

Gamma Radiation Safety

For Gauges Using Gamma Sources

Safety Guide

P/N 717904

Revision A



**RADIOACTIVE
MATERIALS**

AUTHORIZED PERSONNEL ONLY

RADIATION AREA

Gamma Radiation Safety

For Gauges Using Gamma Sources

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Revision History

Revision Level	Date	Comments
Rev. A	03-07	Initial release (ERO 5553).

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Chapter 1

Gauge Safety & Regulatory Requirements – U.S.

Radioactive Material Control – General

Instruments and devices containing radioactive material are subject to regulation by the U.S. Nuclear Regulatory Commission (NRC), an Agreement State, or in Canada, by the Canadian Nuclear Safety Commission (CNSC). An Agreement State is a state with which the NRC has entered into a written agreement under Section 274(b) of the Atomic Energy Act of 1954, as amended (see also Title 10 CFR Part 150.15). Because of the similarities between the programs (Agreement States and the NRC), references to U.S. regulations in this section will discuss the NRC requirements. It is the licensee's responsibility to comply with respective regulatory agency requirements. To assist you, a list of regulatory agency offices is located at the end of this section. The approach utilized in assuring the safety of a manufactured device containing radioactive material is to regulate the manufacturer or distributor (if the gauge or device is not manufactured in the licensing country). The inherent safety of the device is studied, and conditions for assuring its safety are contained in the manufacturer's U.S. specific license, under which the device is produced and distributed in the U.S., or under the Canadian Device Approval Certificate, under which the device is distributed in Canada. Additional conditions, incident to the use of the device, are covered in the regulations and customer's license under which the user takes possession. The following paragraphs discuss the inherent safety features of Thermo Scientific gauges, the magnitude of the radiation hazard, and the user's regulatory responsibility.

Safety of the Thermo Scientific Industrial Gauge

As with any device containing radioactive material there are two general areas of concern relative to the safe use of these devices. The first is to ensure that the radioactive material remains securely contained within the source housing under all conditions. This is a primary goal of the manufacturer and is accomplished by the engineering design and construction of the source and the source housing. Both the source capsule (manufactured by others) and source housing (manufactured by Thermo Fisher) are extremely rugged in design and can withstand severe shock, vibration, and elevated temperatures with little probability of release of radioactive material. The source capsules used in the gauging devices emit

very penetrating radiation. This characteristic requires the shield to be relatively massive, but it also allows the radioactive material to be doubly encapsulated in stainless steel. According to the manufacturer, the source pellet (radioactive material) is placed into a small steel cylinder that is welded closed and tested for leakage. After testing, this capsule is then placed inside another stainless steel cylinder, which is also welded closed. This double encapsulation ensures that the source material remains contained even under extreme accident conditions. Sources used in Thermo Scientific source housings have been subjected to and passed tests demonstrating conformance with standards set in American National Standards Institute ANSI N-542 (1977), the U.S. Department of Transportation (DOT), and Canadian Nuclear Safety Commission (CNSC) specifications for “special form” material.

The high integrity of the source construction is additionally supported by the design and construction of the source housing. The source housing is very rugged. Thermo Fisher tests and certifies its source housings as meeting the DOT and CNSC criteria for “Type A” packaging criteria. These tests include dropping the container and dropping a rod onto the container from specified heights, soaking the container in water, stacking the containers, and vibration testing. When the shutter is in the “off” (stored/closed) position, the source is entirely shielded and the radiation outside of the housing is reduced to a very low level (normally less than 5 mR/hr. [50 μ Sv/hr.] at 30 cm). This allows work to be done in the vicinity of the device or for storage of the gauge for extended periods of time without significant hazard. When the shutter is placed in the “on” (open or measure) position, however, a beam of radiation is emitted, which can present a hazard unless properly managed. This brings us to the second area of concern: prevention of unnecessary radiation exposure.

The user of the device is generally responsible for controlling radiation exposure by ensuring that the shutter is in the off position any time the device is not installed in a proper operating configuration, any time individuals are working in a vessel being monitored, and whenever the gauge is not in use. The beam emitted when the shutter is on resembles the shape of a flashlight. Gamma radiation cannot be focused or reflected like light, but the situation is similar in that the housing collimates the radiation being emitted. The result is a narrow beam between the source housing and the detector. There should never be a situation in which personnel are allowed direct access to the space between the source and the detector when the shutter is open. Although the radiation level in other areas near the gauge will be quite low, even with the beam on, personnel must be made aware of the presence of the gauge and its location so that they do not spend unnecessary time in the immediate vicinity. Radiation levels in all directions except the useful beam will approximate normal background levels at a distance of approximately 15 ft. (4.6 m). Besides the source housing, all other elements of the installation must be considered in

assessing the total safety of the system. These elements should include the method of gauge mounting, characteristics of the process material, the ambient environment considering vibration and temperature, and any maintenance requirements. In certain cases, supplementary shielding may need to be included at the time of installation. The advice of a qualified technician at the time of installation is generally valuable in addressing these elements.

Additional Safety Notes

In the event of an accident, fire, or explosion that may have damaged the source housing or shutter mechanism, notify the regulatory authorities listed in your license and Thermo Fisher. Personnel should keep a reasonable distance away from the gauge until it is determined by appropriate measurements that the area is safe. Personnel fully trained in the use of the survey instrument being used must make such measurements. Erroneous measurements have been made when the operator was unfamiliar with the characteristics of the survey instruments and the radiation fields being measured. The following table may be used to estimate a reasonable distance. If the source size is uncertain, stay at least 40 ft. (12 m) away until the source type and size have been determined. A reasonable distance should be maintained above, below, and around the device. These “safe distances” measure approximately 2 mR in any one hour (20 µSv in any one hour) at the respective points. For Co-60 sources the safe distances should, at a minimum, be doubled.

Table 1–1.

Remain this distance from an unshielded source after an accident

Radioactive Material	Source Size	Safe Distance
Cs-137	200 mCi (7.4 GBq)	20 ft. (6 m)
Cs-137	500 mCi (18.5 GBq)	30 ft. (9 m)
Cs-137	1000 mCi (37 GBq)	36 ft. (11 m)
Cs-137	2000 mCi (74 GBq)	50 ft. (15 m)
Cs-137	4000 mCi (148 GBq)	70 ft. (21 m)

If the source housing containing radioactive material is lost or stolen, notify the regulatory authorities listed on the license or at the end of this section immediately.

Under no circumstances should you remove the source from the source housing, nor allow anyone else to do so without first contacting Thermo Fisher or the appropriate regulatory authority.

Should you discontinue using the gauge, contact Thermo Fisher. The final disposition of radioactive material must be handled by someone specifically licensed. Radiological emergency assistance can always be obtained from

the regulatory offices listed in your license or at the end of this section and our technical support department at 713-272-0404.

Regulatory Responsibilities – U.S.

Items containing certain quantities of radioactive material may be obtained and possessed only under a license that permits the possession and use of that device. Generally, there are only two types of licenses under which such devices may be possessed in the industrial market. These are the general license and the specific license.

General License

Certain devices may be distributed for particular uses under the provisions of what is referred to as a general license. The general license for nuclear gauges under NRC jurisdiction is contained in the federal regulations as 10CFR31.5. Agreement States have nearly identical wording included in their individual State Regulations. Excerpts from the NRC and Texas Department of Health, Bureau of Radiation Control regulations pertaining to general licensing are attached. Although one may not need to apply to a regulatory agency, and no documentation is received other than from the manufacturer, a general license is a license in the strictest sense of the word. Several Agreement States are implementing general license programs that may require registering with and paying a license fee to the regulatory agency.

For convenience, the wording on the general license tag that is placed on general licensed devices is reproduced below.

REMOVAL OF THIS LABEL IS PROHIBITED
1. The receipt, possession, use and transfer of this device are subject to the general license provisions of the United States Nuclear Regulatory Commission (NRC) or Agreement State regulations.
2. Abandonment or disposal is prohibited. Transfers must be in accordance with NRC or Agreement State regulations.
3. Continued operation is prohibited if there is any indication of failure of the source shielding or shutter. Thermo Fisher should be notified.
4. Only persons specifically authorized by the NRC or an Agreement State may install, relocate, dismantle or repair the source containment portion of this device.
5. This device shall be leak tested, following manufacturer instructions, at intervals not to exceed three years. The licensee must maintain records of the results on file.
6. The device shall be check for proper shutter mechanism function (if applicable) every six months. The licensee must maintain records of the results on file.
7. Additional information on regulatory and safety requirements are contained in the manual furnished by Thermo Fisher.

Specific License

A specific license is a document formally issued by a regulatory agency following submission of an application form (and fee) by the user. Specific licenses specify authorized possession limits and conditions of use for each gauge. In certain instances it is necessary to obtain a specific license for the simple possession and use of a Thermo Scientific gauge. In other cases the user may wish to apply for a specific license in order to take advantage of the additional flexibility available in meeting the specific needs of a particular application. Any additional activities or flexibility allowed, however, is limited to those consistent with the application submitted and the training of the personnel involved.

Limitations pertaining to the possession and use of radioactive materials are extrapolated from NRC or Agreement State regulations and stated in the specific license. The following items are sometimes overlooked by the user and are often cited by regulators for non-compliance.

1. The licensee must maintain the following records: receipt records, leak test certificates, radioactive materials license or a copy of the regulations, installation, servicing, and removal records, records of transfer or disposal, and six months of physical inventory records and shutter mechanism function check records.

2. The licensee may remove the source housing from the shipping crate for inspection and, in many cases, may mount the device in its designated location. The device may also be stored in an area that provides security from unauthorized access or removal.
3. The licensee may not remove shutter-inhibiting shipping bolts and/or locks unless the radioactive materials license authorizes the radiation commissioning (installation) in addition to possession. The licensee must have written procedures in place and radiation survey instrumentation to be authorized to commission a gauge.
4. Leak testing is performed at specified intervals: three years for fixed gamma gauges and six months for portable units, unsealed sources, and alpha emitters. The license also states at what intervals leak testing will be performed according to procedures submitted by the user. If the licensee does not have permission to analyze the leak test wipes, Thermo Fisher can provide a kit with specific procedures for gauges.
5. Relocating the source housing once it has been commissioned requires a specific license condition authorizing that particular activity. The licensee may not remove the device once the initial radiation survey is performed and the shutter unlocked. Without proper authorization, survey instrumentation, and trained individuals, removing a gauging device from a properly installed position may involve an exposure hazard and violates regulations.
6. The licensee may not tamper with or attempt to modify the source housing or remove the source capsule.

Regulatory Responsibilities – Canada

Items containing certain quantities of radioactive material may be obtained and possessed only under a license that permits the possession and use of that device. This is a “Nuclear Substances and Radiation Devices License” issued by the CNSC. Licenses are issued to users under the terms of the Canadian Nuclear Safety and Control Act, which established the CNSC and the associated regulations. Licensees are required to obtain or possess any radioactive materials in quantities not exempted under the Nuclear Substances and Devices Regulation. The regulation states:

“exemption quantity” means

- (a) in respect of a radioactive nuclear substance set out in column 1 of the schedule, the corresponding quantity set out in column 2 of the schedule;

(b) in respect of a radioactive nuclear substance that is not set out in column 1 of the schedule,

(i) 10 kBq, where the atomic number of the substance is equal to or less than 81,

(ii) 10 kBq, where the atomic number of the substance is greater than 81 and the substance, or its short-lived radioactive progeny, does not emit alpha radiation, and

(iii) 500 Bq, where the atomic number of the substance is greater than 81 and the substance or its short-lived radioactive progeny emits alpha radiation; and

(c) in respect of more than one radioactive nuclear substance, any combined quantity of those substances in which the sum of the quotients obtained by dividing the quantity of each substance by its corresponding exemption quantity, as referred to in paragraphs (a) and (b), is equal to, or greater than one.

CNSC licenses are required for virtually all radioactive material and devices containing radioactive material delivered to sites in Canada. Licenses are issued by CNSC upon completion of an application form and payment of the applicable fee.

Licenses specify allowed activities. The license includes limitations pertaining to the possession and use of radioactive materials extrapolated from the CNSC regulations and clearly stated in the license.

The following items are sometimes overlooked by the user and are often cited by regulators for non-compliance.

1. The licensee must maintain the following records: receipt records, leak test certificates, radioactive materials license, a copy of the regulations, installation, servicing, and removal records, records of transfer or disposal, and an up-to-date inventory as stipulated in the regulations.
2. The licensee may not remove the source housing from the shipping crate for mounting unless this activity is specifically authorized on the license. The device must also be stored in a posted area that provides security from unauthorized access or removal.
3. The licensee may not remove the source housing from the shipping container unless the CNSC license specifically authorizes commissioning (installation) in addition to possession. The licensee must have CNSC approved procedures in place and radiation survey instrumentation to be authorized to commission a gauge.

4. Leak testing is performed at specified intervals: typically every year for fixed or portable units that are in service, every 2 years for fixed or portable units that are in storage, and every 6 months for unsealed sources. In most cases the licensee may take the leak test sample in the field but will not have permission to analyze the leak test wipes. Thermo Fisher can provide a kit with specific procedures for gauges.
5. Relocating the source housing once it has been commissioned requires a specific license condition authorizing that particular activity. Without proper authorization, survey instrumentation, and trained individuals, removing a gauging device from a properly installed position may involve an exposure hazard and violates the license and regulations.
6. The licensee may not tamper with or attempt to modify the source housing or remove the source capsule.

U.S. Agreement States & NRC Contact Information

*32 Agreement States

- Alabama: Kirksey E. Whatley, Director
State Department of Public Health
Office of Radiation Control
201 Monroe Street
Montgomery, AL 36130-3017
Phone: 334-206-5391
Fax: 334-288-7207
kwhatley@adph.state.al.us
<http://www.adph.org/radiation>
- Arizona: Aubrey V. Godwin, Director
Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040
Phone: 602-255-4845, ext. 222
Fax: 602-437-0705
agodwin@arra.state.az.us
- Arkansas: Bernard Bevill, Interim Team Leader
Division of Radiation Control & Emergency Management
Department of Health
4815 West Markham Street, Slot #30
Little Rock, AR 72205-3867
Phone: 501-661-2301
Fax: 501-661-2236
brbevill@healthyarkansas.com

- California: Edgar D. Bailey, CHP, Chief
Division of Food & Radiation Safety Radiological Health
Branch 601 North 7th Street
Sacramento, CA 94234-7320
Phone: 916-322-3482
Fax: 916-324-3610
ebailey@dhs.ca.gov
<http://www.dhs.cahwnet.gov/rhb/index.htm>
- Colorado: Eugene Potter, CHP, Program Manager
Laboratory & Radiation Services Division
Radiation Services
8100 Lowry Blvd.
Denver, CO 80230-6928
Phone: 303-692-3685
Fax: 303-692-3692
eugene.potter@state.co.us
http://www.cdphe.state.co.us/Ir/RS/li_hom.asp
- Florida: William A. Passetti, Chief
Department of Health
Bureau of Radiation Control
4052 Bald Cypress Way, Bin C21
Tallahassee, FL 32399-1741
Phone: 850-245-4266
Fax: 850-487-0435
bill_passetti@doh.state.fl.us
<http://www.doh.state.fl.us/environment/radiation>
- Georgia: Thomas Hill, Manager
Department of Natural Resources
Radioactive Materials Program
4244 International Parkway, Suite 114
Atlanta, GA 30354
Phone: 404-362-2675
Fax: 404-362-2653
thill@dnr.state.ga.us
<http://www.ganet.org/dnr/environ/>
- Illinois: Gary Wright, Director
Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704
Phone: 217-785-0600
Fax: 217-782-9762
wright@idns.state.il.us
<http://www.state.il.us/idns>

Gauge Safety & Regulatory Requirements – U.S.

U.S. Agreement States & NRC Contact Information

- Iowa: Donald A. Flater, Chief
Iowa Department of Public Health
Bureau of Radiological Health
407 S.W. 7th Street, Suite D
Des Moines, IA 50309
Phone: 515-281-3478
Fax: 515-725-0318
dflater@idph.state.ia.us
http://www.idph.state.ia.us/hpevh/radiological_health.asp
- Kansas: Thomas A. Conley, CHP, RRPT, Chief, Radiation and
Asbestos Control Section
Bureau of Air and Radiation Department of Health and
Environment
1000 SW Jackson Street, Suite 310
Topeka, KS 66612-1366
Phone: 785-296-1565
Fax: 785-296-0984
tconley@kdhe.state.ks.us
<http://www.kdhe.state.ks.us/radiation/>
- Kentucky: Robert L. Johnson, Manager
Cabinet for Health Services Radiation Health and Toxic
Agents Branch
275 East Main Street
Frankfort, KY 40621-0001
Phone: 502-564-7818
Fax: 502-564-1492
robertL.johnson@mail.state.ky.us
<http://publichealth.state.ky.us/radiation.htm>
- Louisiana: Michael Henry, Senior Environmental Scientist
Office of Environmental Services
Permits Division
7220 Bluebonnet Road (70810)
Baton Rouge, LA 70884-2135
Phone: 225-765-0892
Fax: 225-765-0222
mhenry@ldeq.org
<http://www.deq.state.la.us/>

- Maine: Jay Hyland, PE, Program Manager
Radiation Control Program
Division of Health Engineering
161 Capitol Street
Augusta, ME 04333-0011
Phone: 207-287-5676
Fax: 207-287-3059
jay.hyland@maine.gov
<http://www.state.me.us/dhs/eng/rad/>
- Maryland: Roland G. Fletcher, Environmental Program Manager III
Air and Radiation Management Administration
Radiological Health Program
1800 Washington Boulevard, Suite 750
Baltimore, MD 21230-1724
Phone: 410-537-3301
Fax: 410-537-3198
rfletcher@mde.state.md.us
http://www.mde.state.md.us/programs/airprograms/radiological_health/index.asp
- Massachusetts: Robert Walker, Director
Department of Public Health
Radiation Control Program
174 Portland St., 5th Floor
Boston, MA 02114
Phone: 617-727-6214
Fax: 671-727-2098
bob.walker@state.ma.us
<http://www.state.ma.us/dph/rcp/radia.htm>
- Mississippi: Robert W. Goff, Director
State Department of Health
Division of Radiological Health
3150 Lawson Street
Jackson, MS 39215-1700
Phone: 601-987-6893
Fax: 601-987-6887
rgoff@msdh.state.ms.us
<http://www.health.ms.gov>

Gauge Safety & Regulatory Requirements – U.S.
U.S. Agreement States & NRC Contact Information

- Nebraska: Julia Schmitt, Program Manager
Regulation and Licensure
Department of Health & Human Services
301 Centennial Mall South
Lincoln, NE 68509-5007
Phone: 402-471-0528
Fax: 402-471-0169
julia.schmitt@hhs.state.ne.us
<http://www.hhs.state.ne.us/rad/radindex.htm>
- Nevada: Stanley R. Marshall, Supervisor
Bureau of Health Protection Services
Radiological Health Section
1179 Fairview Drive, Suite 102
Carson City, NV 89701-5405
Phone: 775-687-5394
Fax: 775-687-5751
smarshall@nvhd.state.nv.us
<http://health2k.state.nv.us/bhps/rhs/>
- New Hampshire: Vacant, Administrator
Department of Health and Human Services
Radiological Health Bureau
6 Hazen Drive
Concord, NH 03301-6527
Phone: 603-271-4688
Fax: 603-225-2325
<http://www.dhhs.state.nh.us/DHHS/BRH/default.htm>
- New Mexico: Cecilia Williams, Chief
Environment Department
Radiation Control Bureau, Field Operations Division
1190 St. Francis Drive, Room S2100
Santa Fe, NM 87502-0110
Phone: 505-476-8531
Fax: 505-476-3232
<http://www.nmenv.state.nm.us>
- New York: State Health Department:
Adela Salame-Alfie, Ph.D., Assistant Director
New York State Health Department
Bureau of Environmental Radiation Protection
547 River Street
Troy, NY 12180-2216
Phone: 518-402-7550
Fax: 518-402-7554
asa01@health.state.ny.us

State Environment Department:

Vacant, Director

Division of Solid & Hazardous Material

Bureau of Radiation

625 Broadway, 8th Floor

Albany, NY 12233-7255

Phone: 518-402-8605

Fax: 518-402-9025

<http://www.dec.state.ny.us/website/dshm/hazrad/rad.htm>

State Labor Department:

Clayton J. Bradt, CHP, Principal Radiophysicist,
Radiological Health Unit

New York State Department of Labor

Division of Safety and Health

NYS Office Campus, Building 12, Room 169

Albany, NY 12240

Phone: 518-457-1202

Fax: 518-485-7406

usccjb@labor.state.ny.us

New York City Health Department:

Gene Miskin, Director

New York City Department of Health

Bureau of Radiological Health

2 Lafayette Street, 11th Floor

New York, NY 10007

Phone: 212-676-1556

Fax: 212-676-1548

gmiskin@health.nyc.gov

North Carolina: Beverly Hall, Chief

Radiation Protection Section

Department of Environmental & Natural Resources

3825 Barrett Drive

Raleigh, NC 27609-7221

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beverly.hall@ncmail.net<http://www.drp.enr.state.nc.us>

- North Dakota: Terry O'Clair, Director
North Dakota Department of Health
Division of Air Quality
1200 Missouri Avenue, Room 304
Bismarck, ND 58506-5520
Phone: 701-328-5188
Fax: 701-328-5200
toclair@state.nd.us
<http://www.health.state.nd.us/ndhd/environ/ee/rad/rad.htm>
- Ohio: Roger L. Suppes, Chief
Ohio Department of Health
Bureau of Radiation Protection
Columbus, OH 43266-0118
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Fax: 614-466-0831
rsupes@gw.odh.state.oh.us
- Oklahoma: Mike Broderick, Environmental Program Admin.
Radiation Management Section
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Oklahoma City, OK 73101-1677
Phone: 405-702-5100
Fax: 405-702-5101
mike.broderick@deqmail.state.ok.us
- Oregon: Terry D. Lindsey, Program Director
Oregon Health Services
Radiation Protection Services
800 NE Oregon Street, Suite 260
Portland, OR 97232-2162
Phone: 503-731-4014
Fax: (503) 731-4081
terry.d.lindsey@state.or.us
<http://www.ohd.hr.state.or.us/rps/>
- Rhode Island: Marie Stoeckel, Chief
Department of Health
Division of Occupational & Radiological Health
3 Capitol Hill, Room 206
Providence, RI 02908-5097
Phone: 401-222-7755
Fax: 401-222-2456
maries@doh.state.ri.us
<http://www.healthri.org/environment/occupational/Home.htm>

- South Carolina: Pearce OKelley, Chief
Department of Health & Environmental Control
Radiological Health Branch
2600 Bull Street
Columbia, SC 29201
Phone: 803-545-4403
Fax: 803-545-4412
okelletp@dhec.sc.gov
<http://www.scdhec.net/hr/radhlth/>
- Tennessee: Lawrence E. Nanney, Director
L and C Annex, Third Floor
Division of Radiological Health
401 Church Street
Nashville, TN 37243-1532
Phone: 615-532-0360
Fax: 615-532-7938
eddie.nanney@state.tn.us
<http://www.state.tn.us/environment/rad/radppo/html>
- Texas: Richard A. Ratliff, PE, LMP, Chief
Texas Department of Health
Bureau of Radiation Control
1100 West 49th Street
Austin, TX 78756-3189
Phone: 512-834-6679
Fax: 512-834-6708
richard.ratliff@tdh.state.tx.us
<http://www.tdh.state.tx.us/radiation/>
- Utah: William Sinclair, Director
Department of Environmental Quality
Division of Radiation Control
168 North 1950 West
Salt Lake City, UT 84114-4850
Phone: 801-536-4255
Fax: 801-533-4097
bsinclair@utah.gov
<http://www.radiationcontrol.utah.gov>

Washington: Gary Robertson, Director
Department of Health
Division of Radiation Protection
7171 Cleanwater Lane, Bldg. #5
Olympia, WA 98504-7827
Phone: 360-236-3210
Fax: 360-236-2255
gary.robertson@doh.wa.gov
<http://www.doh.wa.gov/ehp/rp>

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Radiation Protection Section
Division of Public Health
Post Office Box 2659
Madison, WI 53701-2659
Phone: 608-267-4792
Fax: 608-267-4799
schmips@dhfs.state.wi.us

U.S. Nuclear Regulatory Commission

Safety Hotline: 800-695-7403

Headquarters: One White Flint North or Two White Flint North
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852-2738
Telephone: 301-415-7000

Region I: CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI and VT:
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415
Telephone: 800-432-1156

REGION II: AL, FL, GA, KY, MS, NC, PR, SC, TN, VA, VI, WV and
Panama Canal:

Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region II
Atlanta Federal Center
61 Forsyth Street, SW, Suite 23T85
Atlanta, GA 30303-3415
Telephone: 800-577-8510

REGION III: IA, IL, IN, MI, MN, MO, OH and WI:

Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351
Telephone: 800-522-3015

REGION IV: AK, AR, AZ, CA, CO, HI, ID, KS, LA, MT, NE, ND, NM,
NV, OK, OR, TX, UT, WA, WY and Pacific Trust Territories:

Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region IV
Harris Tower
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064
Telephone: 800-952-9677

Excerpts from the NRC General License Requirements

Title 10 CFR 31.5A

“General License” means an authorization granted by the regulations and a company or entity becomes a General Licensee (GL) when they receive a generally licensed device.

- I. The GL should assure that:
 - A. All labels affixed to the device at the time of receipt and bearing the statement that removal of the label is prohibited are maintained thereon;
 - B. The device is tested for leakage and proper operation of the on and off mechanism/ indicator, if any, at no longer than six months or as specified on the label. Records of those tests must be maintained for three years after the next test.
 - C. Any testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment must be performed in accordance with instructions on the label and by a specific licensee authorized to provide such a service. Records of performance of these activities must be maintained and should contain at least:
 1. the date the activity was performed,
 2. the name of the person performing the activity,
 3. the company name and their specific license number, and
 4. a brief description of the activity that was performed.

D. If failure or damage occurs to the device or if the leak test results are greater than 0.005 μCi removable contamination, then:

1. The operation must be suspended until repaired by an authorized specific licensee.
2. The device if transferred for disposal must be performed by an authorized specific licensee.
3. The general licensee (company or entity) must notify the NRC, within 30 days, of incident with a brief description of the event, and any remedial action that may have been taken.

E. The device can be transferred* to another GL only if the:

1. device remains at the same location (i.e., same plant in the installed or stored location), and
2. a copy of 10 CFR 31 regulations is provided, and
3. safety documents identified in the label is provided, and
4. licensee notifies the NRC within 30 days of transfer with specific information.

* A device cannot be transferred to another GL at another location (e.g., from Company A in Anytown, USA to Company Z in Anytown, USA) without being redistributed by the manufacturer.

II. Physical Inventory: The licensee should also conduct a physical (i.e., visual) inventory/inspection, every six months, of all devices they are authorized to possess. This requirement, although not specifically in 10 CFR 31, is often dictated by the manufacturer's license commitments or in the "Registry of Radioactive Sealed Sources and Devices." The purpose to assure accountability of the devices and making sure that all tags are clearly legible and visible.

III. Compliance with Other NRC Regulations: The GL needs only to comply with 10 CFR 20.2201 and 20.2202 for reporting radiation incidents, theft, or loss and is exempt from all other requirements of 10 CFR 19, 20, and 21.

Chapter 25 of the Texas Administrative Code



The following regulations are **excerpts only** and outline your responsibilities as a licensee and the conditions under which you must possess, use, and transfer these devices. Regulations can be confusing to read and interpret; therefore, following is a brief summary of those items of which you should be most aware. The regulations refer to the Chapter 25 Texas Administrative Code (TAC).

Note This summary does not alleviate your responsibility for reading the regulations. ▲

Note These are excerpts from the Texas Regulations for Control of Radiation as they apply to any person who receives, acquires, possesses, or uses radioactive material under the General License Provisions of the regulations. If you are in another state, other (similar) regulations will apply and you must obtain and read a copy of the pertinent state or NRC regulations. ▲

289.251(f) “General License” and 289.251(j) “General License Acknowledgements”

Following are summaries of the requirements in the state of Texas for companies receiving generally licensed devices.

1. Part 289.251(k)(1)(C), requires the general licensee, within 30 days of receipt, acquisition, or possession of a generally licensed device to file an application for a general license acknowledgement (GLA).
2. If you have a GLA from the Agency you must make sure that all the devices listed on the GLA are properly listed (i.e., model number, activity, and isotope).
3. The GLA holder is not required to add new devices on the GLA in cases where the manufacturer, model, and isotope are already listed on the GLA. For example, if the GLA already lists a Model 5201 gauge containing Cs-137, you would not need to modify the GLA if you received another 5201 containing Cs-137.
4. It is your responsibility to abide by all the conditions listed on the GLA. In addition, a GLA Self Inspection/Evaluation Form will be sent out, most likely with the annual invoice. You will need to complete the form and send it to the Agency.
5. If you need to change anything on the GLA, an amendment must be sent on BRC Form 40-1, 40-2 or company letterhead. Part 289.251(o)(1) requires notification within 30 days of any changes to

the information contained on your application. If you use your company letterhead to request an amendment, make sure that all information required for the change on the application form is included in the letter.

289.201(e)(3) “Inspections”

Each licensee shall make available to the agency for inspection, upon reasonable notice, records maintained in accordance with this chapter.

289.201(d) “Records”

- (1) Each licensee shall maintain records showing the receipt, transfer, and disposal of all licensed sources of radiation. These records shall be maintained by the licensee or registrant until disposal is authorized by the Agency. Additional record requirements are specified elsewhere in this chapter. All records required by these rules shall be accurate and factual.
- (2) Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

289.201(f) “Tests”

Each licensee and registrant shall perform, upon instructions from the Agency, or shall permit the Agency to perform such reasonable tests as the Agency deems appropriate or necessary...

289.201(g) “Tests for Leakage and/or Contamination of Sealed Sources”

- (1) The licensee in possession of any sealed source shall assure that:
 - (A) each sealed source, except as specified in paragraph (2), is tested for leakage or contamination and the test results are received before the sealed source is put into use, unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee;
 - (B) each sealed source, that is not designated to emit alpha particles, is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Agency, after evaluation of information specified in 289.252(h)(7)(D) and (E) of this title (relating to Licensing of Radioactive Material);
 - (C) each sealed source, that is designated to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Agency, after evaluation of information specified in 289.252(h)(7)(D) and (E) of these rules or by an agreement state, a licensing state, or the NRC;
 - (D) at any other time there is reason to suspect that any sealed source that is required to be tested for leakage and contamination might

have been damaged or might be leaking, the licensee shall assure that the sealed source is tested for leakage or contamination before further use;

- (E) tests for leakage of all sealed sources ... shall be capable of detecting the presence of 0.005 μCi (185 Bq) of radioactive material on a test sample. Test samples shall be taken from a sealed source or from the surfaces of the container in which the sealed source is stored or mounted where contamination might accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the “off” position.
- (2) A licensee need not perform tests for leakage or contamination on the following:
 - (A) sealed sources containing only radioactive material with a half-life of less than 30 days;
 - (B) sealed sources containing radioactive material as a gas;
 - (C) sealed sources containing 100 μCi (3.7 MBq) or less of beta- or photon- emitting material or 10 μCi (270 GBq) or less of alpha-emitting material;
 - (D) sealed sources containing only hydrogen-3;
 - (E) seeds of iridium-192 encased in nylon ribbon; and
 - (F) sealed sources ... which are stored, not being used, and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of transfer.
 - (3) Analysis of test for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the agency, an agreement state, a licensing state, or NRC to perform such services.
 - (4) Test results shall be kept in units of μCi (microcurie) or Bq (Becquerel) and maintained for inspection by the agency.
 - (5) The following shall be considered evidence that a sealed source is leaking:
 - (A) presence of 0.005 μCi (185 Bq) or more of removable contamination on any test sample;
 - (6) The license shall immediately withdraw a leaking source from use and shall take action to prevent contamination. The leaking sealed source shall be repaired or transferred for disposal in accordance with 289.202 of this title.

- (7) Reports of test results for leaking or contaminated sealed sources shall be made in accordance with 289.202(bbb) of this title.

289.202(ww) “Reports of Stolen, Lost, or Missing Sources of Radiation”

- (1) Each licensee shall report to the Agency by telephone as follows:
- (A) immediately after such occurrence becomes known to the licensee, stolen, lost, missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in subsection (ggg)(3) of this section, under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or
 - (B) within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than ten times the quantity specified in subsection (ggg)(3) of this section that is still missing.
- (2) Each licensee required to make a report in accordance with paragraph (1) of this subsection, shall within 30 days after making the telephone report, make a written report to the agency setting forth the following:
- (A) a description of the licensed source of radiation involved, including the kind, quantity, and chemical and physical form;
 - (B) a description of the circumstances under which the loss or theft occurred;
 - (C) a statement of disposition, or probable disposition of the licensed source of radiation;
 - (D) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
 - (E) actions that have been taken, or will be taken, to recover the source of radiation; and
 - (F) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed sources of radiation.
- (3) Subsequent to filing the written report, the licensee shall also report additional substantive information on the loss or theft within 30 days after the licensee learns of such information.
- (4) The licensee shall prepare any report filed with the Agency in accordance with this subsection so that the names of individuals who have received exposure to radiation are stated in a separate and detachable portion of the report.

289.251(k) “General License Acknowledgements of Radioactive Material other than Source Material”

Certain measuring, gauging, and controlling devices:

- (A) A general license is issued to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of their business, and state or local government agencies to receive, acquire, possess, use, or transfer in accordance with the provisions of subparagraphs (B)-(E) of this paragraph, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition.
- (B) The general license in subparagraph (A) of this paragraph applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with authorizations contained in a specific license issued by the Agency in accordance with 289.252(l) of this title or in accordance with authorizations contained in a specific license issued by the NRC, an Agreement State, or a licensing state, which authorizes distribution of devices to persons generally licensed by the NRC, an agreement state or licensing state.
- (C) Within 30 days following receipt, acquisition, or possession of radioactive material in a device, except for calibration, stabilization, and reference sources, electron capture detector cells, ion mobility spectrometers, beta backscatter gauges, and static meters issued in accordance with the general license in subparagraph (A) of this paragraph, the general licensee shall file an application for an acknowledgement on a form prescribed by the Agency. The application shall be signed by the individual duly authorized to act for or on behalf of the general licensee. In filing the application for acknowledgement, the general licensee shall furnish the following information and any other information specifically requested by the agency:
 - (i) name and mailing address of the general licensee;
 - (ii) information about each device including the manufacturer, model number, serial number of the device and sealed source, and the radioisotope and activity (as indicated on the label);
 - (iii) name and telephone number of the responsible person designated as a representative of the holder of a general license acknowledgement in accordance with subparagraph (E)(xii) of this paragraph;

- (iv) address at which the device(s) is/are used and/or stored. For portable devices, the address of the primary place of storage;
 - (v) certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label; and
 - (vi) certification by the responsible representative of the general licensee that they are aware of the requirements of this section.
- (D) Each application shall be accompanied by BRC Form 252-1, Business Information Form, and the applicable fee as required by Part 289.204 of this title.
- (E) Any person who receives, acquires, possesses, uses, or transfers radioactive material in a device in accordance with the general license in subparagraph (A) of this paragraph shall do the following:
- (i) assure that all labels bearing a statement that removal of the label is prohibited, are affixed to the device at the time of receipt, are maintained on the device, and are clearly visible and legible. The general licensee shall comply with all instructions and precautions provided by such labels;
 - (ii) assure that the device is tested for leakage of radioactive material and proper operation of the “on-off” mechanism and indicator, if any, at no longer than six month intervals or at such other intervals as specified in the label...
 - (iii) shall assure that the tests required in clause (ii) of this subparagraph and other testing, installation (removal of the manufacturer’s lock and initial alignment of the radiation beam), servicing, and removal from location of installation involving the radioactive materials, shielding, or containment, are performed:
 - (I) in accordance with the instructions provided by the labels;
 - (II) in accordance with written instructions provided by the manufacturer as specified in 289.252(l)(3) of this title; or
 - (III) by a person holding a specific license from the agency, the NRC, an agreement state, or a licensing state to perform such activities;
 - (iv) maintain records showing compliance with the requirements of clauses (ii) and (iii) of this subparagraph. The records shall show the results of tests. The records also shall identify the device tested by manufacturer, model number, serial number of the device and serial number of the sealed source, and show the dates of performance and the names of persons performing

testing, installation, servicing, and removal from location of installation, of the radioactive material, its shielding, or containment;

- (v) maintain assignment records for portable or mobile devices for inspection by the Agency at the location listed in the general license acknowledgement. These records shall include:
 - (I) a unique identification (e.g., serial number) of each portable or mobile device;
 - (II) the location(s) where each portable or mobile device is assigned;
 - (III) and the date(s) each portable or mobile device is assigned to the location(s) in accordance with subclause (II) of this clause.
- (vi) maintain utilization records for each portable or mobile device used at the location(s) in accordance with clause (v)(II) of this subparagraph for inspection by the agency at that location(s);
- (vii) have a copy of the appropriate operating and instruction manual at each temporary site for agency inspection;
- (viii) upon occurrence of a failure of or damage to, or any indication of a possible failure or damage to, the radioactive material shielding or the “on-off” mechanism, or upon the detection of 0.005 Ci or more of removable radioactive contamination, immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the agency, the NRC, an Agreement State, or a licensing state to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within 30 days, furnish the agency with a report containing a brief description of the event and the remedial action taken and in the case of detection of 0.005 Ci or more of removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use. Under these circumstances, the requirements in Part 289.202(eee) of this title may be applicable, as determined by the agency on a case-by-case basis;
- (ix) shall not abandon the device containing radioactive material;
- (x) except as provided in clause (xi) of this subparagraph, shall transfer or dispose of the device containing radioactive material only by transfer to a person holding a specific licensee of the

agency in accordance with 289.252(l) of this title, or an equivalent specific license issued by the NRC, an Agreement State or a licensing state, whose specific license authorizes the receipt of the device, or as otherwise authorized by the Agency in writing, and within 30 days after transfer of a device to a specific licensee, shall furnish to the Agency and Agreement State with a report containing identification of the device by manufacturer's name, model and serial number of the device and the serial number of the sealed source, the name, address and license number of the person receiving the device (except when the device is temporarily transferred to the specific licensee for repair of the device); and the date of transfer;

(xi) transfer the device to another general license(e) only:

(I) when the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this rule and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency the manufacturer's name, the model and serial number of the device transferred, the serial number of the sealed source transferred, the name and address of the transferee, and the name and telephone number of the responsible individual identified by the transferee in accordance with clause (xii) of this subparagraph to have knowledge of and authority to take actions to ensure compliance with the appropriate agency requirements and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or

(II) where the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by the holder of a general license acknowledgement.

(xii) to appoint an individual responsible for having knowledge of the appropriate agency requirements and the authority for taking required actions to comply with appropriate agency requirements. The general licensee, through this appointed individual, shall ensure day-to-day compliance with appropriate Agency requirements. This appointment does not relieve the general licensee of responsibility in this regard;

(xiii) to report changes of address (including change in name of the holder of a general license acknowledgement) to the agency within 30 days of the effective date of change. If it is a portable device, report of address change is only required for a change in the device's primary place of storage; and

(xiv) not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by clause (ii) of this subparagraph need not be performed during the period of storage only. However, when devices are put back into services or transferred to another person, and have not been tested within the required test interval, they shall be tested for leakage before transfer and the shutter tested before use.

(F) The general license in subparagraph (A) of this paragraph does not authorize the manufacture of devices containing radioactive material.

(G) The written instructions specified in subparagraph (E)(iii)(II) of this paragraph shall be followed while performing the testing and shall be maintained for inspection by the agency.

289.251(m) “Specific Terms and Conditions of Licenses”

- (1) Each general license acknowledgement issued in accordance with this part shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to applicable rules and orders of the Agency.
- (2) Each person holding a general license issued by the Agency in accordance with this section shall confine use and possession of the material licensed to the locations and purposes authorized in the general license acknowledgement.
- (3) Each holder of a general license acknowledgement shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy.
- (4) The notification in paragraph (3) of this subsection shall include:
 - (i) the bankruptcy court in which the petition for bankruptcy was filed; and
 - (ii) the date of the filing of the petition.
- (5) A copy of the “Petition for Bankruptcy” shall be submitted to the agency in written notification.

289.251(n) “Termination of General License Acknowledgements”

- (1) Each holder of a general license acknowledgement shall notify the Agency immediately, in writing, and request termination of the general license acknowledgement when the holder of the general license acknowledgement decides to terminate all activities involving materials specified in the general license acknowledgement.

Gauge Safety & Regulatory Requirements – U.S.

Chapter 25 of the Texas Administrative Code

289.257 “Packaging and Transportation of Radioactive Material”

Contact Thermo Fisher for information on the proper transfer, redistribution, and transportation of generally licensed gauges.

Chapter 2

Gauge Safety & Regulatory Requirements – Canada

General Nuclear Safety & Control Regulations

Exemptions from Licensing for Naturally Occurring Substances (Section 10)

10. Naturally occurring nuclear substances, other than those that are or have been associated with the development, production, or use of nuclear energy, are exempt from the application of all provisions of the Act and the regulations made under the Act except the following:
 - (a) the provisions that govern the transport of nuclear substances; and
 - (b) in the case of a nuclear substance listed in the schedule to the Nuclear Non-proliferation Import and Export Control Regulations, the provisions that govern the import and export of nuclear substances.

Obligations of Licensees (Section 12)

12. (1) Every licensee shall
 - (a) ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the Act, the regulations made under the Act, and the license;
 - (b) train the workers to carry on the licensed activity in accordance with the Act, the regulations made under the Act, and the license;
 - (c) take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security;
 - (d) provide the devices required by the Act, the regulations made under the Act, and the license and maintain them within the manufacturer's specifications;
 - (e) require that every person at the site of the licensed activity use equipment, devices, clothing, and procedures in accordance with the Act, the regulations made under the Act, and the license;
 - (f) take all reasonable precautions to control the release of radioactive nuclear substances or hazardous substances within the site of the licensed activity and into the environment as a result of the licensed activity;

- (g) implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, prescribed equipment or prescribed information, or the illegal use of a nuclear facility;
- (h) implement measures for alerting the licensee to acts of sabotage or attempted sabotage anywhere at the site of the licensed activity;
- (i) take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement;
- (j) instruct the workers on the physical security program at the site of the licensed activity and on their obligations under that program; and
- (k) keep a copy of the Act and the regulations made under the Act that apply to the licensed activity readily available for consultation by the workers.

Obligations of Workers (Section 17)

17. Every worker shall

- (a) use equipment, devices, facilities, and clothing for protecting the environment or the health and safety of persons, or for determining doses of radiation, dose rates or concentrations of radioactive nuclear substances, in a responsible and reasonable manner and in accordance with the Act, the regulations made under the Act, and the license;
- (b) comply with the measures established by the licensee to protect the environment and the health and safety of persons, maintain security, control the levels and doses of radiation, and control releases of radioactive nuclear substances and hazardous substances into the environment;
- (c) promptly inform the licensee or the worker's supervisor of any situation in which the worker believes there may be
 - (i) a significant increase in the risk to the environment or the health and safety of persons;
 - (ii) a threat to the maintenance of security or an incident with respect to security;
 - (iii) a failure to comply with the Act, the regulations made under the Act, or the license;
 - (iv) an act of sabotage, theft, loss, or illegal use or possession of a nuclear substance, prescribed equipment, or prescribed information; or

- (v) a release into the environment of a quantity of a radioactive nuclear substance or hazardous substance that has not been authorized by the licensee;
- (d) observe and obey all notices and warning signs posted by the licensee in accordance with the Radiation Protection Regulations; and
- (e) take all reasonable precautions to ensure the worker's own safety, the safety of the other persons at the site of the licensed activity, the protection of the environment, the protection of the public, and the maintenance of security.

Transfer of Material (Section 13)

13. No licensee shall transfer a nuclear substance, prescribed equipment, or prescribed information to a person who does not hold the license, if any, that is required to possess the nuclear substance, prescribed equipment, or prescribed information by the Act and the regulations made under the Act.

Posting of Licenses (Section 14)

14. (1) Every licensee other than a licensee who is conducting field operations shall post, at the location specified in the license or, if no location is specified in the license, in a conspicuous place at the site of the licensed activity,
- (a) a copy of the license, with or without the license number, and a notice indicating the place where any record referred to in the license may be consulted; or
 - (b) a notice containing
 - (i) the name of the licensee,
 - (ii) a description of the licensed activity,
 - (iii) a description of the nuclear substance, nuclear facility, or prescribed equipment encompassed by the license, and
 - (iv) a statement of the location of the license and any record referred to in it.
- (2) Every licensee who is conducting field operations shall keep a copy of the license at the place where the field operations are being conducted.
- (3) Subsections (1) and (2) do not apply to a licensee in respect of
- (a) a license to import or export a nuclear substance, prescribed equipment, or prescribed information;
 - (b) a license to transport a nuclear substance; or

- (c) a license to abandon a nuclear substance, a nuclear facility, prescribed equipment, or prescribed information.

Publication of Health & Safety Information (Section 16)

- 16. (1) Every licensee shall make available to all workers the health and safety information with respect to their workplace that has been collected by the licensee in accordance with the Act, the regulations made under the Act, and the license.
- (2) Subsection (1) does not apply in respect of personal dose records and prescribed information.

Reports & Records (Sections 27 to 29)

- 27. Every licensee shall keep a record of all information relating to the license that is submitted by the licensee to the Commission.
- 28. (1) Every person who is required to keep a record by the Act, the regulations made under the Act, or a license shall retain the record for the period specified in the applicable regulations made under the Act or, if no period is specified in the regulations, for the period ending one year after the expiry of the license that authorizes the activity in respect of which the records are kept.
- (2) No person shall dispose of a record referred to in the Act, the regulations made under the Act, or a license unless the person
 - (a) is no longer required to keep the record by the Act, the regulations made under the Act or the license; and
 - (b) has notified the Commission of the date of disposal and of the nature of the record at least 90 days before the date of disposal.
- (3) A person who notifies the Commission in accordance with subsection (2) shall file the record, or a copy of the record, with the Commission at its request.
- 29. (1) Every licensee who becomes aware of any of the following situations shall immediately make a preliminary report to the Commission of the location and circumstances of the situation and of any action that the licensee has taken or proposes to take with respect to it:
 - (a) a situation referred to in paragraph 27(b) of the Act;
 - (b) the occurrence of an event that is likely to result in the exposure of persons to radiation in excess of the applicable radiation dose limits prescribed by the Radiation Protection Regulations;
 - (c) a release, not authorized by the license, of a quantity of radioactive nuclear substance into the environment;

- (d) a situation or event that requires the implementation of a contingency plan in accordance with the license;
- (e) an attempted or actual breach of security or an attempted or actual act of sabotage at the site of the licensed activity;
- (f) information that reveals the incipient failure, abnormal degradation, or weakening of any component or system at the site of the licensed activity, the failure of which could have a serious adverse effect on the environment or constitutes or is likely to constitute or contribute to a serious risk to the health and safety of persons or the maintenance of security;
- (g) an actual, threatened, or planned work disruption by workers;
- (h) a serious illness or injury incurred or possibly incurred as a result of the licensed activity;
- (i) the death of any person at a nuclear facility; or
- (j) the occurrence of any of the following events:
 - (i) the making of an assignment by or in respect of the licensee under the Bankruptcy and Insolvency Act,
 - (ii) the making of a proposal by or in respect of the licensee under the Bankruptcy and Insolvency Act,
 - (iii) the filing of a notice of intention by the licensee under the Bankruptcy and Insolvency Act,
 - (iv) the filing of a petition for a receiving order against the licensee under the Bankruptcy and Insolvency Act,
 - (v) the enforcement by a secured creditor of a security on all or substantially all of the inventory, accounts receivable, or other property of the licensee that was acquired for, or used in relation to, a business carried on by the licensee,
 - (vi) the filing in court by the licensee of an application to propose a compromise or an arrangement with its unsecured creditors or any class of them under section 4 of the Companies' Creditors Arrangement Act,
 - (vii) the filing in court by the licensee of an application to propose a compromise or an arrangement with its secured creditors or any class of them under section 5 of the Companies' Creditors Arrangement Act,
 - (viii) the making of an application for a winding-up order by or in respect of the licensee under the Winding-up and Restructuring Act,

- (ix) the making of a liquidation, bankruptcy, insolvency, reorganization, or like order in respect of the licensee under provincial or foreign legislation, or
 - (x) the making of a liquidation, bankruptcy, insolvency, reorganization, or like order in respect of a body corporate that controls the licensee under provincial or foreign legislation.
- (2) Every licensee who becomes aware of a situation referred to in subsection (1) shall file a full report of the situation with the Commission within 21 days after becoming aware of it, unless some other period is specified in the license, and the report shall contain the following information:
- (a) the date, time, and location of becoming aware of the situation;
 - (b) a description of the situation and the circumstances;
 - (c) the probable cause of the situation;
 - (d) the effects on the environment, the health and safety of persons, and the maintenance of security that have resulted or may result from the situation;
 - (e) the effective dose and equivalent dose of radiation received by any person as a result of the situation; and
 - (f) the actions that the licensee has taken or proposes to take with respect to the situation.
- (3) Subsections (1) and (2) do not require a licensee to report a situation referred to in paragraphs (1)(a) to (j) if the license contains a term or condition requiring the licensee to report that situation, or any situation of that nature, to the Commission.

Incomplete Records (Section 31)

31. (1) Every licensee who becomes aware of an inaccuracy or incompleteness in a record that the licensee is required to keep by the Act, the regulations made under the Act, or the license shall file a report of the inaccuracy or incompleteness with the Commission within 21 days after becoming aware of it, and the report shall contain the following information:
- (a) the details of the inaccuracy or incompleteness; and
 - (b) any action that the licensee has taken or proposes to take with respect to the inaccuracy or incompleteness.

- (2) Subsection (1) does not apply to a licensee if
 - (a) the license contains a term or condition that requires the licensee to report inaccuracies or incompleteness in a record to the Commission; or
 - (b) the inaccuracy or incompleteness in the record could not reasonably be expected to lead to a situation in which the environment, the health and safety of persons, or national security is adversely affected.

Nuclear Substances & Radiation Device Regulations

Exempted Activities (Section 5)

- 5. (1) Subject to subsections (2) and (3), a person may carry on any of the following activities without a license to carry on that activity:
 - (a) possess, transfer, import, export, use, mine, produce, refine, convert, enrich, process, reprocess, manage, or store a nuclear substance, if the quantity of the nuclear substance does not exceed its exemption quantity;
 - (b) possess, transfer, import, export, use, abandon, produce, or service a sealed source that contains less than the exemption quantity of a nuclear substance, if not more than 10 such sealed sources are possessed by the person in any calendar year;
 - (c) possess, transfer, import, export, use, or abandon a radiation device, other than an exposure device, if the quantity of the nuclear substance or substances contained in the device is less than 10 times the exemption quantity; or
 - (d) possess, transfer, use, abandon, produce, refine, convert, enrich, process, reprocess, manage, store, or dispose of deuterium or a compound containing deuterium, if the quantity of deuterium is less than 10 kg in any calendar year.
- (2) Subsection (1) does not apply in respect of Category I, II, or III nuclear material, as defined in section 1 of the Nuclear Security Regulations.
- (3) Paragraphs (1)(a) to (c) do not apply in respect of the import or export of a nuclear substance, sealed source, or radiation device to which the Nuclear Non-proliferation Import and Export Control Regulations apply.
- (4) For greater certainty, the exemptions established in subsection (1) relate only to the activities specified in that subsection and do not derogate from the license requirement imposed by section 26 of the Act in relation to other activities.

Device Certification (Section 11)

11. (1) No person shall use a radiation device unless
- (a) it is a certified model; or
 - (b) it is used in accordance with a license that authorizes its use for development purposes.
- (2) No person shall transfer a radiation device for use within Canada unless it is a certified model.

Safety Instructions (Section 17)

17. Every licensee shall make available to all workers, at the site of the licensed activity, copies of any instructions referred to in the license concerning radiation safety and accidents, including fires and spills, in which a nuclear substance may be involved.

Leak Testing (Section 18)

18. (1) Subject to subsection (2), every licensee who possesses, uses, or produces either a sealed source containing 50 mBq or more of a nuclear substance or a nuclear substance as shielding shall, at the following times, conduct leak tests on the sealed source or shielding using instruments and procedures that enable the licensee to detect a leakage of 200 Bq or less of the nuclear substance:
- (a) where the sealed source or shielding is used after being stored for 12 or more consecutive months, immediately before using it;
 - (b) where the sealed source or shielding is being stored, every 24 months;
 - (c) where an event that may have damaged the sealed source or shielding has occurred, immediately after the event; and
 - (d) in all other cases,
 - (i) where the sealed source or shielding is located in a radiation device, every 12 months, and
 - (ii) where the sealed source or shielding is not located in a radiation device, every six months.
- (2) Subsection (1) does not apply in respect of a sealed source that is
- (a) gaseous; or
 - (b) contained in a static eliminator that has been retained by the licensee for less than 15 months.

- (3) Where a licensee, in the course of conducting a leak test on a sealed source or on shielding, detects the leakage of 200 Bq or more of a nuclear substance, the licensee shall
- (a) discontinue using the sealed source or shielding;
 - (b) discontinue using the radiation device in which the sealed source or shielding is located or may have been located;
 - (c) take measures to limit the spread of radioactive contamination from the sealed source or shielding; and
 - (d) immediately after complying with paragraphs (a) to (c), notify the Commission that the leakage has been detected.

Transfer Documents (Section 19)

19. (1) Every licensee who transfers a radiation device shall provide the transferee with the instructions referred to in the radiation device certificate for dealing with accidents, including fires and spills.
- (2) A licensee who transfers a sealed source or a nuclear substance as shielding shall provide the transferee with a record of the most recent leak test conducted in accordance with section 18.

Survey Meters (Section 20)

20. No person shall use, for the purpose of the Act, the regulations made under the Act or an order or a license, a radiation survey meter that has not been calibrated within the 12 months preceding its use.

Accidents (Section 21)

21. Where a radiation device is involved in an accident or is subjected to conditions other than those in which it is designed to operate, the licensee shall discontinue using it until the licensee performs a test or an inspection which establishes that it is functioning properly.

Storage Area Signs (Section 23)

23. Every licensee who stores a nuclear substance shall post and keep posted, in a readily visible location at the place or on the vehicle where the nuclear substance is stored, a legible sign that indicates the name or job title and the telephone number of a person who can initiate the accident procedure referred to in the license that has been issued in respect of the nuclear substance and who can be contacted 24 hours a day.

Retention of Records (Section 36)

36. (1) Every licensee shall keep the following records:

- (a) a record of the following information in respect of any nuclear substance in the licensee's possession that is referred to in the license:
 - (i) the name, quantity, form, and location of the nuclear substance,
 - (ii) where the nuclear substance is a sealed source, the model and serial number of the source,
 - (iii) where the nuclear substance is contained in a radiation device, the model and serial number of the device,
 - (iv) the quantity of the nuclear substance used, and
 - (v) the manner in which the nuclear substance was used;
 - (b) a record of the name of each worker who uses or handles a nuclear substance;
 - (c) a record of any transfer, receipt, disposal, or abandonment of a nuclear substance, including
 - (i) the date of the transfer, receipt, disposal, or abandonment,
 - (ii) the name and address of the supplier or the recipient,
 - (iii) the number of the license of the recipient,
 - (iv) the name, quantity, and form of the nuclear substance transferred, received, disposed of, or abandoned,
 - (v) where the nuclear substance is a sealed source, the model and serial number of the source, and
 - (vi) where the nuclear substance is contained in a radiation device, the model and serial number of the device;
 - (d) a record of the training received by each worker; and
 - (e) a record of every inspection, measurement, test or servicing performed by the licensee in accordance with the Act, the regulations made under the Act, or the license.
- (2) Every licensee shall retain a record referred to in paragraph (1)(d) for the period ending three years after the termination of employment of the worker.

- (3) Every person who is required to keep a record referred to in paragraph (1)(e) shall retain the record for the period ending three years after the expiry date of the last license that was issued to the person in respect of the nuclear substance.

Radiation Protection Regulations

Radiation Protection Programs (Section 4)

4. Every licensee shall implement a radiation protection program and shall, as part of that program,
 - (a) keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as is reasonably achievable, social and economic factors being taken into account, through the implementation of
 - (i) management control over work practices,
 - (ii) personnel qualification and training,
 - (iii) control of occupational and public exposure to radiation, and
 - (iv) planning for unusual situations; and
 - (b) ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity
 - (i) by direct measurement as a result of monitoring, or
 - (ii) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the quantity and concentration using that method, by estimating them.

Recording of Doses (Section 5)

5. (1) For the purpose of keeping a record of doses of radiation in accordance with section 27 of the Act, every licensee shall ascertain and record the magnitude of exposure to radon progeny of each person referred to in that section, as well as the effective dose and equivalent dose received by and committed to that person.
- (2) A licensee shall ascertain the magnitude of exposure to radon progeny and the effective dose and equivalent dose
 - (a) by direct measurement as a result of monitoring; or
 - (b) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the amount of exposure and doses using that method, by estimating them.

Source Head Labels (Section 20)

20. (1) No person shall possess a container or device that contains a radioactive nuclear substance unless the container or device is labeled with
- (a) the radiation warning symbol set out in Schedule 3 and the words “RAYONNEMENT —DANGER — RADIATION”; and
 - (b) the name, quantity, date of measurement, and form of the nuclear substance in the container or device.
- (2) Subsection (1) does not apply in respect of a container or device
- (a) that is an essential component for the operation of the nuclear facility at which it is located;
 - (b) that is used to hold radioactive nuclear substances for current or immediate use and is under the continuous direct observation of the licensee;
 - (c) in which the quantity of radioactive nuclear substances is less than or equal to the exemption quantity; or
 - (d) that is used exclusively for transporting radioactive nuclear substances and labeled in accordance with the Packaging and Transport of Nuclear Substances Regulations.

Posting Signs (Section 21)

21. (1) Every licensee shall post and keep posted, at the boundary of and at every point of access to an area, room, enclosure, or vehicle, a durable and legible sign that bears the radiation warning symbol set out in Schedule 3 and the words “RAYONNEMENT — DANGER —RADIATION”, if
- (a) there is a radioactive nuclear substance in a quantity greater than 100 times its exemption quantity in the area, room, enclosure, or vehicle; or
 - (b) there is a reasonable probability that a person in the area, room, enclosure, or vehicle will be exposed to an effective dose rate greater than 25 Sv/h.
- (2) Subsection (1) does not apply in respect of a vehicle that is placarded in accordance with the Packaging and Transport of Nuclear Substances Regulations.

Packaging & Transport Regulations

References to IAEA regulations in the following extracts are from IAEA “Safety Series No 6,” “Regulations for the Safe Transport of Radioactive Material” 1985 Edition (as amended 1990).

Applicability (Section 2)

2. (1) Subject to subsection (2), these Regulations apply in respect of the packaging, and transport of nuclear substances, including the design, production, use and maintenance of packaging and packages and the preparation, consigning, handling, loading, carriage, storage during transport, receipt at final destination, and unloading of packages.
- (2) These Regulations, except for sections 3, 4, 5, and 6, do not apply in respect of the packaging and transport of a nuclear substance
 - (a) having a specific activity of 70 kBq/kg or less;
 - (b) while it is being used in a person for medical purposes;
 - (c) that is contained in a sample of material taken for bioassay purposes;
 - (d) by a licensee on private property for the purpose of the licensed activity, where access to the property is controlled;
 - (e) that is contained in human or animal tissue or a liquid scintillation medium, where the specific activity of the nuclear substance averaged over the mass of the material does not exceed 10^{-6} A2/kg;
 - (f) that is contained in a consignment of radiation devices, as defined in the Nuclear Substances and Radiation Devices Regulations, where no license is required for each device under sections 5 to 8 of those Regulations, the activity of the nuclear substance in each device does not exceed 10^{-3} A2 and the consignment consists of not more than 10 such devices; or
 - (g) that is an integral part of a conveyance and required for transport purposes.

General Obligations (Section 15)

15. (1) Every person who transports, or causes to be transported, radioactive material shall act in accordance with the requirements of the Transportation of Dangerous Goods Regulations.
- (2) Every consignor, other than a consignor of an excepted package, shall act in accordance with paragraphs 448 to 459 of the IAEA Regulations.
- (3) Every consignor of an excepted package shall act in accordance with paragraph 452 of the IAEA Regulations.

- (4) Every consignor of radioactive material shall advise the consignee that the material is going to be transported.
- (5) Every carrier of radioactive material shall act in accordance with paragraphs 460 to 466, 468 to 475, and 478 to 482 of the IAEA Regulations.
- (6) Every carrier of radioactive material shall transport the material in accordance with the consignor's instructions.
- (7) Every carrier of radioactive material shall implement and maintain work procedures to ensure compliance with these Regulations and shall keep a record of those procedures.



Note Due to the specialized requirements that exist for the shipping of radioactive materials we recommend that you contact Thermo Fisher to assist you with shipments that originate in Canada. ▲

Canadian Gauge Leak Test Procedure

Leak testing will be performed on all sources at the interval specified in the CNSC license and following any incident that may have compromised the integrity of the source containment or prior to the transfer of a source from a licensee. All leak tests shall be performed by means of a wipe sample per the attached procedure and Thermo Fisher shall read the sample. If it is determined that leakage in excess of 200 Bq was found on the wipe sample the source shall be removed from service, isolated, and the CNSC shall be notified within 24 hours.

Wipe Sampling Procedure General

The wipe sampling of all sealed sources shall be performed at intervals no greater than that specified in the licensee's CNSC license and the regulations.

Sampling may only be performed by an individual who is familiar with the requirements of Regulatory Document R-116 "Requirements for Leak Testing Selected Sealed Radiation Sources."

The individual performing the wipe sampling must know the type and activity of each sealed source as well as source containment.

The individual performing the wipe sampling must be aware and capable of minimizing the potential contamination and radiation hazards associated with the source and the sampling process. The individual performing the wipe sampling must have sufficient sampling materials, sample containers, and blank sampling certificates to perform the test(s) and must be in possession of and following these procedures.

The preferred method of leak testing sources shall be by means of a wetted cotton tipped applicator and shall verify the source containment by sampling all areas of possible emission such as weld joints and rivets on the external case of the source.

Procedure

1. Prepare a wetting solution of water and a small amount of detergent in a small vial or bottle. The concentration of detergent should be such that when sealed and shaken, foam appears in the airspace at the top of the vial or bottle. This solution will allow the removal of any radioactive contamination from the wiped areas of the source along with any surface dirt that may contain the contamination.
2. Obtain a number of clean, uncontaminated cotton tipped applicators or if these are unavailable, a number of clean, uncontaminated gauze pads. The wipe material must be chosen to allow access to the external seams, flanges, and surfaces of the device.
3. At the source, close the shutter mechanism in accordance with the instructions in the manufacturer's manual. For most Thermo Scientific source heads mounted on pipes or vessels, the shutter is closed by means of a slide or pivoting mechanism which moves an attenuating mass into the beam path. If the source incorporates a slide mechanism simply grip the slide handle and move it to the closed position. If the source incorporates a pivoting shield, grasp the shutter handle that protrudes from the right side of the housing and pull it to the closed position. Remember to lock the shutter in the closed position with the lock provided.
4. Visually inspect the source head, paying particular attention to the welded seams. If discontinuous welding is observed or any cracks suspected, notify the manufacturer immediately. Inspect all gauge tags to ensure that they are clear and legible. If the gauge is chain mounted, inspect the chain and/or seams for any signs of stress. If any sign of stress is evident, notify the manufacturer immediately.
5. Thoroughly wet the first applicator or pad and carefully wipe along all of the visible weld joints and over any rivets on the back and sides of the source housing. Samples may also be taken in the vicinity of the shutter mechanism if it is accessible and only if the shutter is closed. If the source is very dirty more than one wetted applicator or pad may be required. Wiping should be performed with enough pressure to transfer the outer layer of dust/dirt from the source housing to the applicator or pad.

6. The used applicator or pad should then be placed in a sealed container such as a sealable plastic bag or vial. On the exterior of the container clearly mark in indelible ink the source serial number, tag number, or other unique identification number. Attach to the bag or vial a certificate bearing the following information:
 - a. Sampler's name, address, and telephone number
 - b. Licensee's name, address, CNSC license number, telephone number, and contact name
 - c. Make, model, serial number, isotope, and tag number (if applicable) of the source
 - d. Brief description of the wipe sampling method
 - e. Identification on the corresponding sample container
 - f. Sampling date
 - g. Signature of the sampler

All information must be provided in order to complete the leak test certificate.
7. All of the sealed containers and documentation should be packed in a suitable form for shipment to Thermo Fisher for analysis.



Note Shipments should not be made by post! ▲

8. Shipments must be received by the measurer and read within 10 days of sampling to be valid. Any samples received after more than 10 days must be retaken.

Wipe Test Certificate

Certificate no.: _____

General Information

Licensee: _____ CNSC license no.: _____

Address: _____

Contact: _____

Phone: _____ Fax: _____

Measurer: _____

Address: _____

Phone: _____ Fax: _____

Source Information

Manufacturer: _____

Model: _____ Serial no.: _____ Isotope: _____

Measurement Date: _____ Tag no.: _____ Location: _____

Sample Information

Sampling method: _____

Container identification no.: _____

Sample date: _____

Sampler's signature: _____

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