

NRC INSPECTION MANUAL

IMNS/NMSS

Temporary Instruction 2800/030

VERIFICATION OF THE STATUS OF DEVICES AUTHORIZED FOR USE UNDER A GENERAL LICENSE

APPLICABILITY: 2800

2800/030-01 INSPECTION OBJECTIVES

01.01 To determine the status of missing general licensees, and the location of the devices which are subject to registration.

01.02 To obtain information concerning the general licensees that can be used by the Headquarters Project Manager (PM) to update the database in preparation for the implementation of the registration program.

2800/030-02 BACKGROUND

In April 1998 the Commission issued a Staff Requirements Memo (SRM-98-071), which in part directed the staff to improve NRC's tracking and accounting of certain general licensees as well as the devices that they possess. As a result of the SRM, the staff developed two rule changes to 10 CFR Part 31. These changes established requirements for a general license registration program. The first rule, which became final on August 9, 1999, applies to all 10 CFR 31.5 general licensees, and required general licensees to respond, in writing, to written requests for information from staff. The second rule change proposes a registration program for licensees possessing devices containing at least: 37 MBq millicurie (1 mCi) cobalt-60, 370 MBq (10 mCi) cesium-137, 3.7 MBq (0.1 mCi) strontium-90, 37 MBq (1 mCi) americium-241, or 37 MBq (1 mCi) curium-244.

NRC mailed copies of the Federal Register Notice for the first rule changes to all general licensees approximately 47,000 included in the General License Data Base (GLDB), on December 15, 1998. A number of mailings were returned due to an incorrect or insufficient address, of which approximately 800 would be general licensees subject to registration. NRC contracted with Oak Ridge National Laboratory (ORNL), which maintains the GLDB for NRC, to sort the returned mail and identify all licensees that would be subject to registration. ORNL is attempting to contact these general licensees using additional information in the GLDB (contact names and telephone numbers), Internet searches, searches through local chambers of commerce, inquiries to device vendors, and other means. ORNL will identify those general licensees that cannot be contacted or located. NRC estimates that this number will be around 500. For each of these licensees, ORNL will provide a completed copy of the Form TI-1 (Appendix A) on each licensee they attempted to contact. The NRC Project Manager (PM) for the registration program will forward this information to the appropriate region for follow-up inspections. Note: The information provided by the PM to the region may be proprietary and needs to be handled with the proper controls during the inspections. For example; information that associates a general licensee with a specific vendor is proprietary (e.g., a customer list).

2800/030-03 INSPECTION REQUIREMENTS

03.01 The inspector should attempt to locate the general licensee (GL) and the generally licensed devices (GLD) that meet the proposed registration criteria listed above. Other devices that

are possessed by licensees need not be inspected under this TI; however, if health and safety problems are evidenced that involve other devices, they should be handled during the inspection. Due to the limited amount of resources available, the inspection should focus on finding the GLD, that are subject to registration, and need not include inspection of items outside the scope of this TI, which are of limited safety significance.

Initial priorities were established, by headquarters, based upon the criteria outlined in 03.02. However, it is recognized that circumstances vary, and onsite inspectors need the flexibility to pursue findings as they develop. Therefore, deviation from either the initial priorities, and/or resource allocations are permitted, based on the judgment of the inspectors or regional management.

03.02 Follow up for locating missing licensees and devices should be prioritized based upon a combination of the following:

- a. Activity of the source and/or the total number of devices at a given location;
- b. Normal operational radiation levels around the device;
- c. The length of time that has elapsed since the general licensee was last contacted, either by the manufacturer or any other party such as a repair facility (Start with the most recently contacted licensee's first); and
- d. Geographic location, trying to schedule visits in conjunction with inspections of specific licensees.

03.03 Attempt to locate the general licensee by the means listed in Appendix E.

Note: some companies may not know that they are general licensees, that they possess GLD, or that those devices use radioactive material. Note that ORNL, in attempting to contact these general licensees, may have already utilized many of the methods in discussed in Appendix E. The attempts that ORNL has made to contact these general licensees shall be documented in each individual general licensee file. Duplication of these attempts is left to the discretion of the inspector.

03.04 For those general licensees who are located, inform them of their status as a general licensee, and secure a mailing address and contact name. Attempt to address their compliance status by telephone or letter: e.g., do they know where the device is located; are they aware of the hazard it may present to employees or the public, if it is mishandled; if they no longer have it; do they know what happened to it; can they document proper disposal? If compliance status cannot be resolved, then as prioritization permits, perform a limited, on-site inspection.

- a. Provide instruction as necessary
 1. Upon arriving at the site, contact the facility manager or a sufficiently high level safety manager to explain the purpose of your inspection. Remember that many of the general licensees may not be aware of their status. Discuss with the manager both the intent and the objectives of the inspection, with the goal of enlisting their cooperation. Encourage the licensee to work with you and their staff to identify and correct any violations promptly. If access to the site is denied, contact Regional Management for further instructions.
 2. Provide the licensee with a copy of FORM TI-4 (Appendix D), 10 CFR 31.5, vendor contact information, and a list of service companies (found on the CRCPD website¹) if needed.
 3. Explain to the licensee the NRC general license accountability and reporting requirements.
 4. For users that are responsible for abandoned or demolished facilities the inspector should work with the licensee to determine if the device is still retrievable.

¹WWW.CRCPD.ORG (Conference of Radiation Control Program Directors, Inc.) (Under Free Publications/Orphan Source Documents)

5. For users who are unaware of their device(s), regulatory requirements, potential hazards associated with the device(s), or who do not have copies of the operations manual and/or maintenance procedures for the device(s):
 - (a) Determine whether any health and safety hazards exist for the current conditions of the device(s);
 - (b) Instruct the licensee on basic health and safety practices and GL requirements;
 - (c) Request that the licensee contact the vendor to obtain a users manual and/or maintenance manual; and
 - (d) For cases when there appears to be an immediate hazard, contact Regional Management to decide on the most appropriate course of action.
- b. Determine either the location or disposition of the devices listed on Form TI-2
 1. Be familiar with the size, shape, color, other physical features, and typical uses that may help identify the gauge when conducting a site inspection. Device descriptions and typical uses of a device can be found in the certificates of device registration (SSD sheets). If the SSD sheet information is not sufficient to assist in identifying a device, contact the Materials Safety and Inspection Branch for additional background information.
 2. Discuss the location of each device. The licensee may have lost one or more devices and/or may not be able to account for one or more devices. The licensee may have also made an unauthorized transfer or disposal of a device (s) (e.g., transferred to scrap recycler or sent to a non-rad disposal site). Encourage licensees to search their facilities to determine the whereabouts of all of their devices. This includes a search for the likely path that the device may have left their facility and/or a search for paperwork that indicates the location of the device. Interview employees who may have been familiar with the device, such as instrument technicians.
 3. For devices sent to vendors, verify documentation that acknowledges vendor receipt of the material, if possible. Note that the Database may list devices that have been returned to the vendor for a replacement device, and the original device was never deleted from the Database.
 4. For transfers (other than to a vendor) of devices, obtain from the licensee all information about the transfer, including date of transfer, name, address, and telephone number of the recipient.
 5. If a device cannot be accounted for, review the available device history with the licensee. Helpful information may include records of when the device was last in active use, when it was last leak tested, where it may have been stored when taken out of service, who may have taken it out of service and stored it, who is responsible for device accountability, and so on. Discuss any process lines or building that have been decommissioned or scrapped. Follow these leads as much as is reasonable to try to locate the devices.
 6. If the device may be on-site:
 - (a) Discuss actions the licensee may take to search for the device;
 - (b) Conduct surveys of areas where the gauge may have been stored or left in place after taking it out of service, if the source is ¹³⁷Cs or ⁶⁰Co and enough activity is expected to be left in the source to produce a detectable field. Do not conduct surveys if the source was ⁹⁰Sr or ²⁴¹Am, but instead conduct a tour of those areas of the facility in which the gauge may have been left after being taken out of service, or where it may have been stored and forgotten. Consider the possibility that the gauge may have been stored with other scrap equipment or scrap metal.

7. If the device may have been shipped offsite:
 - (a) Discuss actions the licensee may take to locate the device. The licensee should make a reasonable attempt to locate devices and/or paperwork documenting the location of the devices;
 - (b) Obtain as much information as possible about the possible transferee or disposal site including date of transfer, name, address, and telephone number of the recipient, type of business of the recipient, and how the transfer was made (e.g., as scrap as part of decommissioning a specific process line). If uncertain, determine date lines when it may have been decommissioned and which scrap dealers were involved, or which scrap dealers are typically used;
 - (c) When practical note any potential unauthorized transfer, loss, or unauthorized disposal of devices and discuss general license requirements with the licensee; and
 - (d) If the device may be retrievable, discuss the possible licensee's actions to retrieve the device. Ability to retrieve the source is dependent on the date of transfer, business of transferee, and availability of information.

c. Verify integrity of the devices possessed (including proper labeling)

1. When practical, examine all devices at the facility and determine if the device appears to be generally consistent with the SSD sheets, i.e., proper shielding is in place, labeling is present, and the device is being properly used or stored. Have the user demonstrate use of the device and describe its maintenance and service. Determine any health and safety concerns and discuss concerns with your regional management to decide on the most appropriate course of action.
2. Verify the presence of the sources in the gauges by using a survey instrument. Gauges with Cs-137 or Co-60 sources will have a sufficient radiation field around the housing to permit easy detection with a μ -R meter. Gauges with Sr-90, Am-241, or Cm-244 may not emit sufficient radiations to permit detection in this manner, therefore, verification should be done by other means (e.g., checking to verify that the measuring gauge still works, or, if appropriate, measuring radiation emitted from the window of the gauge). If possible, photograph the condition of gauges. The NRC is striving to improve its training of both regional and headquarters inspectors. Working with actual photographs will help in future decision making, education of the general licensees and the public, as well as, identification of the various types of the devices to assist in the location of devices when searching in the public domain such as scrap facilities.

03.05 The Regions should determine when to terminate looking for either the licensee or the lost device based on a combination of the following:

- a. Activity of the source in the device;
- b. Normal operational radiation levels around the device; and
- c. The length of time that has elapsed since the general licensee was last contacted, by either by the manufacturer or any other party. The assumption being, the longer the amount of time elapsed since the last contact with the licensee, the less likely it is that the device will be located.

03.06 Follow-up actions to the inspection include verification of transfers to other recipients. If the recipient received the device under a specific license, call the licensee to verify that they have received the device and obtain adequate information that verifies that the licensee is authorized to receive the device. Request the specific licensee contact the vendor to determine how to deface the part of the labeling that indicates that the device is being used under a general license. If the recipient is a general licensee or a non-licensee, determine whether they still have the device and contact the PM. The PM will check the database to see if they are listed, update the database as appropriate, and schedule a follow-up inspection of the GL, if needed. A follow-up inspection should be performed of those general licensees or non-licensees who received a device as a result

of an unauthorized transfer. Notify Agreement States or other Regions if the devices are believed to have been transferred to their jurisdiction.

2800/030-04 REPORTING REQUIREMENTS

Each region shall document its findings on Forms TI-1 (Appendix A), Form TI-2 (Appendix B), and TI-3 (Appendix C). Indicate the status for each device on Form TI-2. If the licensee has additional GLD that would be subject to registration, include them on form TI-2 and provide all of the information indicated on the form. Note also how the general licensee obtained the gauge, that is, by purchase from a licensed vendor or manufacturer, transfer from another general licensee or an unauthorized user, or any other means.

Within 30 days after the inspection, including follow-up inspections, provide FORMS TI-1, TI-2, and TI-3, photos, and other information to the PM listed at the end of this TI.

2800/030-05 COMPLETION SCHEDULE

The goal is for initial inspections to be completed within 1 year of the effective date of this TI. All follow-up inspections should be completed within 1 year after the initial inspection.

2800/030-06 EXPIRATION

This TI will remain in effect until all sites identified in the site list have been inspected and the follow-up inspections have been completed.

2800/030-07 CONTACT

The project manager for this TI and the general license accountability project is Michael Raddatz, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards (MSIB/IMNS/NMSS). His telephone number is 301-415-6334, mail stop is T8F5. Call the project manager on any questions you may have in connection with this TI.

2800/030-08 STATISTICAL DATA REPORTING

Time spent in implementing this TI, including preparation in the region as well as on site inspection, should be charged to RITS Code 231131/A10162.

2800/030-09 ORIGINATING ORGANIZATION INFORMATION

09.01 Organizational Responsibility. The Materials Safety and Inspection Branch initiated this TI.

09.02 Resource Estimate. It is expected that each site will require an average of 10-15 hours of inspection time. This estimate includes preparation, onsite time, close out, and travel. It is expected that inspections of these sites will be combined with routine inspections of nearby sites to minimize travel time and costs related to this TI. However, it is recognized that some sites on the list may not be close to any regularly inspected licensee or scheduled inspection, and in such cases, a special trip will have to be made to conduct the inspection. Actual inspections at a specific site may require substantially more or less time, depending on the circumstances.

END

Appendices:

Appendix A: Form TI-1

Appendix B: Form TI-2

Appendix C: Form TI-3

Appendix D: Form TI-4
Appendix E: Possible Methods of Search for General Licensees

APPENDIX A

FORM TI-1 CASE RESOLUTION		
Case Status	<input type="checkbox"/> Open	<input type="checkbox"/> Closed
RCODE: _____		
Region: _____		
OLD - Complete Name, Address, Contact, Phone Number:		
NEW - Complete Name, Address, Contact, Phone Number:		
Agreement State Licensee? (Double Check)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Moved to an Agreement State?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Describe Follow-up: (Telephone, Internet, Chamber of Commerce, Other)		
Describe Communication with Registration Vendor:		
Vendor Follow-up Action:		
Final Action Taken:		
Cause of Bad Address/Lesson Learned:		

APPENDIX B

Page ____ of ____

FORM TI-2 DEVICE INFORMATION

RCODE: _____								
ID	Model Number ¹	Serial Number	Isotope	Activity	Sold Date	Vendor	Status (A ² or N ³)	Comments
For additional GLD's received by the licensee identified during the inspection:								
ID	Model Number	Serial Number	Isotope	Activity	Sold Date	Vendor	How obtained	Comments

FORM TI-3 GENERAL LICENSEE INSPECTION DOCUMENTATION

RCODE: _____

¹Include only registerable gauges identified by Headquarters as "open" cases.

²Accounted for: A device is accounted for if (1) the device is located at the licensee's facility, (2) it has been verified that the device has been transferred to an authorized recipient or properly disposed, or (3) a reasonable assurance has been provided that the device has been transferred to an authorized recipient or properly disposed.

³Not Accounted for: A device is not accounted for if the location of the device is unknown and/or the licensee cannot provide a reasonable assurance that the device has been transferred to an authorized recipient for proper disposal.

APPENDIX C

General Licensee Information:	
<input type="checkbox"/>	Check Box if Current Complete Name, Mailing Address, Contact, and Phone Number is Same as Provided by ORNL. If not, include correct information below:
<input type="checkbox"/>	
Results of inspection: (check the appropriate boxes)	
<input type="checkbox"/>	The general licensee of record is located at the address of record and
<input type="checkbox"/>	all GLD are accounted for
<input type="checkbox"/>	<u>not</u> all GLD are accounted for
<input type="checkbox"/>	The general licensee of record is <u>not</u> located at the address of record, however GLD are being used under new ownership at the address of record and
<input type="checkbox"/>	all GLD are accounted for
<input type="checkbox"/>	<u>not</u> all GLD are accounted for
<input type="checkbox"/>	The general licensee of record is <u>not</u> located at the address of record, however they are using GLD at another location and
<input type="checkbox"/>	all GLD are accounted for
<input type="checkbox"/>	<u>not</u> all GLD are accounted for;
<input type="checkbox"/>	Neither the general licensee of record nor the facility operated by the general licensee are located at the address of record and the site has been abandoned or is being used for an alternate purpose.
<input type="checkbox"/>	Other: (explain)
Gauge Information:	
ID	For each gauge for which status is unaccounted for (see last column of Form TI-2), provide any conclusions about location of the gauge:

APPENDIX D

FORM TI-4 GUIDANCE FOR GENERAL LICENSEES

1) What is a general licensee (GL)?

A general licensee is a person or organization that acquires, uses, or possesses a generally licensed device, and has received the device through an authorized transfer by the device manufacturer/distributor, or by change of company ownership where the device remains in use at a particular location. If you receive, or have received, a device through an unauthorized means, contact your regulatory authority immediately.

2) What is a generally licensed device (GLD)?

GLD are devices containing radioactive material and are typically used to detect, measure, gauge, or control the thickness, density, level, or chemical composition of various items. Examples of such devices are gas chromatography (detector cells), density gauges, fill-level gauges and static elimination devices.

3) What are the requirements for a General Licensee?

GLs are subject to the NRC regulations listed in 10 CFR 31.5. These requirements include, but are not limited to:

Accountability and Control:

- GLs shall not abandon the devices

Routine Maintenance:

- Maintain labels
- Comply with the instructions and precautions provided on the labels. Perform leak tests and shutter tests every six months, or as otherwise indicated on the label, and maintain records of tests for three years.

If the Device Becomes Damaged or Fails a Shutter or Leak Test:

- Suspend operation of the device.
- Have the device repaired or properly disposed of by the manufacturer or other specific licensee.
- Report to the NRC within 30 days a brief description of the event and remedial actions taken and a plan (if contamination is greater than 0.005 micro curies (185 Bq)) for ensuring that the premises and environs are acceptable for unrestricted use.

Other Reporting Requirements:

- Report transfer or disposal of the device (Note: this report is not needed if obtaining a replacement device).
- Report needs to include identification of device by manufacturer's name and model number, serial number, name, address and license number of recipient, and date of transfer.
- Report change of ownership of the facility (where device remains in use at a particular location). Report needs to include manufacturer's name and model number, serial number, name and address of the transferee, and name of the responsible individual of the transferee.
- These reports must be submitted within 30 days of occurrence to:

Director of NMSS
ATTN: GLTS
USNRC, Washington, DC 20555

A complete listing of requirements for GLs includes the following sections of Title 10 of the Code of Federal Regulations: 20.2201, 20.2202, 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.63, and 31.5.

4) What is NRC registration of general licensed devices?

APPENDIX D

Starting in 2000, NRC plans to have certain GLs annually register their devices with NRC. This will include responding to NRC requests concerning location of the devices and information about the GL (e.g., correct contact person). The request may also include verification of required testing.

5) Which GLs will be subject to NRC registration?

GLs that possess at least one device containing one of the following isotopes at or above the activity shown:

Isotope	Activity	
	(mCi)	(MBq)
Americium-241	1	37
Cesium-137	10	370
Cobalt-60	1	37
Curium-244	1	37
Strontium-90	0.1	3.7

6) Are there fees associated with the General License or registration?

There are no fees associated with the General License for the initial year of the registration program. However, starting the second year of registration, GLs required to register with NRC will be required to submit a fee. It is estimated that the fee will be \$350-\$400 per GL per year.

7) What if I do not want to be subject to registration?

If a GL does not want to be subject to registration, they can transfer or dispose of their devices that would be subject to registration.

8) How can I transfer or dispose of a GLD?

GLD can *only* be transferred (for disposal or to obtain a replacement device) to a person holding a specific license pursuant to 10 CFR Parts 30 and 32, such as the device manufacturer. However, in the specific case of change of ownership where a GLD remains in use at a particular location, then the new owner will be the new general licensee.

9) Who can I go to for additional information including health and safety information?

You can call your device manufacturer who should be able to assist you and provide you with health and safety guidance about your specific GLD. Also, if the manufacturer is no longer in business you can call the appropriate NRC regional office who can provide you with a copy of NUREG/BR-0133, Rev. 2, February 1996 entitled "Working Safely with Nuclear Gauges". This document will provide you with basic health and safety guidance on using a nuclear gauge.

Region I (CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT) 610-337-5000, 1-800-432-1156

Region II (AL, FL, GA, KY, MS, NC, SC, TN, VA, WV, Puerto Rico, Virgin Islands) 404-562-4400, 1-800-577-8510

Region III (IA, IL, IN, MI, MN, MO, OH, WI) 708-829-9500, 1-800-522-3025

Region IV (AK, AZ, AR, CA, CO, HI, ID, KS, LA, MT, NE, NV, NM, ND, OK, OR, SD, TX, UT, WA, WY, U.S. territories in the Pacific) 817-860-8100, 1-800-952-9677

APPENDIX D

Questions about NRC's registration program:

Michael Raddatz

301-415-6334

mgr@nrc.gov

The NRC website can be located at: www.nrc.gov

APPENDIX E

POSSIBLE METHODS OF SEARCH FOR GENERAL LICENSEES

- ▶ Use information from the Database provided from ORNL, i.e., general license name, address, contact name, contact telephone number.
- ▶ Other specific licensees, with same/similar name (search of License Tracking System (LTS))
- ▶ Regional base of knowledge
- ▶ Internet search (several available)
- ▶ Telephone information services
- ▶ Inquiries to vendors
- ▶ Travel to the site
- ▶ Interviews with neighboring businesses
- ▶ Regional letter (if P.O. Box is the only available information)
- ▶ Courthouse records
- ▶ Bankruptcy filings (public records)
- ▶ The "Thomas Register" for search on a company name (www.thomasregister.com)
- ▶ NMED search (available on the NRC website)
- ▶ Preliminary Notification search (available on the NRC website)
- ▶ Operations Center event notification search (available on the NRC website)
- ▶ Any other means available