



REGULATORY GUIDE 3.8

Guidance for General Licensees

1. Who is a general licensee?

A general licensee is a company or person that uses or stores a generally licensed (GL) device. The device is obtained through an authorized transfer from 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 through an unauthorized means, contact the Nebraska Department of Health and Human Services, Office of Radiological Health, Radioactive Materials Program (See Question #10).

2. What is a generally licensed (GL) device?

GL devices are devices containing radioactive material and are typically used to detect, measure, or control the 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. One of the more widely used devices are self-illuminating signs.

3. What is the “General License Registration and/or Current Inventory Report”?

The inventory confirms that the Department (Nebraska Department of Health and Human Services, Office of Radiological Health) has an accurate inventory of devices for a general licensee. All general licenses are required to maintain control of their generally licensed devices.

Certain devices authorized in 180 NAC 3-008 are required to be registered each year. Registration of the device depends upon the type and quantity of radioactive material in the device. Registration involves verifying, changing, adding information and signing the “General License Registration and/or Current Inventory Report”

Devices subject to registration are devices used and/or stored in the State that contain at least one of the following radionuclides, in an amount equal to or greater than the indicated quantity at the time of manufacture:

37 megabecquerel (0.1 millicurie) of strontium-90; 37 megabecquerel (1 millicurie) of cobalt-60; 37 megabecquerel (1 millicurie) of any transuranic element, [i.e., atomic number greater than uranium (90), including americium-241, curium-244, plutonium-238, plutonium-239, and californium-252] and 370 megabecquerel (10 millicurie) of cesium-137

NEBRASKA DEPARTMENT OF HEALTH & HUMAN SERVICES (DHHS), REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public acceptable methods of implementing specific parts of Title 180 NAC Nebraska regulations, “Control of Radiation,” to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the DHHS, Division of Public Health, Office of Radiological Health, to make necessary determination to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the DHHS, Division of Public Health, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026. OR radiation.programs@nebraska.gov

Requests for single copies of issued guides (which may be reproduced) should be made in writing to the address above.

Regulatory Guide 3.8 (Rev. 4) 2-2013

4. How do I know if I have a GL device?

Look at the device for any and all labels. GL, devices should have labels containing such words as:

“Caution-Radioactive material:” “The receipt, use, and transfer of the device are subject to a general license”; OR identification of the radioactive material, such as “5 millicuries of cesium-137” or “1 mCi of Am-241.”

Also, review any paperwork such as manuals or brochures that you received with the device. It can provide you with information on the radioactivity contained within the device and whether or not the device is subject to the Nuclear Regulatory Commission (NRC) regulations or an Agreement State Regulation. If you are unable to determine if you have a generally licensed device, contact the manufacturer or this Department.

Possession or use of similar devices may require a specific license. Manufacturers or distributors cannot transfer specifically licensed devices to customers who do not have a specific license to possess such a device. The customer should apply to the Department or the NRC or Agreement State for such a license.

5. What are the requirements for a GL?

GL's are subject to the Nebraska Regulation for the Control of Radiation-Ionizing. General Licensees are required to:

Appoint a responsible individual

This responsible individual will know about the requirements of a General licensee and have the authority to carry out the necessary duties to comply with the regulatory requirements. These requirements are:

Routine Maintenance & Records

- Maintain labels.
- Comply with the instructions and precautions provided on the labels, including any referenced documents such as operating and service manuals.
- If required, perform leak test every six months or at intervals specified in the label and accordance with manufacturer's instructions (unless in storage or otherwise indicated on the label).
- If required, perform shutter test every six months or at intervals specified in the label and in accordance with manufacturer's instructions (unless in storage or otherwise indicated on the label).
- Assure that leak testing, shutter testing and other testing, installation, servicing and removal from installation involving radioactive materials, its shielding or containment are performed in accordance with instructions provided by the labels or by persons holding specific licenses authorized to perform such activities.
- Maintain records of leak testing; testing of on/off mechanism and indicator; or other testing; installation; servicing; and removal from installation that involve radioactive materials, its shielding or containment. The records must be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of.

Requirements 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 distributor.
- Provide to the Department, within 30 days, a brief description of the event and remedial actions taken. If contamination is measured as greater than 185 Bq (0.005 microcuries) or is likely to have resulted from the event, develop and submit a plan to the Department for ensuring that the premises and environs are acceptable for unrestricted use.

Additional Actions to be Taken in the Case of Significant Damage to the Device

- Immediately secure the area and keep people away from the device until the situation is assessed and radiation levels are known. If equipment is involved, isolate it until it is determined there is no contamination present. Perform first aid for any injured individuals but remove them from the area only when medically safe to do so.

- Arrange for a radiation survey to be conducted as soon as possible by a knowledgeable person using an appropriate radiation detector (survey meter). This person could be a representative of a manufacturer or distributor, a local emergency responder, a consultant, or a licensee employee using a radiation survey meter. To accurately assess the radiation hazard, it is essential that the person performing the survey be competent in the use of a radiation survey meter.
- Contact the Department at (402)471-2168 (M-F 8 AM – 5 PM) or after hours at Nebraska State Patrol (402)471-4545 (Ask to speak to the NEMA Duty Officer as you have an incident to report involving radioactive Materials.)

Reporting Requirements for General Licenses 180 NAC 4-008

Type of Report	Contents of Report	Frequency	Send to
General Licensee Registration and/or Current Inventory Report	The following information and any other information specifically requested by the Department: (A) Name, mailing address, phone & fax number (B) Name of responsible individual, title, mailing address, phone & fax number (C) Address where the device is used and/or stored (D) Identification of device by manufacture's (or initial transferor's) name, model number and serial number, radioisotope and activity (E) Certification that the information concerning the devices(s) has been verified through a physical inventory and checking the label (F) Certification by the responsible individual that he/she is aware of the requirements of the general license.	Annual	Program Manager Radioactive Materials Nebraska Dept. of Health and Human Services P.O. Box 95026 Lincoln, NE 68509
Transfer, or disposal	Identification of device by manufacture's (or initial transferor's) name, model number and serial number,; name, address and license number of recipient; and date of transfer	Within 30 days of transfer, disposal or export	Program Manager Radioactive Materials, Nebraska Dept. of Health and Human Services P.O. Box 95026 Lincoln, NE 68509
Transfer report for change of ownership (where device remains in use at a particular location)	Manufacturer's (or initial transferor's) name, number and serial number; name and address of the transferee; and name, title and phone number of the transferee.	Within 30 days of transfer	Program Manager Radioactive Materials Nebraska Dept. of Health and Human Services P.O. Box 95026 Lincoln, NE 68509
Report if device	Brief description of the event and	Within 30	Program Manager

Type of Report	Contents of Report	Frequency	Send to
becomes damaged or fails a shutter or leak test	remedial actions taken and a plan (if contamination is measured or likely) for ensuring that the premises and environs are acceptable of unrestricted use.	days of occurrence	Radioactive Materials Nebraska Dept. of Health and Human Services P.O. Box 95026 Lincoln, NE 68509
Report name change of licensee	New name of general licensee.	Within 30 days of occurrence.	Program Manager Radioactive Materials Nebraska Dept. of Health and Human Services P.O. Box 95026 Lincoln, NE 68509
Report of change of mailing address of the location of use (NOTE: In the case of portable devices, this only applies to the mailing address of the device" primary place of storage.)	New mailing address where device is used or stored.	Within 30 days after moving the device.	Program Manager Radioactive Materials, Nebraska Dept. of Health and Human Services P.O. Box 95026 Lincoln, NE 68509
Report of incidents or lost or stolen devices.	The following information: (A) Description of the radioactive material; (B) Description of the circumstances under which the loss or theft occurred; (C) Disposition of the radioactive material; (D) Radiation exposure to individuals; (E) Actions taken to recover the material; (F) Actions taken to prevent recurrence.	Telephone report within 30 days of occurrence; written report within 30 days of the telephone report.	Program Manager Radioactive Materials Nebraska Dept. of Health and Human Services P.O. Box 95026 Lincoln, NE 68509
Bankruptcy	Notification of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the U.S. Code.	Immediately following the filing of a voluntary or involuntary petition for bankruptcy.	Program Manager Radioactive Materials Nebraska Dept. of Health and Human Services P.O. Box 95026 Lincoln, NE 68509

6. Can I relocate my device(s) from one location to another?

You should contact the manufacturer or distributor to determine if your device(s) has been approved for relocation/installation

7. Is there reciprocity for GL devices?

No, there is no reciprocity provision applicable to general licensees. However, registration in Nebraska is not required for a general licensee using a device in NRC jurisdiction for less than 180 days in any calendar year.

General licensees intending on moving from one jurisdiction to another should contact the applicable Agreement State or NRC before moving to determine the applicable regulations in their jurisdictions. All jurisdictions do not have a comparable general license, and specific provisions of the general license may vary among jurisdictions.

8. How can I dispose of a GL device?

It is unlawful to abandon or dispose of generally licensed devices except by transfer to: (1) a person holding a specific license under 180 NAC 3-008.04, item 3.h., or equivalent NRC or Agreement State regulations, such as the device manufacturer; or (2) a person holding a specific license that authorizes waste collection, such as a waste broker.

Contact the device manufacturer or authorized waste collector for an estimate of what it may cost to dispose of a generally licensed device. Disposal can be costly.

Refer to **Attachment A** for information concerning the transfer or disposal of a generally licensed device from a general licensee to a specific licensee including disposal.

In the case of a change of ownership where a GL device remains in use at a particular location, the new owner will be the new general licensee. The seller must provide copies of 180 NAC 3-008.01, 3-30, 4-057 and 4-058 and any safety documents identified in the device label to the new general licensee.

Refer to **Attachment B** for information concerning transferring a generally licensed device to a general licensee only if the device remains in use at a particular location.

9. Can I keep a device that I am not using?

GL devices not in use can only be stored for two years. After two years, the device must be properly transferred. During this period of non-use, the shutter must be locked in the closed position. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs a quarterly physical inventory of the device while it is in standby.

10. Who can answer additional questions?

You can call the device manufacturer who should be able to assist you with specific questions dealing with the device.

If you have questions about your General License related to the 180 NAC - Nebraska Regulation for the Control of Radiation you can contact:

Nebraska Department of Health and Human Service
Division of Public Health
Radioactive Materials Program
301 Centennial Mall
P.O. Box 95026
Lincoln, NE 68509
(402)471-0560

The Nebraska Department of Health and Human Services, Office of Radiological Health Internet Home Page can be located at <http://www.dhhs.ne.gov/rad/>

11. Are there fees associated with generally licensed devices?

A non-refundable fee shall be paid annually for each general license. The current fee for a general license is \$140.00 per facility. The fee shall be paid in full each year on or before the last day of expiration anniversary month of the license.

12. What if I do not want to be subject to the annual fee?

If a facility does not want to be subject to registration, they can transfer or dispose of their device(s) to a specific licensee whose license authorizes him to receive the device.

The regulations are accessible via the World Wide Web @
http://dhhs.ne.gov/publichealth/Pages/puh_enh_rad_regs_regindex.aspx

ATTACHMENT A

INFORMATION NEEDED FOR TRANSFERRING or DISPOSAL OF A GENERAL LICENSE DEVICE FROM A GENERAL LICENSEE TO A SPECIFIC LICENSEE

A general licensee must furnish a report to the Department within 30 days after the transfer of a device to a specific licensee, per 180 NAC 3-008.04, item h. The specific licensee must have a license that allows for the transfer of the device(s). The report must contain the following information:

TRANSFER'S INFORMATION

General License Number _____

General Licensee's Name _____

Contact Person _____

Contact's Phone Number _____

ITEM(S) TRANSFERRED INFORMATION

*ID #	Date of Transfer	Type of Device	Model Number	Serial Number	Isotope	Activity and Units

*If available include the ID number of the device listed on the "General License Registration and/or Inventory Report" sent with your annual bill.

SPECIFIC LICENSEE TO WHOM THE DEVICE(S) IS TRANSFERRED INFORMATION

Name _____

License Number _____

Address _____

Date of Transfer _____

Signature _____ Date _____

**ATTACHMENT B
 INFORMATION NEED FOR TRANSFERING A GENERAL LICENSE DEVICE
 TO A GENERAL LICENSEE ONLY IF THE
 DEVICE REMAINS IN USE AT A PARTICULAR LOCATION**

In such case the transferor must give the transferee a copy of 180 NAC 3-008.01, 3-030, 4-057 and 4-058 and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor must report to the Department the following:

TRANSFER'S INFORMATION

General License Number _____

General Licensee's Name _____

Contact Person _____

Contacts Phone Number _____

Mailing Address for the location of use _____

ITEM(S) TRANSFERRED INFORMATION

*ID #	Date of Transfer	Type of Device	Model Number	Serial Number	Isotope	Activity and Units

*If available include the ID number of the device listed on the "General License Registration and/or Inventory Report" sent with your annual bill.

Date of Transfer _____

TRANSFEEE INFORMATION

Transferee Name _____

**Name and Title of Responsible Individual identified by the transferee:

Name _____ Title _____

Phone Number _____

Address _____

**The responsible person will be an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibilities in this regard.

Signature _____ Date _____