Appendix D:

Criteria for Acceptable Training Courses for Portable Gauge Users

Criteria for Acceptable Training Courses for Portable Gauge Users

Course Content

The following are areas in which DHFS considers it important that an individual have expertise for the competent operation of portable gauges and XRF devices using sealed sources of radioactive material. The course shall be at least 8 hours in length.

I. PRINCIPLES AND FUNDAMENTALS OF RADIATION SAFETY

A. Types and Characteristics of Radiation
   1. Alpha, Beta, Gamma, X-ray and Neutron Radiation
   2. Exposure: Natural versus Man-made Radiation
   3. Irradiation versus Contamination/Internal vs. External
   4. Radioactive Material Used in Portable Gauges and XRF Devices

B. Units of Radiation Dose and Quantities of Radioactivity
   1. Curie, Rad, Rem and Roentgen
   2. Prefixes
   3. SI Units

C. Basic Math and Calculations Related to Radioactivity
   1. Radioactive Decay
   2. Dose Rates from the sources commonly used
   3. Inverse Square Law

D. Biological Effects of Radiation
   1. Acute, Chronic, and Genetic Effects of Exposure
   2. Radiation Protection Standards
   3. The ALARA Philosophy

E. Radiation levels from Radioactive Sealed Sources
   1. Survey Meter Use for Portable Gauge Users, not including XRF devices

F. Methods of Controlling Radiation Dose
   1. Time
   2. Distance
   3. Shielding

II. STATE AND FEDERAL REGULATIONS

A. Chapter HFS 157, Wisconsin Administrative Code
B. Title 10, Code of Federal Regulations, US Nuclear Regulatory Commission
C. Title 49, Code of Federal Regulations, Transportation

III. LICENSING AND INSPECTION

A. License Items and Conditions
B. Notices, Instructions and Reports to Workers
C. Inspection by the Department

IV. OPERATING AND EMERGENCY PROCEDURES

A. Operating Procedures
   1. Training and Supervision
   2. Personnel Monitoring
   3. Availability of Procedures
   4. Security of the Gauges or Devices When Stored and At The Work Location
   5. ALARA Philosophy
   6. Transportation of the Gauges or Devices and Security
   7. General Rules of Use
   8. Posting Requirements
   9. Routine Maintenance
   10. Radiation Surveys Using Survey Meters at the Work Site for Portable Gauges

B. Emergency Procedures
   1. Preventive Measures
   2. Emergency Response
   3. Notification Requirements
   4. Case Histories

V. TRANSFER/ DISPOSAL REQUIREMENTS

A. State and NRC Regulations
B. Transportation Requirements

VI. PRACTICAL TRAINING

A. Transport/ Storage Containers
B. Hands-on Training Specific to the Gauge or Device
   1. Proper Use
   2. Safe Handling
   3. Calibration of XRF Device Including Substrate Corrections
   4. Demonstration of Measurements of Various Materials
   5. Use of Survey Meters by Portable Gauge Users.

VII. Q&A SESSION

Course Examination

- 25-50 question, closed-book written test -- 70 percent grade

  - Emphasis on radiation safety of portable gauge storage, use, sealed source location, maintenance, and transportation, rather than the theory and art of making portable gauge measurements
  - Review of correct answers to missed questions with prospective gauge user immediately following the scoring of the test

Course Instructor Qualifications

Instructor should have either:

- Bachelor's degree in a physical or life science or engineering
- Successful completion of a portable gauge user course
- Successful completion of an 8 hour radiation safety course AND
- 8 hours hands-on experience with portable gauges

OR

- Successful completion of portable gauge user course
- Successful completion of 40 hour radiation safety course; AND
- 30 hours of hands-on experience with portable gauges.

Note: Licensees should maintain records of training.

Appendix E:

Typical Duties and Responsibilities of the Radiation Safety Officer

The ***RSO's*** duties and responsibilities are illustrated in **Figure 2** and typically include ensuring the following:

- Stopping licensed activities that the ***RSO*** considers unsafe
- Possession, use, storage, and maintenance of sources and gauges or XRFs are consistent with the limitations in the license, the Sealed Source and Device Registration sheet(s), and manufacturer's recommendations and instructions
- Individuals using gauges are properly trained
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals; records of the results of such monitoring are maintained
- Gauges or XRFs are properly secured
- Proper authorities are notified in case of accident, damage to gauges, fire, or theft
- Unusual occurrences involving the gauge (e.g., accident, damage) are investigated, cause(s) and appropriate corrective action are identified, and corrective action is taken
- Audits are performed at least annually and documented, and corrective actions taken
- Licensed material is transported in accordance with all applicable ***DOT*** requirements
- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained and amendment and renewal requests submitted in a timely manner

Appendix F:

Portable Gauge or XRF 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._____
Auditor: _____Date of Audit _____Telephone No._____

_____
(Signature)

1. AUDIT HISTORY

a. Last audit of this location conducted on (date) _____
b. Were previous audits conducted yearly? ***(HFS 157.21)***
c. Were records of previous audits maintained? ***(HFS 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).

2. ORGANIZATION AND SCOPE OF PROGRAM

a. If the mailing address or places of use changed, was the license amended?
b. If ownership changed or bankruptcy filed, was ***DHFS*** prior consent obtained or was the department notified?
c. If the ***RSO*** was changed, was license amended? Does new **RSO** meet ***NRC*** training requirements?
d. If the designated contact person for the department changed, was ***DHFS*** notified?
e. Does the license authorize all of the department-regulated radionuclides contained in gauges possessed?
f. Are the gauges or XRFs as described in the Sealed Source and Device ***(SSD)*** Registration Certificate or Sheet? Have copies of (or access to) ***SSD*** Certificates? Have manufacturers' manuals for operation and maintenance?
g. Are the actual uses of gauges consistent with the authorized uses listed on the license?
h. Is ***RSO*** fulfilling his/her duties?

3. TRAINING AND INSTRUCTIONS TO WORKERS

a. Were all workers who are likely to exceed 100 mrem/yr instructed per (***HFS 157.88 (2)***? Refresher training provided, as needed ***(HFS 157.88 (2)***?
b. Did each gauge or XRF operator attend an approved course prior to using gauges?
c. Are training records maintained for each gauge or XRF operator?
d. Did interviews with operators reveal that they know the emergency procedures?
e. Did this audit include observations of operators using the gauge or XRF in a field situation?
f. Operating gauge or XRF? Performing routine cleaning and lubrication? Transporting gauge or XRF? Storing gauge or XRF?
g. Did the operator demonstrate safe handling and security during transportation, use and storage?
h. HAZMAT training provided as required? ***[49 CFR 172.700, 49 CFR 172.701,CFR 172.702, 49 CFR 172.703, 49 CFR 172.704]***

4. RADIATION SURVEY INSTRUMENTS (For Portable Gauges Users Only)

a. If the licensee possesses its own survey meter, does it meet the department's criteria?

b. If the licensee does not possess a survey meter, are specific plans made to have one available?

c. Is the survey meter needed for non-routine maintenance calibrated as required ***(HFS 157.25 (1)***?

d. Are calibration records maintained ***(HFS 157.31 (3))***?

5. GAUGE AND XRF INVENTORY

a. Is a record kept showing the receipt of each gauge or XRF? ***(HFS 157.31)***

b. Are all gauges or XRFs received physically inventoried every six month?

c. Are records of inventory results with appropriate information maintained?

6. PERSONNEL RADIATION PROTECTION

a. Are ***ALARA*** considerations incorporated into the radiation protection program? ***(HFS 157.21)***

b. Is documentation kept showing that unmonitored XRF users receive <10% of limit? (Portable gauges users are required to have dosimetry)

c. Did unmonitored users' activities change during the year which could put them over 10% of limit?

d. If yes to c. above, was a new evaluation performed?

e. Is external dosimetry required (Portable gauges users are required to have and XRF users receiving >10% of limit are required to have)? And is dosimetry provided to users?

   1) Is the dosimetry supplier ***NVLAP*** approved? ***(HFS 157.25(1)***

   2) Are the dosimeters exchanged monthly for film badges and at industry recommended frequency for ***TLD***s?

   3) Are dosimetry reports reviewed by the ***RSO*** when they are received?

   4) Are the records ***DHFS*** Forms or equivalent? ***(HFS 157.31 (5) and (7))***

      DHFS Form ??? " Cumulative Occupational Exposure History" completed?

      DHFS Form ??? "Occupational Exposure Record for a Monitoring Period" completed?

   5) If a worker declared her pregnancy, did licensee comply with ***(HFS 157.22(8))***?

      Were records kept of embryo/fetus dose per ***(HFS 157.31 (7))***?

f. Are records of exposures, surveys, monitoring, and evaluations maintained? ***(HFS 157.31 (2-3) and (7))***

7. PUBLIC DOSE

a. Are gauges or XRFs stored in a manner to keep doses below 100 mrem in a year? ***(HFS 157.23 (1))***

b. Has a survey or evaluation been performed per ***HFS 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 2 mrem in any one hour? ***(HFS 157.23 (1))***

d. Are gauges or XRFs being stored in a manner that would prevent unauthorized use or removal? ***(HFS 157.28 (1) (a))***

e. Records maintained? ***(HFS 157.31 (3) and (8))***

8. OPERATING AND EMERGENCY PROCEDURES

a. Have operating and emergency procedures been developed?

b. Do they contain the required elements?

c. Does each operator have a current copy (telephone numbers) of the operating and emergency procedures?

9. LEAK TESTS

a. Was each sealed source leak tested every 6 months or at other prescribed intervals?

b. Was the leak test performed as described in correspondence with the department and according to the license?

c. Are records of results retained with the appropriate information included?

d. Were any sources found leaking and if yes, was the department notified?

10. MAINTENANCE OF GAUGES

a. Are manufacturer's procedures followed for routine cleaning and lubrication of gauge and XRF?

b. Does the source or source rod remain attached to the portable gauge during cleaning?

c. Is non-routine maintenance performed where the source or source rod is detached from the gauge? If yes, was it performed according to license requirements (e.g., extent of work, individuals performing the work, procedures, dosimetry, survey instrument, compliance with ***HFS 157.13 (1)*** limits)? *(Applies only to Portable Gauge Users, XRF users are not allowed to perform non-routine maintenance.)*

11. TRANSPORTATION

Portable Gauges

a. DOT-7A or other authorized packages used? ***(49 CFR 173.415, 49 CFR 173.416(b))***

b. Package performance test records on file?

c. Special form sources documentation? ***(49 CFR 173.476(a))***

d. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? ***(49 CFR 172.403, 49 CFR 173.441)***

e. Package properly marked? ***(49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 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, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} ***(49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604)***

i. Shipping papers within drivers reach and readily accessible during transport? ***(49 CFR 177. 817(e))***

j. Secured against movement? ***(49 CFR 177. 834)***

k. Placarded on vehicle, if needed? ***(49 CFR 172.504)***

l. Proper overpacks, if used? ***(49 CFR 173.25)***

m. Any incidents reported to ***DOT*****?** ***(49 CFR 171.15, 16)***

XRF

a. If shipping papers are not required, is there a certification statement ***(49 CFR 173.422(a)(2))*** along with the name of the consignor or consignee included with (on the package or inside the package) the XFR when transported?

12. AUDITOR'S INDEPENDENT SURVEY MEASUREMENTS (IF MADE)

a. Describe the type, location, and results of measurements. Do any radiation level exceed regulatory limits?.

13. NOTIFICATION AND REPORTS

a. Was any radioactive material lost or stolen? Were reports made? ***(HFS 157.32)***

b. Did any reportable incidents occur? Were reports made? ***(HFS 157.32)***

c. Did any overexposures and high radiation levels occur? Reported? ***(HFS 157.32)***

d. If any events (as described in items a through c above) did occur, what was root cause? Were corrective actions appropriate?

e. Is the licensee aware of telephone number for radiation emergencies in the State of Wisconsin? **(608) 258-0099**

14. POSTING AND LABELING

a. ***DHFS-???*** "Notice to Employees" posted? ***(HFS 157.88 (1))***

b. The department regs., license documents posted or a notice posted? ***(HFS 157.88 (1))***

c. Other posting and labeling? ***(HFS 157.29 (2) and (4))***

15. RECORD KEEPING FOR DECOMMISSIONING

a. Records kept of information important to decommissioning? ***(HFS 157.15)***

b. Records include all information outlined ***(HFS 157.15)***

16. BULLETINS AND INFORMATION NOTICES

a. Are the department's Information Notices received?

b. Appropriate training and action taken in response?

17. SPECIAL LICENSE CONDITIONS OR ISSUES

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

18. 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)?

c. Provide any other recommendations for improvement.

19. EVALUATION OF OTHER FACTORS

a. Senior licensee management is appropriately involved with the radiation protection program and/or Radiation Safety Officer (***RSO***) oversight?

b. ***RSO*** has sufficient time to perform his/her radiation safety duties?

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

Appendix G:

Information Needed to Support Portable Gauge Licensee's Request to Perform Non-routine Maintenance

Non-routine maintenance or repair (beyond routine cleaning and lubrication) involves detaching the source or source rod from the device and any other activities during which personnel could receive radiation doses exceeding the department limits. See **Figure 8**. If this maintenance or repair is 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 the department limits.

A typical moisture-density gauge contains 0.37 gigabecquerels (10 millicuries) of cesium-137 and 1.5 gigabecquerels (40 millicuries) of americium-241 as a neutron source. In about 9 minutes, an unshielded cesium-137 source of this activity can deliver 0.05 sievert (5 rems) to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. Some gauges contain sources of even higher activities with correspondingly higher dose rates. The threshold for extremity monitoring is 0.05 sievert (5 rems) per year.

Thus, applicants wishing to perform non-routine maintenance must use personnel with special training and follow appropriate procedures consistent with the manufacturer's instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, personnel dosimetry). Accordingly, provide the following information:

- Describe the types of work, maintenance, cleaning, repair, etc., to be performed that necessitate detaching the source or source rod from the device or that could cause personnel to receive radiation doses exceeding ***DHFS*** limits. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

- Identify who will perform non-routine maintenance, their training and experience, and why they are competent to perform non-routine maintenance.

- Submit procedures for safe handling of the radioactive source while the source or source rod is detached from the gauge. These procedures should ensure the following:

    - doses to personnel and members of the public are within regulatory limits and ***ALARA*** (e.g., use of shielded containers or shielding);
    - the source or source rod is secured against unauthorized removal access or under constant surveillance;
    - appropriate labels and signs are used; and
    - manufacturer's instructions and recommendations are followed.

- Confirm that individuals performing non-routine maintenance on gauges will always wear both whole body and extremity monitoring devices or that an evaluation will be available to demonstrate that these individuals are not likely to receive, in one year, more than 10 percent of the applicable dose limits. The dose limits are illustrated in **Figure 4**.

- Verify possession of at least one survey instrument meeting the following criteria:

    - Be capable of detecting gamma radiation;
    - Be capable of measuring from 0.01 to 0.5 mSv/hr [1 to 50 mrem/hr];
    - Be calibrated at least annually with radionuclide point sources emitting radiation of the type and energy of the sealed sources in the gauge;

- Be calibrated at least 2 points located at approximately 1/3 and 2/3 of each scale; readings within ±20% are acceptable;
- Be calibrated by a person specifically licensed by ***DHFS***, the ***NRC,*** or an Agreement State to calibrate radiation detection instruments; and
- Be checked for functionality prior to use (e.g., with the gauge or a check source).

Note: Records of instrument calibration must be maintained for 3 years after the record is made (***HFS 157.31 (3)***).

- Describe steps to be taken to ensure that radiation levels in areas where non-routine maintenance will take place do not exceed ***HFS 157.23(1)*** limits. For example, applicants can do the following:

  - commit to performing surveys with a survey instrument (as described above);
  - specify where and when surveys will be conducted during non-routine maintenance; and
  - commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by ***HFS 157.31 (3)***.

Appendix H:

Operating and Emergency Procedures

Operating Procedures

- If personnel dosimetry is provided:

    - Always wear your assigned thermoluminescent dosimeter (***TLD***), ***OSL*** or film badge when using the gauge or XRF.
    - Never wear another person's ***TLD, OSL*** or film badge.
    - Never store your ***TLD, OSL*** or film badge near the gauge.

- Before removing the gauge from its place of storage, ensure that, where applicable, each gauge source is in the fully shielded position and that in gauges with a movable rod containing a sealed source, the source rod is locked (e.g., keyed lock, padlock, mechanical control) in the shielded position. Place the gauge in the transport case and lock the case.

- Sign out the gauge or XRF in a log book (that remains at the storage location) including the date(s) of use, name(s) of the authorized users who will be responsible for the gauge, and the temporary jobsite(s) where the gauge will be used.

- Block and brace the gauge to prevent movement during transport and lock the gauge in or to the vehicle. Follow all applicable Department of Transportation (***DOT***) requirements when transporting the gauge.

- Use the gauge or XRF according to the manufacturer's instructions and recommendations.

- Do not touch the unshielded source rod 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.

- Perform routine cleaning and maintenance according to the manufacturer's instructions and recommendations.

- When the gauge or XRF is not in use at a temporary jobsite, place the gauge or XRF in a secured location (e.g., locked in the trunk of a car or locked in a storage shed).

- Prior to transporting the gauge or XRF, ensure that, where applicable, each gauge source is in the fully shielded position. Ensure that in gauges with a movable source rod, the source rod is locked in the shielded position (e.g., keyed lock, padlock, mechanical control). Place the gauge in the transport case and lock the case. Block and brace the case to prevent movement during transportation. Lock the case in or to the vehicle.

- Return the gauge or XRF to its proper locked storage location at the end of the work shift.

- Log the gauge or XRF into the daily use log when it is returned to storage.

- After making changes affecting the gauge storage area (e.g., changing the location of gauges within the storage area, removing shielding, adding gauges or XRFs, changing the occupancy of adjacent areas, moving the storage area to a new location), reevaluate compliance with public dose limits and ensure proper security of gauges or XRFs.

For Portable Gauges Only

- Unless absolutely necessary, do not look under the gauge when the source rod is being lowered into the ground. If you must look under the gauge to align the source rod with the hole, follow the manufacturer's procedures to minimize radiation exposure.

- After completing each measurement in which the source is unshielded, immediately return the source to the shielded position.

- Always maintain constant surveillance and immediate control of the gauge when it is not in storage. At job sites, do not walk away from the gauge when it is left on the ground. Take actions necessary to protect the gauge and yourself from danger of moving heavy equipment.

- Always keep unauthorized persons away from the gauge.

- If gauges are used for measurements with the unshielded source extended more than 3 feet beneath the surface, use piping, tubing, or other casing material to line the hole from the lowest depth to 12 inches above the surface. If the piping, tubing, or other casing material cannot extend 12 inches above the surface, cap the hole liner or take other steps to ensure that the hole is free of debris (and it is unlikely that debris will re-enter the cased hole) so that the unshielded source can move freely (e.g., use a dummy probe to verify that the hole is free of obstructions).

Emergency Procedures for Portable Gauges:

If the source fails to return to the shielded position (e.g., as a result of being damaged, source becomes stuck below the surface) or if any other emergency or unusual situation arises (e.g., the gauge is struck by a moving vehicle, is dropped, is in a vehicle involved in an accident):

- Immediately secure the area and keep people at least 15 feet 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 heavy equipment is involved, detain the equipment and operator 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*

* Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the Radiation Safety Officer (***RSO***), or other knowledgeable licensee staff, licensee's consultant, gauge manufacturer) to be contacted in case of emergency.

- Follow the directions provided by the person contacted above.

Emergency Procedures for XRFs.

If the XRF is lost, damaged or stolen, or if any other emergency or other unusual event occurs arises:

- Immediately secure the area and keep people at least 15 feet away from the XRF 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.
- XRF users and other potentially contaminated individuals should not leave the scene until emergency assistance arrives.
- Notify the persons in order listed below of the situation:

NAME*	WORK PHONE NUMBER*	HOME PHONE NUMBER*

* Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the Radiation Safety Officer (***RSO***), or other knowledgeable licensee staff, licensee's consultant, XRF manufacturer) to be contacted in case of emergency.

- 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 located at the jobsite 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.

- If portable gauges are used for measurements with the unshielded source extended more than 3 feet below the surface, contact persons listed on the emergency procedures need to know the steps to be followed to retrieve a stuck source and to convey those steps to the staff on site.

- Make necessary notifications to local authorities as well as the department required. (Even if not required to do so, you may report ANY incident to the department by calling **(608) 258-0099**, which is staffed 24 hours a day and accepts collect calls.) The department notification is required when gauges containing licensed material are lost or stolen, when gauges are damaged or involved in incidents that result in doses in excess of ***HFS 157.32 (3)*** limits, and when it becomes apparent that attempts to recover a source stuck below the surface will be unsuccessful.

- Notify law enforcement if the gauge or XRF is believed to be lost or stolen.

- Reports to ***DHFS*** must be made within the reporting timeframes specified by the regulations.

- Reporting requirements are found in ***HFS 157.32 (1-3); and HFS 157.32***.

Appendix I: Dosimetry-related Guidance

Part 1: Guidance for Demonstrating that Unmonitored XRF Users Are Not Likely to Exceed 10 Percent of the Allowable Limits

Appendix I, Part 2

Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- 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 licensed materials.

Members of the public include persons who live, work, or may be near locations where portable gauges or XRFs 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 or XRFs are used or stored.

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

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

Licensees must show compliance with both portions of the regulation. Calculations or a combination of calculations and measurements (e.g., using an environmental ***TLD***) are often used to prove compliance.

Calculational Method

Note: For ease of use by most portable 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 calculational 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: (1) each gauge is a point source, (2) typical radiation levels encountered when the source is in the shielded position are taken from either the Sealed Source & Device (SSD) Registration Sheet or the manufacturer's literature, and (3) no credit is taken for any shielding found between the gauges and the unrestricted areas. Part 1 of the calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the "inverse square law" to determine if the distance between the gauge and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers distance and the 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 calculational method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example 1

To better understand the calculational method, we will look at Moisture-Density Measurements, Inc., a portable gauge licensee. Yesterday, the company's president noted that the new gauge storage area is very close to his secretary's desk and he asked Joe, the Radiation Safety Officer (***RSO***), to determine if the company is complying with ***DHFS*** regulations.

The secretary's desk is near the wall separating the reception area from the designated, locked gauge storage area, where the company is storing its three gauges. Joe measures the distances from each gauge to the wall and looks up in the manufacturer's literature the radiation levels individuals would encounter for each gauge. **Figure 10** is Joe's sketch of the areas in question, and **Table 1** summarizes the information Joe has on each gauge.

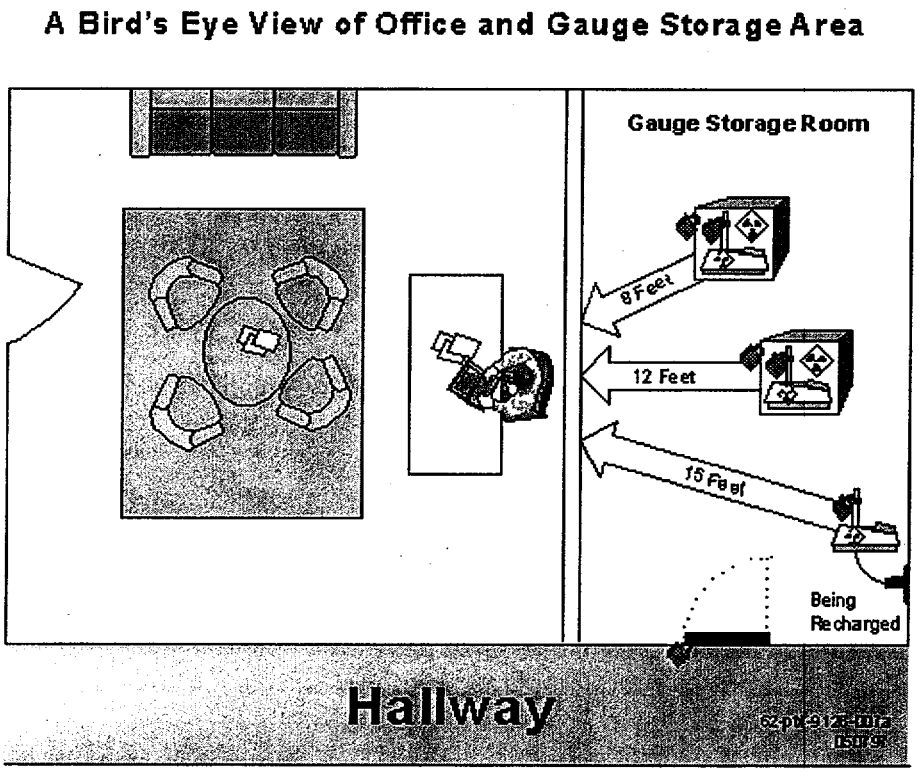

Figure 10. , Diagram of Office and Gauge Storage Area. This sketch shows the areas described in Examples 1 and 2.

Table 1, Information Known about Each Gauge			
DESCRIPTION OF KNOWN INFORMATION	**GAUGE 1**	**GAUGE 2**	**GAUGE 3**
How gauge is stored	Gauge in transport container	Gauge in transport container	Gauge out of transport container and being recharged
Dose rate in mrem/hr encountered at specified distance from the gauge (from manufacturer's literature)	2 mrem/hr at 1 ft	8 mrem/hr at 1 ft	2 mrem/hr at 3 ft
Distance in ft to secretary's chair	8 ft	12 ft	15 ft

Table 1, Information Known about Each Gauge

Example 1: Part 1

Joe's first thought is that the distance between the gauges and the secretary's chair may be sufficient to show compliance with the regulation in ***HFS 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 remain in storage with no other use, and 3) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d). Joe proceeds to calculate the dose she might receive hourly and yearly from each gauge as shown in **Tables 2, 3,** and **4** below.

able 2, Calculational 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 ft^2	$(1)^2$	1
3	Square of the distance (ft) from the gauge to the secretary's desk in an unrestricted area, in ft^2	$(8)^2$	64
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 1 =2	
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, **HOURLY DOSE RECEIVED FROM GAUGE 1**, in mrem in an hour.	2/64 = **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 x 24 x 365 = 0.031 x 8760 = **272**	

Table 3, Calculational Method, Part 1—Hourly and Annual Dose Received from Gauge 2			
		GAUGE 2	
Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	8	8
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft^2	$(1)^2$	1
3	Square of the distance (ft) from the gauge to the secretary's desk in an unrestricted area, in ft^2	$(12)^2$	144
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	8 x 1 = 8	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received in an hour by an individual at the secretary's desk, **HOURLY DOSE RECEIVED FROM GAUGE 2**, in mrem in an hour	8/144 = **.056**	
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 x 24 x 365 =0.056 x 8760 = **491**	

Table 4, Calculational Method, Part 1—Hourly and Annual Dose Received from Gauge 3			
		GAUGE 3	
Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	2	2
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft^2	$(3)^2$	9
3	Square of the distance (ft) from the gauge to the secretary's desk in an unrestricted area, in ft^2	$(15)^2$	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	2 x 9 =18	
5	Divide the result of Step 4 by the result of Step 3 to calculate dose received by an individual at the secretary's desk, **HOURLY DOSE RECEIVED FROM GAUGE 3**, in mrem in an hour	18/225 = **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 x 24 x 365 = 0.08 x 8760 = **701**	

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

Table 5, Calculational Method, Part 1—Total Hourly and Annual Dose Received from Gauge 1, 2, and 3					
tep No.	**Description**	**Gauge 1**	**Gauge 2**	**Gauge 3**	**Sum**
7	**TOTAL HOURLY DOSE RECEIVED** from Step 5 of Tables I-3, I-4, and I-5, in mrem in an hour	0.031	0.056	0.08	0.031 + 0.056 + 0.08 = **0.167**
8	**TOTAL ANNUAL DOSE RECEIVED** from Step 6 of Tables I-3, I-4, and I-5, in mrem in a year	272	491	701	272 + 491 + 701 = **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 calculational method.**					

[**Table 5**, Calculational Method, Part 1---Total Hourly and Annual Dose Received from Gauges 1, 2, and 3]

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 secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the gauges are constantly present (i.e., 24 hr/d), all three gauges remain in storage with no other use). He then recalculates the annual dose received.

Table 6, Calculational Method, Part 2--Annual Dose Received from Gauges 1, 2, and 3		
Step No.	**Description**	**Results**
9	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hr/day; the remainder of the day the secretary is away from the desk area copying, filing, etc.)	5
	B. Average number of days per week in area (e.g., secretary is part time and works 3 days/week)	3
	C. Average number of weeks per year in area (e.g., secretary 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 x 3 x 52 = **780**
11	Multiply the sum in Step 7 by the results of Step 10 = **ANNUAL DOSE RECEIVED FROM GAUGES CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN**, in mrem in a year	0.167 x 780 = **130**

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

Table 6, Calculational Method, Part 2--Annual Dose Received from Gauges 1, 2, and 3

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 the gauges are not always in storage when the secretary is seated at the desk. As he examines the situation, he realizes he must consider each gauge individually.

Table 7, Calculational Method, Part 3---Summary of Information
INFORMATION ON WHEN GAUGES ARE PRESENT IN THE STORAGE AREA: • **GAUGE 1: an old gauge located in the storage area continuously (24 hr/d)** • **GAUGE 2: a new gauge located in the storage area continuously (24 hr/d) for 8 months of the year; for the remaining 4 months of the year it is at temporary job sites** • **GAUGE 3: a new gauge located in the storage area overnight; it is used every day at temporary job sites all year and returned to the storage location at the end of each day. The gauge is usually present during the secretary's first and last hours of work each day.** **INFORMATION FROM EXAMPLE 1, PART 2 ON WHEN THE SECRETARY IS SITTING AT THE DESK** • **5 hours per day** • **3 days per week** • **52 weeks per year**

***Table** 7, Calculational Method, Part 3---Summary of Information*

Table 8, Calculational Method, Part 3---Annual Dose Received from Gauges 1, 2, and 3				
Step No.	**Description**	**GAUGE 1**	**GAUGE 2**	**GAUGE 3**
12	Average number of **hours per day** gauge is in storage while secretary is present	**5**	**5**	**2**
13	Average number of **days per week** gauge is in storage while secretary is present	**3**	**3**	**3**
14	Average number of **weeks per year** gauge is in storage while secretary is present	**52**	**32**	**52**
15	Multiply the results of Step 12 by the results of Step 13 by the results of Step 14 = **TOTAL HOURS EACH GAUGE IS STORED PER YEAR WHILE SECRETARY IS PRESENT**	5 x 3 x 52 = **780**	5 x 3 x 32 = **480**	2 x 3 x 52 = **312**
16	Multiply the results of Step 15 by the results of Step 7 = **ANNUAL DOSE RECEIVED FROM EACH GAUGE**, in mrem in a year	780 x 0.031 = **24**	480 x 0.056 = **27**	312 x 0.08 = **25**
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 IS IN STORAGE**, in mrem in a year	24 + 27 + 25 = **76**		
***NOTE:* If the result in Step 17 is greater than 100 mrem/yr, the licensee must take corrective actions.**				

Table 8, Calculational Method, Part 3---Annual Dose Received from Gauges 1, 2, and 3

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 is in storage are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding located between the gauge storage area and the secretarial workstation--such calculation is beyond the scope of this Appendix
- Take corrective action (e.g., move gauges within storage area, move the storage area, move the secretarial workstation) and perform new calculations to demonstrate compliance
- Designate the area outside the storage area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary as required by ***HFS 157.88 (2)***.

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the gauge storage area. 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., moving any of the gauges closer to the secretarial workstation, adding a gauge to the storage area, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

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

Combination Measurement-Calculational Method

This method, which allows the licensee to take credit for shielding between the gauge and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from each gauge. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making measurements with currently calibrated radiation survey instruments. 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.

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 ***TLD***s in unrestricted areas next to the gauge storage area for 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. Note: ***TLD***s 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 mrem/yr) limit. If licensees use ***TLD***s to evaluate compliance with the public dose limits, they should consult with their ***TLD*** supplier and choose more sensitive ***TLD***s, such as those containing CaF_2 that are used for environmental monitoring.

Example 2

As in Example 1, Joe is the ***RSO*** for Moisture-Density Measurements, Inc., a portable gauge licensee. The company has three gauges stored in a designated, locked storage area that adjoins an unrestricted area where a secretarial work station is located. See **Figure 1** and **Table 1** for information. Joe wants to see if the company complies with the public dose limits at the secretarial station.
During the winter while all the gauges were in storage, Joe placed an environmental ***TLD*** badge in the secretarial work space for 30 days. Joe chose a winter month so he did not have to keep track of the number of hours that each gauge was in the storage area. The ***TLD*** processor sent Joe a report indicating the ***TLD*** received 100 mrem.

Table 9, Combination Measurement-Calculational 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 x 24 x 0.14 = 8760 x 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 100 mrem in a year allowed by the regulations.**		
PART 2		
At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area 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 while the gauges are actually in storage as in Part 3 of Example 1. (Recall that the ***TLD*** measurement was made while all the gauges were in storage--i.e., 24 hr/d for the 30 days that the ***TLD*** was in place.)		

Table 9, Combination Measurement-Calculational Method

Appendix J:

Requests to Perform Leak Testing and Sample Analysis

Information to be Provided Supporting Request

- Identify the individual who will make the analysis and provide his or her qualifications to make quantitative measurements of radioactivity.

- Commit to performing leak testing at the frequency specified in the appropriate SSD Registration Certificate.

- Specify how and where test samples will be taken on the gauge. Describe materials used and methods of handling samples to prevent or minimize exposure to personnel.

- Specify the type of instrument(s) that will be used for measurement, the counting efficiency, and minimum levels of detection for each radionuclide to be measured.

Note: An instrument capable of making quantitative measurements should be used; hand-held survey meters will not normally be considered adequate for measurements.

- Specify the standard sources used to calibrate the instrument; for each, specify the radionuclide, quantity, accuracy, and traceability to primary radiation standards.

Note: Accuracy of standards should be within ±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***).

- Include a sample calculation for conversion of the measurement data to becquerels (or microcuries).

- Provide instructions on actions to take and persons to be notified if sources are found to be leaking.

Model 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.

- Using the instrument identified to, and approved by, ***DHFS***, 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. Calculate efficiency.

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).
- Sign and date the list of sources, data and calculations.
- If the wipe test activity is 185 becquerels (0.005 microcurie) or greater, notify the ***RSO***, so that the source can be withdrawn from use and disposed of properly. Also notify the department.

Appendix K:

Major DOT Regulations; Sample Bill of Lading

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

- Table of Hazardous Materials and Special Provisions ***49 CFR 172.101***, and App. A, Table 2: Hazardous materials table, list of hazardous substances and reportable quantities

- Shipping Papers ***49 CFR 172.200-204***: general entries, description, additional description requirements, shipper's certification

- Package Markings ***49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 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, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440***: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels

- Placarding of Vehicles ***49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556***: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard

- Emergency Response Information, Subpart G, ***49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604***: Applicability and general requirements, emergency response information, emergency response telephone number

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

- Radiation Protection Program for Shippers and Carriers, Subpart I, ***49 CFR 172.800***, etc.

- Shippers - General Requirements for Shipments and Packaging, Subpart I, ***49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.475, 49 CFR 173.476***: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, requirement for determining A_1 and A_2, table of A_1 and A_2 values for radionuclides, radiation level limit, quality control requirements prior to each shipment, approval of special form radioactive materials

- Carriage by Public Highway ***49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842***: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material

Appendix K --

STRAIGHT BILL OF LADING

ORIGINAL—NOT NEGOTIABLE

Shipper No. ____

Carrier No. ____

Date ____

Page 1 of 1

(Name of carrier) (SCAC)

TO: Consignee: Builders, Inc. **

On Collect on Delivery shipments, the letters "COD" must appear before consignee's name or as otherwise provided in Item 430, Sec. 1.

Street: 5678 Jefferson Davis Highway **

Destination: Arlington, VA** Zip Code: 22222**

FROM: Shipper: Moisture Density Measurements, Inc. **

Street: 1234 A Street, NW **

Origin: Washington, DC 20000**

Route

Vehicle Number

No. of Units & Container Type	HM	BASIC DESCRIPTION Proper Shipping Name, Hazard Class, Identification Number (UN or NA) per 172.101, 172.202, 172.203	TOTAL QUANTITY (Weight, Volume, Gallons, etc.)	WEIGHT (Subject to Correction)	RATE	CHARGES (For Carrier Use Only)
1	RQ	Radioactive material, special form				
		n.o.s. 7 UN2974				
		0.41GBq (11 mCi) Cs-137 and				
		1.9GBq (50 mCi) Am-241:Be	2.31 GBq			
			(61 mCi)			
		RADIOACTIVE - YELLOW II				
		TI = 0.4 **				
		USDOT 7A TYPE A				
		Emergency Response Telephone No.: 1-800-000-0000 (24 hr/d)**				
		** SUBSTITUTE APPROPRIATE INFORMATION FOR				
		YOUR GAUGE AND YOUR SHIPMENT				

PLACARDS TENDERED: YES ☐ NO ☐

REMIT C.O.D. TO: ADDRESS

Note — Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property. The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding $ ____ per ____

I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packaged, marked and labeled, and are in all respects in proper condition for transport by rail or highway according to applicable regulations of the U.S. Department of Transportation. NON-APPLICABLE BOXES OR ITEMS MUST BE CHECKED according to applicable regulations and national governmental regulations.

John Jones — Signature

COD Amt: $

Subject to Section 7 of the conditions, if this shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement: The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges.

Signature of Consignor

C.O.D. FEE: PREPAID ☐ COLLECT ☐ $

TOTAL CHARGES: $

FREIGHT CHARGES: Prepaid / Collect / Check box if charges are to be billed

RECEIVED, subject to the classifications and lawfully filed tariffs in effect on the date of the issue of this Bill of Lading, the property described above in apparent good order, except as noted (contents and condition of contents of packages unknown), marked, consigned, and destined as indicated above which said carrier (the word carrier being understood throughout this contract as meaning any person or corporation in possession of the property under the contract) agrees to carry to its usual place of delivery at said destination, if on its route, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed, as to each carrier of all or any of said property over all or any portion of said route to destination and as to each party at any time interested in all or any said property, that every service to be performed hereunder shall be subject to all the terms and conditions in the governing classification on the date of shipment. Shipper hereby certifies that he is familiar with all the bill of lading terms and conditions in the governing classification and the said terms and conditions are hereby agreed to by the shipper and accepted for himself and his assigns.

SHIPPER

PER

CARRIER

PER

DATE

1

Permanent post office address of shipper.

STYLE F65 LABELMASTER Div. of American Labelmark Co., Chicago, IL 60646 312/478-0900

Sample Bill of Lading

Wisconsin
Chapter HFS 157 -Radiation Protection Regulatory Guide

Draft Copy

Guidance for Fixed Gauge Devices.

Department of Health and Family Services
Radiation Protection Section
1 West Wilson Street
P.O Box 2659
Madison, WI 53701-2659
Phone: (608) 267-4797
Fax: (608) 267-3695

EXECUTIVE SUMMARY

Wisconsin Regulatory Guide (WISREGS) are issued to describe and make available to the public acceptable methods of implementing specific parts of Wisconsin Administrative Code, Chapter HFS 157 'Radiation Protection' to delineate techniques used by the staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants, licensees, or registrants. WISREGS are not substitutes for Chapter HFS 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 and Family Services (***DHFS***), 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 at all times and it will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to **Department of Health and Family Services, Radiation Protection Section, 1 West Wilson Street, 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 and Family Services, Radiation Protection Section, 1 West Wilson Street, P.O. Box 2659, Madison, WI 53701-2659**

This Wisconsin Regulatory Guide "Guidance for Fixed Gauge Devices" has been developed to streamline the application process of a fixed gauge device for the applicant. A copy of the application form#### "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 ***K*** 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 ***HFS 157.10*** for a fixed gauge device.

In summary, the applicant will need to do the following to submit an application for a fixed gauge license.

- Use this regulatory guide to prepare the application form####
- Complete the application form#### (***Appendix A***). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments.

  All supplemental pages should be typed on a 8 ½" x 11" paper.
  Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if applicable) and if possible a copy on a diskette or CD (Microsoft Word is preferred).
- Submit the application fee.
- Retain one copy of the licensee application and attachments (if applicable) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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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
BPR	business process redesign
Bq	Becquerel
Ca F2	calcium fluoride
Cf-252	californium-252
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
Ci	Curie
C/kg	coulomb per kilogram
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
d	day
DHFS	Department of Health and Family Services
DOE	United States Department of Energy
DOT	United States Department of Transportation
EDE	effective dose equivalent
FDA	United States Food and Drug Administration
ft	foot
GBq	gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
hr	hour
HFS 157	Wisconsin Administrative Code Chapter HFS 157 'Radiation Protection'
IN	Information Notice
IP	Inspection Procedure
kg	kilogram
Kr-85	krypton-85
LiF	lithium fluoride
m	meter
mCi	millicurie
mo	month
MOU	memorandum of understanding
mR	milliroentgen
mrem	millirem
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
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
OSP	Office of State Programs
P&GD	Policy and Guidance Directive
Q	Quality Factor
R	Roentgen
Rev.	revision
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
TAR	technical assistance request
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
URL	uniform resource locator
wk	week
yr	year

PURPOSE OF REPORT

This report provides guidance to an applicant in preparing a fixed gauge license application as well as the department'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 document, the phrases or terms, "fixed gauge," "gauging devices," or "gauges" are used interchangeably.

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

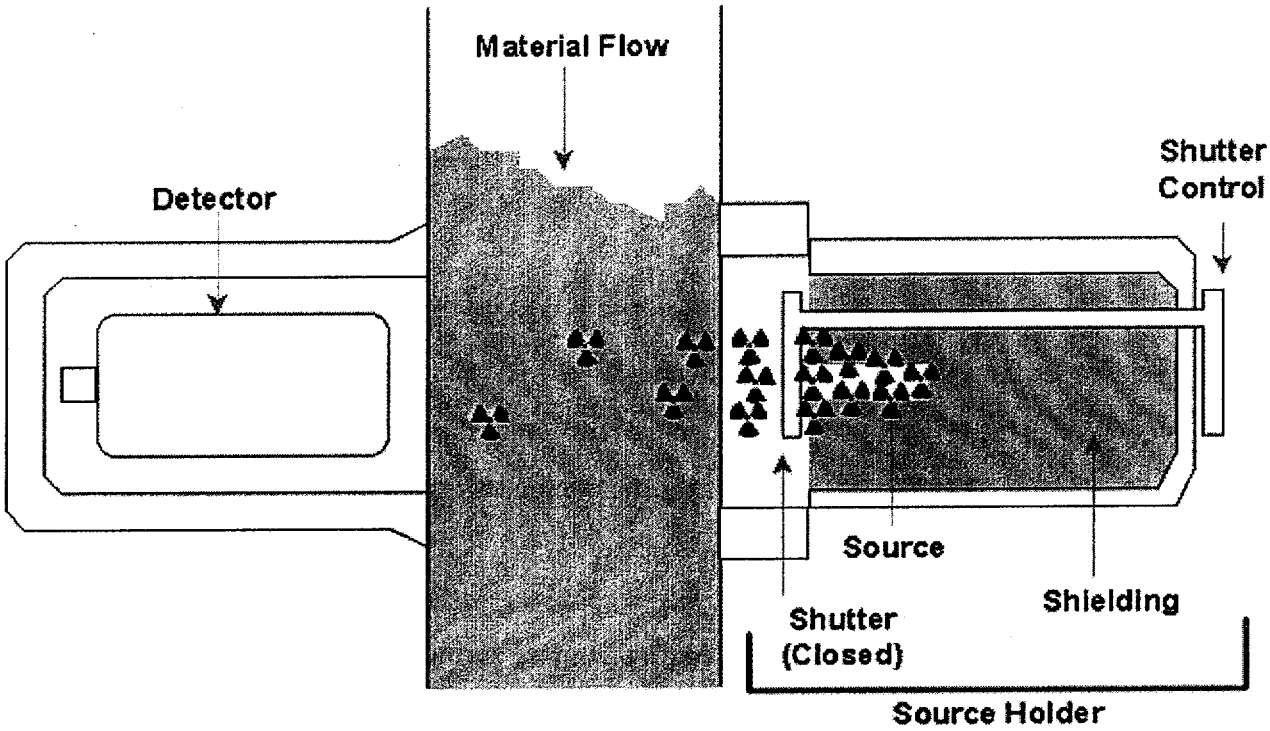

Figure 1. ***Fixed Gauge Basic Design Features***. Cutaway of a typical fixed gauge diagramming the basic design features: the source, source holder, detector, shutter, shutter control or on-off mechanism, and shielding.

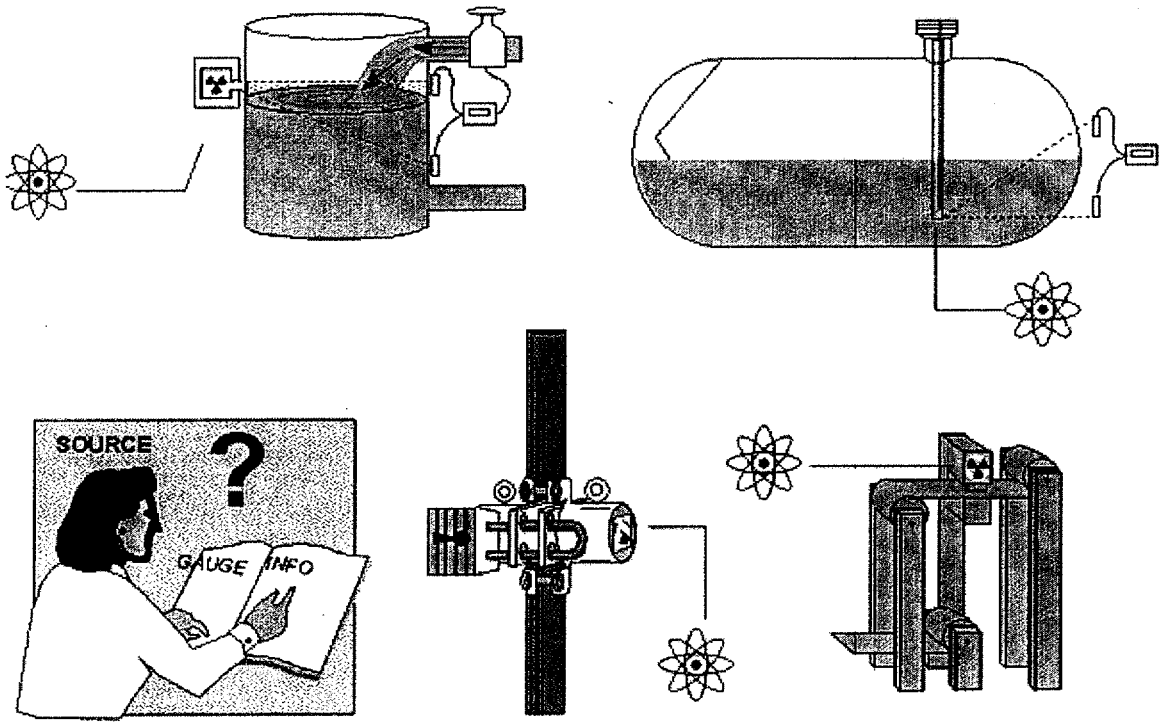

Figure 2. ***Where is the Radioactive Source***? The wide variety of fixed gauge designs results in different radiation safety considerations.

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

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

- Rule -- references the applicable parts of Chapter HFS 157 'Radiation Protection';
- 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.

Appendix C contains information needed for transfer of control. ***Appendix E*** contains a sample SSD Registration Certificate. ***Appendixes F*** through ***P*** contain additional information on various radiation

safety topics. ***Appendix Q*** is a sample fixed gauge license; it contains the conditions most often found on these licenses, although not all licenses will have all conditions.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent (EDE), committed dose equivalent (CDE), committed effective dose equivalent (CEDE), or total effective dose equivalent (TEDE). These terms are defined in Chapter HFS 157, Subchapter I. 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 HFS 157, Subchapter I 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 rad = 1 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 ***HFS 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 property of the citizens of Wisconsin in accordance with department 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 and adequate radiation safety program has been established. These requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule and these instructions prior to submitting the application.

MANAGEMENT RESPONSIBILITY

The department recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. The department also believes that consistent compliance with ***HFS 157*** provides reasonable assurance that licensed activities will be conducted safely. ***DHFS*** has found that effective management is 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 ***HFS 157***;
- Completeness and accuracy of the radiation safety records and all information provided to the department;
- 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;
- Selecting and assigning a qualified individual to serve as the Radiation Safety Officer (RSO) for their licensed activities.

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read and follow *HFS 157*.

The following subchapters of Chapter HFS 157 "Radiation Protection" contain regulations 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 the above documents, call ***Department of Health and Family Services, Radiation Protection Section*** at (608) 267-4797.

HOW TO FILE

PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application.
- Complete ***DHFS*** form#### (***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.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- 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.

Note: In this document, dose or radiation dose is used as defined in. HFS 157.03, i.e., a generic term that means absorbed dose, dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. These latter terms are also defined in HFS 157.03.

WHERE TO FILE

Applicants wishing to process or use radioactive material in Wisconsin are subject to the requirements of *HFS 157* and must file a license application with:

Department of Health and Family Services
Radiation Protection Section
1 West Wilson Street
P.O. Box 2659
Madison, WI 53701-2659
Phone: (608) 267-4797
Fax: (608) 267-3695

LICENSEE FEES

The appropriate fee must accompany each application or license amendment request. Refer to ***HFS 157.10*** to determine the amount of the fee. The department 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 the department's disposition of an application or the withdrawal of an application.

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

Direct all questions about the department's fees or completion of **Item 11** of ***DHFS*** Form#### ***(Appendix A***) to the ***Department of Health and Family Services, Radiation Protection Section*** at (608) 267-4797.

CONTENTS OF AN APPLICATION

Item 1: License Action Type

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

ITEM 1. TYPE OF APPLICATION (Check All That Apply)

☐ NEW LICENSE

☐ RENEWAL License #_____

☐ AMENDMENT License #_____

Item 2: Applicant's Name and Mailing Address

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material. A division or department within a legal entity may not be a licensee. An individual may be designated, as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent.

Note: The department must be notified in the event of change of ownership or control and bankruptcy proceedings; see below for more details.

Timely Notification of Change of Ownership or Control:

Regulations: ***HFS 157.13***

Criteria: Licensees must provide full information and obtain the department's **written consent prior** to transferring ownership or control of the license (commonly refereed to as "transferring the license").

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid ***DHFS*** 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.

Response from Applicant:

None from an applicant for a new license

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

Notification of Bankruptcy Proceedings.

Regulations: ***HFS 157.13(10)***

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

Response from Applicant:

None at time of application for a new license

Item 3: Person to Be Contacted about this Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer, unless the applicant has named a different person as the contact. ***DHFS*** will contact this individual if there are questions about the application.

Notify ***DHFS*** if the contact person or his or her telephone number changes so that ***DHFS*** 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.

Applicants should note that deviations from the suggested responses and submission of alternative procedures may require custom review.

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

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

A ***DHFS*** 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 report called "Fixed Gauges Used at Temporary Job

Sites." That section offers examples of operations where fixed gauges might be used at temporary job sites and gives information that should be provided to the department to support a request for these operations.

Note: As discussed later in the section "Financial Assurance and Record Keeping for Decommissioning," licensees do 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)

Regulations: ***HFS 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
- 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 ***DHFS*** limits (e.g., installation, initial radiation survey, gauge relocation, and removal of the gauge from service). See "Radiation Safety Program - Maintenance" in this report and ***Appendix N***, "Non Routine Operations."

Discussion: The person responsible for the radiation protection program is called the Radiation Safety Officer (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 3** and described in ***Appendix F***. ***DHFS*** 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.

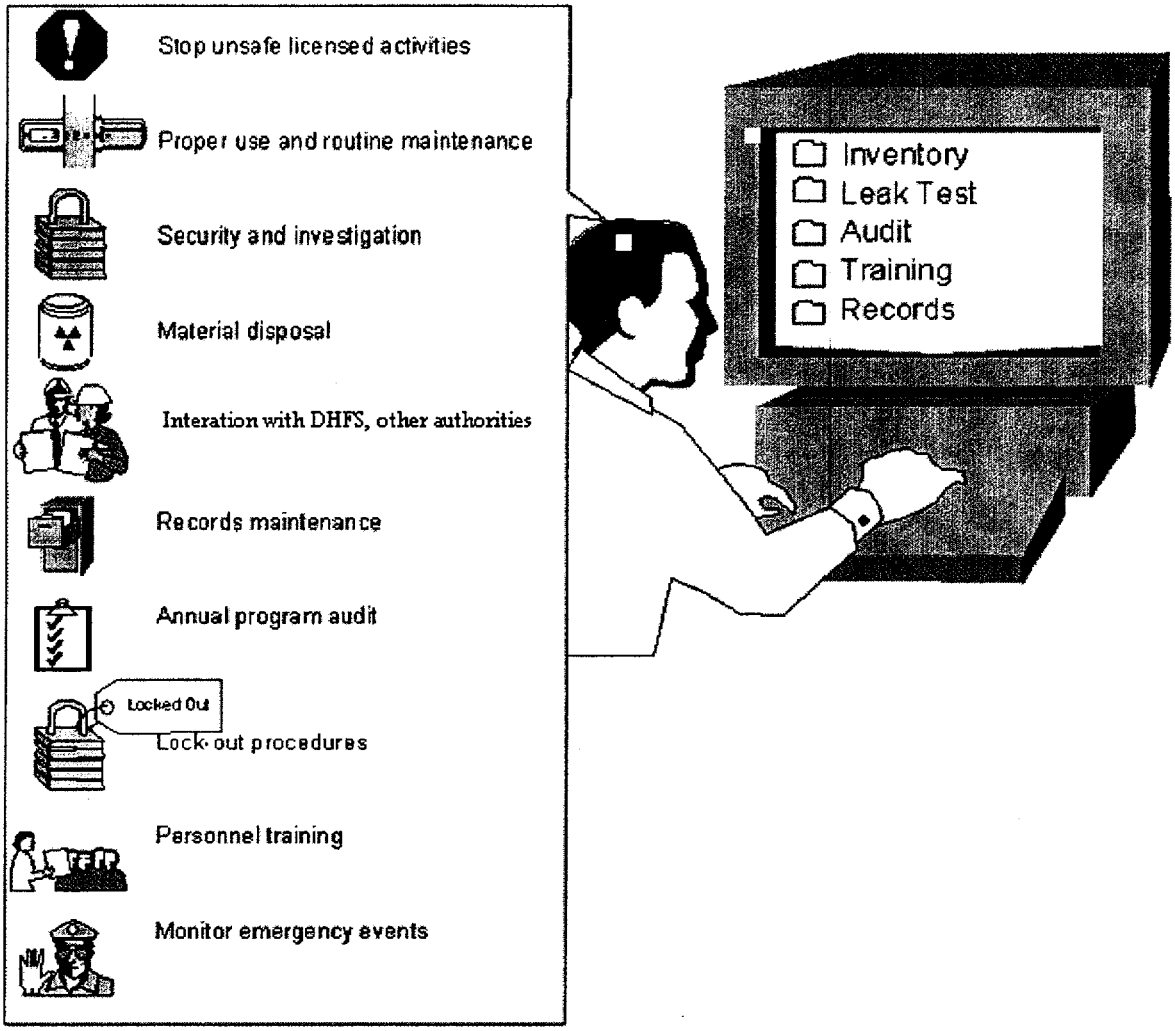

Figure 3. ***RSO Responsibilities.*** Duties and responsibilities of RSOs.

Response from Applicant: Provide the following:

ITEM 5. RADIATION SAFETY OFFICER (RSO) *(Attach evidence of training and experience and check one box)*

NAME:_____ TELEPHONE (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 entitled "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience- Radiation Safety Officer" in WISREG "Guidance for Fixed Gauge Devices."

AND

Before being named as the RSO, future RSOs will have successfully completed one of the training courses described in Criteria in the section entitled " Individual(s) Responsible for Radiation Safety Program and Their Training and Experience- 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.

Note:

- It is important to notify ***DHFS***, as soon as possible, of changes in the designation of the RSO;

- Alternative responses will be evaluated using the criteria listed above

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

Regulations: ***HFS 157.13(2)***

Criteria: Authorized users (AUs) must have adequate training and experience. Successful completion of one of the following is evidence of adequate training and experience:

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

Applicants requesting 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, must provide additional training. See the section in this report entitled "Radiation Safety Program - Maintenance" and ***Appendix N*** "Information Needed to Support Applicant's Request to Perform Non-Routine Operations".

Discussion: An AU is a person whose training and experience meet the department'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: Provide the following:

ITEM 6. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Check one box)

☐ Before using radioactive material, authorized users will have successfully completed one of the training courses described in Criteria in the section entitled " Training for Individuals Working In or Frequenting Restricted Areas" in WISREG " Guidance for Fixed Gauge Devices."

NOTE: IF USING IN-HOUSE TRAINING PROGRAM SUBMIT, COPY OF COURSE CONTENT, SAMPLE COURSE EXAMINATION AND COURSE INSTRUCTOR QUALIFICATIONS.

OR

☐ Documentation of the training and experience for the proposed gauge user(s) is/are attached.

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

Radioactive Material

Item 7: Radioactive Material and Item 8. Chemical and Physical Form

Part 1: Sealed Sources and Devices

Regulations: ***HFS 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 department, the **NRC** or an Agreement State.

Discussion: **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 4**.

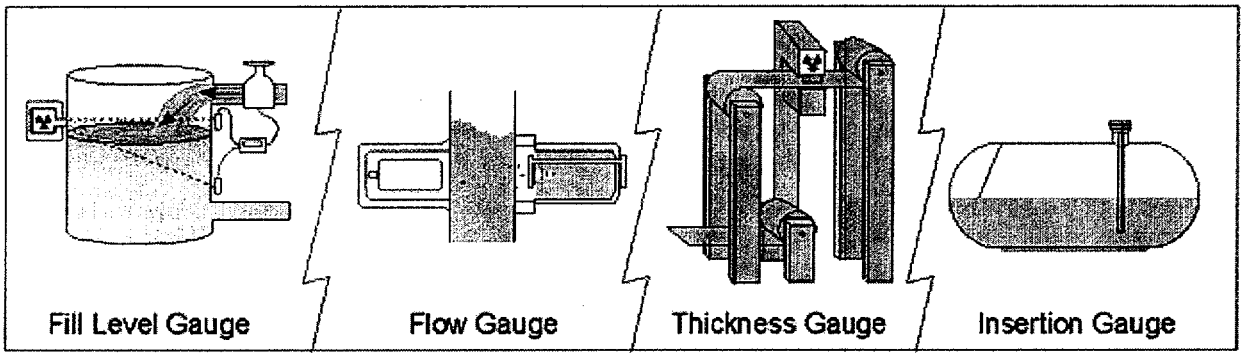

Figure 4. Examples of Several Different Types of Fixed Gauges.

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 ***DHFS's*** prior permission in a license amendment. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSD Registration Certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce 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 ***DHFS***, 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 department, 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 Registration Certificate.

Response from Applicant:

ITEM 7. RADIOACTIVE MATERIAL *(ATTACH ADDITIONAL PAGES IF NECESSARY)*			
ELEMENT AND MASS NUMBER	☐ Cobalt-60	☐ Krypton-85	☐ Americium-241
	☐ Cesium-137	☐ Strontium-90	☐ Ra-226
	☐ Other Isotope (*please specify*): _____		
ITEM 8. CHEMICAL AND PHYSICAL FORM	**SEALED SOURCES**		
SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER			
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 Registration Certificate)*			
SEALED SOURCE AND DEVICE REGISTRATION SHEET NUMBER			
INTENDED USE			

Note: Information on SSD registration certificates is also available electronically on the **NRC**'s Sealed Source and Devices Bulletin Board System (SS&D BBS) which can be accessed on the Internet at: http://www.hrsrd.ornl.gov/nrc/ssdrform.htm. SSD registration certificates include reviews by the **NRC** and Agreement States. Contact the department for assistance with locating specific SSD registration certificates.

Part 2: Financial Assurance and Recordkeeping for Decommissioning

Regulations: ***HFS 157.13(9)(b) and (10); HFS 157.15***

Criteria: Fixed gauge licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in ***HFS 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 ***HFS 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 ***HFS 157.13(10).***
- The department 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 applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the thresholds in ***HFS 157.15.***The thresholds for typical radionuclides used for fixed gauge sealed sources are shown in **Table 1**.

Table 1 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

A licensee would need to possess hundreds of gauges before the financial assurance requirements would apply. Since the standard gauge license does not specify the maximum number of gauges that a licensee may possess (allowing flexibility in obtaining additional gauges specifically authorized by the license as needed without amending its license), it contains a condition requiring the licensee to limit its possession of fixed gauges to quantities not requiring financial assurance. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance.

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

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All fixed gauge licensees need to maintain records of structures and equipment where each gauge was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. If no records exist regarding structures and equipment where gauges were used or stored, licensees shall make all reasonable efforts to create such records based 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.

Response from Applicant:

No response is needed from most applicants. If financial assurance is required submit evidence.

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

References: *NRC Regulatory Guide 3.66* "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72," is available from the department upon request.

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

Regulations: ***HFS 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 department license.

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

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

Response from Applicant: Provide either of the following:

ITEM 7. RADIOACTIVE MATERIAL *(ATTACH ADDITIONAL PAGES IF NECESSARY)*			
ELEMENT AND MASS NUMBER	☐ Cobalt-60	☐ Krypton-85	☐ Americium-241
	☐ Cesium-137	☐ Strontium-90	☐ Ra-226
	☐ Other Isotope (*please specify*): _____		
ITEM 8. CHEMICAL AND PHYSICAL FORM	**SEALED SOURCES**		
SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER			
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 Registration Certificate)*			
SEALED SOURCE AND DEVICE REGISTRATION SHEET NUMBER			
INTENDED USE			

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 10.13**) indicate in purpose of use.

Item 9: Facilities and Equipment

Regulations: ***HFS 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 the department with specific information demonstrating that the proposed new conditions will not impact the safety or integrity of the source or device.

Chapter HFS 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. Chapter HFS 157 'Radiation Protection' also 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.

You should keep in mind that the device needs to be in storage or physically watched by authorized users at all times. It is not acceptable for a device to be chained to a post or left lying unattended at the place of use during lunch or breaks, because the device would then be accessible to unauthorized persons.

Response from Applicant: Provide one of the following:

ITEM 9. FACILITIES AND EQUIPMENT (*Check boxes and attach diagram.*)

☐ Diagrams of radioactive material area(s) of use are attached.

☐ 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.

Note:

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

References: Information Notices are available in the "Reference Library" on **NRC**'s Home Page at http://www.nrc.gov: Information on SSD registration certificates is also available electronically on the **NRC**'s Sealed Source and Devices Bulletin Board System (SS&D BBS) which can be accessed on the Internet at: http://www.hrsrd.ornl.gov/nrc/ssdrform.htm. SSD registration certificates include reviews by the **NRC** and Agreement States. Contact the department for assistance with locating specific SSD registration certificates.

Item 10: Radiation Safety Program

Item 10.1: Radiation Safety Program - Audit

Regulations: ***HFS 157.21; HFS 157.31(13)***

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 department and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (***HFS 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 the department. 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 the department'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; IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," provides guidance on this subject. The department 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 department will normally exercise discretion and may elect not to cite a violation. The department'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. ***DHFS*** 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 10.1 RADIATION SAFETY PROGRAM -AUDIT

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

References: Information Notices (i.e., IN 96-28) are available in the "Reference Library" on **NRC**'s Home Page at http://www.nrc.gov.

Item 10.2: Radiation Safety Program – Termination of Activities

Regulations: ***HFS 157. 32(8); HFS 157.13; HFS 157.15; HFS 157.31***

Criteria: The licensee must do the following:

- Notify ***DHFS***, in writing, within 60 days of:
  - the expiration of its license
  - a decision to permanently cease licensed activities at the *entire site* (regardless of contamination levels)
  - a decision to permanently cease licensed activities in *any separate building or outdoor area*, if they contain residual radioactivity making them unsuitable for release according to department requirements.
  - no principal activities having been conducted *at the entire site* under the license for a period of 24 months
  - no principal activities having been conducted for a period of 24 months in *any separate building or outdoor area*, if they contain residual radioactivity making them unsuitable for release according to department requirements.

- Submit decommissioning plan, if required by ***HFS 157.13***.

- Conduct decommissioning, as required by ***HFS 157.13***.

- Submit, to the department a completed ***DHFS*** Form ####, "Request for Termination of Specific License and Disposition of Radioactive Material" (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).

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

Discussion: As noted in several instances discussed in "Criteria," before a licensee can decide whether it must notify ***DHFS***, 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 department requirements. A licensee's determination that a facility is not contaminated is subject to verification by department inspection.

For guidance on the disposition of radioactive material, see the section on "Waste Management -Gauge Disposal or Transfer." For guidance on decommissioning records, see the section on "Radioactive Materials - Financial Assurance and Record Keeping for Decommissioning."

Response from Applicant:

ITEM 10.2 RADIATION SAFETY PROGRAM-TERMINATION OF ACTIVITIES (*Check Box*)

☐ We will notify ***DHFS***, on a departmental form, within 30 days of the decision to permanently cease radioactive material use. *s.* ***HFS 157.13 (11) (c)***

Item 10.3: Survey Equipment and Item 10.4: Instrument Calibration

Regulations: ***HFS 157.13(2); HFS 157.25(1); HFS 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: Usually it is not necessary for fixed gauge licensees to possess a survey meter. However, surveys according to ***HFS 157.25(1)*** will be required if an applicant plans to conduct non-routine operations. This includes installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed source, and non-routine maintenance and repair of components related to the radiological safety of the gauge. Because some of these operations may increase the risk of radiation exposure, individuals performing these operations should be carefully monitored with a survey meter. Such survey meters should be properly calibrated. Proper calibration is particularly 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 ***DHFS***. Licensees who perform surveys pursuant ***to HFS 157.25(1)*** must possess a survey meter that:

- Measures at least 0.3 through 200 mR per hour (50 microcoulombs per kilogram)
- Is capable of measuring the radiation being emitted from the gauge's sealed source
- Is checked for functionality with a source of radiation at the beginning of each day of use (e.g., with the gauge or a check source)
- Is calibrated:
    - At intervals not to exceed 12 months
    - Using a source of radiation similar to those found in the gauges
    - To ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than ± 20% on each scale
    - After any servicing or repair (other than a simple battery exchange)
    - By the instrument manufacturer or person specifically authorized by the department, the **NRC** or an Agreement State.

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 **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.

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

Response from Applicant:

ITEM 10.3 SURVEY EQUIPMENT (*Check one box*)

☐ We will either possess and use, or have access to and use, a radiation survey meter that meets the Criteria in the section entitled " Radiation Safety Program – Instruments" in WISREG "Guidance for Fixed Gauge Devices."

OR

☐ We will submit an alternative procedure for determining source integrity after an incident involving the fixed gauge device. (Procedure attached)

And

ITEM 10.4 INSTRUMENT CALIBRATION (*Check one box*)

☐ Surveys according to ***s. HFS 157.25 (1)*** will be performed by a person specifically authorized by ***DHFS***, the **NRC** or an Agreement State to perform these surveys.

OR

☐ We will use survey instruments that meet the Criteria in the section entitled 'Radiation Safety Program – Instruments' in WISREG "Guidance for Fixed Gauge Devices".

AND ONE OF THE FOLLWING

- ☐ Each survey meter will be calibrated by the manufacturer or other person authorized by ***DHFS***, the **NRC** or an Agreement State to perform survey meter calibrations.
- ☐ We will implement the model survey meter calibration program published in Appendix I entitled 'Survey Instrument Calibration' in WISREG "Guidance for Fixed Gauge Devices."
- ☐ We will submit alternative calibration procedures for ***DHFS*** review.

Notes:

- Alternative responses will be reviewed against the criteria listed above.
- The department license will state that the instrument manufacturer will perform survey meter calibrations or a person specifically authorized by the department, 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.

Item 10.5: Material Receipt and Accountability

Regulations: ***HFS 157.13; HFS 157.31; HFS 157.28(1)(a); HFS 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 the department, to account for all sealed sources.

Discussion: As illustrated in **Figure 5**, 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 Information Notice 88-02, "Lost or Stolen Gauges," dated February 2, 1988.

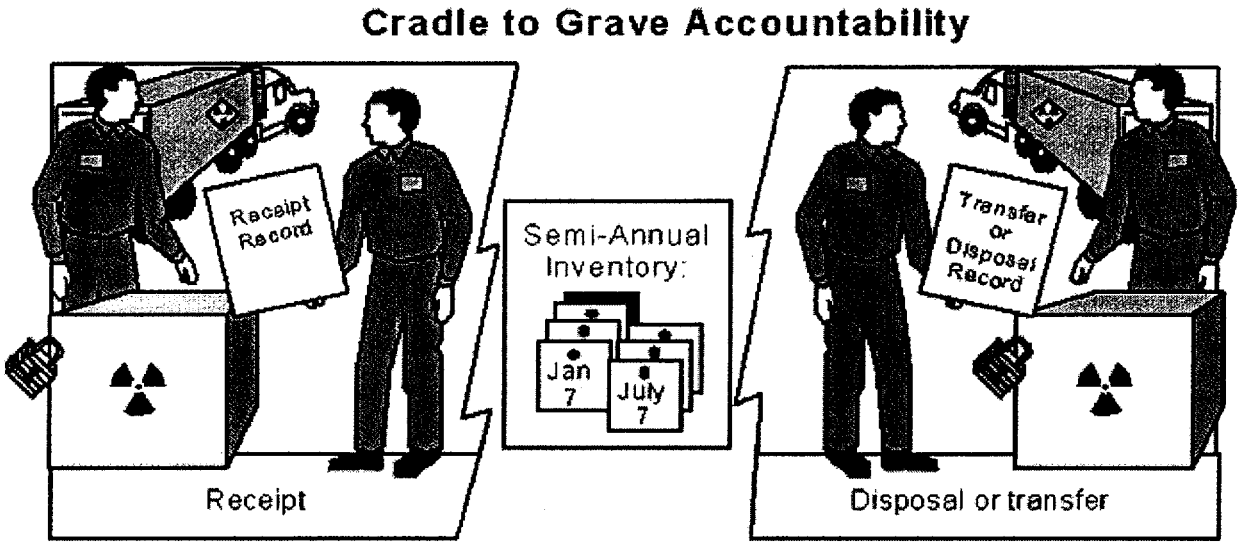

Figure 5. ***Material Receipt and Accountability.*** Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories.

Receipt, transfer, and disposal records must be maintained for the times specified in **Table 2**. 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 2 Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until ***DHFS*** terminates the license
Important to Decommissioning*	Until the site is released for unrestricted use
* See the section entitled "Financial Assurance and Recordkeeping for Decommissioning."	

Response from Applicant:

ITEM 10.5 MATERIAL RECEIPT AND ACCOUNTABLITY (*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. *s. HFS 157.15*

References: Information Notices (i.e. IN 88-02) are available in the "Reference Library" on **NRC**'s Home Page at http://www.nrc.gov

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Item 10.6: Occupational Dose

Regulations: ***HFS 157.25(2); HFS 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 6**

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.

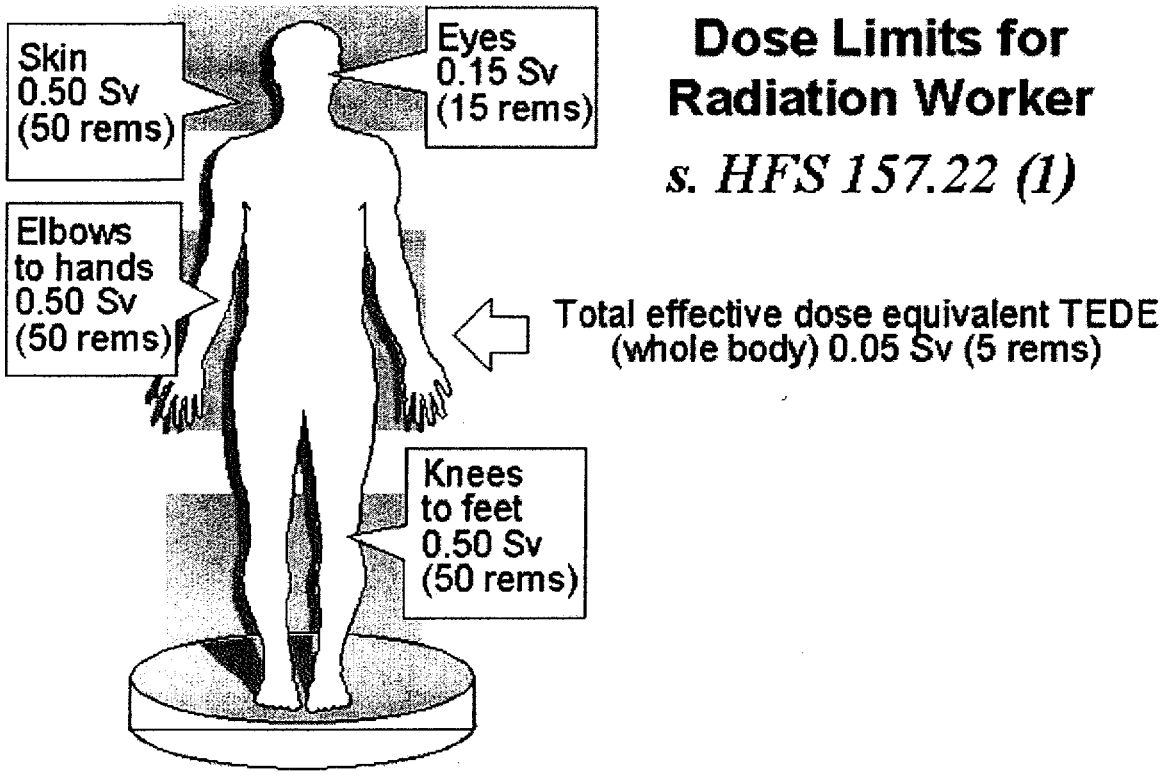


Figure 6. ***Annual Dose Limits for Occupationally Exposed Adults.***

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 6** 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 6**. 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 6.**

When personnel monitoring is needed, most licensees use either film badges, thermoluminescent dosimeters (TLDs) or Optically Stimulated Luminescence (OSLs) that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. The exchange frequency for TLDs is usually 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 10.6 OCCUPATIONAL DOSIMETRY (*Check one box*)
☐ We will maintain, for inspection by ***DHFS***, 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. ***HFS 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:

- Alternative responses will be evaluated using the criteria listed above.
- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with department requirements (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, whose URL is 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 10.7 Public Dose

Regulations: ***HFS 157.23(1-2); HFS 157.03; HFS 157.28(1)(a-b); HFS 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.
- Prevent unauthorized access, removal, or use of fixed gauges.

Discussion: Public dose is defined in Chapter HFS 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. IN 81-37, "Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices," dated December 15, 1981, provides information about two events that resulted or may have resulted in unnecessary radiation exposure to members of the public and to maintenance workers. 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 7.**

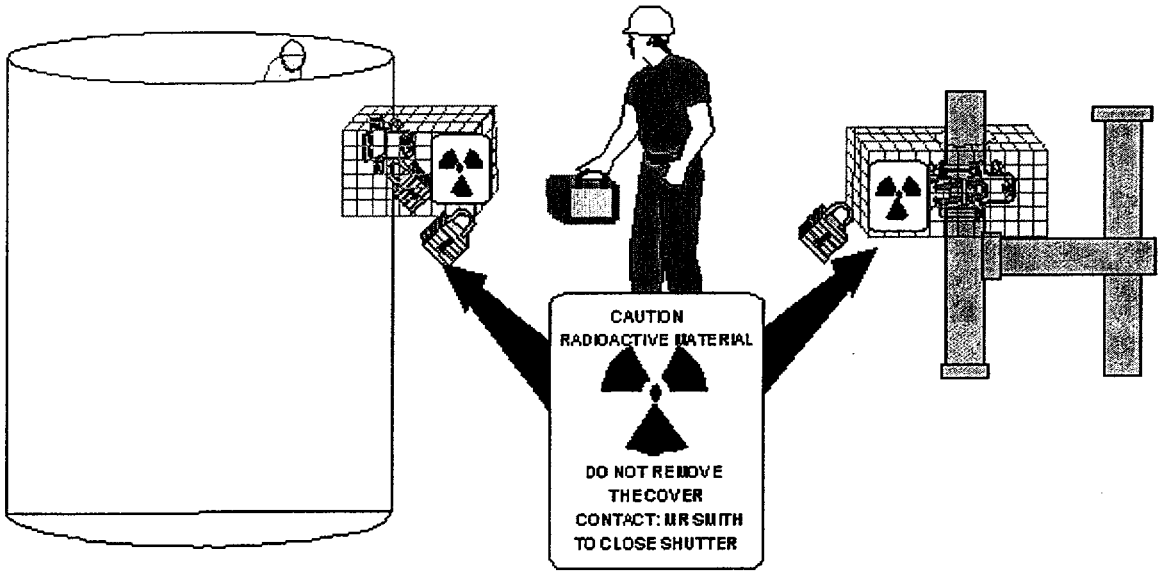


Figure 7. ***Limiting Public Dose.***

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 department 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 10.7 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: IN 81-37, "Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices," dated December 15, 1981, and IN 88-02, "Lost or Stolen Gauges," dated February 2, 1988 are located on the **NRC**'s webpage at http://www.nrc.gov.

Item 10.8 Operating and Emergency Procedures

Regulations: ***HFS 157.13; HFS 157.21; HFS 157.28(1)(a-b); HFS 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 the department, 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 the department 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 the department, the **NRC** or an Agreement State.
    - Require timely reporting to ***DHFS*** pursuant to ***HFS 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: ***DHFS*** 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 8** 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).

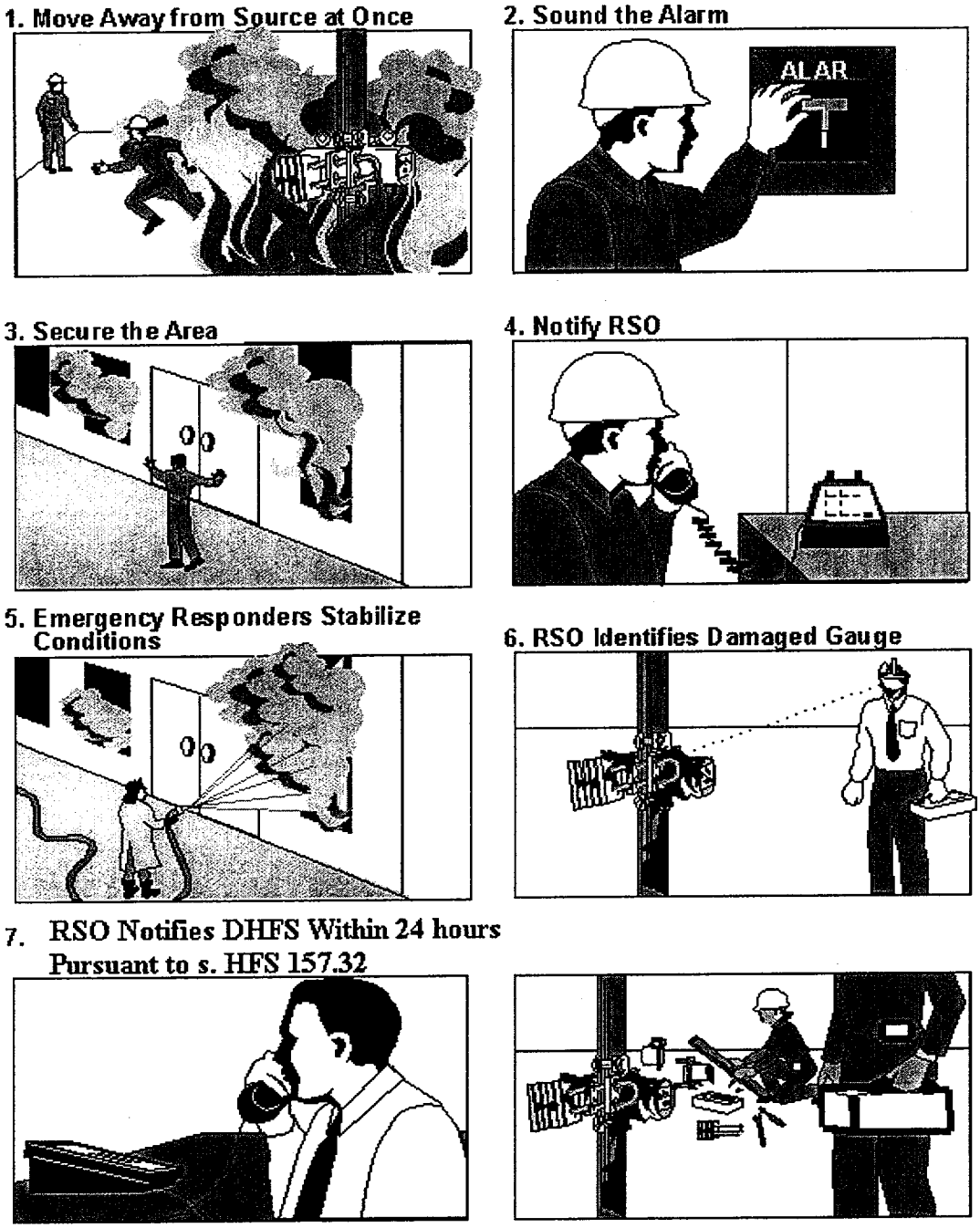


Figure 8. ***Proper Handling of Incident.*** Licensee personnel implement emergency procedures when a fire melts the lead shielding of a gauge producing the potential for elevated exposure levels.

DHFS 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).

The department must be notified when gauges are lost, stolen, or certain other conditions occur. The RSO must be proactive in evaluating whether ***DHFS*** notification is required. Refer to ***Appendix P*** and the regulations (***HFS 157.32***) for a description of when and where notifications are required.

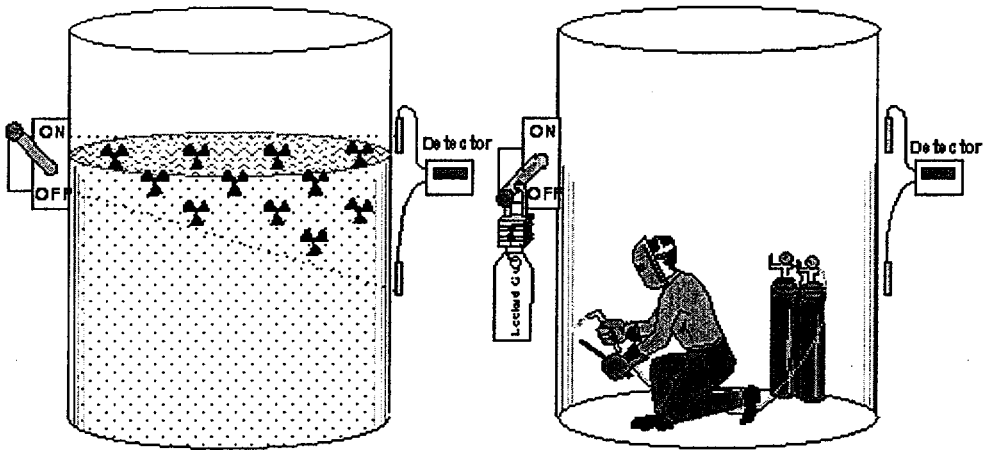


Figure 9. ***Lock-out Procedures***. Typical lock-out procedures include locking the shutter into the "off" position and tagging the shutter control mechanism to indicate the gauge is locked-out.

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:

ITEM 10.8 OPERATING AND EMERGENCY PROCEDURES (*Check one box*)

☐ 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.

OR

☐ We will develop, implement and maintain operating and emergency procedures that will meet criteria in the section entitled 'Radiation Safety Program – Operating and Emergency Procedures' in WISREG " Guidance for Fixed Gauge Devices." **(Attach Procedures)**

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 10.13**) must be submitted.

References: IN 81-37, "Unnecessary Radiation Exposures to the Public and Workers During Events Involving Thickness and Level Measuring Devices," dated December 15, 1981; IN 86-31, "Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges," dated May 5, 1986; IN 88-02, "Lost or Stolen Gauges," dated February 2, 1988; IN 88-90 "Unauthorized Removal of Industrial Nuclear Gauges," dated November 22, 1988; and IN 94-15, "Radiation Exposures during an Event Involving a Fixed Nuclear Gauge," dated March 2, 1994 are located on the **NRC**'s webpage at Http://www.nrc.gov.

Item 10.9 Leak Tests

Regulations: ***HFS 157.06(3); HFS 157.25(1); HFS 157.31(3)***

Criteria: The department 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 the department, 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 the department, 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 10** 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.

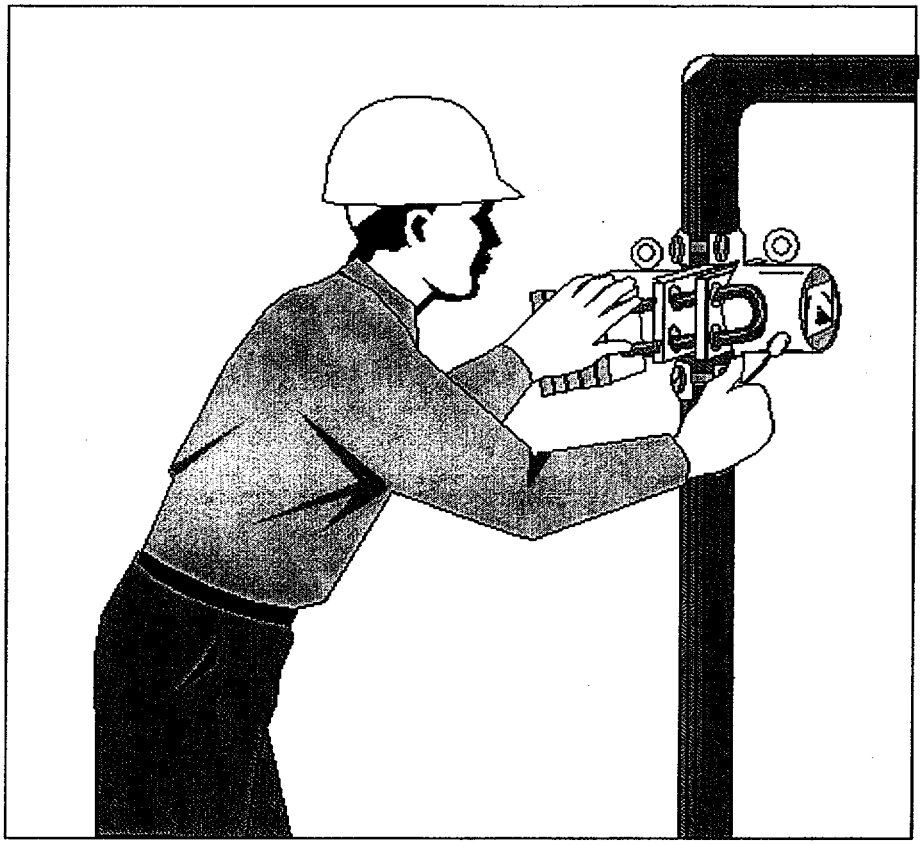


Figure 10. ***Leak Test Sample.*** A leak test sample is collected according to the gauge manufacturers and the leak test kit supplier's instructions.

Response from Applicant:

ITEM 10.9 LEAK TEST (*Check one box*)

☐ Leak tests will be performed by an organization authorized by ***DHFS***, 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 ***DHFS***, the **NRC** or an Agreement State to provide leak test kits to other licensees according to kit suppliers instructions.

License number of organization authorized to perform or analyze leak test (Specify whether Department, **NRC**, or other 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, ***DHFS*** staff will authorize via a license condition.

References: Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985 is available on the **NRC**'s webpage at Http://www.nrc.gov

Item 10.10 Maintenance

Regulations: ***HFS 157.21; HFS 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 the department limits.

Non-routine repair or maintenance must be performed by the fixed gauge manufacturer or distributor or a person specifically authorized by the department, 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.***

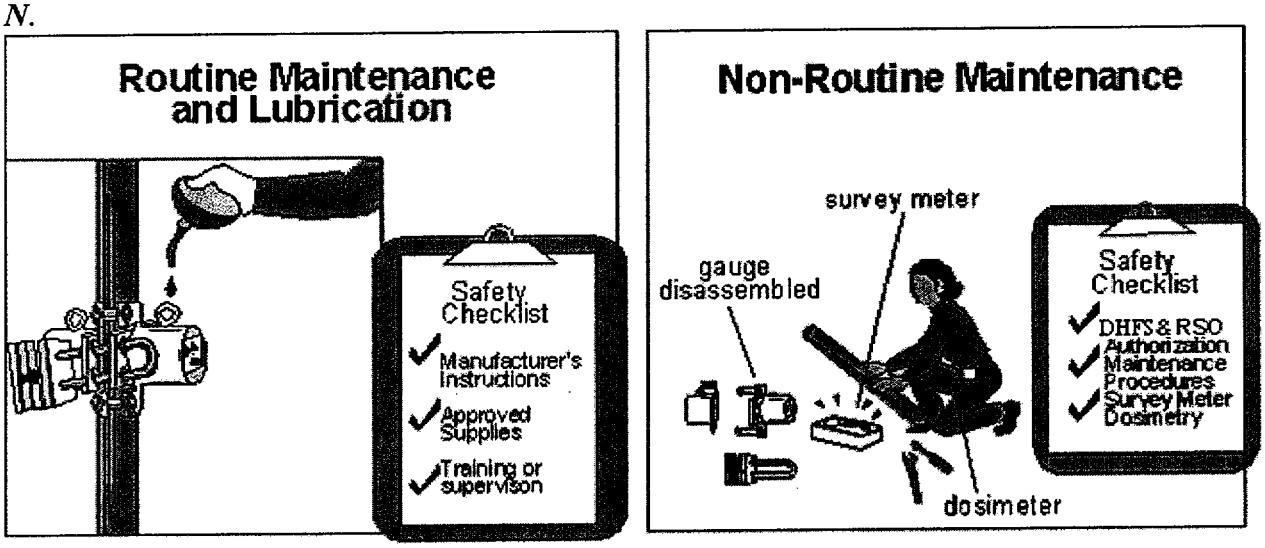


Figure 11. ***Maintenance.*** Licensees need to perform routine maintenance to ensure proper operation of the fixed gauge. For non-routine maintenance, most licensees rely on the gauge manufacturer, distributor or other service companies.

Discussion: The department 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. Generally, before any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

- The tasks to be performed
- The protocol or procedures to be followed
- The radiation safety procedures including possible need for compensatory measures (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 the department 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 department, **NRC** or Agreement State authorization is required to install a gauge. However, a licensee may initially mount a gauge, without specific department, **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 department, 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 the department, the **NRC** or an Agreement State to perform such operations.

A condition in the department'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 the department, 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 the department, 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 10.10 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.

OR

☐ We have provided the information listed in Appendix Z of WISREG "Guidance for Fixed Gauge Devices" to support a request to perform this work "in house." **(Procedure Attached)**

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.

Item 10.11: Fixed Gauge Disposal and Transfer

Regulations: ***HFS 157.30 (1); HFS 157.13 (11&15); HFS 157.31***

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

Discussion: When disposing of fixed gauges, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer or distributor of the device, a commercial firm licensed by the department, 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 ***HFS 157.13 (15).*** In addition, all packages containing radioactive sources must be prepared and shipped in accordance with the department rules and DOT regulations. Records of the transfer must be maintained as required by ***HFS 157.31.***

Response from Applicant:

ITEM 10.11 FIXED GAUGE DISPOSAL AND TRANSFER

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

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 Information Notice 86-31, "Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges," dated May 5, 1986, and IN 88-02, "Lost or Stolen Gauges," dated February 2, 1988.

References: IN 86-31, "Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges," dated May 5, 1986 and IN 88-02, "Lost or Stolen Gauges," dated February 2, 1988 are available at the **NRC**'s webpage http://www.nrc.gov.

Item 10.12 Transportation

Regulations: ***HFS 157.92(3); 49 CFR Parts 171-178; HFS 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 the department, the **NRC** or Agreement State.

OR

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

Discussion: Some fixed gauge licensees have the manufacturer, distributor or other person specifically licensed to transport gauges by the department, the **NRC** or Agreement State arrange for preparing and shipping licensed material. If licensees decide to transport their own gauges, they are responsible for compliance with DOT regulations 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 regulations and provides an example of a shipping paper. During an inspection, the department uses the provisions of Chapter HFS 157 'Radiation Protection' subchapter 13 to examine and enforce transportation requirements applicable to gauge licensees.

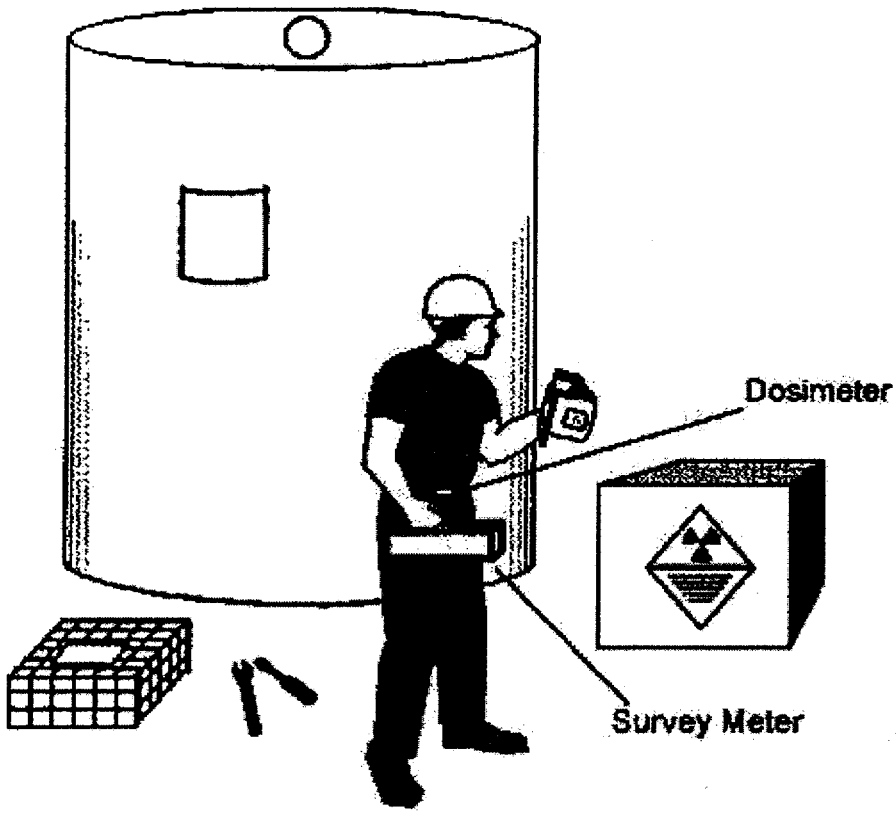


Figure 12. ***Transportation.*** Illustration of a fixed gauge being disassembled and packaged for transport.

Response from Applicant:

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 (1998 revision)" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425.

Item 10.13 Fixed Gauges Used at Temporary Job Sites

Regulations: ***HFS 157.13; HFS 157.21; HFS 157.28; HFS 157.32***

Criteria: Each applicant requesting authorization to perform work with fixed gauges at temporary job sites should do the following:

Develop, implement, maintain, and distribute operating and emergency procedures containing the following elements:

- Instructions for transporting radioactive material to ensure compliance with DOT regulations
- 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 13**)
- Steps to take, and who to contact, when a gauge has been lost or damaged (e.g., local officials, RSO, etc.) (See **Figure 13**)
- 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.

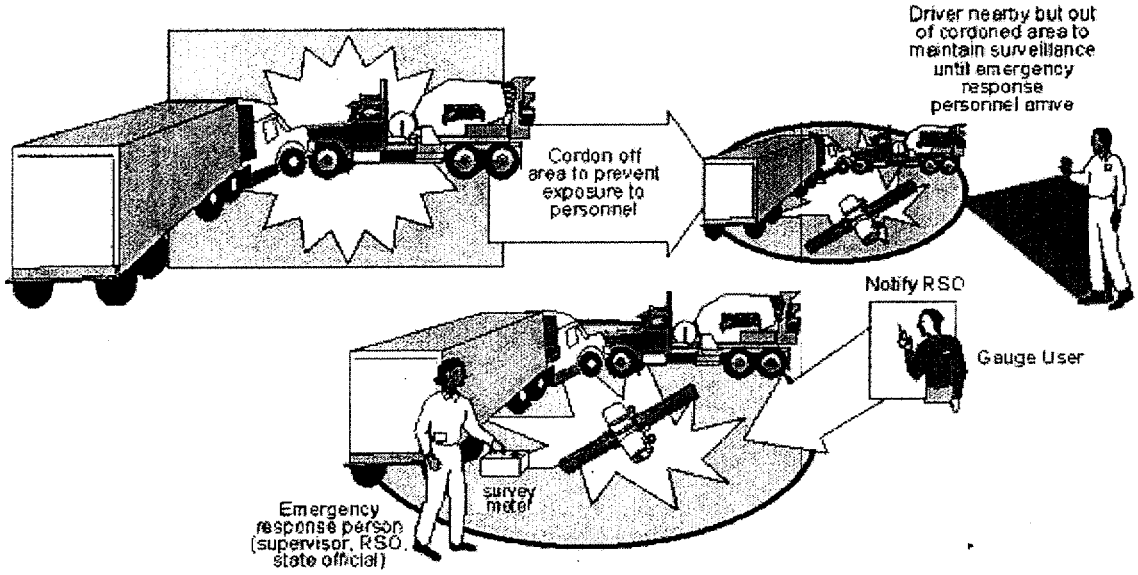


Figure 13. ***Proper Handling of Incident.*** Licensee personnel implement emergency procedures when a traffic accident results in a damaged gauge and potentially elevated exposure levels.

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. The department considers such a location to be a field office. Licensees must apply for and receive a license amendment specifically listing each field office location.

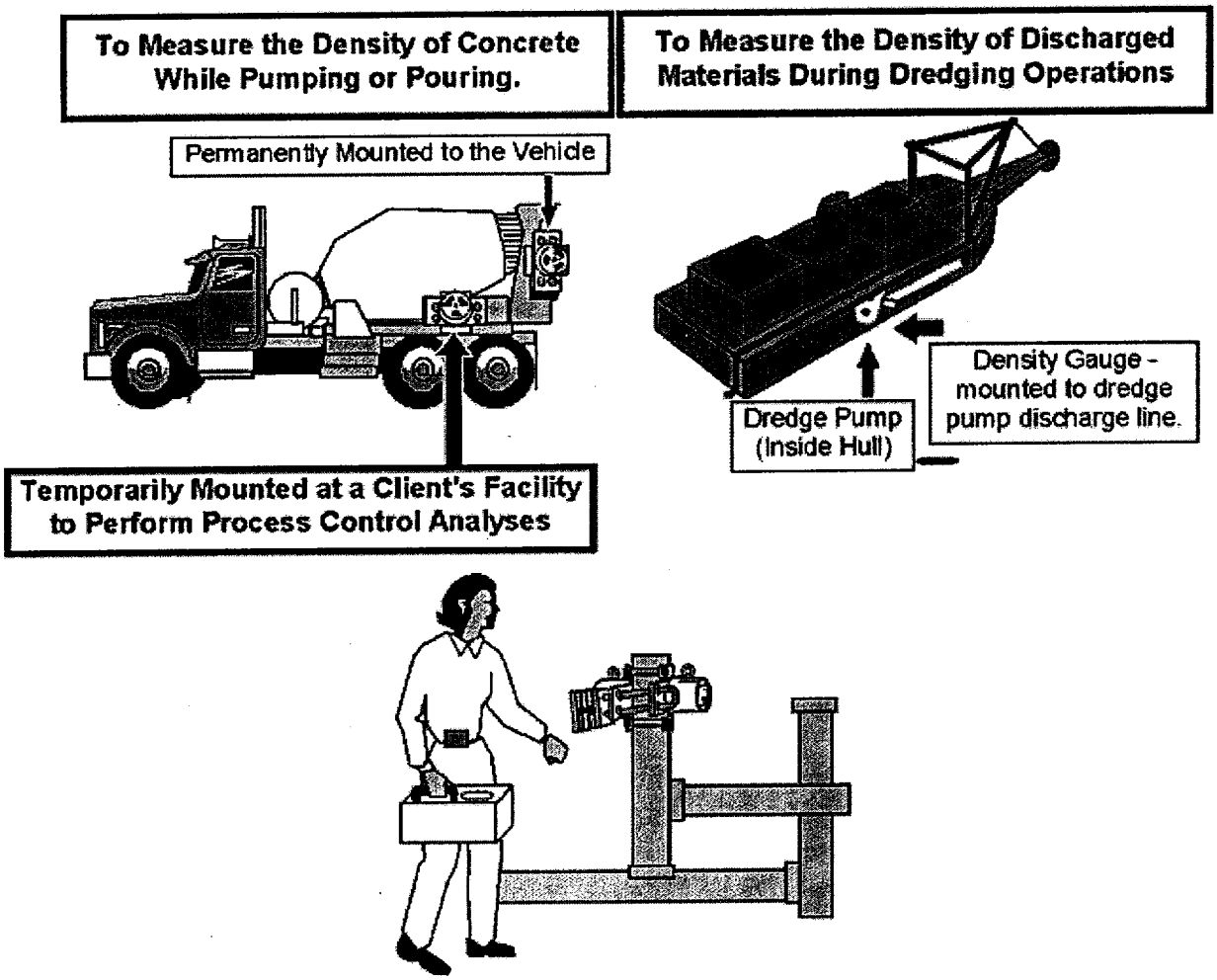
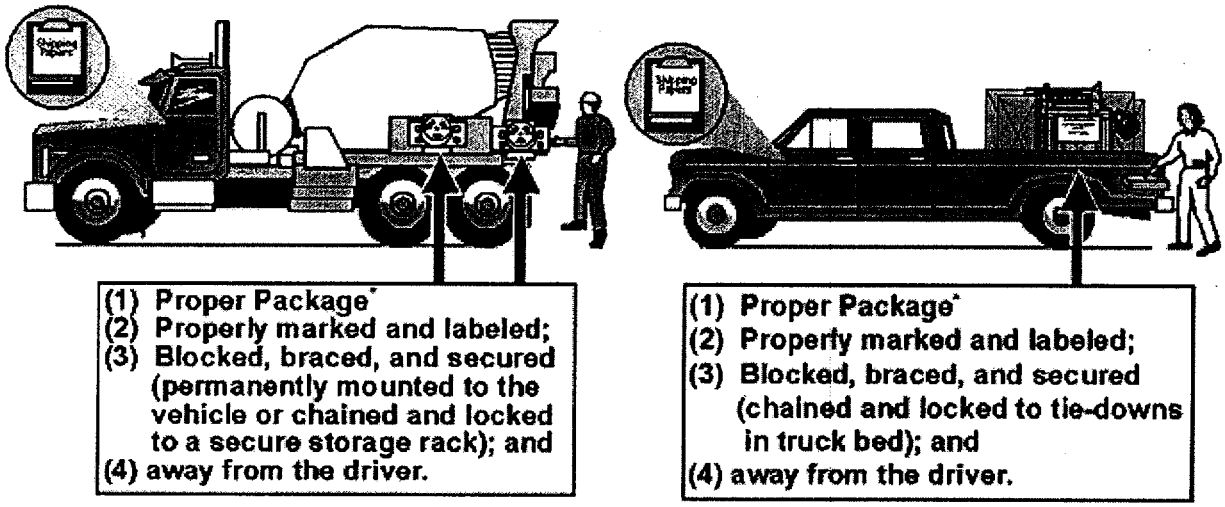


Figure 14. ***Examples of Uses for Fixed Gauges at Temporary Job Sites.***

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 14.**



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

Figure 15. ***DOT Transportation Requirements.***

Applicants must develop, implement, and maintain safety procedures for off-site transport of radioactive material to ensure compliance with DOT regulations. **Figure 15** illustrates some important DOT requirements for gauge licensees. During an inspection, the department will use the provisions of Chapter HFS 157 'Radiation Protection' subchapter 13 to examine and enforce transportation requirements applicable to fixed gauge licensees. ***Appendix O*** lists major DOT regulations and provides examples of shipping documents, placards, and labels.

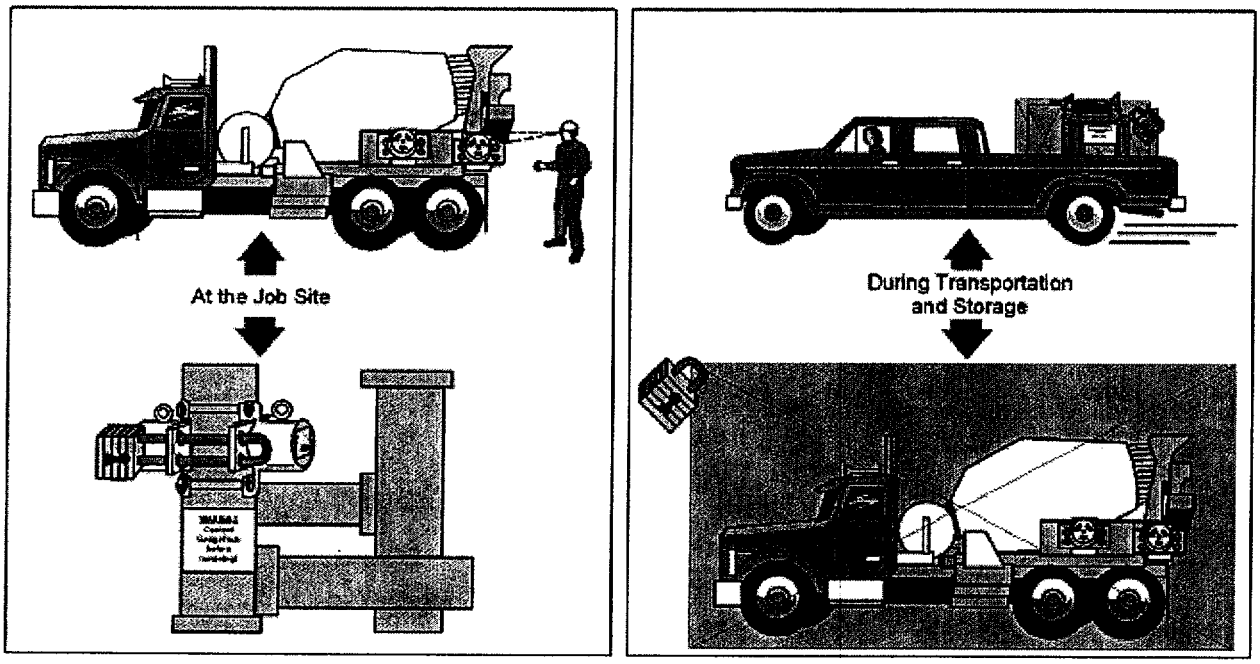


Figure 16. ***Security.*** Examples of Methods used to Secure Fixed Gauges at Temporary Job Sites.

When working at a temporary job site, licensees generally have to follow the rules 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 16**.

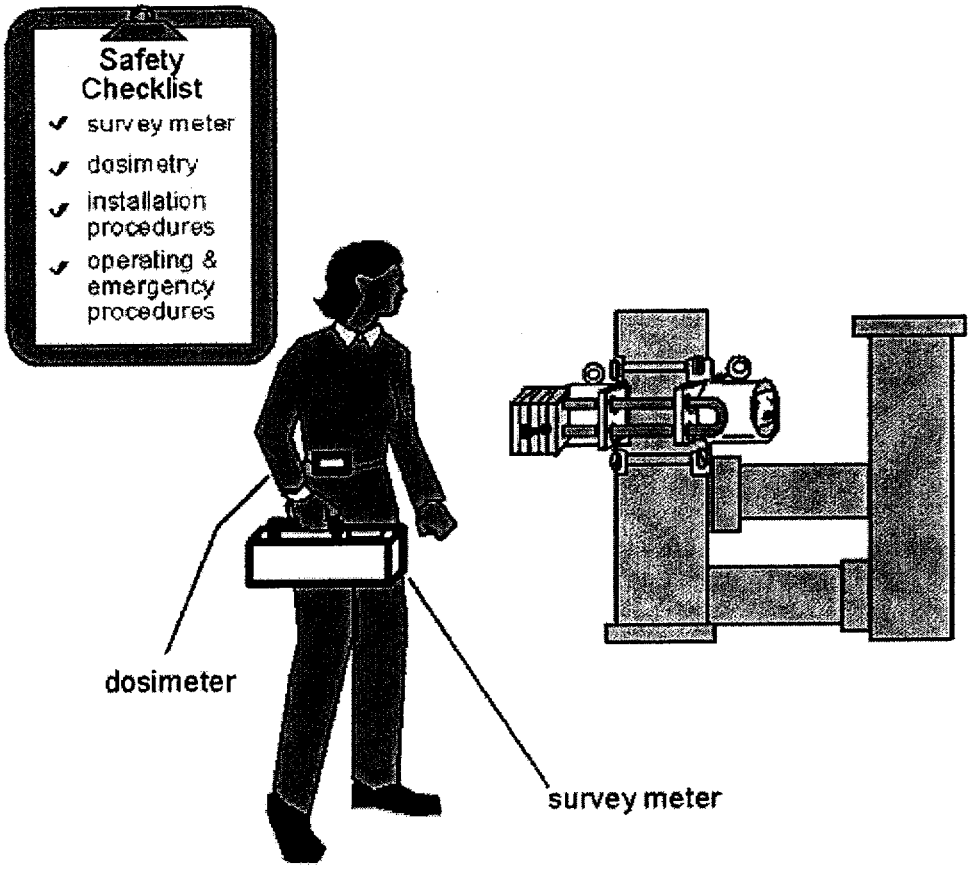


Figure 17. ***Installation of Fixed Gauges at Temporary Job Sites.*** Examples of the Additional Precautions Needed when Installing Fixed Gauges at Temporary Job Sites.

While installing gauges, personnel could receive radiation doses exceeding department 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 17**.

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 18**.

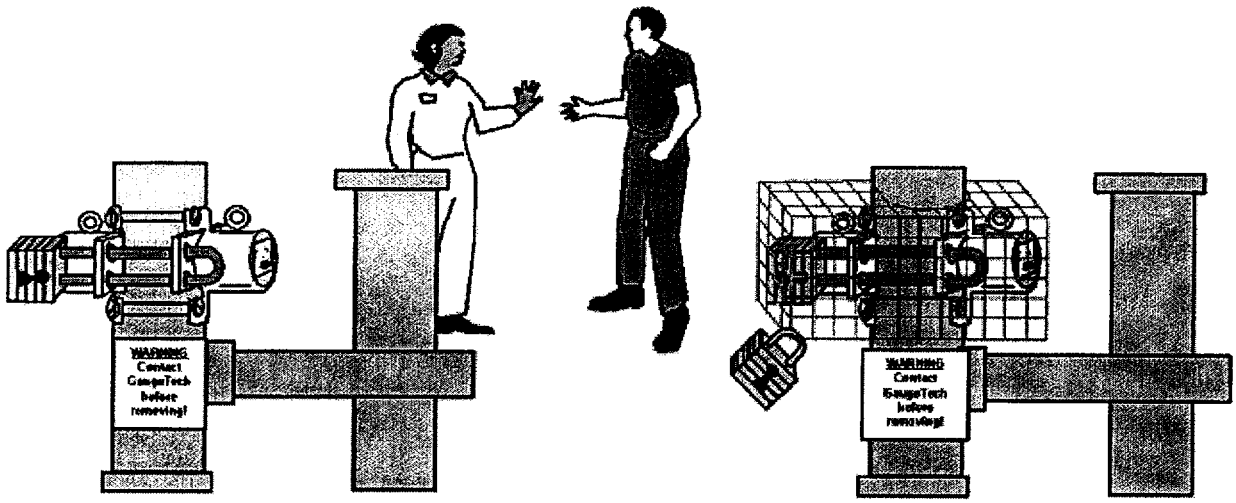


Figure 18. ***Security***. Additional Security Measures following Installation of Fixed Gauges at a Temporary Job Site.

Response from Applicant:

If fixed gauges are used at Temporary Job Sites, we will submit procedures for the use of the fixed gauges.

The Next Two Items on DHFS Form### are to be completed on the Form itself.

Item 11: Fees

On ***DHFS Form ????***, enter the fee category and the amount. Enclose fee with the application.

Item 12: Certification

Individuals acting in a private capacity are required to sign and date ***DHFS Form ???***. Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date ***DHFS Form ????***. **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. The department **will return all unsigned applications for proper signature.**

Note:

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

Appendix A:
State of Wisconsin
Department of Health and Family Services
Radiation Protection Section
Form#####

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

State of Wisconsin
Department of Health and Family Services
Radiation Protection Section
1 West Wilson Street, Room 150
P.O. Box 2659
Madison, WI 53701-2659
Phone: (608)267-4797
Fax: (608)267-3695

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE AUTHORIZING THE USE OF SEALED SOURCES IN FIXED GAUGE DEVICES

Instructions – Complete all items if this is an initial application or an application for renewal of a license. Refer to WISREG " Guidance for Fixed Gauge Devices." Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the State of Wisconsin, Department of Health and Family Services (*DHFS*). *DHFS is requesting disclosure of information. Failure to provide any information may result in denial or delay of a radioactive material license.*

APPLICATION TYPE

ITEM 1. TYPE OF APPLICATION (Check All That Apply)

☐ NEW LICENSE

☐ RENEWAL License #_____

☐ AMENDMENT License #_____

CONTACT INFORMATION

ITEM 2. NAME AND MAILING ADDRESS OF APPLICANT:	**ITEM 3. PERSON TO CONTACT REGARDING APPLICATION:**
APPLICANT'S PHONE NUMBER (Including Area Code):	**CONTACT'S PHONE NUMBER** (Including Area Code):

LOCATION OF RADIOACTIVE MATERIAL

ITEM 4. ADDRESS(ES) WHERE RADIOACTIVE MATERIAL WILL BE (Do Not Use P.O. Box):

☐ USED ☐ STORED ☐ USED AND STORED

(ATTACH ADDITIONAL PAGES IF NECESSARY)

ADDRESS	PHONE NUMBER

RADIATION SAFETY OFFICER

ITEM 5. RADIATION SAFETY OFFICER (RSO) *(Attach evidence of training and experience and check one box)*

NAME:_____ TELEPHONE (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 entitled "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience- Radiation Safety Officer" in WISREG "Guidance for Fixed Gauge Devices."

AND

Before being named as the RSO, future RSOs will have successfully completed one of the training courses described in Criteria in the section entitled " Individual(s) Responsible for Radiation Safety Program and Their Training and Experience- 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.

AUTHORIZED USERS

ITEM 6. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Check one box)

☐ Before using radioactive material, authorized users will have successfully completed one of the training courses described in Criteria in the section entitled " Training for Individuals Working In or Frequenting Restricted Areas" in WISREG " Guidance for Fixed Gauge Devices."

NOTE: IF USING IN-HOUSE TRAINING PROGRAM SUBMIT, COPY OF COURSE CONTENT, SAMPLE COURSE EXAMINATION AND COURSE INSTRUCTOR QUALIFICATIONS.

OR

☐ Documentation of the training and experience for the proposed gauge user(s) is/are attached.

RADIOACTIVE MATERIALS

ITEM 7. RADIOACTIVE MATERIAL *(ATTACH ADDITIONAL PAGES IF NECESSARY)*

ELEMENT AND MASS NUMBER	☐ Cobalt-60	☐ Krypton-85	☐ Americium-241
	☐ Cesium-137	☐ Strontium-90	☐ Ra-226
	☐ Other Isotope (*please specify*): _____		

ITEM 8. CHEMICAL AND PHYSICAL FORM	SEALED SOURCES
SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER	
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 Registration Certificate)*	
SEALED SOURCE AND DEVICE REGISTRATION SHEET NUMBER	

INTENDED USE

FACILITIES AND EQUIPMENT

ITEM 9. FACILITIES AND EQUIPMENT (*Check boxes and attach diagram.*)

☐ Diagrams of radioactive material area(s) of use are attached.

☐ 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.

RADIATION SAFETY PROGRAM

ITEM 10. RADIATION SAFETY PROGRAM

ITEM 10.1 RADIATION SAFETY PROGRAM -AUDIT

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

ITEM 10.2 RADIATION SAFETY PROGRAM-TERMINATION OF ACTIVITIES (*Check Box*)

☐ We will notify ***DHFS***, on a departmental form, within 30 days of the decision to permanently cease radioactive material use. *s. HFS 157.13 (11) (c)*

ITEM 10.3 SURVEY EQUIPMENT (*Check one box*)

☐ We will either possess and use, or have access to and use, a radiation survey meter that meets the Criteria in the section entitled " Radiation Safety Program – Instruments" in WISREG "Guidance for Fixed Gauge Devices."

OR

☐ We will submit an alternative procedure for determining source integrity after an incident involving the fixed gauge device. (Procedure attached)

ITEM 10.4 INSTRUMENT CALIBRATION (*Check one box*)

☐ Surveys according to ***s. HFS 157.25 (1)*** will be performed by a person specifically authorized by ***DHFS***, the **NRC** or an Agreement State to perform these surveys.

OR

☐ We will use survey instruments that meet the Criteria in the section entitled 'Radiation Safety Program – Instruments' in WISREG "Guidance for Fixed Gauge Devices".

AND ONE OF THE FOLLWING

☐ Each survey meter will be calibrated by the manufacturer or other person authorized by ***DHFS***, the **NRC** or an Agreement State to perform survey meter calibrations.

☐ We will implement the model survey meter calibration program published in Appendix I entititled 'Survey Instrument Calibration' in WISREG "Guidance for Fixed Gauge Devices."

☐ We will submit alternative calibration procedures for ***DHFS*** review.

ITEM 10.5 MATERIAL RECEIPT AND ACCOUNTABLITY (*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. ***s. HFS 157.15***

ITEM 10.6 OCCUPATIONAL DOSIMETRY (*Check one box*)

☐ We will maintain, for inspection by ***DHFS***, 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. *HFS 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.

ITEM 10.7 PUBLIC DOSE

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

ITEM 10.8 OPERATING AND EMERGENCY PROCEDURES (*Check one box*)

☐ We will implement and maintain the operating and emergency procedures in Appendix Z of WISREG "Guidance for Fixed Gauge Devices" and provide copies of these procedures to all gauge users.

OR

☐ We will develop, implement and maintain operating and emergency procedures that will meet criteria in the section entitled 'Radiation Safety Program – Operating and Emergency Procedures' in WISREG " Guidance for Fixed Gauge Devices." **(Attach Procedures)**

ITEM 10.9 LEAK TEST (*Check one box*)

☐ Leak tests will be performed by an organization authorized by ***DHFS***, 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 ***DHFS***, the **NRC** or an Agreement State to provide leak test kits to other licensees according to kit suppliers instructions.

License number of organization authorized to perform or analyze leak test (Specify whether Department, **NRC**, or other 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)**

ITEM 10.10 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.

OR

☐ We have provided the information listed in Appendix Z of WISREG "Guidance for Fixed Gauge Devices" to support a request to perform this work "in house." **(Procedure Attached)**

I' 1 10.11 FIXED GAUGE DISPOSAL AND TRANSFER

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

SPECIFIC LICENSE FEE

ITEM 11. LICENSE FEES (***REFER TO s. HFS 157.10***)

CATEGORY:	AMOUNT:

CERTIFICATION (*To be signed by an individual authorized to make binding commitments on behalf of the applicant.*)

ITEM 12

I HEREBY CERTIFY THAT THIS APPLICATION WAS PREPARED IN CONFORMANCE WITH CHAPTER HFS 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:	DATE:
NAME (Print or Type):	TITLE:

Appendix B:

Reserved

Appendix C:

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain the department's prior written consent before transferring control of the license; commonly referred to as "transferring the license." Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, state this.

1. The new name of the licensed organization. If there is no change, the licensee should state this.

2. The new licensee contact and telephone number(s) to facilitate communications.

3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of radioactive material. The licensee should include information concerning the qualifications, training and responsibility of new individuals.

4. An indication of whether the transferor will remain in non-licensed business without the license.

5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.

6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).

7. A detailed description of any changes in the use, possession, location, or storage of the radioactive material.

8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.

9. An indication of whether all surveillance items and records (e.g., calibrations, leak test, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.

10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to ***HFS 157.15***; public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the department for license terminations.

11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in ***HFS 157.15***. Include information about how the transferee and transferor propose to divide the transferor's assets and responsibility for any cleanup needed at the time of transfer.

13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to the department by the transferor. These include, but are not limited to: maintaining decommissioning records required by ***HFS 157.15***; implementing decontamination activities and decommissioning the site; and completing corrective actions for open inspection items and enforcement actions.

    With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

    With regards to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferee provides a commitment to close out all such action with the department before license transfer.

14. Documentation that the transferor and transferee agree to transfer control of the radioactive material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and regulations.

References: The information above is contained in Information Notice 89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities," is available at the **NRC**'s webpage at Http://www.nrc.gov.

Appendix D:

Reserved

Appendix E

Sample SSD Registration Certificate

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 department regulations and the conditions of the license. (See **Figure 3**) 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 the department, 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 ***HFS 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
- 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 ***HFS 157.88(1)*** (Subchapter III and X of Chapter 157 'Radiation Protection', license documents, operating procedures, ***DHFS*** Form ### "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 regulations
- 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*** - "Non-Routine Operations."

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? ***HFS 157.21***

C. Were records of previous audits maintained? ***HFS 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 the department's prior consent obtained or was the department notified?

C. Radiation Safety Officer

1. If the RSO was changed, was license amended?
2. Does new RSO meet the department requirements?
3. Is RSO fulfilling his or her duties?
4. To whom does the RSO report too?

D. If the designated contact person for the department changed, was the department notified?

E. Sealed Sources and Devices

1. Does the license authorize all of the department's regulated radionuclides contained in gauges?
2. Are the gauges as described in the Sealed Source and Device (SSD) Registration 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 HFS 157.88(2)***? Annual training provided, as needed ***HFS 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 the department's criteria? ***HFS 157.31(3)***

B. Are calibration records maintained? ***HFS 157.31(3)***

Gauge Inventory

A. Is a record kept showing the receipt of each gauge? ***HFS 157.31***

B. Are all gauges physically inventoried every six months?

C. Are records of inventory results with appropriate information maintained?

Personnel Radiation Protection

A. Are ALARA considerations incorporated into the radiation protection program? ***HFS 157.21***

B. Were prospective evaluations performed showing that unmonitored individuals receive less than or equal to 10% of the limit? ***HFS 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? ***HFS 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 ***DHFS*** Forms or equivalent? ***HFS 157.31(5); HFS 157.31(7)***
   a. ***DHFS*** Form##### "Cumulative Occupational Exposure History" completed?
   b. ***DHFS*** Form##### "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 ***HFS 157.22(8)***?
   b. Were records kept of embryo/fetus dose per ***HFS 157.31(7)***?

F. Are records of exposures, surveys, monitoring, and evaluations maintained? ***HFS 157.31***

Public Dose

A. Is public access to gauges controlled in a manner to keep doses below 1mSv (100 mrem) in a year? ***HFS 157.23(1)***

B. Has a survey or evaluation been performed per ***HFS 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? ***HFS 157.23(1)***

D. Is gauge access controlled in a manner that would prevent unauthorized use or removal? ***HFS 157.28(1)(a)***

E. Records maintained? ***HFS 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 the department notification or reporting required? ***HFS 157.32(1-3)***

Leak Tests

A. Was each sealed source leak tested every 6 months or at other prescribed intervals?

B. Was the leak test performed according to the license?

C. Are records of results retained with the appropriate information included?

D. Were any sources found leaking and if yes, was ***DHFS*** notified?

Maintenance of Gauges

A. Are manufacturer's or distributor's procedures followed for routine cleaning and lubrication of gauge?

B. Was each on-off mechanism tested for proper operation every 6 months or at other prescribed intervals?

C. Are repair and maintenance of components related to the radiological safety of the gauge performed by the manufacturer, distributor or person specifically authorized by the department, the **NRC** or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with ***HFS 157.23(1)*** limits)?

D. 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 the department? ***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? ***HFS 157.25(1-2)***

Notification and Reports

A. Was any radioactive material lost or stolen? Were reports made? ***HFS 157.32***

B. Did any reportable incidents occur? Were reports made? ***HFS 157.32; HFS 157.13***

C. Did any overexposures or high radiation levels occur? Reported? ***HFS 157.32***

D. If any events (as described in items a through c above) did occur, what was the root cause? Were corrective actions appropriate?

E. Is the management/RSO/shift foreman licensee aware of the telephone number for ***DHFS*** office hours (608) 267-4797 or 24 hour emergency number (608) 258-0099.

Posting and Labeling

A. ***DHFS*** Form#### "Notice to Workers" posted? ***HFS 157.88(1)***

B. The department rule, license documents posted or a notice posted? ***HFS 157.88(1)***

C. Other postings and labelings? ***HFS 157.29(1-2)***

Record Keeping for Decommissioning

A. Records kept of information important to decommissioning? ***HFS 157.15***

B. Records include all information outlined in ***HFS 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 ± 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 ±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 that 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.
Contact the department to obtain copies of Draft RG FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985.

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 ***HFS 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 3 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 3 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 hands 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 5000mrem 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.

Calculational 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 calculational 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 & 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 calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the gauge and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers distance and the 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 calculational method through Part 1 or Part 2. The results of these calculations typically result in higher

radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example 1.

To better understand the calculational 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 the department'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 K.1** is Joe's sketch of the areas in question, and **Table K-1** summarizes the information Joe has on each gauge.

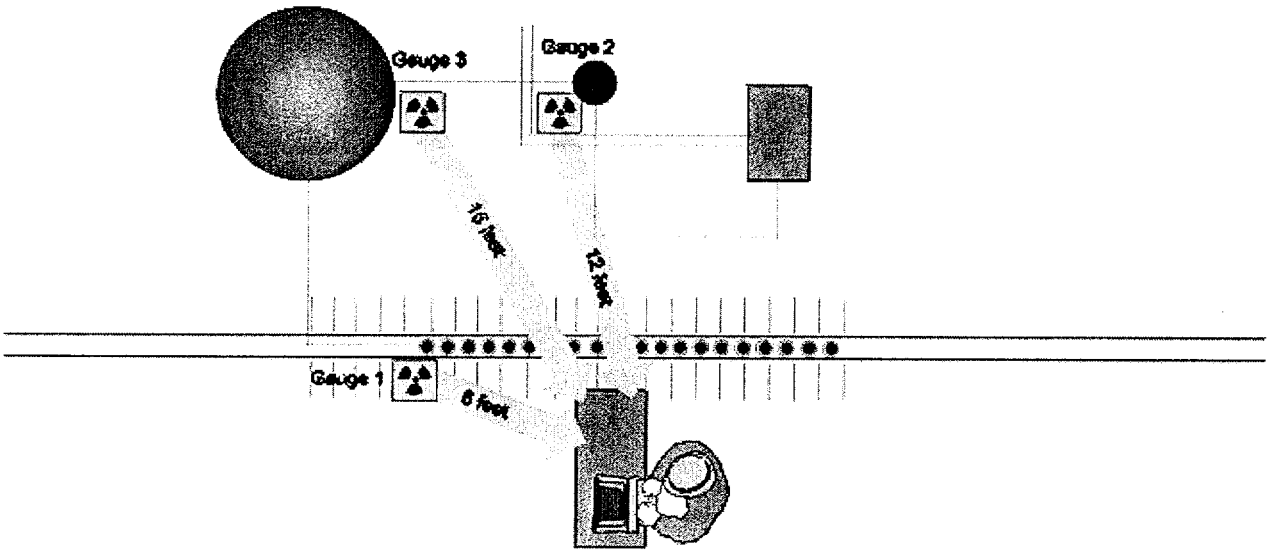


Figure 19 ***Diagram of Bottling Line and Fixed Gauges.*** This sketch shows the areas described in Examples 1 and 2.

Table 4. 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 regulation in ***HFS 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 K-2, K-3, and K-4** below.

Table 5. Calculational 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 = **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 x 24 x 356 = 0.031 x 8760 = **272**	

Table 6. Calculational Method, Part 1: Hourly and Annual Dose Received from Gauge 2

			Gauge 2
Step No.	**Description**	**Input Data**	**Results**
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/hr	8	8
2	Square of the distance (ft) at which the Step 1 rate was measured, in square feet	(1)^2	1

Gauge 2			
Step No.	**Description**	**Input Data**	**Results**
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 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 2**, in mrem in an hour	8/144 = **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 x 24 x 365 = 0.056 x 8760 = **491**	

Table 7 Calculational Method, Part 1: Hourly and Annual Dose Received from Gauge 3

Gauge 3			
Step No.	**Description**	**Input Data**	**Results**
1	Dose received in an hour at known distance from gauge (e.g., from manufacturer's data), in mrem/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 x 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 = **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 x 24 x 365 = 0.08 x 8760 = **701**	

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

Table 8. Calculational Method, Part 1: Total Hourly and Annual Dose Received from Gauges 1, 2, and 3

Step No.	Description	Gauge 1	Gauge 2	Gauge 3	Sum
7	**TOTAL HOURLY DOSE RECEIVED** from Step 5 of Tables K-2, K-3 and K-4, in mrem in an hour	0.031	0.056	0.08	0.031 + 0.056 + 0.08 = **0.167**
8	**TOTAL ANNUAL DOSE RECEIVED** from Step 6 of Tables K-2, K-3 and K-4, in mrem in a year	272	491	701	272 + 491 + 701 = **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 9. Calculational Method, Part 2: Annual Dose Received from Gauges 1, 2, and 3

Step No.	Description	Results
9	A. Average number of hours per day that individual spends in area of concern (e.g., worker present at bottling control panel 5 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 x 3 x 52 = **780**
11	Multiply the sum in Step 7 by the results of Step 10 = **ANNUAL DOSE RECEIVED FROM GAUGES CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN,** in mrem in a year	0.167 x 780 = **130**

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

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

Example 1, Part 3

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

Table 10. Calculational Method, Part 3: Summary of Information

INFORMATION ON GAUGES:

- **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).

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

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

Table 11 Calculational Method, Part 3: Annual Dose Received from Gauges 1, 2, and 3

Step No.	Description	Gauge 1	Gauge 2 "On"	Gauge 2 "Off"	Gauge 3
12	Average number of **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

Step No.	Description	Gauge 1	Gauge 2 "On"	Gauge 2 "Off"	Gauge 3
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 1/4th, 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 ***HFS 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: *HFS 157.31(8)* requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement - Calculational Method

This method, which allows the licensee to take credit for shielding between the gauge and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from each gauge. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 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.

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 K.1** and **Table K-1** 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 12 Combination Measurement - Calculational 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 x 24 x 0.14 = 8760 x 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 regulations.*

Part 2

At this point Joe can adjust for a realistic estimate of the time the worker spends at the bottling control panel as he did in Part 2 of Example 1.

Part 3

If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he can make adjustments for realistic estimates of the time 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), film badge or OSL when using the gauge.
    - Never wear another person's TLD, film badge or OSL.
    - Never store your TLD, film badge or OSL near the gauge.
- Use the gauge according to the manufacturer's or distributors 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 the department as required. ***Appendix P*** contains typical department incident notifications required for fixed gauge licensees. (Even if not required to do so, you may report ANY incident to the department by calling (608) 258-0099, which is staffed 24 hours a day and accepts collect calls.) ***DHFS*** 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 ***HFS 157.32(3)*** limits. Reporting requirements are found in ***HFS 157.32***.

Note: *1. Fill in with (and update, as needed) the names and telephone numbers of appropriate personnel (e.g., the RSO, AUs, or other knowledgeable licensee staff, licensee's consultant, gauge manufacturer, distributor or representative, fire department, or other emergency response organization, as appropriate, and the department) 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 ± 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:

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

Where:
cpm = counts per minute
std = standard
bkg = background
Bq = Becquerel

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

For example:

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

- Sign and date the list of sources, data and calculations. Retain records for 3 years.
- 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 ***DHFS***.

Reference: See the **NRC** webpage at http://www.nrc.gov to obtain a copy of Draft RG FC 412-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

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 department limits. See **Figure 11**.

Any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device 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 department limits. Radionuclides and activities in fixed gauges vary widely. For illustrative purposes in less than one minute, an unshielded cesium-137 source with an activity of 100 millicuries can deliver 0.05 Sv (5 rems) 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 rems) 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 personnel dosimetry (if required)). Accordingly, provide the following information:

Describe the types of work, maintenance, cleaning, repair that involve:

- Installation, relocation, or alignment of the gauge
- Components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
- Replacement and disposal of sealed sources
- Removal of a gauge from service
- A potential for any portion of the body to come into contact with the primary radiation beam; or
- Any other activity during which personnel could receive radiation doses exceeding department limits.

The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

A licensee may initially mount a gauge, without specific ***DHFS***, 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 the department, the **NRC** or an Agreement State to perform such operations.

- Identify who will perform non-routine operations and their training and experience. Acceptable training would include manufacturer's or distributor's courses for non-routine operations or equivalent.
- Submit procedures for non-routine operations. These procedures should ensure the following:
    - doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
    - the source is secured against unauthorized removal or access or under constant surveillance;
    - appropriate labels and signs are used;
    - manufacturer's or distributor's instructions and recommendations are followed;
    - any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration; and
    - before being returned to routine use, the gauge is tested to verify that it functions as designed and source integrity is not compromised.

- Confirm that individuals performing non-routine operations on gauges will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits.

- Verify possession of at least one survey instrument that meets the criteria in "Radiation Safety Program - Instruments in WISREG, ' Guidance for Fixed Gauge Devices."

- Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed ***HFS 157.23 (1)*** limits. For example, applicants can do the following:

    - commit to performing surveys with a survey instrument (as described above);
    - specify where and when surveys will be conducted during non-routine operations; and
    - commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by ***HFS 157.31 (3)***.

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 Regulations, 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 HFS 157 'Radiation Protection' Subchapter 13.

Appendix P:

DHFS Incident Notifications

DHFS Incident Notifications

Table 13 Typical *DHFS* Incident Notifications Required for Fixed Gauge Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	Immediate	30 days	*HFS 157.32(1)*
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	*HFS 157.32(2)*
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	*HFS 157.32(2)*
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	*HFS 157.32(2)*
Extremity dose greater that 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	*HFS 157.32(2)*
Whole body dose greater than 0.05 Sv (5 rems)	None	30 days	*HFS 157.32(3)*
Dose to individual member of the public greater than 1mSv (100 mrems)	None	30 days	*HFS 157.32(3)*
Filing petition for bankruptcy under 11 U.S.C.	None	Immediately after filing petition	*HFS 157.13(9)(b) and (10)*
Expiration of License	None	60 days	*HFS 157.13(11)*
Decision to permanently cease licensed activities at entire site	None	60 days	*HFS 157.13(11)*
Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use	None	60 days	*HFS 157.13(11)*
No principal activities conducted for 24 months at the entire site	None	60 days	*HFS 157.13(11)*

Event	Telephone Notification	Written Report	Regulatory Requirement
No principle activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted used	None	60 days	***HFS 157.13(11)***
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	***HFS 157.13(17)***
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	***HFS 157.13(17)***
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	***HFS 157.13(17)***

Note: Telephone notifications shall be made to ***DHFS*** at **(608) 267-4797** and in an emergency to **(608) 258-0099.**

Appendix Q:

Sample Fixed Gauge License

Wisconsin
Chapter HFS 157 -Radiation Protection Regulatory Guide

Draft Review

Guidance for Commercial Radiopharmacy Licenses.

Department of Health and Family Services
Radiation Protection Section
1 West Wilson Street
P.O Box 2659
Madison, WI 53701-2659
Phone: (608) 267-4797
Fax: (608) 267-3695

EXECUTIVE SUMMARY

Wisconsin Regulatory Guide (WISREGS) are issued to describe and make available to the public acceptable methods of implementing specific parts of Wisconsin Administrative Code, Chapter HFS 157 'Radiation Protection' to delineate techniques used by the staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants, licensees, or registrants. WISREGS are not substitutes for Chapter HFS 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 and Family Services (***DHFS***), 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 and Family Services, Radiation Protection Section, 1 West Wilson Street, 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 and Family Services, Radiation Protection Section, 1 West Wilson Street, P.O. Box 2659, Madison, WI 53701-2659**

This Wisconsin Regulatory Guide "Guidance for Commercial Radiopharmacy Licenses" has been developed to streamline the application process for a Commercial Radiopharmacy License. A copy of the application form#### "Application for Radioactive Material License For Commercial Radiopharmacies" is located in ***Appendix A*** of this guide.

Appendix A through T 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 ***HFS 157.10*** for a Commercial Radiopharmacy License.

In summary, the applicant will need to do the following to submit an application for a commercial radiopharmacy license.

- Use this regulatory guide to prepare the application form####
- Complete the application form#### (***Appendix A***). See 'Contents of Application' of the guide for additional information.
- Include any additional attachments.

  All supplemental pages should be typed on a 8 ½" x 11" paper.
  Please identify all attachments with the applicant's name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if applicable) and if possible a copy on a diskette or CD (Microsoft Word is preferred).
- Submit the application fee.
- Retain one copy of the licensee application and attachments (if applicable) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

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

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Abbreviations

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANP	authorized nuclear pharmacist
ANSI	American National Standards Institute
AU	authorized user
bkg	background
BPR	business process redesign
Bq	becquerel
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
Ci	curie
cm	centimeter
cpm	counts per minute
DAC	derived air concentration
DDE	deep-dose equivalent
DFP	decommissioning funding plan
DHFS	Department of Health and Family Services
DIS	decay in storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
dpm/cm^2	disintegrations per minute per square centimeter
EDE	effective dose equivalent
FA	financial assurance
FDA	United States Food and Drug Administration
G-M	Geiger-Mueller
GPO	Government Printing Office
HFS 157	Wisconsin Administrative Code Chapter HFS 157 'Radiation Protection'
IN	Information Notice
IP	inspection procedure
mGy	milliGray
MDA	minimum detectable activity
MOU	Memorandum of Understanding
mR	milliroentgen
mrem	millirem
mrem/hr	millirem per hour
mSv	millisievert
mSv/hr	millisievert per hour
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	Optically Stimulated Luminescence
PET	Positron Emission Tomography
P&GD	Policy and Guidance Directive

QA	quality assurance
R	roentgen
RQ	reportable quantity
RSO	radiation safety officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French, Le Systeme Internationale d'Unites)
SSD	sealed source and device
std	standard
Sv	sievert
TAR	technical assistance request
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
USDA	United States Department of Agriculture
WISREG	Wisconsin Regulatory Guide

Purpose of Report

This report provides guidance to an applicant applying for a commercial radiopharmacy license, as well as providing ***DHFS*** with the appropriate criteria for evaluating such applications. Within this document, the terms , "commercial radiopharmacy," "radiopharmacy," "nuclear pharmacy," and "pharmacy" are used interchangeably.

Commercial radiopharmacy licenses are those licenses issued by the department, pursuant to ***HFS 157.13*** for the possession and use of radioactive materials for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under ***HFS 157.59*** through ***HFS 157.72***. Within this document, preparation includes the making of radiopharmaceuticals from reagent kits (i.e., technetium-99m MAA (macroaggregated albumin)), and from raw materials (i.e., PET radiopharmaceuticals, the compounding of radioiodine capsules for diagnostic and therapeutic medical use). Commercial radiopharmacies may also be authorized to transfer for commercial distribution *in vitro* test kits described in ***HFS 157.11***, radiopharmaceuticals to licensees authorized to possess them for other than human medical use (i.e., veterinary medicine and research licensees), and radiochemicals to those licensees authorized to possess them, pursuant to ***HFS 157.11*** and ***HFS 157.13***. In addition, ***HFS 157.13*** authorizes radiopharmacies to redistribute (transfer) sealed sources for calibration and medical use initially distributed by a manufacturer licensed pursuant to ***HFS 157.13***.

Specific guidance for applicants requesting to manufacture and initially distribute molybdenum-99/technetium-99m generators, *in vitro* kits, radiochemicals and sealed sources is included in **NRC** NUREG 1556, Vol 12, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Manufacturing and Distribution Licenses," and is not within the scope of this guidance for commercial radiopharmacies. These activities require specific department, **NRC** or Agreement State authorization and must be included on a specific license.

Furthermore, specific guidance for applicants requesting authorization to manufacture, distribute, and redistribute radioactive drugs to persons exempt from licensing (i.e., carbon-14 tagged urea) is included in **NRC** NUREG - 1556, Vol. 8, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Exempt Distribution Licenses," and also is not within the scope of this guidance. These activities require specific ***DHFS*** and ***NRC*** authorization and the issuance of a separate ***NRC*** license for exempt distribution.

This WISREG identifies the information needed to complete ***DHFS***, Form ### (***Appendix A***) "Application For a Radioactive Material License For Commercial Radiopharmacies."

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

- Rule -- references the portions of ***HFS 157*** 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.

Appendix E is a sample commercial radiopharmacy license, containing the conditions most often found on these licenses, although not all licenses will have all conditions. ***Appendices F through S*** contain additional information on various radiation safety topics, including model procedures. ***Appendix T*** includes a table of ***DHFS*** incident notification and reporting requirements applicable to commercial radiopharmacies.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent (EDE), committed dose equivalent (CDE), committed effective dose equivalent (CEDE), or total effective dose equivalent (TEDE). These terms are defined in ***HFS 157.03***. 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 ***HFS 157.20*** through ***HFS 157.33*** sets dose limits in terms of rem, not rad or roentgen (R). When the radioactive material emits beta and gamma rays, for practical reasons, we assume that 1 R = 1 rad = 1 rem. For alpha emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from 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 alpha particles are addressed in the ***Tables 157.06 A and B in HFS 157.06(5).***

MANAGEMENT RESPONSIBILITY

The department recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. The department also believes that consistent compliance with ***HFS 157*** provides reasonable assurance that licensed activities will be conducted safely. ***DHFS*** has found that effective management is 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 ***HFS 157***;
- Completeness and accuracy of the radiation safety records and all information provided to the department;
- 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;
- Selecting and assigning a qualified individual to serve as the Radiation Safety Officer (RSO) for their licensed activities.

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read and follow *HFS 157.*

The following subchapters of Chapter HFS 157 "Radiation Protection" contain regulations applicable to commercial radipharmacy 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 the above documents, call ***Department of Health and Family Services, Radiation Protection Section*** at (608) 267-4797.