	Information Notice
kg	Kilogram
LiF	lithium fluoride
m	Meter
mCi	Millicurie
mo	Month
mR	Milliroentgen
mrem	Millirem
mSv	Millisievert
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	Optically Stimulated Luminescence
Q	Quality Factor
R	Roentgen
RG	Regulatory Guide
RQ	reportable quantities
RSO	radiation safety officer
SDE	shallow-dose equivalent

Sr-90	strontium-90
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	sealed source and device
std	Standard
Sv	Sievert
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
wk	Week
yr	Year

PURPOSE OF GUIDE

This WISREG provides guidance to an applicant in preparing a fixed gauge license application as well as DHS's criteria for evaluating a fixed gauge license application. It is not intended to address the research and development of fixed gauges or the commercial aspects of manufacturing, distribution, and service of such devices. Within this guide, the phrases or terms, "fixed gauge," "gauging devices," or "gauges" are used interchangeably.

This guide addresses a variety of radiation safety issues associated with fixed gauges of many designs.

Figure 1 is a cutaway diagram of a typical fixed gauge showing basic design features. **Figure 2** illustrates various designs of fixed gauges based, in part, on their intended use and the location of the radioactive source within the gauges. 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). Because of differences in design, manufacturers provide appropriate instructions and recommendations for proper operation and maintenance. In addition, with gauges of varying designs, the sealed sources may be oriented in different locations within the devices, resulting in different radiation safety problems.

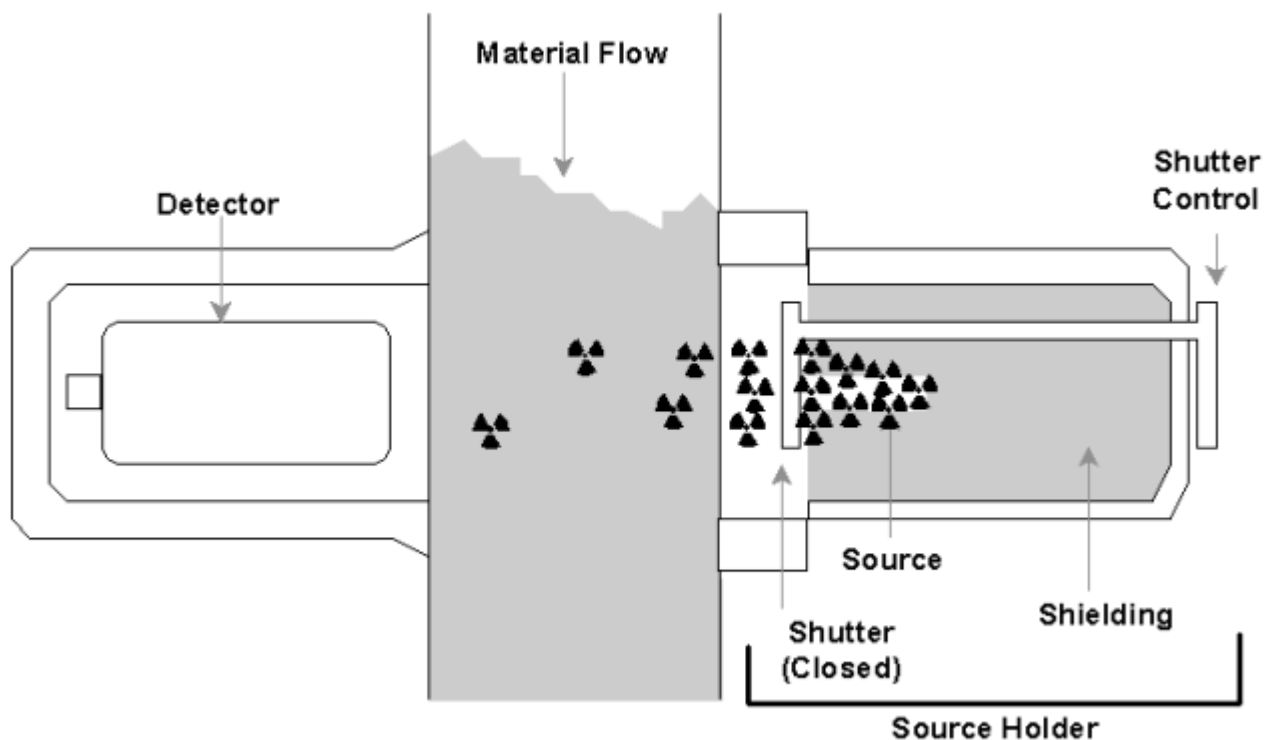


Figure 1. Fixed Gauge Basic Design Features. Cutaway of a typical fixed gauge diagramming the basic design features: the source, source holder, detector, shutter, shutter control or on-off mechanism, and shielding.

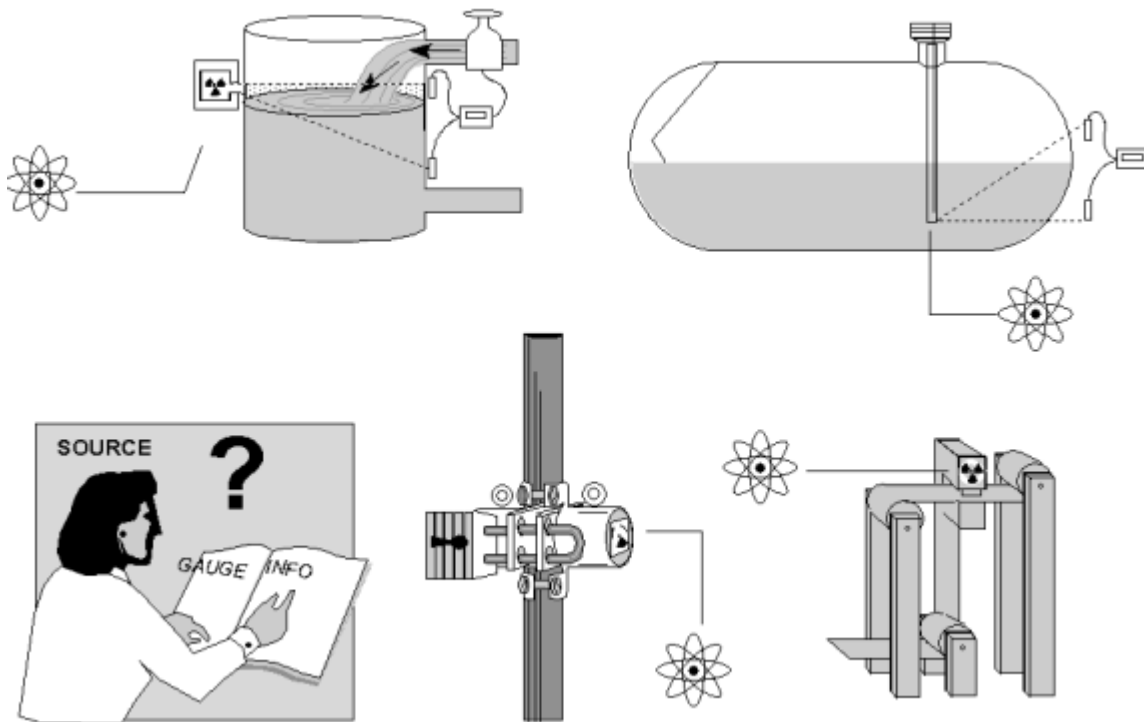


Figure 2. Where is the Radioactive Source? The wide variety of fixed gauge designs results in different radiation safety considerations

This guide identifies the information needed to complete Form F-45009 (**Appendix A**), "Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices."

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

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

In this document, dose or radiation dose means absorbed dose, dose equivalent, committed dose equivalent (CDE), committed effective dose equivalent (CEDE), or total effective dose equivalent (TEDE). These terms are defined in **Chapter DHS 157 'Radiation Protection', Subchapter I 'General Provisions'**. Rem, and its SI equivalent Sievert (1 rem = 0.01 Sievert (Sv)), are used to describe units of radiation exposure or dose. This is done because **Chapter DHS 157 'Radiation Protection', Subchapter**

I ‘General Provisions’ sets dose limits in terms of rem, not rad or roentgen (R). When the sealed sources used in gauges emit beta and gamma rays, for practical reasons, we are assuming that $1 R = 1 \text{ rad} = 1 \text{ rem}$. Less common are sealed sources used in gauges that emit neutrons or alpha particles. For neutron and alpha emitting sealed sources, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from neutrons and alpha particles requires the use of an appropriate quality factor (Q) value. Q values are used to convert absorbed dose (rad) to dose equivalent (rem). Q values for neutrons and alpha particles are addressed in *DHS 157.06(4)*.

The information submitted in the application must be sufficient to demonstrate that the proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of Wisconsin according to DHS guidelines. Submission of an incomplete application or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will delay completion of the application’s review and may be avoided by a thorough study of the rule(s) and these instructions prior to submitting the application.

WHO REGULATES FACILITIES IN WISCONSIN?

In the special situation of work at federally-controlled sites in Wisconsin, it is necessary to know the jurisdictional status of the land to determine whether Nuclear Regulatory Commission (NRC) or DHS has regulatory authority. NRC has regulatory authority over land determined to be under “exclusive federal jurisdiction,” while DHS has jurisdiction over non-exclusive federal jurisdiction land (see **Table 1**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. DHS recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or DHS regulatory requirements, as appropriate.

Table 1: Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-federal entity in non-Agreement State (see map on next page), U.S. territory, or possession	NRC
Non-federal entity in WI at non-federally controlled site	DHS
Non-federal entity in WI at federally-controlled site <i>not</i> subject to exclusive Federal jurisdiction	DHS
Non-federal entity in WI at federally-controlled site subject to exclusive federal jurisdiction	NRC

Locations of NRC Offices and Agreement States

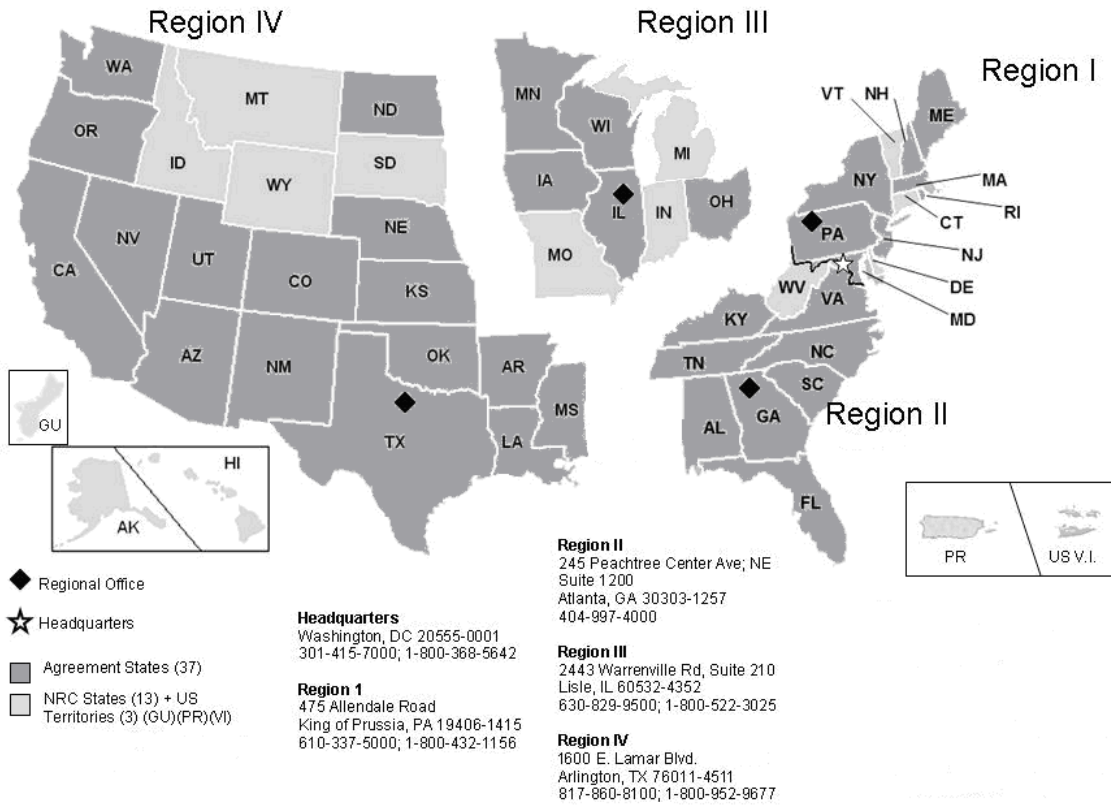


Figure 3. U.S. Map. Location of NRC Offices and Agreement States.

Reference: A current list of Agreement States, states that have entered into agreements with the NRC that give them the authority to license and inspect radioactive materials used or possessed within their borders, (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC’s Regional Offices. NRC Office of Federal and State Materials and Environmental Management Programs (FSME) also provides the current list of Agreement States at: <http://nrc-stp.ornl.gov/>.

MANAGEMENT RESPONSIBILITY

DHS recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. DHS believes that consistent compliance with **Chapter DHS 157 ‘Radiation Protection’** provides reasonable assurance that licensed activities will be conducted safely. Through its experience, DHS has found that effective management has been shown to be key to a well-run radiation safety program. Management refers to a senior-level manager who has responsibility for overseeing licensed activities.

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

- Radiation safety, security and control of radioactive materials, and compliance with **Chapter DHS 157 ‘Radiation Protection’**;
- Completeness and accuracy of the radiation safety records and all information provided to DHS;
- Knowledge about the contents of the license and application;
- Committing adequate resources (including space, equipment, personnel, time and if needed, contractors) to the radiation protection program to ensure that public and worker safety is protected from radiation hazards and compliance with the rule is maintained; and
- Selecting and assigning a qualified individual to serve as the Radiation Safety Officer (RSO) for their licensed activities.
- Notifying DHS in writing within 10 days following filing of petition for voluntary or involuntary bankruptcy.

Management may delegate individuals (i.e., an RSO or other designated individual) to submit amendment requests to DHS. A correspondence delegation letter must be completed, signed by management, and submitted to DHS. A sample letter has been included in **Appendix Q**.

SAFETY CULTURE POLICY STATEMENT

Safety culture is 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. Wisconsin Radiation Protection Section expects individuals and organizations performing regulated activities to establish and maintain a positive safety culture sufficient to ensure compliance with the provisions of **Chapter DHS 157**. Licensee and registrants are required to implement a radiation protection program under *DHS 157.21(1)*. Since a radiation protection program is the foundation on which compliance is achieved, a strong safety culture is critical.

Traits of a Positive Safety Culture

Experience has shown that certain personal and organizational traits are present in a positive safety culture. The following are traits of a positive safety culture:

- **Leadership Safety Values and Actions-** Leaders demonstrate a commitment to safety in their decisions and behaviors
- **Problem Identification and Resolution-** Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance
- **Personal Accountability-** All individuals take personal responsibility for safety
- **Work Processes-** The process of planning and controlling work activities is implemented so that safety is maintained
- **Continuous Learning-** Opportunities to learn about ways to ensure safety are sought out and implemented
- **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
- **Effective Safety Communication-** Communications maintain a focus on safety
- **Respectful Work Environment-** Trust and respect permeate the organization
- **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

More information is available electronically at <http://www.dhs.wisconsin.gov/radiation/>

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read and follow **Chapter DHS 157 'Radiation Protection'**.

The following subchapters of **Chapter DHS 157 'Radiation Protection'** contain requirements applicable to Fixed Gauge licenses.

- Subchapter I: 'General Provisions'
- Subchapter II: 'Licensing of Radioactive Materials'
- Subchapter III: 'Standards for Protection from Radiation'
- Subchapter X: 'Notices, Instructions and Reports to Workers'
- Subchapter XI: 'Inspection by the Department'
- Subchapter XII: 'Enforcement'
- Subchapter XIII: 'Transportation'

To request copies of Chapter DHS 157 'Radiation Protection', call Department of Health Services (DHS), Radiation Protection Section at (608) 267-4797 or for electronic copy go to our web site at:

<http://www.dhs.wisconsin.gov/radiation/>

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from DHS in preparing an application.
- Complete DPH Form F-45009 “*Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices*” (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Do not submit proprietary information.
- Mark facility diagrams and other sensitive information “Withhold from public disclosure under s. 19.36(1), WI Stats.” See Wisconsin Regulatory Issue Summary 2006-01.
- Submit an original, signed application along with attachments.
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of responses as shown in this document or submission of alternative procedures may require a custom review.

Personal employee information, i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information, should not be submitted.

If you have any questions about the application process, please contact this office at (608) 267-4797.

WHERE TO FILE

Applicants wishing to possess or use radioactive material in Wisconsin are subject to the requirements of **Wisconsin Administrative Code Chapter DHS 157 'Radiation Protection'** and must file a license application with:

*Department of Health Services
Radiation Protection Section
P.O. Box 2659
Madison, WI 53701-2659*

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to *DHS 157.10* to determine the amount of the fee. DHS will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of DHS's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to *DHS 157.10*.

Direct all questions about DHS's fees or completion of **Item 11** of Form F-45009 "*Application for Radioactive Material License Authorizing the use of Sealed Sources in Fixed Gauge Devices*" (**Appendix A**) to DHS, Radiation Protection Section at (608) 267-4797.

CONTENTS OF AN APPLICATION

Item 1: Type of Application

On the application check the appropriate box and list the license number for renewal and amendments.

Response from Applicant:

Item 1. Type Of Application (Check one box) <input type="checkbox"/> New License <input type="checkbox"/> Renewal License Number _____
--

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.

Note: DHS must be notified in the event of change of mailing address, change of ownership or control and bankruptcy proceedings; see below for more details.

Response from Applicant:

Item 2. Name And Mailing Address Of Applicant: <hr/> Applicant's Telephone Number (Include Area Code):

Item 2.1: Timely Notification of Change of Ownership or Control

Rule: *DHS 157.13*

Criteria: Licensees must provide full information and obtain DHS's **written consent prior** to transferring ownership or control of the license.

Discussion: Changes in ownership may be the results of mergers, buyouts, or majority stock transfers. Although it is not DHS's intent to interfere with the business decisions of licensee's, it is necessary for licensees to obtain DHS's prior written consent. This is to ensure the following:

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

Note: **Appendix C** identifies the information to be provided about changes of ownership or control.

Item 2.2: Notification of Bankruptcy Proceedings

Rule: *DHS 157.13(10)*

Criteria: Within 10 days following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify DHS in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. DHS needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled, and whether there are any public health and safety concerns (e.g., contaminated facility). DHS shares the results of its

determinations with other involved entities (e.g., trustees), so that health and safety issues can be resolved before bankruptcy actions are completed.

Item 3: Person to Contact Regarding Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed Radiation Safety Officer (RSO), unless the applicant has named a different person as the contact. DHS will contact this individual if there are questions about the application.

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

Response from Applicant:

Item 3. Person To Contact Regarding Application:
 <hr/>
Contact's Telephone Number (Include Area Code):

Item 4: Address(es) Where Radioactive Material Will Be Used or Possessed

Most applicants need to provide one type of information in response to **Item 3**:

- Description of storage and use.

Specify the street address, city or other descriptive address (such as on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown) for each facility location. The descriptive address should be sufficient to allow a DHS inspector to find the use/storage location. A Post Office Box address is not acceptable.

Obtaining a DHS license does not relieve a licensee from complying with other applicable Federal, State, or local Regulation (e.g., local zoning requirements for storage locations).

A DHS license amendment is required before locating a gauge at an address not already listed on the license, whether that gauge is an additional unit or a relocation of an existing unit.

For information on conducting operations at temporary job sites (i.e., locations where work is conducted for limited periods of time, refer to the section in this guide called “Fixed Gauges Used at Temporary Job Sites.” That section offers examples of operations where fixed gauges might be used at temporary job sites and gives information that should be provided to DHS to support a request for these operations.

Response from Applicant:

Item 4. Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use Post Office Box)	
Address	Telephone Number (Include Area Code)
Address	Telephone Number (Include Area Code)
Address	Telephone Number (Include Area Code)

Note: As discussed later in **Item 8, Part 2 “Financial Assurance and Record Keeping for Decommissioning,”** licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For fixed gauge licensees, acceptable records are sketches or written descriptions of specific locations where each gauge was used or stored and any information relevant to damaged devices or leaking radiation sources.

Item 5: Radiation Safety Officer (RSO)

Rule: *DHS 157.13(2)*

Criteria: Radiation Safety Officers (RSOs) must have adequate training and experience. Successful completion of training of one of the following is evidence of adequate training and experience.

- Fixed gauge manufacturer's or distributor's course for users or for RSO's; or
- Equivalent course that meets **Appendix G** criteria

Additional training is required for RSOs of programs that perform non-routine 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 DHS limits (e.g., installation, initial radiation survey, gauge relocation, and removal of the gauge from service). **See Item 10.9 'Maintenance'** in this guide and **Appendix N**.

Discussion: The person responsible for the radiation protection program is called the RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. RSO duties are illustrated in **Figure 4** and described in **Appendix F**. DHS requires the name of the RSO on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

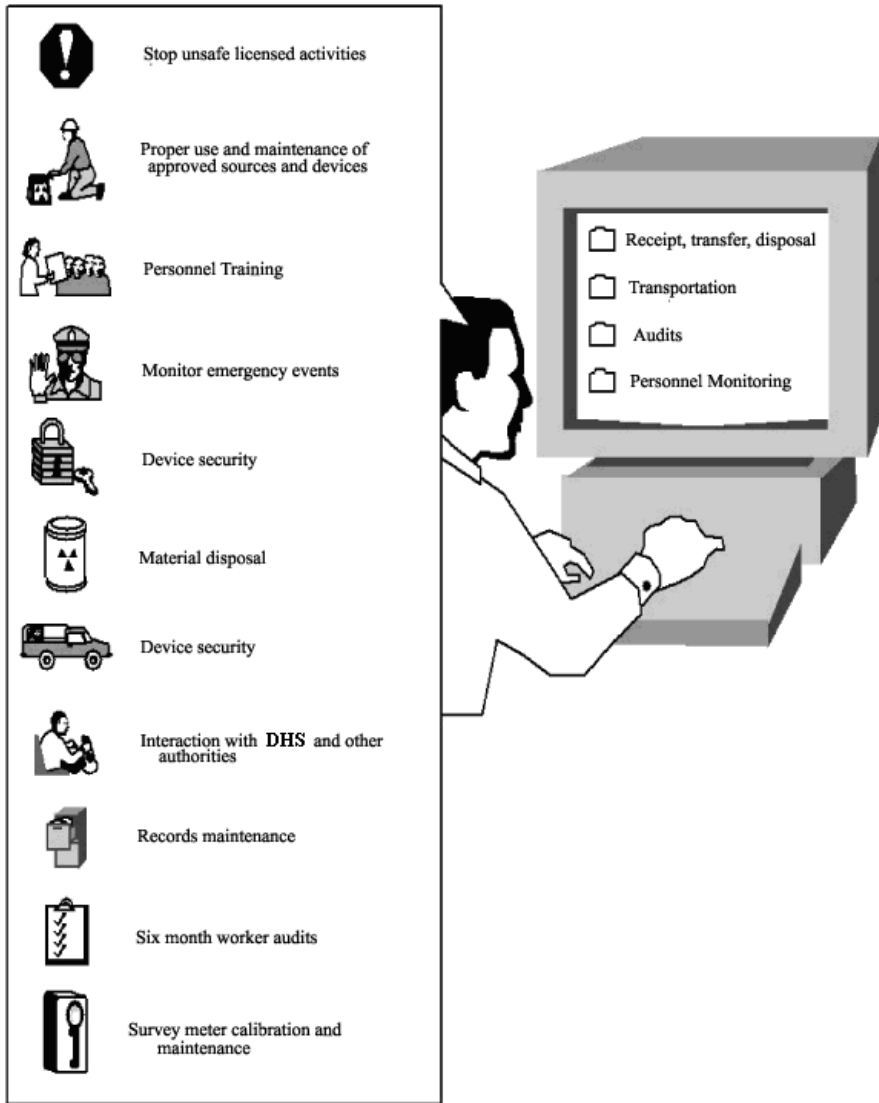


Figure 4: RSO Responsibilities. Duties and responsibilities of RSOs.

Response from Applicant:

Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)

Name: _____ Telephone Number (Include area code): _____

Before obtaining radioactive material, the proposed RSO will have successfully completed one of the training courses described in Criteria in the section titled "Radiation Safety Officer" in WISREG 'Guidance For Fixed Gauge Devices'

Or

Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached. Before being named as the RSO, future RSOs will have successfully completed one of the training courses described in Criteria in the section titled 'Radiation Safety Officer' in WISREG "Guidance For Fixed Gauge Devices.'

Note:

- It is important to notify DHS and obtain a license amendment prior to changing the RSO.
- Alternative responses will be evaluated using the criteria listed above

Item 6: Training for Individuals Working In or Frequenting Restricted Areas

Rule: *DHS 157.13(2)*

Criteria: Authorized users (AUs) must have adequate training and experience. DHS will accept successful completion of one of the following as evidence of adequate training and experience:

- Fixed gauge manufacturer's or distributors course for users; or
- An equivalent course that meets **Appendix G** criteria.

Discussion: An AU is a person whose training and experience meet DHS's criteria, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. AUs must 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:

<p>Item 6. Training For Individuals Working In Or Frequenting Restricted Areas (Check one box)</p> <p><input type="checkbox"/> Before using radioactive material, authorized users will have successfully completed one of the training courses described in Criteria in the section titled " Training for Individuals Working In or Frequenting Restricted Areas" in WISREG " Guidance For Fixed Gauge Devices."</p> <p>NOTE: IF USING IN-HOUSE TRAINING PROGRAM SUBMIT, COPY OF COURSE CONTENT, SAMPLE COURSE EXAMINATION AND COURSE INSTRUCTOR QUALIFICATIONS.</p> <p style="text-align: center;">Or</p> <p><input type="checkbox"/> Documentation of the training and experience for the proposed gauge user(s) is/are attached.</p>
--

Radioactive Material

Item 7: Radioactive Material and Chemical and Physical Form

Part 1: Sealed Sources and Devices

Rule: *DHS 157.13(1-2)*

Criteria: Applicants must provide the manufacturer's or distributor's name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by the NRC or an Agreement State.

Discussion: The NRC or an Agreement State performs a safety evaluation of fixed gauges before authorizing a manufacturer or distributor to distribute the gauges to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Before the SSD registration process was formalized, some older gauges may not have been evaluated in a separate document, but were specifically approved on a license. Licensees can continue to use these gauges that are specifically listed on their licenses. Some examples of fixed gauges are shown in **Figure 5**.

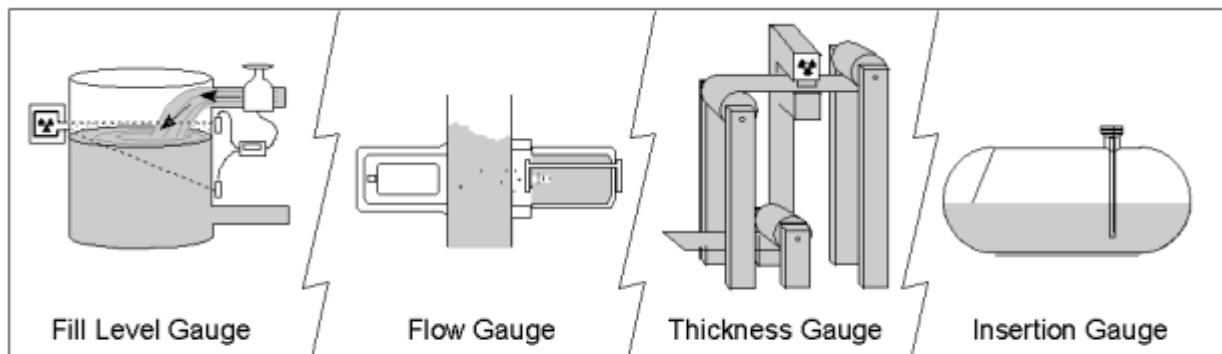


Figure 5: *Examples of Fixed Gauges.*

Consult with the proposed manufacturer or distributor to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with NRC or an Agreement State. Licensees 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 DHS'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 Certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by DHS, licensees are required to use gauges according to their respective SSD Registration Certificates. Accordingly, applicants may want to obtain a copy of the certificate and review it with the manufacturer or distributor or with the NRC or the issuing Agreement State to ensure that it correctly reflects the radiation safety properties of the source or device. See **Appendix E** for an example of a fixed gauge SSD Certificate.

Part 2: Financial Assurance and Recordkeeping for Decommissioning

Rule: *DHS 157.13(9)(b) and (10); DHS 157.15*

Criteria: Fixed gauge licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in *DHS 157.15* must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures, equipment, locations where gauges are used or stored, and leaking sources. Pursuant to *DHS 157.15*, licensees must transfer these records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned according to *DHS 157.13(10)*; or
- DHS before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most fixed gauge licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does

not exceed the thresholds in *DHS 157.15*. The thresholds for typical radionuclides used for fixed gauge sealed sources are shown in **Table 2**. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance.

Table 2: Examples of Minimum Inventory Quantities Requiring Financial Assurance

Radionuclide (Sealed Sources)	Activity in Gigabecquerels	Activity in Curies
Co-60	3.7×10^5	10,000
Kr-85	3.7×10^7	1,000,000
Sr-90	3.7×10^4	1,000
Cs-137	3.7×10^6	100,000
Am-241	3.7×10^3	100
Ra-226	3.7×10^3	100
Cf-252	3.7×10^3	100

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

The same rule also requires that licensees maintain records important to decommissioning in an identified location. All fixed gauge licensees need to maintain records of structures and equipment where each gauge was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. If no records exist regarding structures and equipment where gauges were used or stored, licensees shall make all reasonable efforts to create such records based upon historical information (e.g., employee recollections). In addition, if fixed gauge licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For fixed gauge licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each gauge was used or stored and a copy of the most recent leak test for each gauge.

Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with **DHS 157.13(10)** or to DHS before the license is terminated.

References: NRC NUREG-1757, Vol. 3 ‘Consolidated NMSS Decommissioning Guidance- Financial Assurance, Recordkeeping, and Timeliness’ is available on the NRC website at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v3/>

Part 3: Purpose(s) for Which Radioactive Material Will Be Used

Rule: *DHS 157.13(2)*

Criteria: Gauges should be used only for the purposes for which they were designed, according to the manufacturer's or distributor's recommendations and instructions, as specified in an approved SSD Registration Certificate, and as authorized on a DHS license.

Discussion: Uses other than those listed in the SSD Registration Certificate require review and approval by DHS. 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 integrity of the source or source shielding, or other radiation safety-critical components of the device. DHS will evaluate the radiation safety program for each type and use of gauge requested.

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

Note:

- Allowed uses of fixed gauges normally include process control methods such as measuring the thickness of paper, the density of coal, the level of material in vessels and tanks, etc.
- Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.
- If the applicant wishes to be authorized for fixed gauge use at temporary jobsites (see **Item 10.12**) indicate in purpose of use.

Response from Applicant:

RADIOACTIVE MATERIALS			
Item 7 Radioactive Material (Attach additional pages if necessary)			
Element And Mass Number	<input type="checkbox"/> Cobalt-60	<input type="checkbox"/> Krypton-85	<input type="checkbox"/> Americium-241
	<input type="checkbox"/> Cesium-137	<input type="checkbox"/> Strontium-90	<input type="checkbox"/> Radium-226
	<input type="checkbox"/> Other Isotope (Please specify)		
List name of Sealed Source Manufacturer or Distributor and Model Number		List Name of Device Manufacturer or Distributor and Model Number	
Maximum Quantity (Not to exceed either the maximum activity per source or device as specified in the Sealed Source and Device Certificate)		Sealed Source And Device Registration Sheet Number	
Intended use			

Item 8: Facilities and Equipment

Rule: *DHS 157.13(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
- 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 need to consult the sections on the SSD Registration Certificate entitled, "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" to determine the appropriate gauge for a location. In those instances when a proposed location is not consistent with the SSD Registration Certificate, 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 DHS with specific information demonstrating that the proposed new conditions will not impact the safety or integrity of the source or device.

Chapter DHS 157 ‘Radiation Protection’ states that an application will be approved if, among other things, the applicant’s proposed equipment, facilities, and procedures are adequate to minimize danger to the public’s health and safety. *DHS 157.28(1)&(2)* states that (1) sources of radiation shall be secured against unauthorized removal from the place of storage and (2) sources of radiation in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

Response from Applicant:

<p>Item 8. Facilities And Equipment (Check boxes and attach diagram)</p> <p><input type="checkbox"/> Diagrams of radioactive material area(s) of use are attached.</p> <p style="text-align: center;">AND</p> <p><input type="checkbox"/> The fixed gauge is secured to prevent unauthorized removal or access and these security features will not impact the safety or integrity of the source or device.</p>
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Note:

- Any deviations from an SSD Registration Certificate will require specific DHS approval.
- Alternative responses will be evaluated using the criteria listed above.

Item 9: Radiation Safety Program

Item 9.1: Audit Program

Rule: *DHS 157.21; DHS 157.31(2)*

Criteria: Licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure the following:

- Compliance with DHS and DOT Regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (*DHS 157.21*); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: **Appendix H** contains a suggested audit program that is specific to the use of fixed gauges and is acceptable to DHS. All areas indicated in **Appendix H** may not be applicable to every licensee and all items may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit need not be reviewed at the next audit.

Currently DHS's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of fixed gauge users to determine if, for example, Operating and Emergency Procedures are available and are being followed, etc.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; NRC Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," provides guidance on this subject. The DHS will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the DHS will normally exercise discretion and may elect not to cite a violation. DHS's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. DHS 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 follow-up.

Response from Applicant:

Item 9.1 Audit Program

The applicant is not required to, and should not, submit its audit program to the DHS for review during the Licensing phase. This matter will be examined during an inspection.

References: Information Notices are available in the electronically at NRC's web site, <http://www.nrc.gov>.

Item 9.2: Termination of Activities

Rule: *DHS 157.32(8); DHS 157.13; DHS 157.15; DHS 157.31*

Criteria: The licensee must do the following:

- Notify DHS, in writing, within 60 days of:
 - The expiration of its license;
 - A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to DHS requirements;
 - No principal activities have been conducted at the entire site under the license for a period of 24 months;
 - No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to DHS requirements.
- Submit a decommissioning plan, if required by *DHS 157.13(11)(f)*;
- Conduct decommissioning, as required by *DHS 157.13(11)(j)* and *DHS 157.13(11)(l)*; and
- Submit to DHS, a completed DPH Form F-45007 'Certificate of Disposition of Materials' (**Appendix B**) and demonstrate that the premises are suitable for release for unrestricted use (e.g. results of final survey).

- Before a license is terminated, send the records important to decommissioning to DHS. If licensed activities are transferred or assigned in accordance with *DHS 157.13(10)(b)*, transfer records important to decommissioning to the new licensee.

Discussion: Before a licensee can decide whether it must notify DHS, the licensee must determine whether residual radioactivity is present and if so, whether the levels make the building or outdoor area unsuitable for release according to **Chapter DHS 157 ‘Radiation Protection’**. A licensee's determination that a facility is not contaminated is subject to verification by DHS inspection.

For guidance on the disposition of radioactive material, see the section on "Fixed Gauge Disposal and Transfer." For guidance on decommissioning records, see the section on "Financial Assurance and Record Keeping for Decommissioning."

Response from Applicant:

Item 9.2 Termination Of Activities

No response is required from the applicant during the application process. Refer to section titled "Termination of Activities" in WISREG "Guidance for Fixed Gauge Devices" for further information.

Item 9.3: Survey Instruments

Rule: *DHS 157.13(2); DHS 157.25(1); DHS 157.31(3)*

Criteria: Licensees must 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: Since 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 hospitals, universities, other DHS, NRC or Agreement State licensees, or local emergency response organization). It is important to determine as soon as possible after an incident, by the use of a radiation survey meter, whether the shielding and source are intact. DHS requires that the licensee submit a description of how assistance will be obtained in

performing a radiation survey in the event of an emergency, if the licensee does not have a calibrated radiation survey instrument.

However, surveys will be required according to *DHS 157.25(1)* for non-routine operations. This includes installation, initial radiation surveys, relocation, removal from service, alignment, replacement, disposal of the sealed source, and non-routine maintenance and repair of components related to the radiological safety of the gauge (see **Item 10.9 ‘Maintenance’**). Licensees may either utilize the manufacturer, a service provider, or themselves to conduct these non-routine operations, Individuals performing these operations shall carefully monitor with a survey meter that:

- Shall be capable of measuring 0.3 mR per hour through at least 200 mR per hour;
- Shall be capable of measuring the radiation being emitted from the gauge’s source; and
- Is checked for functionality with a radiation source each day the survey meter will be used.

Such survey meters should be properly calibrated. Proper calibration is important for initial surveys since the results can be used as a basis for public dose estimates. For those licensees requesting authorization to calibrate their own survey instruments, **Appendix I** contains calibration procedures acceptable to DHS. Each radiation survey instrument shall be calibrated according to the following requirements:

- At energies and geometry appropriate for use;
- At intervals not to exceed 12 months and after each instrument servicing;
- For linear scale instruments, at 2 points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at 2 points of at least one decade; and for digital instruments, at appropriate points; and
- At an accuracy within 20% of the true radiation level on each scale.

For those licensees using gauges containing only beta, neutron or alpha-emitting radionuclides, specialized survey instruments may be required.

Notes:

- Alternative responses will be reviewed against the criteria listed above.
- DHS license will state that the instrument manufacturer will perform survey meter calibrations or a person specifically authorized by DHS, the NRC or an Agreement State, unless the applicant

specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must submit additional information for review. See **Appendix I** for more information.

- Regardless of whether an applicant is authorized to calibrate survey meters or contracts an authorized firm to perform calibrations, the licensee must retain calibration records for at least 3 years.

Response from Applicant:

<p>Item 10.3 Survey Instruments (Check all that apply)</p> <p><input type="checkbox"/> We will have access to a survey meter that meets the Criteria in the section titled "Survey Instruments" in WISREG "Guidance for Fixed Gauge Devices." (Description attached) Or</p> <p><input type="checkbox"/> We will possess a survey meter that meets the Criteria in the section titled "Survey Instruments" in WISREG "Guidance for Fixed Gauge Devices." AND ONE OF THE FOLLOWING</p> <p><input type="checkbox"/> Each survey meter will be calibrated by an organization licensed by DHS, the NRC or an Agreement State to perform survey meter calibrations. Or</p> <p><input type="checkbox"/> We will implement the model survey meter calibration program published in Appendix I in WISREG "Guidance for Fixed Gauge Devices." Or</p> <p><input type="checkbox"/> We will submit alternative calibration procedures for DHS review. (Procedures are attached)</p>

Item 9.4: Material Receipt and Accountability

Rule: *DHS 157.13; DHS 157.31; DHS 157.28(1)(a); DHS 157.32(1)*

Criteria: Licensees must do the following:

- Maintain records of receipt, transfer, and disposal of fixed gauges; and
- Conduct physical inventories at intervals not to exceed 6 months, or some other interval justified by the applicant and approved by DHS, to account for all sealed sources.

Discussion: As illustrated in **Figure 6**, radioactive materials must be tracked from "cradle to grave" in order to ensure gauge accountability, identify when gauges could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. Significant problems can arise from failure to ensure the accountability of gauges. See NRC Information Notice 88-02, "Lost or Stolen Gauges," dated February 2, 1988.

Cradle to Grave Accountability

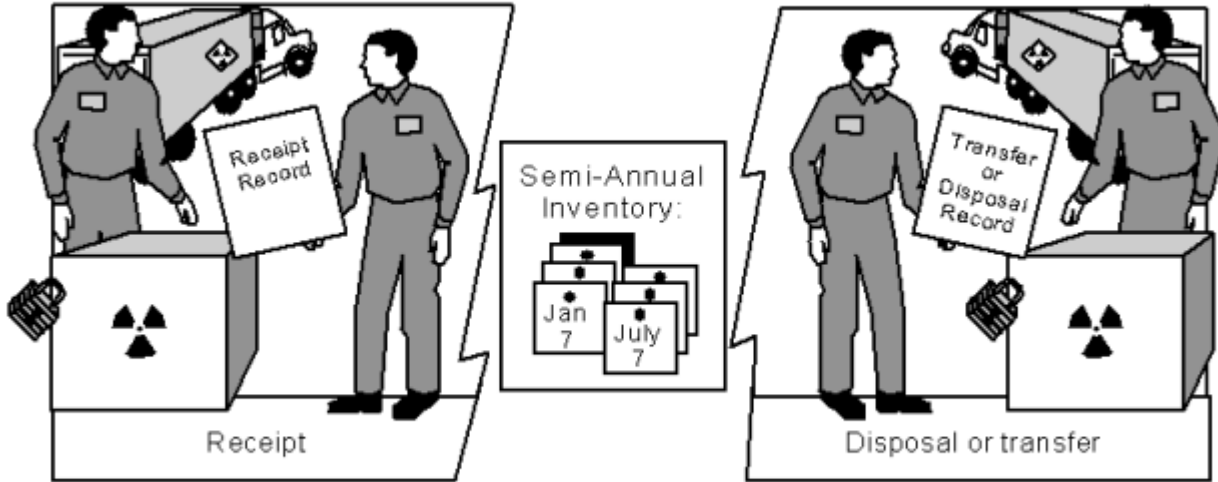


Figure 6. Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories.

Receipt, transfer, and disposal records must be maintained for the times specified in **Table 3**. Typically, these records contain the following types of information:

- Radionuclide and activity (in units of becquerels or curies) of radioactive material in each sealed source
- Manufacturer's or distributor's name, model number, and serial number (if appropriate) of each device containing radioactive material
- Location of each sealed source and device
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's or distributor's name and model number, serial number).

Table 3: Record Maintenance

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

* See **Item 8 Part 2** titled "**Financial Assurance and Recordkeeping for Decommissioning.**"

Response from Applicant:

Item 9.4 Material Receipt And Accountability (Check one box)

- Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.
- Or
- We will submit a description of the frequency and procedures for ensuring that no gauge has been lost, stolen or misplaced. (Procedures are attached)

References: Information Notices are available electronically at NRC's web site <http://www.nrc.gov>.

Item 9.5: Occupational Dose

Rule: *DHS 157.25(2); DHS 157.22(1, 7-8)*

Criteria: Applicants must do either of the following:

- Perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in **Figure 7;**

OR

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

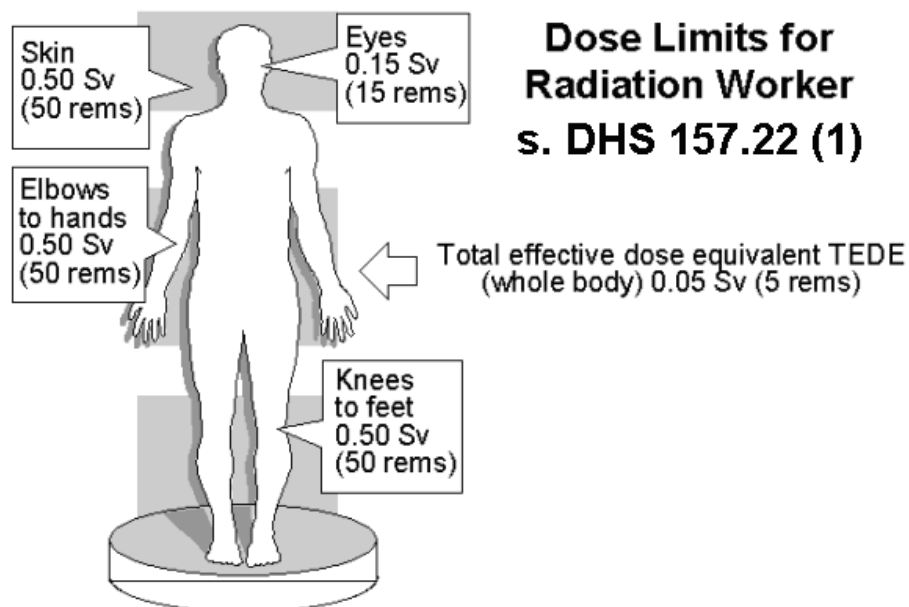


Figure 7. Annual Dose Limits for Occupationally Exposed Adults.

Discussion: Under conditions of routine use, the typical fixed gauge user does not require a personnel monitoring device (dosimetry). A gauge user also does not require dosimetry when proper emergency procedures are used. **Appendix J** provides guidance on performing a prospective evaluation demonstrating that fixed gauge users are not likely to exceed 10% of the limits as shown in **Figure 7** and thus, are not required to have personnel dosimetry.

Individuals who perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service are more likely to exceed 10% of the limits as shown in **Figure 7**. Applicants may be required to provide dosimetry (whole body and perhaps extremity monitors) to individuals performing such services or must perform a prospective evaluation demonstrating that unmonitored individuals performing such non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in **Figure 7**.

When personnel monitoring is needed, most licensees use either thermoluminescent dosimeters (TLDs) or Optically Stimulated Luminescence dosimeters (OSLs) that are supplied by a NVLAP-approved processor. The exchange frequency for dosimeters is usually monthly or quarterly. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Response from Applicant:

Item 9.5 Occupational Dose (Check one box)

We will maintain, for inspection by DHS, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in s. DHS 157.22.

Or

We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

Notes:

- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with **Chapter DHS 157, ‘Radiation Protection’** (e.g., to respond to worker requests).

References: National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available electronically at

<http://ts.nist.gov/nvlap>. NIST Publication 810 can be purchased from GPO at <http://www.gpo.gov>. ANSI N322 may be ordered electronically at <http://www.ansi.org>, or by writing to ANSI, 1430 Broadway, New York, NY 10018.

Item 9.6 Public Dose

Rule: *DHS 157.23(1-2); DHS 157.03; DHS 157.28(1)(a & b); DHS 157.31(8)*

Criteria: Licensees must do the following:

- Ensure that fixed gauges will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv [100 mrem] in one year, and the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour, from licensed operations; and
- Prevent unauthorized access, removal, or use of fixed gauges.

Discussion: Public dose is defined in **Chapter DHS 157 ‘Radiation Protection’** as “the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant or to any other source of radiation under the control of licensee or registrant.” Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individuals assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

In the case of fixed gauges, members of the public include persons who live, work, or may be near locations where fixed gauges are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where gauges are used or stored. Since a fixed gauge presents a radiation field, the applicant must use methods to limit the public dose such that the radiation level in an unrestricted area (e.g., a nearby walkway or area near the gauge that requires frequent maintenance) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour.

Because fixed gauges are generally permanently mounted (e.g., chained and locked to a storage rack), they may not need to be in a locked area to prevent loss, theft, or unauthorized removal. Operating and emergency procedures regarding security and lock-out procedures specified in this document should be sufficient to limit the exposure to the public during use or storage and after accidents. NRC IN 94-15, "Radiation exposures during an event involving a fixed nuclear gauge," dated March 2, 1994, provides

information about two events that resulted or may have resulted in unnecessary radiation exposure to members of the public and to maintenance workers. NRC IN 88-02, "Lost or Stolen Gauges," dated February 2, 1988, 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 hostile environments (e.g., high temperatures, caustic chemicals, etc.), warning signs may be difficult to maintain, so mandatory training programs may be necessary to caution employees.

Engineering controls reduce radiation levels in areas that are accessible to the public. Shielding the gauge with a protective barrier (e.g., using brick, concrete, lead, or other solid walls) or placing the gauge within an enclosure to prevent access to higher radiation levels are examples of engineering controls. See **Figure 8**.

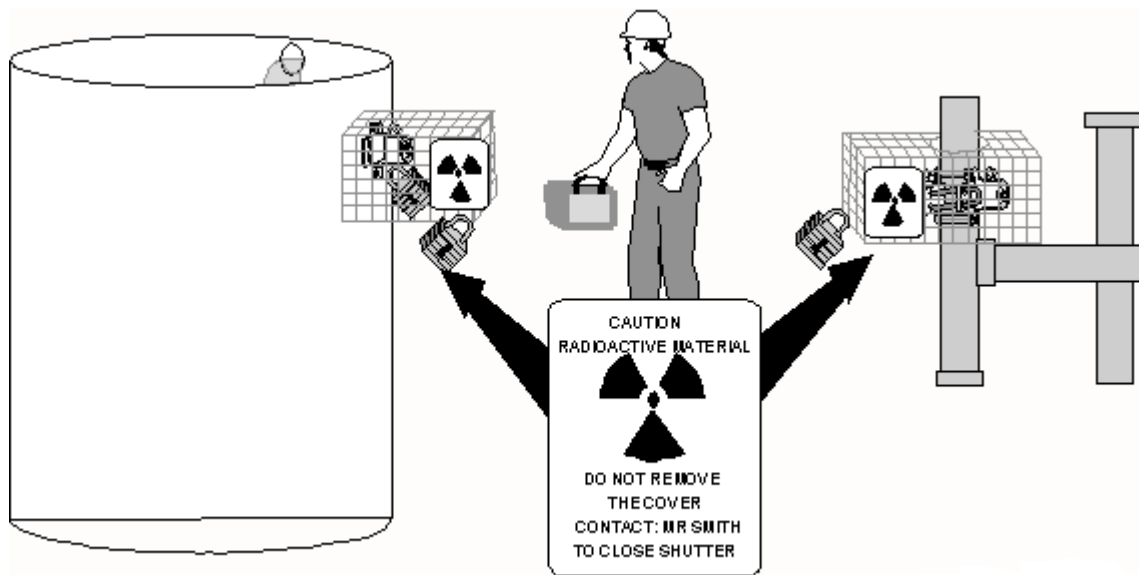


Figure 8. Limiting Public Dose. When dose rates in an area are high enough that a member of the public could receive a dose in excess of 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year, licensees must take additional measures to prevent public access to these higher dose rates, such as 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 K** for an example.

If, after making a public dose estimate, the conditions used to make the evaluation change (e.g., changes the location of gauges, changes the type or frequency of gauge use, adds gauges, changes 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 DHS inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for individual members of the public. See **Appendix K** for examples of methods to demonstrate compliance.

Response from Applicant:

Item 9.6 Public Dose

No response is required, in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

References: Information Notices are available electronically at NRC's web site, <http://www.nrc.gov>.

Item 9.7 Operating and Emergency Procedures

Rule: *DHS 157.13; DHS 157.21; DHS 157.28(1)(a-b); DHS 157.32*

Criteria: Each applicant should do the following:

- Develop, implement, and maintain operating procedures containing the following elements for each type of fixed gauge:
 - Instructions for operating the gauge
 - Instructions for performing routine cleaning and maintenance (e.g., calibration and lubrication) according to the manufacturer's or distributors recommendations and instructions
 - Instructions for testing each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the SSD certificate

- Instructions for lock-out procedures, if applicable, that are adequate to assure that no individual or portion of an individual's body can enter the radiation beam
 - Instructions to prevent unauthorized access, removal, or use of fixed gauges
 - Steps to take to keep radiation exposures ALARA
 - Steps to maintain accountability (i.e., inventory)
 - Instructions to ensure that non-routine operations such as installation, initial radiation survey, repair and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service are performed by the manufacturer, distributor or person specifically authorized by DHS, the NRC or an Agreement State
 - Steps to ensure that radiation warning signs are visible and legible.
- Develop, implement, and maintain emergency procedures for gauge malfunction or damage containing the following elements for each type of fixed gauge:
 - Stop use of the gauge.
 - Restrict access to the area.
 - Contact responsible individuals. (Telephone numbers for the RSO, AUs, the gauge manufacturer or distributor, fire department, and DHS should be posted or easily accessible.)
 - Do not attempt repair or authorize others to attempt repair of the gauge except as specifically authorized in a license issued by DHS, the NRC or an Agreement State.
 - Require timely reporting to DHS pursuant to *DHS 157.32*.
 - Take additional steps, dependent on the specific situations.
 - Provide copies of operating and emergency procedures to all gauge users.
 - Post copies of operating and emergency procedures at each location of use or if posting procedures is not practicable, post a notice which briefly describes the procedures and states where they may be examined.

Discussion: DHS will permit an applicant greater flexibility if one or more of the following safety conditions are met. The applicant should clearly indicate which safety conditions are met for each fixed gauge:

- The air gap between the radiation source and detector of the device is less than 45 cm (18 inches)
- The air gap of the device would not allow insertion of a 30 cm (12 inches) 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 cm (18 inches) from the radiation source with the device shutters, if any, in the open position does not exceed 1 mSv/hour (0.1 rem/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.

Operating and emergency 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. Copies of operating and emergency procedures should be provided to all gauge users. In addition, licensees must post current copies of operating and emergency procedures applicable to licensed activities at each site. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined.

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 and emergency procedures is contained in **Appendix L. Figure 9** illustrates proper response to 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).

DHS considers security of licensed material 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 secure 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).

DHS must be notified when gauges are lost, stolen, or certain other conditions occur. The RSO must be proactive in evaluating whether DHS notification is required. Refer to Appendix P and <i>DHS 157.32</i> for a description of when and where notifications are required.

1. Move Away from Source at Once



2. Sound the Alarm



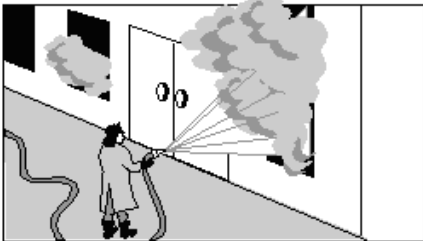
3. Secure the Area



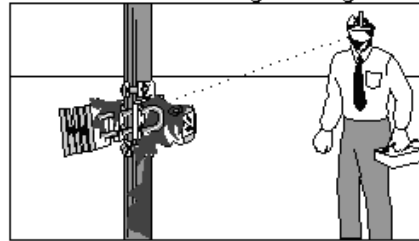
4. Notify RSO



5. Emergency Responders Stabilize Conditions



6. RSO Identifies Damaged Gauge



7. RSO Notifies DHS Within 24 hours Pursuant to s. DHS 157.32

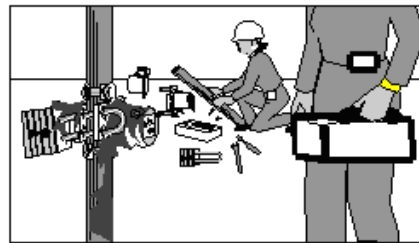


Figure 9. Proper Handling of Incident. Licensee personnel implement emergency procedures when a fire melts the lead shielding of a gauge producing the potential for elevated exposure levels.

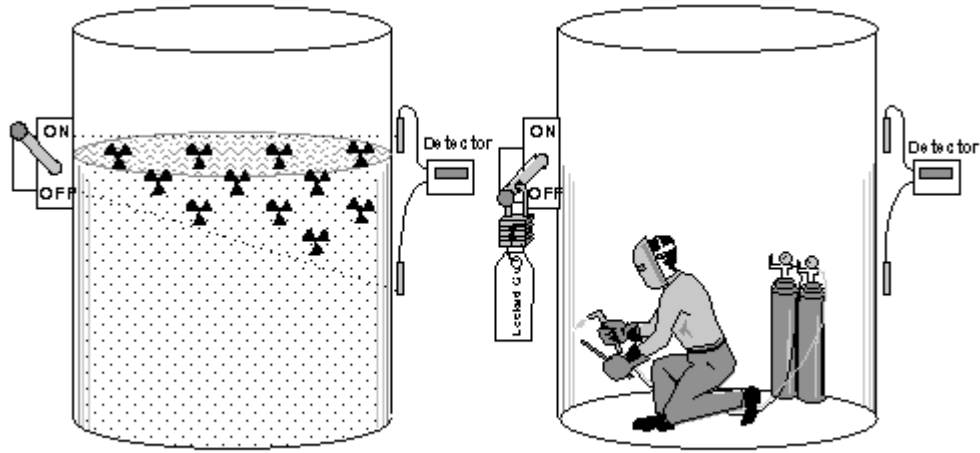


Figure 10. Lock-out Procedures. Typical lock-out procedures include locking the shutter into the "off" position and tagging the shutter control mechanism to indicate the gauge is locked-out.

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

<p>Item 9.7 Operating And Emergency Procedures (Check one box)</p> <p><input type="checkbox"/> We will implement and maintain the operating and emergency procedures in Appendix L of WISREG "Guidance for Fixed Gauge Devices" and provide copies of these procedures to all gauge users.</p> <p style="text-align: center;">Or</p> <p><input type="checkbox"/> We will develop, implement and maintain operating and emergency procedures that will meet criteria in the section titled "Operating and Emergency Procedures" in WISREG "Guidance for Fixed Gauge Devices." (Procedures are attached)</p>

Note:

- Alternative procedures will be evaluated using the criteria listed above.
- If fixed gauges are used at Temporary Job Sites, additional procedures for the use of the fixed gauges addressing such issues as security (see **Item 9.12**) must be submitted.

References:

- NRC IN 89-25, “Unauthorized Transfer of Ownership or Control of Licensed Activities” dated December 7, 1994
- NRC IN 88-02, “Lost or Stolen Gauges” dated February 2, 1988
- NRC IN 88-90, “Unauthorized Removal of Industrial Nuclear Gauges” dated November 22, 1988
- NRC IN 94-15, “Radiation Exposures During an Event Involving a Fixed Nuclear Gauge” dated March 2, 1994
- NRC IN 2009-05, “Contamination Events Resulting from Damage to Sealed Radioactive Sources During Gauge Dismantlement and Nonroutine Maintenance Operations” dated February 3, 2009
- NRC IN 2011-09, “Fixed Gauge Shutter Failures due to Operating in Harsh Working Environments” dated May 18, 2011

Item 9.8 Leak Test

Rule: *DHS 157.06(3); DHS 157.25(1); DHS 157.31(3)*

Criteria: DHS requires testing to determine whether there is any radioactive leakage from the source in the fixed gauge. Records of the test results must be maintained.

Discussion: When issued, a license will require performance of leak tests at intervals approved by DHS, the NRC or an Agreement State as specified in the SSD Registration Certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

Manufacturers, distributors, consultants, and other organizations may be authorized by DHS, the NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the fixed gauge manufacturer's and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. See **Figure 11** below. Licensees may also be authorized to conduct the entire leak test sequence themselves. **Appendix M** contains information to support a request to perform leak testing and sample analysis.

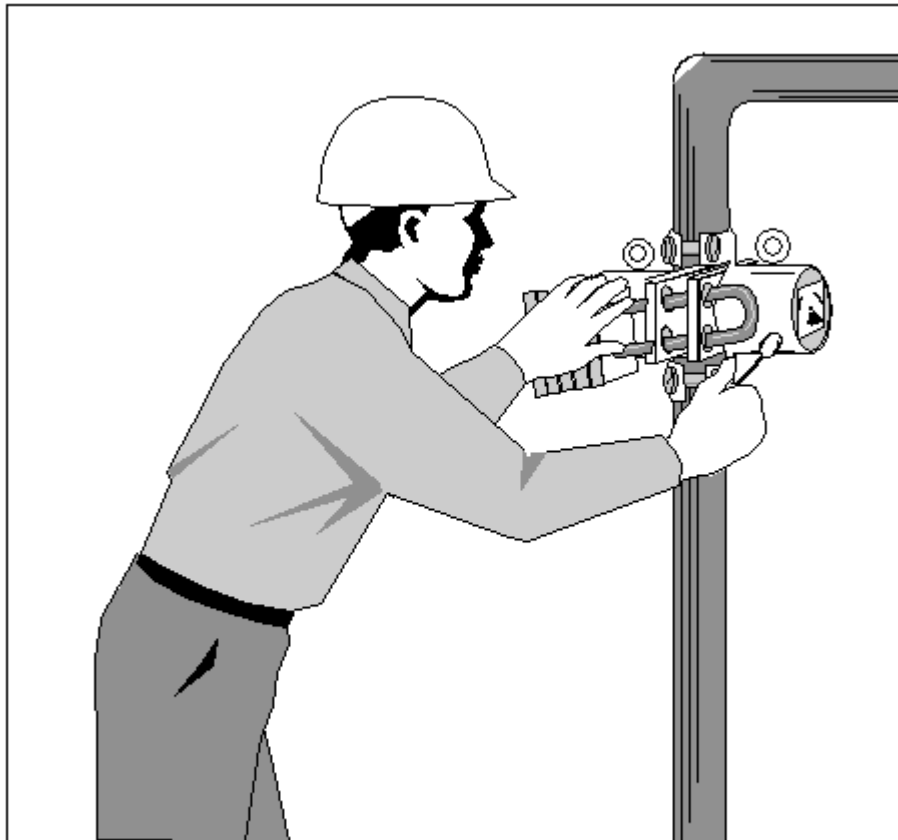


Figure 11. Leak Test Sample. A leak test sample is collected according to the gauge manufacturers and the leak test kit supplier's instructions.

Response from Applicant:

Item 9.8 Leak Test (Check one box)

- Leak tests will be performed by an organization authorized by DHS, the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by DHS, the NRC or an Agreement State to provide leak test kits to other licensees according to kit suppliers' instructions.

List the name and license number of organization authorized to perform or analyze leak test (Specify whether DHS, NRC, or other Agreement State):

Organization Name _____ License Number _____

Note: An alternate organization may be used to perform or analyze leak test, without amending the license, provided the organization is specifically authorized by DHS, NRC or an Agreement State.

Or

- We will perform our own leak testing and sample analysis. We will follow the model procedures in Appendix K of WISREG "Guidance for Fixed Gauge Devices."

Or

- We will submit alternative procedures. (Procedures are attached)

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

References: NUREG-1556 Volume 18, 'Program-Specific Guidance About Service Provider Licenses', dated November 2000 is available on the NRC's webpage at www.nrc.gov.

Item 9.9: Maintenance

Rule: *DHS 157.21; DHS 157.13(9)(b) and (10)*

Criteria: Licensees must 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, external lubrication of shutter mechanism, calibration, and electronic repairs) must consider ALARA and ensure that the gauge functions as designed and source integrity is not compromised.

Non-routine 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 DHS limits.

Non-routine repair or maintenance must be performed by the fixed gauge manufacturer or distributor or a person specifically authorized by DHS, the NRC or an Agreement State. Information to support requests for specific authorization to perform non-routine maintenance or repair is addressed in **Appendix N**.

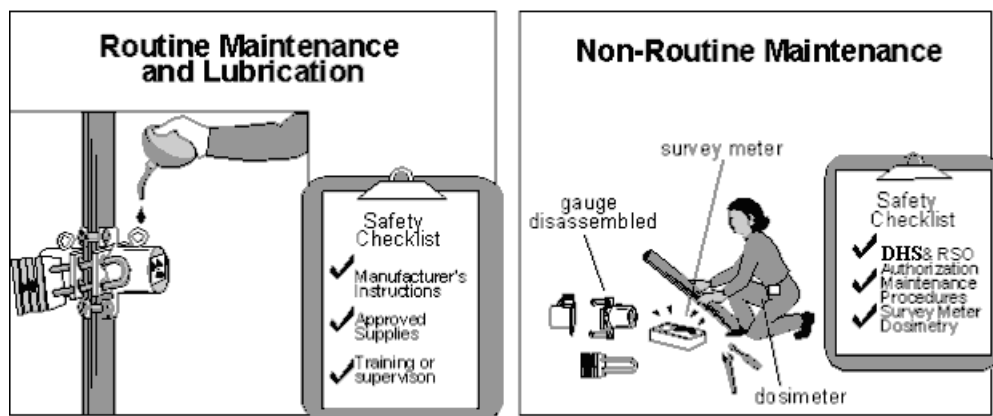


Figure 12. Maintenance. Licensees need to perform routine maintenance to ensure proper operation of the fixed gauge. For non-routine maintenance, most licensees rely on the gauge manufacturer, distributor or other service companies.

Discussion: DHS permits fixed gauge licensees to perform routine maintenance of the gauges provided that they follow the gauge manufacturer's or distributors written recommendations and instructions.

Before any maintenance or repair work is done, licensees need to evaluate the adequacy of the following:

- The protocol or procedures to be followed
- The radiation safety procedures including possible need for compensatory measures (e.g., steps taken to compensate for lack of or reduced shielding)
- ALARA considerations
- Training and experience of personnel performing the work
- The qualification of parts, components, 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, lubrication, calibration, and electronic repairs.

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 DHS 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 DHS, NRC or Agreement State authorization is required to install a gauge. However, a licensee may initially mount a gauge, without specific DHS, NRC or Agreement State authorization, if the gauge's SSD Certificate explicitly permits it and under the following guidelines:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor
- The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by the NRC or an Agreement State
- The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded
- The gauge must be received in good condition (package was not damaged)
- The gauge must not require any modification to fit in the proposed location.

The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by DHS, the NRC or an Agreement State to perform such operations.

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

Response from Applicant:

Item 9.9 Maintenance (Check one box for routine cleaning and lubrication and one for non-routine maintenance)

ROUTINE CLEANING AND LUBRICATION:

We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer's recommendations and instructions.

Or

Alternative procedures are attached.

NON-ROUTINE MAINTENANCE:

We will utilize the manufacturer or another person specifically licensed to perform non-routine maintenance or repair operations that require the removal of the source from the device. Radiation surveys required by s. DHS 157.25(1) will be performed by a person specifically authorized by DHS, the NRC or an Agreement State.

Or

We will perform non-routine maintenance in-house and will provide the information listed in Appendix N of WISREG "Guidance for Fixed Gauge Devices" to perform this work.

Note:

- Alternative procedures for performing routine maintenance will be evaluated using the criteria listed above.

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

References: NRC IN 2009-05 "Contamination of Events Resulting from Damage to Sealed Radioactive Sources during Gauge Dismantlement and Nonroutine Maintenance Operations" dated February 3, 2009; and NRC IN 2011-09 "Fixed Gauge Shutter Failures due to Operating in Harsh Working Environments" dated May 18, 2011. Information Notices are available electronically at NRC's web site, <http://www.nrc.gov>.

Item 9.10: Fixed Gauge Disposal and Transfer

Rule: *DHS 157.30 (1); DHS 157.13 (11&15); DHS 157.31*

Criteria: Licensed materials must be disposed of in accordance with **Chapter DHS 157 'Radiation Protection'** by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: When disposing of fixed gauges, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer or distributor of the device, a commercial firm

licensed by DHS, the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the radioactive material (i.e., its license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in *DHS 157.13(15)*. In addition, all packages containing radioactive sources must be prepared and shipped in accordance with DHS rules and DOT Regulation. Records of the transfer must be maintained as required by *DHS 157.31*.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. Significant problems can arise from improper gauge transfer or failure to dispose of gauges in a proper and timely manner. See NRC Information Notice 89-24, "Unauthorized transfer of ownership or control of licensed activities," dated December 7, 1994, and IN 88-02, "Lost or Stolen Gauges," dated February 2, 1988.

Response from Applicant:

Item 9.10 Fixed Gauge Disposal And Transfer (Check box)

- We will return the gauge to the manufacturer for disposal or transfer the device to a specific licensee authorized to receive radioactive material.

References: NRC IN 89-24, "Unauthorized transfer of ownership or control or licensed activities," dated December 7, 1994 and NRC IN 88-02, "Lost or Stolen Gauges," dated February 2, 1988. Information Notices are available electronically at NRC's web site, <http://www.nrc.gov>.

9.11: Transportation

Rule: *DHS 157.92(3); 49 CFR Parts 171-178; DHS 157.21*

Criteria: Applicants must either:

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

OR

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

Discussion: Some fixed gauge licensees have the manufacturer, distributor or other person specifically licensed to transport gauges by DHS, the NRC or Agreement State arrange for preparing and shipping licensed material. If licensees decide to transport their own gauges, they are responsible for compliance with DOT regulation which require, in part, specific labeling and surveying of the package before shipping. To appropriately survey the package the surveyor must use instruments that can measure radiation exposure rates around the package and detect contamination on the package. **Appendix O** lists major DOT Regulation and provides an example of a shipping paper. During an inspection, DHS uses the provisions of **Chapter DHS 157 ‘Radiation Protection’, Subchapter XIII ‘Transportation’** to examine and enforce transportation requirements applicable to gauge licensees.

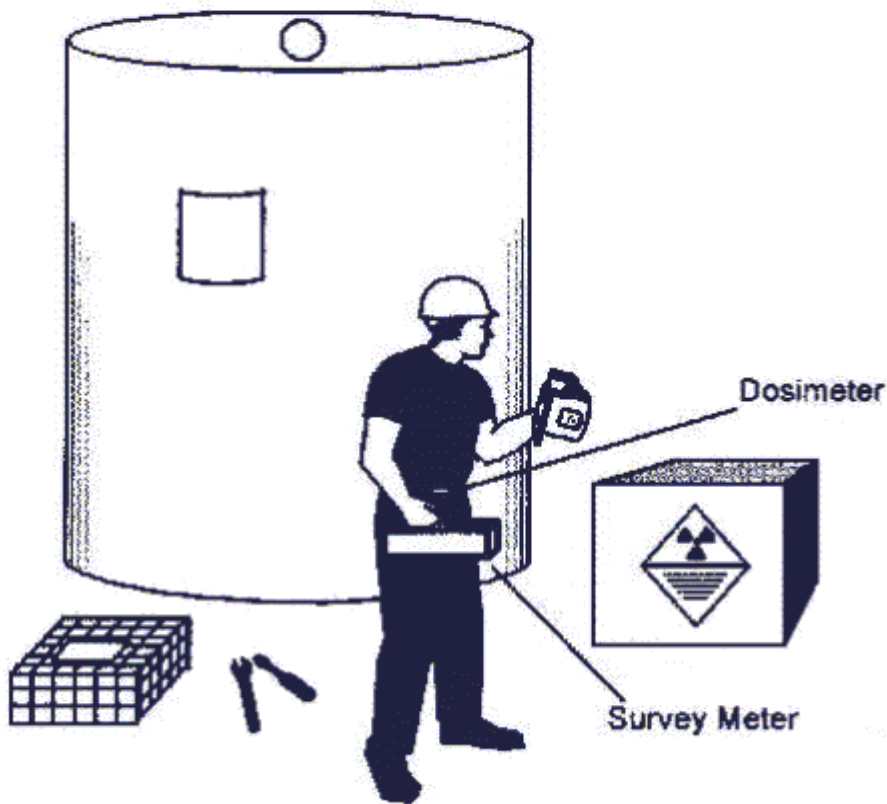
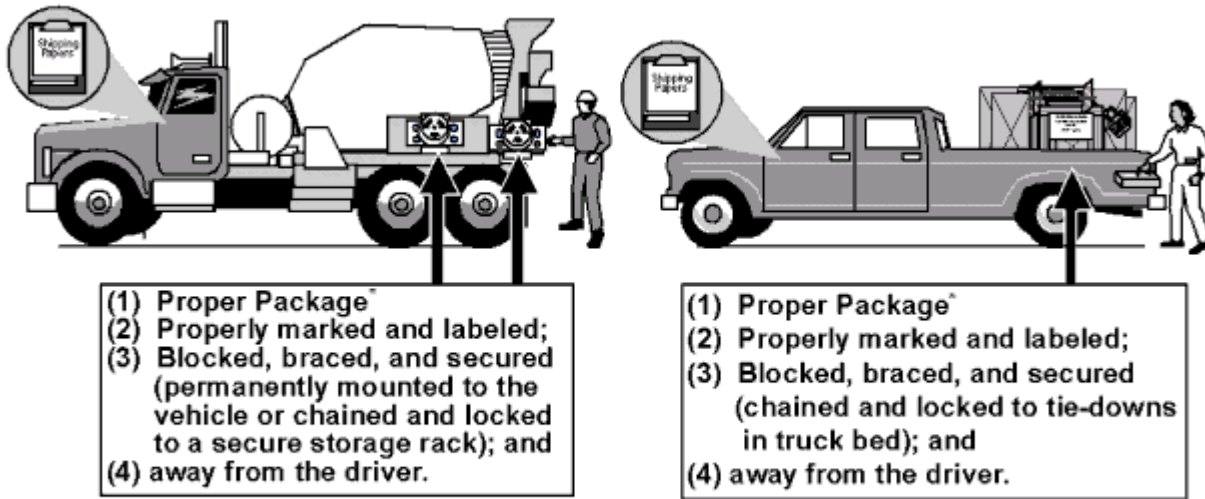


Figure 13: Transportation. Illustration of a fixed gauge being disassembled and packaged for transport.



*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 14. DOT Transportation Requirements.

Response from Applicant:

Item 9.11 Transportation

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

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (2011 revision)" can be obtained from the following website <http://phmsa.dot.gov/regulations>.

Item 9.12: Fixed Gauges Used at Temporary Job Sites

Rule: *DHS 157.13; DHS 157.21; DHS 157.28; DHS 157.32*

Criteria: Each applicant requesting authorization to perform work with fixed gauges at temporary job sites should develop, implement, maintain, and distribute operating and emergency procedures containing the following elements:

- Instructions for transporting radioactive material to ensure compliance with DOT Regulation
- Instructions for using gauges at temporary job sites and performing routine maintenance according to the manufacturer's or distributors recommendations and instructions
- Instructions for maintaining security during storage and transportation

- Instructions to keep gauges under control and immediate surveillance or secured to prevent unauthorized use or access.
- Steps to take to keep radiation exposures ALARA
- Steps to maintain accountability during use
- Steps to control access to a potentially damaged gauge (See **Figure 15**)
- Steps to take, and who to contact, when a gauge has been lost or damaged (e.g., local officials, RSO, etc.) (See **Figure 15**)
- If gauges are to be installed at temporary job sites, the operating and emergency procedures should contain instructions on using personal dosimetry and survey instruments and conducting surveys
- Provide copies of operating and emergency procedures to all gauge users and at each job site.

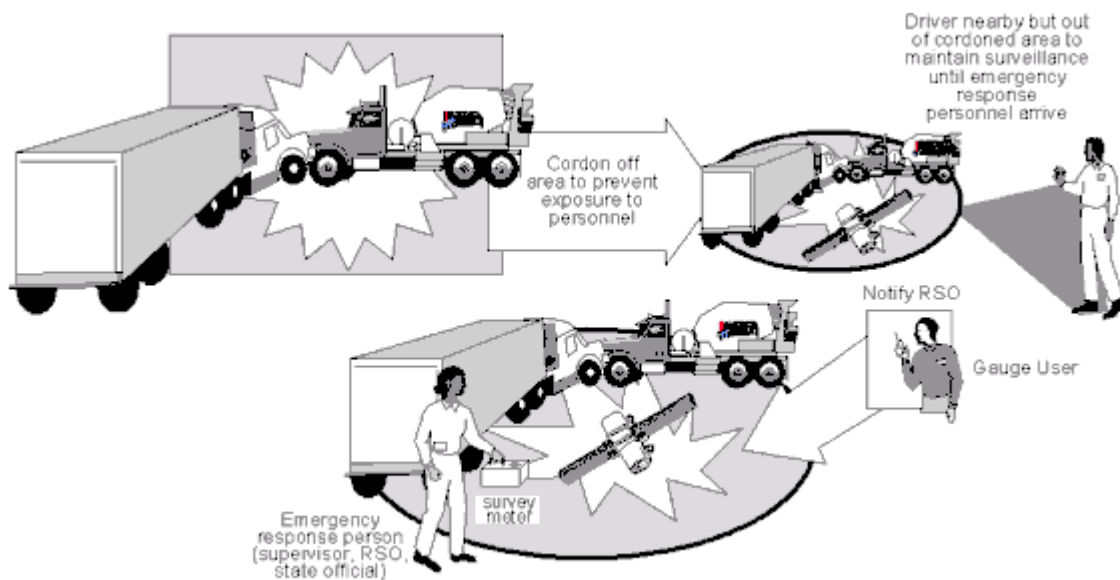


Figure 15. Proper Handling of Incident. Licensee personnel implement emergency procedures when a traffic accident results in a damaged gauge and potentially elevated exposure levels.

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

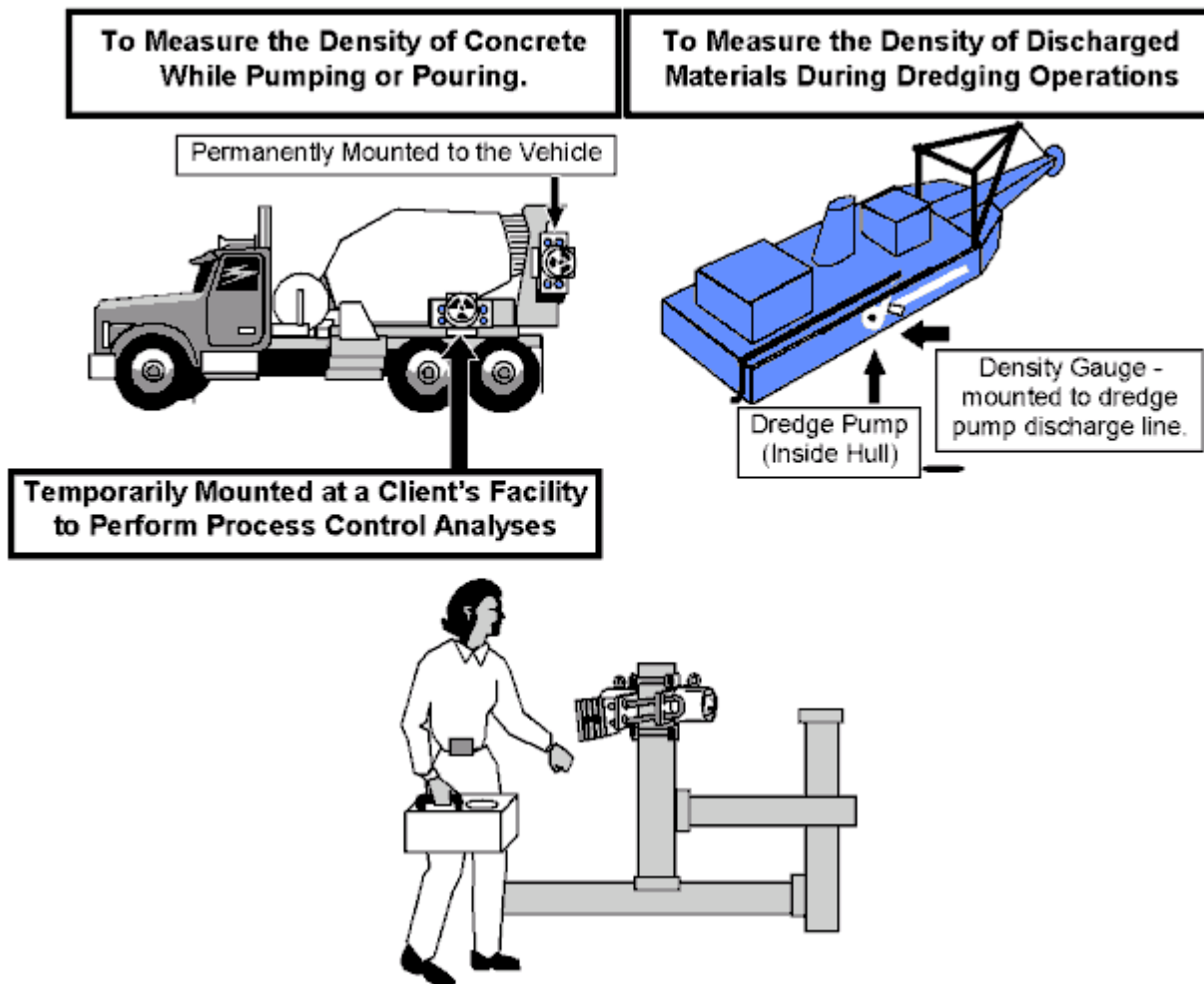


Figure 16. *Examples of Uses for Fixed Gauges at Temporary Job Sites.*

There are two categories of fixed gauges used at temporary job sites: Gauges that are permanently mounted to vehicles or trailers, and gauges that are transported to plants or refineries and temporarily installed on process equipment to conduct short-term QA/QC studies. See **Figure 16**.

Applicants must develop, implement, and maintain safety procedures for off-site transport of radioactive material to ensure compliance with DOT Regulation. **Figure 14** illustrates some important DOT requirements for gauge licensees. During an inspection, DHS inspectors will use the provisions of **Chapter DHS 157 ‘Radiation Protection’, Subchapter XIII ‘Transportation’** to examine and enforce transportation requirements applicable to fixed gauge licensees. **Appendix O** lists major DOT Regulation and provides examples of shipping documents, placards, and labels.

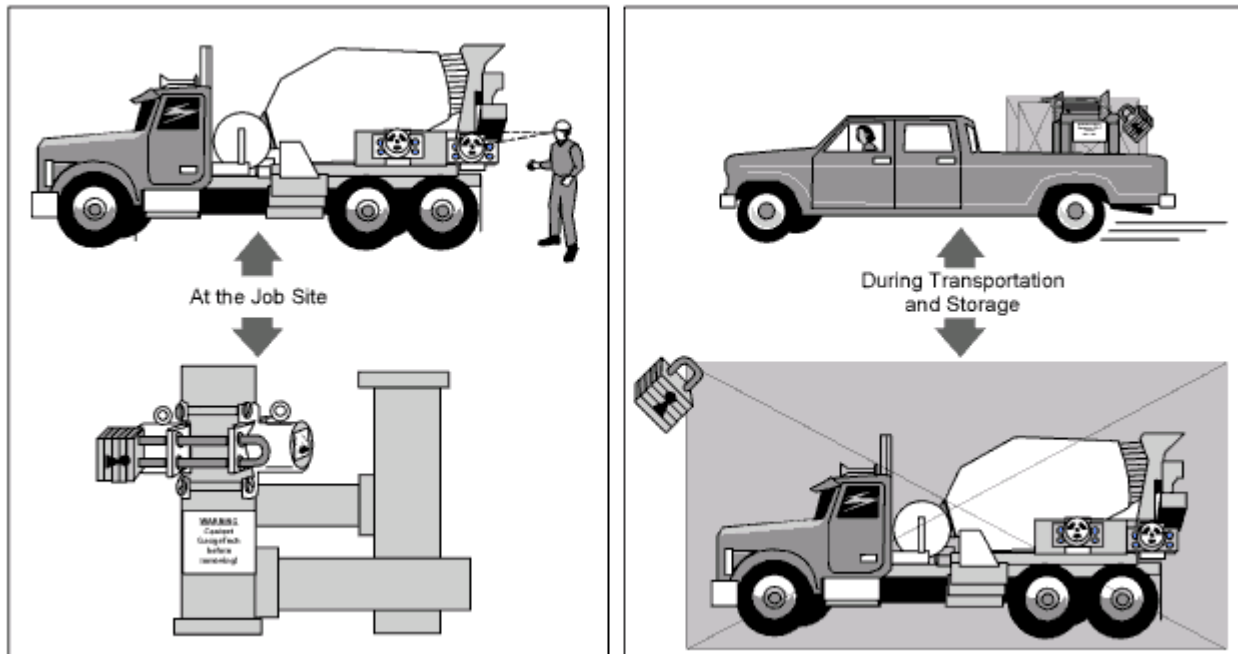


Figure 17. Security. *Examples of Methods used to Secure Fixed Gauges at Temporary Job Sites.*

When working at a temporary job site, licensees generally have to follow the regulations and procedures of the organization that owns or controls the site. Thus, licensees may not be able restrict access to areas in the same manner that they could at their own facilities. Furthermore, non-licensee personnel may not be familiar with fixed gauges or radioactive material. Therefore, to avoid lost or stolen gauges and to prevent unnecessary radiation exposures to members of the public, licensees must keep gauges under constant surveillance, or secured against unauthorized use or removal. See **Figure 17**.

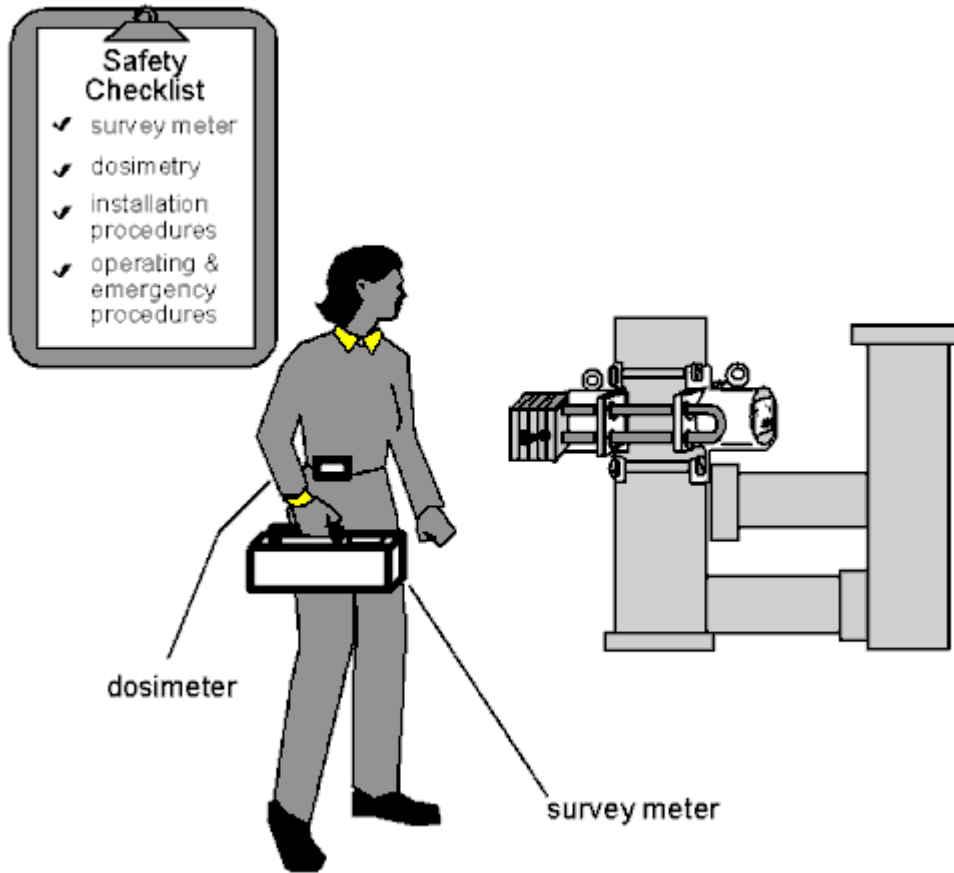


Figure 18. *Installation of Fixed Gauges at Temporary Job Sites. Examples of the Additional Precautions Needed when Installing Fixed Gauges at Temporary Job Sites.*

While installing gauges, personnel could receive radiation doses exceeding DHS limits if proper radiation safety principles are not followed. Licensee personnel performing installations should be assigned and wear personal dosimetry and use a survey meter to monitor radiological conditions. See **Figure 18**.

After installing a gauge at a temporary job site, a radiation survey should be conducted to ensure that dose rates in unrestricted areas will not exceed 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year. If surveys indicate that a member of the public (e.g., client personnel) could receive a dose exceeding these limits, licensees would need to adopt additional security measures to prevent public access such as maintaining constant surveillance or erecting physical barriers. See **Figure 19**.

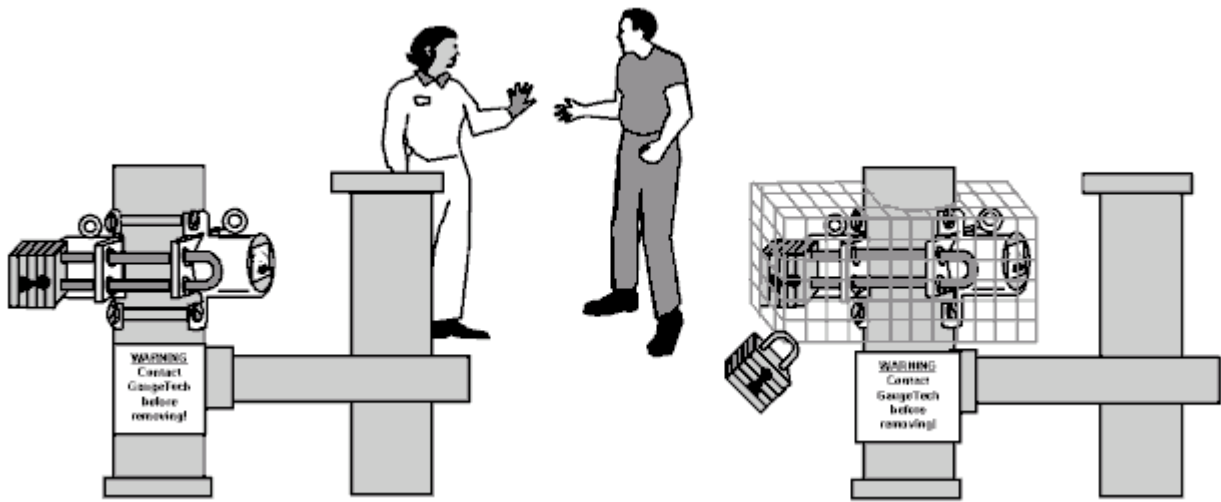


Figure 19. Security. Additional Security Measures following Installation of Fixed Gauges at a Temporary Job Site.

Response from Applicant:

Item 9.12 Fixed Gauges used at Temporary Job Sites (Check one box)	
<input type="checkbox"/> We will submit procedures for the use of fixed gauges at temporary job sites. (Procedures are attached)	
Or	
<input type="checkbox"/> No temporary job sites used.	

Item 10: License Fees

On DPH Form F-45009 ‘Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices’, enter the fee category and the amount. Enclose fee with the application.

Response from Applicant:

Item 10. License Fees (Refer to Wisconsin Administration Code s. DHS 157.10)	
Category:	License fee enclosed (for new applications only)
	<input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed _____

Item 11: Certification

Individuals acting in a private capacity are required to sign and date DPH Form F-45009 ‘Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices’. Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date DPH

Form F-45009 ‘Application for Radioactive Material License Authorizing the Use of Sealed Sources in Fixed Gauge Devices.’ **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant.** As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. **DHS will return all unsigned applications for proper signature.**

DHS generally only accepts license correspondence from a senior representative of the applicant or licensee. If the representative would like to delegate authority to another individual (i.e., the Radiation Safety Officer) to submit routine amendment requests on behalf of the licensee or respond to DHS requests for information, the representative should complete and sign the optional box in Item 13, designating one or more individuals for this purpose. **A representative of the licensee’s senior management must sign all license renewal applications.**

Note:

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

Response from Applicant:

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)	
Item 11	
I hereby certify that this application was prepared in conformance with Wisconsin Administrative Code, Chapter DHS 157 "Radiation Protection" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant or Authorized Individual	Date signed
Print Name and Title of above signatory	
OPTIONAL: CORRESPONDENCE AUTHORITY	
I have delegated correspondence authority for matters pertaining to our Radioactive Materials License to _____. The designee named here has approval to submit amendment requests concerning this Radioactive Materials License. I understand that license renewal applications must be signed by a member of upper management.	
SIGNATURE - Applicant Or Authorized Individual	Date signed

Appendix A:

DPH Form F-45009

***‘Application for Radioactive Material License Authorizing
the Use of Sealed Sources in Fixed Gauge Devices’***

To access this form please go to
<http://www.dhs.wisconsin.gov/forms/F4/F45009.pdf>

Appendix B:

DPH Form F-45007

‘Certificate of Disposition of Materials’

To access this form please go to
<http://www.dhs.wisconsin.gov/forms/F4/F45007.pdf>

Appendix C:
Information Needed for Transfer of Control

Definitions

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of a DHS-licensed operation.

Transferor: A transferor is a DHS licensee selling or otherwise giving up control of a licensed operation.

Discussion

Licensees must provide full information and obtain DHS's ***prior written consent*** before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). State if any items are not applicable.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact whom DHS may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to DHS, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Licensees should refer to NRC Information Notice 89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities," available on the NRC's webpage at <http://www.nrc.gov>.

Appendix D:

Reserved

Appendix E

Sample SSD Registration Certificate

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Sealed Source
(Amended in its Entirety)

NO.: NR-***-S-***-S

DATE:

PAGE 1 of 3

SOURCE TYPE: *Provide a short description of the source type.*

MODEL: ABC

MANUFACTURER/DISTRIBUTOR:

*Name
Street
City, State Zip
(If manufacturer and distributor are the same, keep
subheading as shown. If different, delete the word
manufacturer from the subheading.)*

MANUFACTURER:

*Name
Street
City, State Zip
(This subheading and information is not necessary if
manufacturer and distributor are the same.)*

ISOTOPE:

List Isotopes

MAXIMUM ACTIVITY:

*XX Gbq (XX mCi)
units should be such that the amount is in the 1 to 999 range*

LEAK TEST FREQUENCY:

6 Months

PRINCIPAL USE:

Provide a short description of the principal use

CUSTOM SOURCE:

Yes X No

CUSTOM USER:

*Name
Street
City, State Zip
(Delete entire subsection if not applicable.)*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S

DATE: PAGE 2 OF 3

SOURCE TYPE: *Provide a short description of the source type.*

DESCRIPTION: *Provide the complete description of the source.*

LABELING:

The source is engraved with the radiation symbol, isotope, activity, model number, serial number, date of assay, name of the distributor, and the words "CAUTION - RADIOACTIVE MATERIAL". The text is XX mm (XX in.) high and is on the end/side of the source capsule.

DIAGRAM:

Reference all attachments to the document including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use in measuring....The source may be used in harsh environments but shall not be subjected to environments that exceed its ANSI N542-1977 classification, 97C00000. The estimated working life of the source is XX years.

PROTOTYPE TESTING:

A prototype of the Model ABC source was constructed and subjected to the tests provided in ANSI N 43.6-1997 or ISO 2919-1999 and achieved a classification of 96C00000.

SOURCE TYPE: *Provide a short description of the source type.*

EXTERNAL RADIATION LEVELS: *X mR/hr at 30 cm from Y*

QUALITY ASSURANCE AND CONTROL:

XXXX Corporation maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. A copy of the program is on file with NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S

DATE: PAGE 3 OF 3

SOURCE TYPE: *Provide a short description of the source type.*

The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 Bq (0.005 μ Ci) of removable contamination.

The source shall not be subjected to conditions that exceed its ANSI N43.6-1997 or ISO 2919-1999 classification, 96C00000.

This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on review of the Model ABC sealed source, its ANSI classification, and the information and test data cited below, we {continue to} conclude that the source is acceptable for licensing purposes.

Furthermore, we {continue to} conclude that the source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the Model ABC sealed source are hereby incorporated by reference and are made a part of this registry document.

XXXX Corporation's application dated December 25, 0000, with enclosures thereto.

XXXX Corporation's letters dated July 4, 0000, and December 25, 0000, with enclosures thereto.

XXXX Corporation's facsimiles dated July 4, 0000, and December 25, 0000.

Appendix F:

Duties and Responsibilities of the Radiation Safety Officer

Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with both DHS rules and the conditions of the license. (See **Figure 4**) The RSO's duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures are ALARA
- Development, maintenance, distribution, and implementation of up-to-date operating and emergency procedures
- Individuals that use fixed gauges are properly trained
- Possession, installation, relocation, use, storage, routine maintenance and non-routine operations of fixed gauges are consistent with the limitations in the license, the SSD Registration Certificate(s), manufacturer's or distributor's recommendations and instructions
- Safety consequences of non-routine operations are analyzed before conducting any such activities that have not been previously analyzed
- Non-routine operations are performed by the manufacturer, distributor or person specifically authorized by DHS, the NRC or an Agreement State
- Prospective evaluations are performed demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel monitoring devices are provided
- Personnel monitoring devices, if required, are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in *DHS 157.23(1)*
- Fixed gauges are properly secured
- Notification of proper authorities of incidents such as damage to or malfunction of fixed gauges, fire, loss, or theft
- Investigation of unusual occurrences involving the fixed gauge (e.g., malfunctions or damage), identification of cause(s), implement of appropriate and timely corrective action(s)
- Radiation safety program audits are performed at intervals not to exceed 12 months and should include development, implementation, and documentation of timely corrective actions

- When the licensee identifies violations of rules or license conditions or program weaknesses, corrective actions are developed, implemented, and documented.
- Radioactive material is transported according to all applicable DOT requirements
- Radioactive material is disposed of properly
- Appropriate records are maintained
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner
- Posting of documents required by *DHS 157.88(1)* (Subchapter III and X of **Chapter 157 ‘Radiation Protection’**, license documents, operating procedures, emergency procedures, and DPH Form F-45027 "Notice to Employees").

Appendix G:

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 lecture, videotape, or self-study emphasizing practical subjects important to safe use of the gauge:

Radiation Safety

- Radiation vs. contamination
- Internal vs. external exposure
- Biological effects of radiation
- Types and relative hazards of radioactive material possessed
- ALARA concept
- Use of time, distance, and shielding to minimize exposure
- Location of sealed source within the gauge

Regulatory Requirements

- Applicable Rule
- License conditions, amendments, renewals
- Locations of use and storage of radioactive materials
- Material control and accountability
- Annual audit of radiation safety program
- Transfer and disposal
- Recordkeeping
- Prior events involving fixed gauges
- Handling incidents
- Recognizing and ensuring that radiation warning signs are visible and legible
- Licensing and inspection by regulatory agency
- Need for complete and accurate information
- Employee protection
- Deliberate misconduct

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

- Operating and emergency procedures
- Routine vs. non-Routine maintenance
- Lock-out procedures

On-the-job training must be done under the supervision of an AU or RSO

- Supervised Hands-on Experience Performing:

- Operating procedures
- Test runs of emergency procedures
- Routine maintenance
- Lock-out procedures

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 RSO's are qualified to work independently with and are knowledgeable of the radiation safety aspects of all types of gauges to be possessed by the applicant. This may be demonstrated by written or oral examination or by observation.

Course Instructor Qualifications

Instructor should have:

- Bachelor's degree in a physical or life science or engineering
- 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; and
- 8 hours hands-on experience with fixed gauges

OR

- Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of 40 hour radiation safety course; and
- 30 hours of hands-on experience with fixed gauges.

OR

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

Note: Additional training is required for those applicants intending to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service. See **Appendix N**.

Appendix H:
Suggested Fixed Gauge Audit Checklist

Suggested Fixed Gauge Audit Checklist

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Licensee's name:	License No.:
Date of this Audit:	Date of Last Audit:
Auditor Signature:	Date:
Management Signature:	Date:

Audit History

- A. Last audit of this location conducted on (date) _____
- B. Were previous audits conducted at intervals not to exceed 12 months? *[DHS 157.21]*
- C. Were records of previous audits maintained for 3 years? *[DHS 157.31(2)]*
- D. Were any deficiencies identified during last two audits or two years, whichever is longer?
- E. Were corrective actions taken? (Look for repeated deficiencies)

Organization and Scope of Program

- A. If the mailing address or places of use changed, was the license amended?
- B. If ownership changed or bankruptcy filed, was DHS's prior consent obtained or was DHS notified?
- C. Radiation Safety Officer
 - 1. If the RSO was changed, was license amended?
 - 2. Does new RSO meet DHS requirements?
 - 3. Is RSO fulfilling his or her duties?
 - 4. To whom does the RSO report too?
- D. If the designated contact person changed, was DHS notified?
- E. Sealed Sources and Devices
 - 1. Does the license authorize all of DHS's regulated radionuclides contained in the gauges?
 - 2. Are the gauges as described in the Sealed Source and Device (SSD) Certificate?
 - 3. Have copies of (or access to) SSD Certificates?
 - 4. Have manufacturers' or distributor's manuals for operation and maintenance?
 - 5. Are the actual uses of gauges consistent with the authorized uses listed on the license?
 - 6. Are the locations of the gauges compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSD Registration Certificates?

Training and Instructions to Workers

- A. Were all workers who are likely to exceed or exceed 1 mSv (100 mrem) in a year instructed per *DHS 157.88(2)*? Annual training provided, as needed *DHS 157.88(2)*? Records maintained?
- B. Did each AU receive training and instruction given at the time of gauge installation or equivalent training and instruction before using gauges?
- C. Are training records maintaining for each AU?
- D. Did individuals who perform non-routine operations receive training before performing these operations?
- E. Did interviews with AUs reveal that they know the emergency 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. HAZMAT training provided, if required? [*49 CFR 172.700; 172.701; 172.702; 172.703; 172.704*]

Radiation Survey Instruments

- A. If the licensee is required to possess a survey meter, does it meet DHS's criteria?
- B. Are calibration records maintained? [*DHS 157.31(3)*]

Gauge Inventory

- A. Is a record kept showing the receipt of each gauge? [*DHS 157.06*]
- B. Are all gauges physically inventoried every six months? [**L/C**]
- C. Are records of inventory results with appropriate information maintained?

Personnel Radiation Protection

- A. Are ALARA considerations incorporated into the radiation protection program? [*DHS 157.21*]
- B. Were prospective evaluations performed showing that unmonitored individuals receive less than or equal to 10% of the limit? [*DHS 157.25(2)*]
- C. Did unmonitored individuals' activities change during the year which could put the over 10% of the limit?
- D. If yes to C. above, was a new evaluation performed?

- E. Is external dosimetry required (individuals likely to receive >10% of limit)? And is dosimetry provided to those individuals?
1. Is the dosimetry supplier NVLAP approved? *[DHS 157.25(1)]*
 2. Are the dosimeters exchanged at the appropriate frequency (for example monthly for film badges)?
 3. Are dosimetry reports reviewed by the RSO when they are received?
 4. Are the records DHS Forms or equivalent? *[DHS 157.31(5); DHS 157.31(7)]*
 - a. DPH Form F-45003 “Occupational Exposure Record for a Monitoring Period” completed?
 5. Declared pregnant worker/embryo/fetus
 - a. If a worker declared her pregnancy, did licensee comply with *DHS 157.22(8)*?
 - b. Were records kept of embryo/fetus dose per *DHS 157.31(7)*?
- F. Are records of exposures, surveys, monitoring, and evaluations maintained? *[DHS 157.31]*

Public Dose

- A. Is public access to gauges controlled in a manner to keep doses below 1mSv (100 mrem) in a year? *[DHS 157.23(1)]*
- B. Has a survey or evaluation been performed per *DHS 157.25(1)*? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- C. Do unrestricted area radiation levels exceed 0.02mSv (2mrem) in any one hour? *[DHS 157.23(1)]*
- D. Is gauge access controlled in a manner that would prevent unauthorized use or removal? *[DHS 157.28(1)(a)]*
- E. Records maintained? *[DHS 157.31(8)]*

Operating and Emergency Procedures

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

3. Was DHS notification or reporting required? *[DHS 157.32(1-3)]*

Leak Tests

- A. Was each sealed source leak tested every 6 months or at other prescribed intervals? *[DHS 157.24]*
- B. Was the leak test performed according to the license?
- C. Are records of results retained with the appropriate information included? *[DHS 157.31(4)]*
- D. Were any sources found leaking and if yes, was DHS notified? *[DHS 157.24]*

Maintenance of Gauges

- A. Are manufacturer's or distributor's procedures followed for routine cleaning and lubrication of gauge? *[L/C]*
- B. Was each on-off mechanism tested for proper operation every 6 months or at other prescribed intervals?
- C. If an on-off mechanism failed, was DHS notified per *DHS 157.13(17)*?
- D. Are repair and maintenance of components related to the radiological safety of the gauge performed by the manufacturer, distributor or person specifically authorized by DHS, the NRC or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with *DHS 157.23(1)* limits)?
- E. Are labels, signs, and postings identifying gauges containing radioactive material, radiation areas, and lock-out procedures/warnings clean and legible?

Transportation

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

- A. DOT-7A or other authorized package used? *[49 CFR 173.415; 173.416(b)]*
- B. Package performance test records on file if licensee performs shipment?
- C. Special form sources documentation? *[49 CFR 173.476(a)]*
- D. Package has two labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? *[49 CFR 172.403; 173.441]*
- E. Package properly marked? *[49 CFR 172.301; 172.304; 172.310; 172.324]*
- F. Package closed and sealed during transport? *[49 CFR 173.475(f)]*
- G. Shipping papers prepared and used? *[49 CFR 172.200(a)]*

- H. Shipping papers contain proper entries? { Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity (SI units required), category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)}
[49 CFR 172.200; 172.201; 172.202; 172.203; 172.204; 172.604]
- I. Shipping papers within drivers reach and readily accessible during transport? [49 CFR 177.817(e)]
- J. Package secured against movement? [49 CFR 177.834]
- K. Placards on vehicle, if needed? [49 CFR 172.504]
- L. Proper overpacks, if needed? [49 CFR 173.25]
- M. Any incidents reported to DOT or DHS? [49 CFR 171.15; 171.16]

Auditor's Independent Survey Measurements (if made)

- A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits? [DHS 157.25(1-2)]

Notification and Reports

- A. Was any radioactive material lost or stolen? Were reports made? [DHS 157.32]
- B. Did any reportable incidents occur? Were reports made? [DHS 157.32; DHS 157.13]
- C. If an on-off mechanism failed, was DHS notified within 24 hours per DHS 157.13(17)?
- D. Did any overexposures or high radiation levels occur? Reported? [DHS 157.32]
- E. If any events (as described in items a through c above) did occur, what was the root cause? Were corrective actions appropriate?
- F. Is the management/RSO/shift foreman licensee aware of the telephone number for DHS office hours (608) 267-4797 or 24 hour emergency number (608) 258-0099.

Posting and Labeling

- A. "Notice to Employees" F-45027 posted? [DHS 157.88(1)]
- B. DHS rule, operating and emergency procedures license documents posted or a notice posted? [DHS 157.88(1)]
- C. Other postings and labelings? [DHS 157.29(1-2)]

Record Keeping for Decommissioning

- A. Records kept of information important to decommissioning? [DHS 157.15]

B. Records include all information outlined in *DHS 157.15*?

Bulletins and Information Notices

A. Department bulletins, department Information Notices, NRC Information Notices, NMSS Newsletters, received?

B. Appropriate training and action taken in response?

Special License Conditions or Issues

A. Did auditor review special license conditions or other issues (e.g., non-routine operations)?

Deficiencies Identified in Audit; Corrective Actions

A. Summarize problems/deficiencies identified during audit.

B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at ALL licensed locations (not just location audited)? Include date(s) when corrective actions are implemented.

C. Provide any other recommendations for improvement.

Evaluation of Other Factors

A. Senior licensee management is appropriately involved with the radiation protection program and/or RSO oversight?

B. RSO has sufficient time to perform his or her radiation safety duties?

C. Licensee has sufficient staff to support the radiation protection program?

Appendix I:
Model Survey Instrument Calibration Program

Model Survey Instrument Calibration Program

Training

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

- Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:
 - Principles and practices of radiation protection
 - Radioactivity measurements, monitoring techniques, and the use of instruments
 - Mathematics and calculations basic to using and measuring radioactivity
 - Biological effects of radiation.
- On-the-job training will be considered complete if the individual has:
 - Observed authorized personnel performing survey instrument calibration; and
 - Conducted survey meter calibrations under the supervision, and in the physical presence of an individual already authorized to perform calibrations.

Facilities and Equipment

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

Model Procedure for Calibrating Survey Instruments

- A radioactive sealed source(s) will be used for calibrating survey instruments, and this source will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by National Institutes of Standards and Technology (NIST)
 - Contain a radionuclide which emits radiation of identical or similar type and energy as the sealed sources that the instrument will measure
 - Be strong enough to emit a radiation field that is representative of the field being emitted by the gauge. For calibration of instruments intended to measure gamma radiation, the exposure rate should be at least 30 mR/hour (7.7 microcoulomb/kilogram per hour) at 100 cm [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of Co-60].
- Inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration.

- A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than $\pm 20\%$.
- There are three kinds of scales frequently used on radiation survey meters. They are calibrated either as described in ANSI N323A-1996, "American National Standard Radiation Protection Instrumentation Test and Calibration - Portable Survey Instruments," or as follows:
 - Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately $1/3$ and $2/3$ of the decade.
 - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately $1/3$ and $2/3$ of the decade.
 - Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points should be at approximately $1/3$ and $2/3$ of the decade.
- Readings above 200 mR/hour (50 microcoulomb/kilogram per hour) need not be calibrated. However, higher scales should be checked for operation and approximately correct response.
- Survey meter calibration reports will indicate the procedure used and the results of the calibration. The reports will include:
 - The owner or user of the instrument
 - A description of the instrument that includes the manufacturer's name, model number, serial number, and type of detector
 - A description of the calibration source, including the exposure rate at a specified distance on a specified date, and the calibration procedure
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
 - For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
 - The exposure rate from a check source, if used
 - The signature of the individual who performed the calibration and the date on which the calibration was performed.
- The following information will be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
 - The date of calibration and the next calibration due date
 - The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1996, "American National Standard Radiation Protection Instrumentation Test and Calibration -Portable Survey Instruments." Copies may be ordered electronically at <http://www.ansi.org>, or by writing to ANSI, 1430 Broadway, New York, NY 10018.

Appendix J:

Guidance for Demonstrating that Unmonitored Individuals Are not Likely to Exceed 10 Percent of the Allowable Limits

Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in *DHS 157.22(1)*. To demonstrate that dosimetry is not required, a licensee needs to perform a prospective evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing frequent routine maintenance on the gauge. However, for most gauges even these activities result in the individual receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses which its workers might receive to assess whether dosimetry is required; this is a prospective evaluation.

Example

One gauge manufacturer has estimated the doses to the extremities and whole body of a person replacing the assay plate on one of its series of gauges. Each gauge in the series is authorized to contain up to 7.4 gigabecquerels (200 millicuries) of Cs-137. The manufacturer based its estimate on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer had the following types of 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/hr [2 mrem/hr] at 46 cm [18.1 in] from the shield)
- Time the hands were exposed to the shielded source (e.g., 6 min)
- 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/hr [15 mrem/hr])

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) TEDE (whole body) and
- 0.015 mSv (1.5 mrem) to the hands.

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

The applicable shallow-dose equivalent (SDE) (extremities) is 500 mSv (50 rems) per year and 10% of that value is 50 mSv (5 rems or 5000 millirems) per year. If one of these procedures delivers 0.015 mSv (1.5 mrem), then an individual could perform 3,333 of these procedures each year and remain within 10% of the applicable limit.

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

Guidance to Licensees

Licensees who wish to demonstrate that they are not required to provide dosimetry to their workers need to perform prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may not be appropriate to individual licensee situations. In their evaluations, licensees need to use information appropriate to the type(s) of gauge(s) they intend to use; this information is generally available from the gauge manufacturer or the SSD Registration Certificate maintained by the NRC and Agreement States.

Table 4 may be helpful in performing a prospective evaluation.

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they continue to be up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, work with new gauges containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table 4 Dosimetry Evaluation

Dosimetry Evaluation for _____		Model _____	Gauge _____
A.	Time needed to perform the entire routine maintenance procedure.	_____ minutes/60	_____ hour
B.	Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the gauge while the sealed source is in the shielded position.	_____ mrem/hr	
C.	Time the <u>hands</u> were exposed to the shielded source.	_____ minutes/60	_____ hour
D.	Expected extremity dose rate received by the individual, determined using measured or manufacturer-provided data for the shielded source at the typical distance from the hands to the shielded source.	_____ mrem/hr	

Formula: (_____ # hours in Row A) x (_____ mrem/hr in Row B) = (_____ mrem per routine procedure) x (_____ # of routine maintenance procedures each year) = _____ mrem* **Whole Body Dose**

Formula: (_____ # hours in Row C) x (_____ mrem/hr in Row D) = (_____ mrem per routine procedure) x (_____ # of routine maintenance procedures each year) = _____ mrem ** **Extremity Dose**

* *Expected whole Body Dose Less Than 500 mrem requires no dosimetry*

** *Expected Extremity Dose Less Than 5000 mrem requires no dosimetry*

Appendix K:

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

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

Licensees must ensure that:

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

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 radioactive materials and who work in the vicinity where gauges are used or stored.

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

Unrestricted areas may include offices, shops, laboratories, a nearby walkway, an area near the gauge that requires frequent maintenance, areas outside buildings, and nonradioactive 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 1 and 2 above. Calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance.

Calculation Method

For ease of use by most fixed gauge licensees, the examples in this *Appendix* use conventional units. The conversions to SI units are as follows: 1 ft = 0.305 m; 1 mrem = 0.01 mSv.

The Calculation method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications:

- each gauge is a point source;
- typical radiation levels encountered when the source is in the shielded position are taken from either the Sealed Source and Device Certificate & Device (SSD) Registration Certificate or the manufacturer's literature; and
- No credit is taken for any shielding found between the gauges and the unrestricted areas.

Part 1 of the Calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the gauge and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers distance and the portion 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 Calculation 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 which could be received.

Example 1

To better understand the Calculation method, we will look at ABC Bottling, Inc., a fixed gauge licensee. Yesterday, while on a walk-through during product changeover, 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 if the company is complying with DHS's rule.

Joe measures the distances from each gauge to the bottling control panel and looks up in the manufacturer's literature the radiation levels individuals would encounter for each gauge. **Figure 20** is Joe's sketch of the areas in question, and **Table 5** summarizes the information Joe has on each gauge.

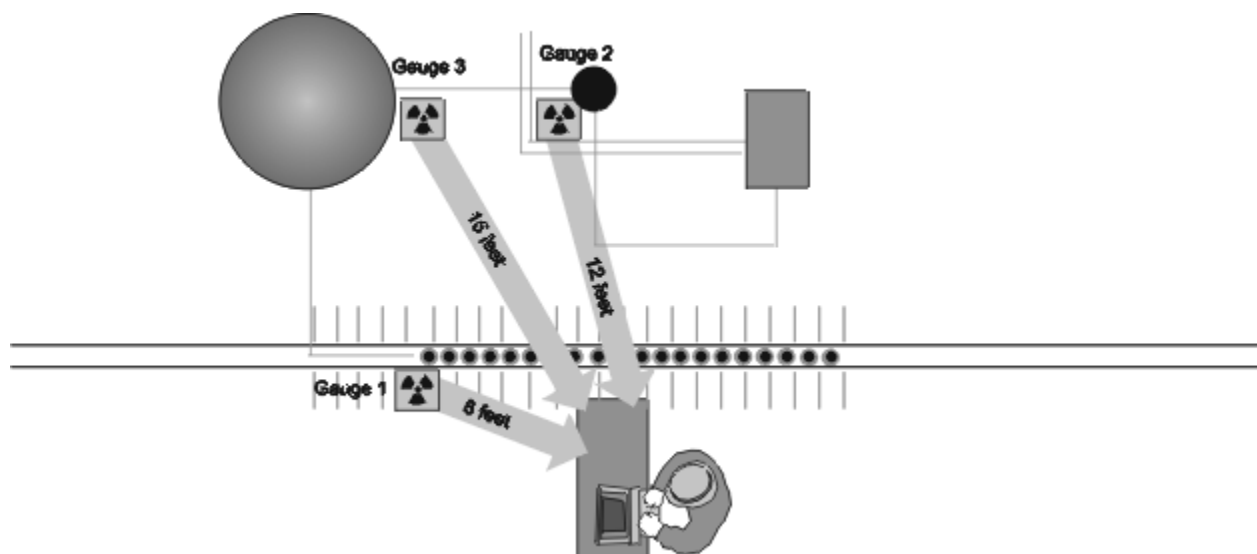


Figure 20. Diagram of Bottling Line and Fixed Gauges. This sketch shows the areas described in Examples 1 and 2.

Table 5: 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/hr encountered at specified distance from the gauge (from manufacturers literature)	2 mrem/hr at 1 ft	8 mrem/hr at 1 ft	2 mrem/hr at 3 ft
Distance in ft 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 rule in *DHS 157.23(1)*. So, taking a worst case approach, he assumes: 1) the gauges are constantly present (i.e., 24 hr/d), 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 hr/d). Joe proceeds to calculate the dose the QC supervisor might receive hourly and yearly from each gauge as shown in **Tables 6,7 and 8** below.

Table 6: Calculation Method, Part 1: Hourly and Annual Dose Received from Gauge 1

Gauge 1			
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/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in square feet	(1) ²	1
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in square feet	(8) ²	64
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 1 = 2	

5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by the worker at the bottling control panel, HOURLY DOSE RECEIVED FROM GAUGE 1 , in mrem in an hour	$2/64 = \mathbf{0.031}$
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 1 , in mrem in a year.	$0.031 \times 24 \times 365 = 0.031 \times 8760 = \mathbf{272}$

Table 7: Calculation 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/hr	8	8
2	Square of the distance (ft) at which the Step 1 rate was measured, in square feet	$(1)^2$	1
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in square feet	$(12)^2$	144
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	$2 \times 1 = 2$	
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by the worker at the bottling control panel, HOURLY DOSE RECEIVED FROM GAUGE 2 , in mrem in an hour	$8/144 = \mathbf{0.56}$	
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 2 , in mrem in a year.	$0.056 \times 24 \times 365 = 0.056 \times 8760 = \mathbf{491}$	

Table 8: Calculation 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/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in square feet	$(3)^2$	9
3	Square of the distance (ft) from the gauge to the bottling control panel in an unrestricted area, in square feet	$(15)^2$	225

4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	$2 \times 9 = 18$
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by the worker at the bottling control panel, HOURLY DOSE RECEIVED FROM GAUGE 3 , in mrem in an hour	$18/225 = \mathbf{0.08}$
6	Multiply the result of Step 5 by 24 hr/d x 365 d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGE 3 , in mrem in a year.	$0.08 \times 24 \times 365 = 0.08 \times 8760 = \mathbf{701}$

To determine the total hourly and total annual dose received, Joe adds the pertinent data from the preceding tables.

Table 9: Calculation 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 K-2, K-3 and K-4, in mrem in an hour	0.031	0.056	0.08	$0.031 + 0.056 + 0.08 = \mathbf{0.167}$
8	TOTAL ANNUAL DOSE RECEIVED from Step 6 of Tables K-2, K-3 and K-4, in mrem in a year	272	491	701	$272 + 491 + 701 = \mathbf{1464}$

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/yr, proceed to Part 2 of the calculation 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 notes that an individual could receive a dose of 1,464 mrem in a year, much higher than the 100 mrem limit.

Example 1, Part 2

Joe reviews his assumptions and recognizes that the QC supervisor is not at the bottling control panel 24 hr/d. 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 (i.e., 24 hr/d), all three gauges remain on (i.e., shutter is open). He then recalculates the annual dose received.

Table 10: Calculation 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 hr/day; the remainder of the day the worker is away from the area performing other duties that are 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/week)	3
	C. Average number of weeks per year in area (e.g., worker works all year)	52
10	Multiply the results of Step 9.A. by the results of Step 9.B. by the results of Step 9.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5 \times 3 \times 52 = \mathbf{780}$
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 in a year	$0.167 \times 780 = \mathbf{130}$

Note: If Step 11 exceeds 100 mrem in a year, proceed to Part 3 of the Calculation 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 11: Calculation Method, Part 3: Summary of Information

<p>INFORMATION ON GAUGES:</p> <ul style="list-style-type: none"> • Gauge 1: operates continuously (24 hrs/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/hr at 1ft, one-fourth of the radiation level as 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 hrs/day). <p>INFORMATION FROM EXAMPLE 1, PART 2, ON WHEN THE WORKER IS PRESENT AT THE BOTTLING CONTROL PANEL:</p> <ul style="list-style-type: none"> • 5 hours per day • 3 days per week • 52 weeks per year
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Table 12: Calculation 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 hours per day gauge operates when worker is present at the bottling control panel	5	1	4	5
13	Average number of days per week gauge operates when worker is present at the bottling control panel	3	3	3	3
14	Average number of weeks per year 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 x 3 x 52 = 780	1 x 3 x 52 = 156	4 x 3 x 52 = 624	5 x 3 x 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 1/4 th , so divide the results of Step 7 by 4) = ANNUAL DOSE RECEIVED FROM EACH GAUGE, in mrem in a year	780 x 0.031 = 24	156 x 0.056 = 8.7	624 x (0.056/4) = 8.7	60 x 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 in a year	24 + 8.7 + 4.8 = 46.2			

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

Joe is pleased that the result in Step 17 shows compliance with the 100 mrem/yr limit. Had the result in Step 17 been higher than 100 mrem/yr, 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
- Train the QC supervisor as required by *DHS 157.88(2)*.

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 ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. 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.

RECORD KEEPING: *DHS 157.31(8)* requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement - Calculation 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 2080 hours (i.e., a work year of 40 hr/wk for 52 wk/yr) 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 G-M survey instruments.
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Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs. TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD 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 1 mSv/yr (100 rem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF₂ that are used for environmental monitoring. 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 1 mSv/yr (100 mrem/yr) 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 which is operated by a worker who does not work with the fixed gauges. See **Figure 20** and **Table 5** for information. Joe wants to see if the company complies with the public dose limits at the bottling control panel.

Joe placed an environmental TLD badge at the bottling control panel for 30 days. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table 13: Combination Measurement - Calculation Method

Step No.	Description	Input Data and Results
Part 1		
1	Dose received by TLD, in mrem	100
2	Total hours TLD exposed	24 hr/d x 30 d/mo = 720
3	Divide the results of Step 1 by the results of Step 2 to determine HOURLY DOSE RECEIVED , in mrem in an hour	0.14
4	Multiply the results of Step 3 by 365 d/yr x 24 hr/d = 8760 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM GAUGES , in mrem in a year	$365 \times 24 \times 0.14 = 8760 \times 0.14 =$ 1226

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100mrem in a year allowed by the rule.

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 spent in the area of concern as in Part 3 of Example 1. (Recall that the TLD measurement was made while all the gauges were operating; i.e., 24 hr/d for the 30 days that the TLD was in place.)

Appendix L:
Operating and Emergency Procedures

Operating and Emergency Procedures

Operating Procedures:

- If personnel dosimetry is provided:
 - Always wear your assigned thermoluminescent dosimeter (TLD) or OSL when using the gauge.
 - Never wear another person's TLD or OSL.
 - Never store your TLD or OSL near the gauge.
- Use the gauge according to the manufacturer's or distributor's instructions and recommendations. Perform routine cleaning and maintenance according to the manufacturer's or distributor's instructions and recommendations.
- Test each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the SSD 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 beam.
- Prevent employees from entering the radiation beam during maintenance, repairs, or work in, on, or around the bin, tank, or hopper on which the device is mounted by developing lock-out procedures. These procedures should specify who will be responsible for ensuring that the lock-out procedures are followed.
- Prevent unauthorized access, removal, or use of the gauge.
- After making changes affecting the gauge (e.g., changing the location of gauges, removing shielding, adding gauges, changing the occupancy of adjacent areas), reevaluate compliance with public dose limits and ensure proper security of gauges.
- Conduct a physical inventory every 6 months to account for all sealed sources and devices.

Emergency Procedures:

- If the gauge becomes damaged or if any other emergency or unusual situation arises:
 - Stop use of the gauge.
 - Immediately secure the area and keep people away from the gauge until the situation is assessed and radiation levels are known. However, perform first aid for any injured individuals and remove them from the area only when medically safe to do so.
 - If any equipment is involved, isolate the equipment until it is determined there is no contamination present.
 - Gauge users and other potentially contaminated individuals should not leave the scene until emergency assistance arrives.
 - Notify the persons in the order listed below of the situation:

NAME	WORK PHONE NUMBER	HOME PHONE NUMBER

- Follow the directions provided by the person contacted above.

RSO 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 DHS as required. *Appendix P* contains typical DHS incident notifications required for fixed gauge licensees. (Even if not required to do so, you may report ANY incident to DHS by calling (608) 267-4797, during normal business hours, 8 a.m. – 4:30 p.m, or (608) 258-0099, which is staffed 24 hours a day and accepts collect calls.) DHS 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 **DHS 157.32(3)** limits. Reporting requirements are found in **DHS 157.32**.

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

Copies of operating and emergency procedures must be posted at each location of use or if posting procedures is not practicable, a notice that briefly describes the procedures and states where they may be examined may be posted instead.

Copies of operating and emergency procedures should be provided to all gauge users.

Appendix M:
Model Leak Test Program

Model Leak Test Program

Training

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

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

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and the use of instruments
- Mathematics and calculations basic to the use and measurement of radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- 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 tests.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- A NaI(Tl) well counter system with a single or multichannel analyzer or an equivalent detector will be used to count samples from gauges containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system or equivalent detector will be used to count samples from gauges containing beta-emitters (e.g., Sr-90) or alpha emitters (e.g., Am-241).

Frequency for Conducting Leak Tests of Sealed Sources

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

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as gauge serial number, radionuclide, activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.

- Select an instrument that is sensitive enough to detect 185 Bq (0.005 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 standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

For example:

$$\frac{(cpm\ from\ std) - (cpm\ from\ bkgd)}{activity\ of\ std\ in\ Bq} = \text{efficiency in cpm/Bq}$$

Where:

- cpm = counts per minute
- std = standard
- bkg = background
- Bq = Becquerel

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

For example:

$$\frac{(cpm\ from\ wipe\ sample) - (cpm\ from\ bkgd)}{efficiency\ in\ cpm/ Bq} = \text{Bq on wipe sample}$$

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

Reference: See the NRC webpage at <http://www.nrc.gov> to obtain a copy of NUREG-1556 Volume 18, 'Program-Specific Guidance About Service Provider Licenses', dated November 2000.

Appendix N:
**Information Needed to Support Applicant's Request to
Perform Non-Routine Operations**

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Applicants should review the section in this document on "Maintenance," which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Non-routine operations include installation of the gauge, initial radiation survey, repair or maintenance involving or potentially affecting 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), gauge relocation, replacement, and disposal of sealed sources, alignment, removal of a gauge from service, and any other activities during which personnel could receive radiation doses exceeding DHS limits. See **Figure 12**. DHS expects that applicants will adhere to the SSD Certificate when performing non-routine operations, if applicable.

Any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified by the SS & D Certificate 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 registration. 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 non-routine 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 exceeding DHS limits. For illustrative purposes in less than one minute, an unshielded cesium-137 source with an activity of 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. However, gauges can contain sources of even higher activities with correspondingly higher dose rates. The threshold for extremity monitoring is 0.05 Sv (5 rem) per year.

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

Provide the following information:

<i>Subject</i>	<i>Information</i>
Individuals Performing Non-Routine Maintenance	<ul style="list-style-type: none"> • Identify the individuals who will be performing non-routine maintenance • Identify their training and experience to include manufacturers training or in-house training. If performing in-house training submit a copy of the course content, sample course examination, and course instructor qualifications
Types of Work to be Performed	<ul style="list-style-type: none"> • Describe the types of work to include: <ul style="list-style-type: none"> - Installation, relocation or alignment of the gauge, - Replacement or disposal of sealed sources, - Removal of a gauge from service; or - Any other activity during which personnel could receive radiation doses exceeding DHS limits • Describe components related to the radiological safety of the gauge (i.e. source, source holder, source drive mechanism, shutter, shutter control, shielding, and electronics)
Procedures for Non-Routine Maintenance	<ul style="list-style-type: none"> • Commit to following manufacturers procedures for performing non-routine maintenance; or • Submit in-house procedures that ensure: <ul style="list-style-type: none"> - Doses to personnel and members of the public are within regulatory limits and ALARA - The source is secured against unauthorized removal or access - Appropriate labels and signs are used - Before being returned to routine use, the gauge is tested to verify that it functions as designed and source integrity is not compromised.
Whole Body and Extremity Monitoring	<ul style="list-style-type: none"> • Confirm that individuals performing non-routine maintenance operations on gauges will wear both whole body and extremity dosimeters
Survey Meter	<ul style="list-style-type: none"> • Confirm the use of an operable survey meter that meets the criteria in Item 10.3 of this document
Surveys	<ul style="list-style-type: none"> • Commit to performing surveys with a survey instrument (as described above) and specify where and when surveys will be conducted during non-routine maintenance operations • Commit to maintain for 3 years from the date of the survey, records of the survey to include: <ul style="list-style-type: none"> - Who performed the survey - Date of the survey - Instrument used - Measured radiation levels correlated to location of those measurements as required by <i>DHS 157.31(3)</i>

A licensee may initially mount a gauge, without specific DHS, the NRC or Agreement State authorization, if the gauge's SSD Certificate explicitly permits mounting of gauges by users and under the following conditions:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor;
- The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by NRC or an Agreement State;
- The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;
- The gauge must be received in good condition (package was not damaged); and
- The gauge must not require any modification to fit in the proposed location.

Mounting does not include electrical connection, activation, or operation of the gauge. The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by DHS, the NRC or an Agreement State to perform such operations.

Appendix O:
**Major DOT Regulations; Sample Shipping Documents,
Placards and Labels**

Major DOT Regulations; Sample Shipping Documents, Placards and Labels

The major areas in the DOT Regulations that are most relevant for transportation of typical fixed gauges that are shipped as Type A quantities are as follows:

- Hazardous Materials Table, **49 CFR 172.101, Appendix A**, list of hazardous substances and reportable quantities (RQ), Table 2: radionuclides
- Shipping Papers **49 CFR 172.200, 172.201, 172.202, 172.203, 172.204**: general entries, description, additional description requirements, shipper's certification
- Package Markings **49 CFR 172.300, 172.301, 172.303, 172.304, 172.310, 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling **49 CFR 172.400, 172.401, 172.403, 172.406, 172.407, 172.436, 172.438, 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles **49 CFR 172.500, 172.502, 172.504, 172.506, 172.516, 172.519, 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information, **Subpart G, 49 CFR 172.600, 172.602, 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, **49 CFR 172.702, 172.704**: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, **49 CFR 172.801, 172.803, 172.805**: Applicability of the radiation protection program, radiation protection program, recordkeeping, and notifications
- Shippers - General Requirements for Shipments and Packaging, **Subpart I, 49 CFR 173.403, 173.410, 173.412, 173.415, 173.431, 173.433, 173.435, 173.441, 173.443, 173.448, 173.475, 173.476**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A... packages, requirements for determining A1 and A2..., table of A1 and A2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials
- Carriage by Public Highway - General Information and Regulation, **Subpart A, 49 CFR 177.816, 177.817, 177.834(a), 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Note: Type B shipping packages transport quantities of radionuclides greater than Type A allowable quantities. Requirements for Type B packages are in **Chapter DHS 157 'Radiation Protection', Subchapter XIII 'Transportation'**.

Appendix P:
DHS Incident Notifications

DHS Incident Notifications

Table 14 Typical DHS Incident Notifications Required for Fixed Gauge Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	Immediate	30 days	<i>DHS 157.32(1)</i>
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	<i>DHS 157.32(2)</i>
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	<i>DHS 157.32(2)</i>
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	<i>DHS 157.32(2)</i>
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	<i>DHS 157.32(2)</i>
Whole body dose greater than 0.05 Sv (5 rems)	None	30 days	<i>DHS 157.32(3)</i>
Dose to individual member of the public greater than 1mSv (100 mrems)	None	30 days	<i>DHS 157.32(3)</i>
Filing petition for bankruptcy under 11 U.S.C.	None	Within 10 days	<i>DHS 157.13(10)(e)</i>
Expiration of License	None	60 days	<i>DHS 157.13(11)</i>
Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use	None	60 days	<i>DHS 157.13(11)</i>
No principal activities conducted for 24 months at the entire site	None	60 days	<i>DHS 157.13(11)</i>
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted used	None	60 days	<i>DHS 157.13(11)</i>

Event	Telephone Notification	Written Report	Regulatory Requirement
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	<i>DHS 157.13(17)</i>
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	<i>DHS 157.13(17)</i>
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	<i>DHS 157.13(17)</i>

Note: Radiation Protection Section requires a notification within 24 hours for gauges whose shutters fail or any other equipment related to the gauge that is disabled or fails to function as designed.

Telephone notifications shall be made to DHS at (608) 267-4797 during normal business hours (8 a.m. – 4:30 p.m.). DHS’s 24 hour emergency telephone number is (608) 258-0099. Identify the emergency as radiological.

References: NRC IN 2009-18 “Performance of Required Shutter Checks and Reporting of Gauge Shutter Failures” dated September 18, 2009.

Appendix Q:
Sample Correspondence Delegation Letter

[date]

Department of Health Services
Radiation Protection Section
P.O. Box 2659
Madison, WI 53701-2659

To Radioactive Material Program Supervisor:

As [job title] of [name of licensee], I have delegated authority for all matters pertaining to our Radioactive Material License to [name of designee]. [Name of designee] has management approval to sign and submit amendment requests to the Department of Health Services on behalf of [name of licensee]. I understand that license renewals must still be signed by a representative of upper management.

[This document must be signed by a management representative who has independent authority to reassign job duties and/or provide finances, if necessary, to support an effective radiation safety program.]

Signature

Title

Date

Print Name