NRC FORM 699
(11-2017)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Benjamin Scher, Radiation Safety Officer (RSO)	04/25/2019	☑ E-MAIL ☐ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS ben.scher@endress.com	**TELEPHONE NUMBER** (317) 535-1350	
ORGANIZATION Endress+Hauser, Inc., 2355 Endress Pl., Greenwood, IN 46143	**DOCKET NUMBER(S)** 030-37942	
LICENSE NAME AND NUMBER(S) 13-32721-01	**MAIL CONTROL NUMBER(S)** **611031**	

SUBJECT

Additional Information Request concerning the licensee's request to renew the referenced U.S. NRC radioactive materials license, including to allow continued possession, use, training, distribution, installation & non-routine maintenance, etc. of sealed cesium-137 & cobalt-60 sources in its fixed gauging devices

SUMMARY AND ACTION REQUIRED (IF ANY)

This record concerns the licensee's January 11, 2019 application (NRC Accession No. ML19011A093) requesting renewal of the above-listed radioactive materials license for a manufacturing and distribution (Program Code 3214) license for receipt, storage, distribution, installation, non-routine maintenance, leak test sampling, and training & demonstration of sealed cesium-137 and cobalt-60 sources in Endress+Hauser fixed gauging devices, Models QG 020 Series, QG 100 Series, FQG60, FQG61, FQG62, FQG63, FQG66, and QG 2000 Series.

Upon review, we have noted that the application omits information requested in the NRC's NUREG 1556 Vol. 12, rev. 1, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," guidance volume dated May 2018. As discussed, please see attached for information needed to complete our review of your request.

As we will discuss in the next 5 to 10 business days, please provide the requested information within 28 days of this message (on or before May 24, 2019). Include a signed and dated cover letter transmitting your resubmitted application. Submission of your response as a pdf file attached to an email or via facsimile to 630-515-1078 will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. Thank you for your prompt attention to this matter.

NAME OF PERSON DOCUMENTING CONVERSATION

Sara A. Forster, M.S., Health Physicist, Materials Licensing Branch, DNMS, RIII office, sara.forster@nrc.gov

SIGNATURE	DATE OF SIGNATURE
Sara A. Forster	04/25/2019

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)	MAIL CONTROL NUMBER(S)
13-32721-01	**611031**

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

ADDITIONAL INFORMATION NEEDED FOR CONTINUED REVIEW

PLEASE RESUBMIT THE RENEWAL APPLICATION:

(1) Please resubmit the NRC Form 313, signed and dated by you or by other Senior Management official from Endress+Hauser, Inc. or other individual designated to sign on that official's behalf;

(2) Please include the licensee's mailing address as submitted in the January 11, 2019 application.

(3) Please provide responses to the NRC Form 313 Items 5 (radioactive material - radionuclides, sealed source manufacturers and model numbers, and possession limits, both per gauge and overall; 6 (purposes for which material will be used); 7 (RSO and authorized user qualifications and authorities); 8 (training for individuals working in or frequenting restricted areas); 9 (facility diagram and additional facilities and equipment description as applicable); 10 (radiation safety program); and 11 (waste management). The type and scope of information to be provided - including suggested responses - is described in revision 1 to each of the NUREG 1556 volumes, "Program-Specific Guidance about..." "... Possession Licenses for Manufacturing and Distribution," 12 (published May 2018); "... Fixed Gauge Licenses," 4 (published July 2016); "... Service Provider Licenses," 18 (published August 2017); and "... Licenses Authorizing Distribution to General Licensees," 16 (published July 2018). For your convenience, excerpts from those volumes - as most applicable to you - are attached to this request.

(4) Please provide a copy of a Memorandum of Understanding/Delegation of Authority (MOU/DOA) document, signed and dated by both the licensee's Management Representative and the RSO. At a minimum, the MOU/DOA should indicate the RSO's responsibilities and authority for the licensed program and that RSO's acceptance of those duties. Sample RSO duties together with a sample MOU/DOA form may be found in NRC's NUREG 1556 Vol. 18, rev. 1, Appendix C, pp. C-1 to C-4. A copy of this appendix is attached for your reference.

(5) Please include statements, facility diagrams, equipment descriptions, and procedures, as suggested in the attached guidance.

Suggested Format for Providing Information Requested in Items 5 through 11 of U.S. Nuclear Regulatory Commission Form 313

The table below is designed to help applicants develop their applications. A box in a column (❒) indicates that the licensee may agree to use a model procedure, or if not using a model procedure, the licensee is then expected to describe its program or submit its procedures for the particular item.

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
5.	**RADIOACTIVE MATERIAL** **Unsealed or Sealed Sources, or Both** For sealed radioactive materials, do the following: — Identify each radionuclide (element name and mass number) that will be used, and specify the maximum activity per source. Also, specify the maximum number of sources or total activity of each radionuclide. — Provide the manufacturer's or distributor's name and model number for each sealed source and device requested. — Confirm that each sealed source, device, and source and device combination is registered as an approved sealed source or device by NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available. For each sealed source, device, and source and device combination that is not registered, provide the applicable information, as described in 10 CFR 30.32(g) and 32.210.	N/A	❒

Items 5 and 6: Materials To Be Possessed and Proposed Uses

Yes	No	Radionuclide	Manufacturer or Distributor Model No.	Quantity	Use as Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Isotope (Specify): cesium-137	Device manufacturer (or distributor) and model number: _____	Specify activity per source and number of gauges requested.	Yes ❒ Specific description of the gauge use: _____	❒ Not applicable ❒ Uses are: (Submit safety analysis...)
		Isotope (Specify): cobalt-60	Device manufacturer (or distributor) and model number: _____	Specify activity per source and number of gauges requested.	Yes ❒ Specific description of the gauge use: _____	❒ Not applicable ❒ Uses are: (Submit safety analysis...)

Table B–1. License Reviewer Checklist (Continued)			
ITEM NO.	**SUGGESTED RESPONSE**	**AGREE TO USE**	**DESCRIPTION ATTACHED**
5.	**RADIOACTIVE MATERIAL (Continued)** **Unsealed or Sealed Sources, or Both (Continued)** **Financial Assurance and Recordkeeping for Decommissioning** State the following: • "Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g) and 10 CFR 70.51(b)(3), as appropriate, we will maintain records important to decommissioning and will transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and 10 CFR 70.36, as appropriate. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a), as appropriate, prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), as appropriate, to the appropriate NRC regional office."	❒	N/A
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE POSSESSED AND USED** • List the specific use or purpose of each radionuclide that will be possessed and used. • Provide the manufacturer name and model number for each device, manufactured article, or material that becomes the product, by manufacturer and model number. • Provide the manufacturer and model number of each sealed source proposed for possession and use or incorporation into a manufactured article. • Submit information requesting authorization to possess and use any other licensed materials in support of the manufacturing and distribution license.	N/A	❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
7	**Individual(s) Responsible For Radiation Safety Program And Their Training Experience**				
7.1	**Radiation Safety Officer** Provide the name of the proposed RSO who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures. **AND** Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position and demonstrating day-to-day oversight of the radiation safety activities. **AND** Confirm that the RSO will be available for emergencies and can be on-site within 24-48 hours, if applicable. **AND** **Radiation Safety Officer** Provide the specific training and experience of the RSO, and include the specific dates of training in radiation safety. **[NOTE: Since the RSO is the existing RSO, no additional training & experience documentation is needed, at this time.**				❒ ❒ ❒ ❒

Typical Duties and Responsibilities of the Radiation Safety Officer

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety and compliance with the U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and the conditions of the license. Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the radiation safety officer (RSO) considers unsafe are stopped.
- Radiation exposures are kept as low as is reasonably achievable (ALARA).
- Up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed.
- All activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used are overseen.
- Safety consequences of nonroutine operations are analyzed before conducting any such activities that have not been previously analyzed.
- Nonroutine operations are performed by the manufacturer, distributor, or person specifically authorized by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State.
- Any incidents are investigated and any emergencies are responded to.
- Availability to serve as a point of contact for the NRC's, Agreement State's, and licensee's management during routine operations, emergencies, or incidents.
- Proper authorities of incidents, such as damage to sealed sources/devices, loss of licensed material, fire, theft, etc are notified.
- Investigation of unusual occurrences, identify cause(s) and appropriate corrective action(s), and take timely corrective action(s) to prevent recurrence.
- Properly secure licensed radioactive materials.
- Possession, installation, relocation, use, storage, repair and maintenance of sealed sources, devices and radioactive wastes are consistent with the limitations in the license, individual Sealed Source and Device Registration Certificate(s), and the manufacturer's specific recommendations and instructions.
- Prospective evaluations are performed to demonstrate that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a) or that personnel monitoring devices are provided.
- Identification of the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their

supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action. Record and maintain the results of such monitoring.

- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20.1301, "Dose limits for individual members of the public."

- Licensed material is transported in accordance with all applicable NRC and DOT requirements.

- Understanding of and maintenance of up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to the NRC during the licensing process.

- Amendment and renewal requests are submitted in a timely manner.

- All areas in which radioactive material is used are monitored and surveyed.

- The inventory and leak testing of sealed sources is performed/overseen.

- The inventory and calibration of radiation survey instruments is performed/overseen.

- Necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Part 19 and Part 20 and any other applicable regulations.

- Proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the facility, as well as packaging and labeling all radioactive material leaving the facility are overseen.

- Individuals involved with using radioactive materials are properly trained and evaluated.

- The radioactive waste disposal program, including effluent monitoring and record-keeping on waste storage and disposal records is supervised and coordinated.

- Licensed material is disposed of properly.

- The storage of radioactive material not in current use, including waste, is overseen.

- An inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license is maintained.

- Decontamination and recovery activities are overseen.

- Periodic audits are performed, at least annually, of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license.

- The results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for 3 years after the record is made) and provided to management for review; ensure that prompt action is taken to correct deficiencies.

- The audit results and corrective actions are communicated to all personnel who use licensed material.

- When the licensee identifies violation(s) of regulations or license conditions or program weaknesses, corrective action(s) are developed, implemented, and documented.

- All incidents, accidents, and personnel exposure to radiation in excess of ALARA or 10 CFR Part 20 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits.

- Required records that are necessary to support the license and satisfy NRC or Agreement States regulations are maintained.

- Documents are posted as required by 10 CFR 19.11, "Posting of notices to workers," (10 CFR Part 19, license documents, operating procedures, NRC Form 3, "Notice to Employees,"), and 10 CFR 21.6, "Posting Requirements," (10 CFR Part 21 Section 206 of the Energy Reorganization Act of 1974, procedures adopted under Part 21), or a notice is posted indicating where these documents can be examined.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed radiation safety officer and are responsible for ensuring the safe and secure use of radiation. You are responsible for managing the Radiation Protection Program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____ _____
Signature of Management Representative Date

I accept the above responsibilities,

_____ _____
Signature of Radiation Safety Officer Date

cc: Affected department heads

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
7.2	**Authorized Users And Radiation Workers** Provide either of the following: A statement that: "Before using licensed material, authorized users will receive the training described in Appendix D of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'" **OR** A description of the training and experience for proposed authorized users. **AND** A description of the radiation safety training involving the use of licensed material that will be provided as a service to customers, if training is provided by the service provider.	❒	❒		❒ ❒
8	**Training For Individuals Working In Or Frequenting Restricted Areas** Provide either of the following: A statement that: "Before working in the vicinity of licensed materials, personnel will have successfully completed training commensurate with assigned duties." **OR** A description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of refresher training.	❒	❒		❒

Criteria for Acceptable Training and Experience for Authorized Users

Classroom Training

Classroom training may be in the form of lecture, videotape, or self-study that emphasizes practical subject matter important to the safe handling of licensed materials. Duration and technical level of training should be commensurate with the expected hazards encountered during routine and emergency conditions. Training records should be kept in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.51(b) and be available for inspection.

Frequency of Training

Training should be completed:

- Before assuming duties with, or in the vicinity of, radioactive materials
- Whenever there is a significant change in duties, regulations, or the terms and conditions of the license
- Annually for refresher training

Suggested Radiation Safety Topics

- Fundamentals of Radiation Safety:
  - Characteristics of radiation
  - Units of radiation dose and quantity of radioactivity
  - Hazards of exposure to radiation
  - Levels of radiation from licensed material
  - Methods of controlling radiation dose (time, distance, and shielding)
  - As low as is reasonably achievable (ALARA) concept
- Radiation Detection Instruments:
  - Operation
  - Calibration
  - Limitations of radiation survey instruments
  - Radiation survey techniques for measuring radiation field
  - Radiation survey techniques for measuring removable/fixed contamination
  - Handling and proper use of personnel monitoring equipment
- Radiation Protection Equipment and Use:
  - Proper use of protective equipment
  - Decontamination of contaminated protection equipment
- U.S. Nuclear Regulatory Commission (NRC) regulations (10 CFR Parts 19 and 20)
- NRC regulations (10 CFR Parts 21, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, and 71) as applicable

- Licensee's operating and emergency procedures
- Case histories relevant to operations
- Course Examination (Didactic):
  - Successful completion of closed-book written/oral examination depending on the complexity and hazards of authorized activities
  - Review of incorrect answers with student
- On-the Job Training and Examination (Practical):
  - On-the-job training completed under the supervision of a qualified individual [authorized user (AU), radiation safety officer (RSO), or manufacturer's representative authorized by the NRC or an Agreement State] that includes supervised hands-on experience performing the task authorized on the license that is commensurate with the expected hazards during routine and emergency conditions
  - Practical examination consisting of an assessment by the RSO to ensure that each proposed AU is qualified to work independently and that each individual is knowledgeable of the radiation safety aspects of licensed activities. This may be demonstrated by observing the proposed AU perform licensed activities.
- Discussion and/or drill on all applicable emergency procedures annually.
- Retraining on areas found to be deficient in both the practical and didactic areas.

Classroom Course Instructor Qualifications

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or AU on the license and is familiar with the licensee's program). Instructors who provide classroom training to individuals in the principles of radiation and radiation safety should have knowledge and understanding of these principles beyond those obtainable in a course similar to the one given to prospective authorized users. Individuals who provide instruction in the hands-on use of licensed materials should have training and experience that would qualify them to be authorized users, or should possess a thorough understanding of the licensee operations.

Use Code* Low-Risk Activities:

A. analysis of Leak-Test Samples (no collection)

B. analysis of Environmental Samples (no collection)

C. sample Collection and Analysis of Leak Tests

D. sample Collection and Analysis of Environmental Samples

E. calibration of instrument/dosimeter using low-activity sources

F. service/repair of gas chromatographs, X-ray fluorescence analyzers, and/or similar devices

G. training/instruction to individuals on radiation safety-related topics

H. other low-risk services not identified above, where radioactive material is used for commercial service activities

Use Code* High-Risk Activities:

I. service and/or repair of portable nuclear gauges (including removal of source rod)

J. service and/or repair of fixed gauges

K. service and/or repair of fixed gauges mounted on a mobile object, like a truck or railcar

L. storage of radioactive material for other entities

M. use of unsealed material in tracer studies (e.g., use inside pipes in a refinery)

N. use of remote activated robotics in radioactive contaminated areas

O. calibration of survey instruments and personnel dosimetry equipment as a service for others.

P. installation, radiation surveys, routine and preventive maintenance, adjustment or repair of high-dose rate (HDR) remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic components that could expose the sealed source, reduce the shielding, or compromise the radiation safety of the device or safety systems

Q. installation, relocation, removal from service, disposal, radiation surveys, routine or preventive maintenance, adjustment, training, or repair of

(1) self-shielded irradiators [American National Standards Institute (ANSI) Category I irradiators].

(2) Title 10 of the *Code of Federal Regulations* (10 CFR) Part 36 irradiators (ANSI Categories II, III, and IV irradiators)

R. nuclear laundry services

S. retrieval of industrial radiography sealed sources

T. decontamination and decommissioning services (NUREG–1757, Volume 1)

U. waste management services, including, packaging and repackaging of radioactive waste for transportation, commercial incineration, compaction, super compaction, solidification, or vitrification

V. other high-risk services not identified above, excluding activities involving critical mass quantities of special nuclear material

If the applicant desires to perform tracer/field studies in which licensed material is deliberately released to the environment, please provide the following information:

- a complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material
- a copy of the applicant's operating and emergency procedures
- a description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases
- a description of the expected radiation dose to humans
- a sample agreement letter between the applicant and the applicant's customer acknowledging the use of radioactive materials at the customer's site.
- a letter from the appropriate state health authorities, indicating that they have reviewed the applicant's application and concur with the applicant's request

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
9	**Facilities And Equipment** **Low Risk Activities**: For service providers performing low-risk activities, no facility description is required. Provide the location where these services will be performed. **AND** Indicate if services will be performed at temporary jobsites. No facility description is required. **High Risk Activities**: For service providers performing the high-risk activities that will not take possession of radioactive material, provide the location where these services will be performed. Also indicate if services will be performed at temporary jobsites. **OR** For those services listed in the **high-risk group** where permanent facilities are specifically identified on the license, provide the following information, as applicable to the service the applicant intends to perform: Submit a drawing or sketch of the proposed permanent facility that fulfills the following requirements: 1. Identify area(s) assigned for the receipt, storage, security, preparation, handling, waste storage, and measurement of radioactive materials, including sealed sources and devices. 2. Show the relationship and distance between restricted areas and adjacent unrestricted areas. 3. Indicate the scale, or include dimensions on each drawing or sketch. The same scale should be used for all sketches and drawings. The recommended scale is 1/4 inch = 1 foot. Drawings to this scale that do not fit on 8-1/2 x 11-inch paper may be provided as sectional drawings. Please also include a compass directional arrow to indicate "North."				❒ ❒ ❒ ❒ ❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
9	**Facilities And Equipment** 4. Specify shielding materials (e.g., concrete, lead) and means for securing radioactive materials from unauthorized removal. 5. Illustrate area(s) where explosive, flammable, or other hazardous materials may be stored; 6. Identify area(s) where radioactive materials may become airborne. The diagram should contain descriptions of the ventilation systems, with pertinent airflow rates, filtration equipment, sample collection points, and 7. Identify specialized handling tools, facility safety interlocks designed to prevent operation of radiological safety systems, in the event that operation of a system could result in accidental exposure or release of material [e.g., high efficiency particulate air (HEPA) filters, ventilation system, safety door interlocks, etc.] or equipment; In addition, describe: 1. Engineered safety systems (e.g., area monitors, interlocks, alarms); 2. Protective clothing (such as latex or rubber gloves, lab coats or coveralls, respirators, booties, and face shields), auxiliary shielding, absorbent materials, secondary containers for wastewater storage for decontamination purposes, plastic bags for storing such items as contaminated items, etc., that will be available for use when handling unsealed or uncontained radioactive materials;				❒ ❒ ❒ ❒ ❒ ❒

Facilities and Equipment

The applicant should consider the following list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use or otherwise have available. Not every applicant will need to address each topic in its application.

- Restricted areas are defined as areas where the licensee limits access to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted and unrestricted areas and the location of all pertinent safety-related equipment.

- Bench-top or open work areas may be used for sealed sources, small quantities of solid materials in a form not likely to become airborne or dispersed, and small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.

- Security zones are defined as any temporary or permanent area determined and established by the licensee for the physical protection of aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37. The security zone should be designed so that the licensee can monitor, detect without delay, assess, and respond to any unauthorized entries into security zones and any unauthorized removal of radioactive material from the security zone. Monitoring and detection systems may include video surveillance systems and electronic devices for intrusion detection alarms.

- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems, such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems. Ventilation systems for these facilities should be designed so that airborne radioactive material work areas are at negative pressure compared to nonradioactive work areas.

- Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, unsealed volatile licensed materials, and processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 10 CFR Part 20, Appendix B.

- Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during

storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- For the most efficient operation of hoods and glove boxes, minimize storage of materials and equipment inside the work areas.

- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity. If appropriate, supply and exhaust fans can be interlocked such that if exhaust fans shut down, the shutdown of supply fans is also triggered, this interlock system is to prevent laboratory and work areas from becoming positively pressurized with respect to the surrounding parts of the facility.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.

- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.

- To reduce radiation exposure from gamma-emitting radioactive materials, shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods, or in glove boxes.

- To reduce the exposure from high-energy beta-emitting materials, shielding of low-atomic-number material, such as high-density plastic, may be used. In operations using large quantities (i.e., multi-millicurie quantities) of high-energy beta-emitting radionuclides or longer exposure times, it may be necessary to also reduce the bremsstrahlung by adding shielding containing high-atomic-number material such as lead. These shields generally are low-atomic-number materials closest to the source, enclosed by high-atomic-number material.

- Shielded shipping containers are used frequently for continued storage after receipt of materials.

- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials. In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.

- Designated areas should be provided for coats and personal belongings, to avoid contamination.

- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.

- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination buildup.

- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.

- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.

- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H, "Respiratory protection and controls to restrict internal exposure in restricted areas."

- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on the number of users and distance between areas of use, more than one sink may need to be designated.

- Labeled waste containers should be used. These containers may be shielded as necessary and placed near the waste-generating areas and away from areas that personnel frequently occupy. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited. If radioactive waste materials are volatile, the containers should be stored in ventilated areas.

- If compaction of waste is performed, ensure that the facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per 10 CFR 20.1204.

- Adequate air and water effluent-monitoring equipment should be used to demonstrate compliance with the limits found in 10 CFR Part 20, Appendix B, if applicable, and tested for operability at the frequency established by the manufacturer.

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
9	**Facilities and Equipment** 3. The general location of each proposed permanent facility (e.g., an industrial park, an office complex) and its current use. If any proposed permanent facility is a private residence, provide diagrams of the installation that include the building, the proposed restricted area or areas, and adjacent areas, including above and below the restricted areas; provide commitments that restricted areas do not include residential quarters, and explain how radiation levels in unrestricted areas will be maintained at less than 1 mSv [100 mrem] per year.				❐
10	**Radiation Safety Program**				
10.1	**Operating and Emergency Procedures** **Low Risk Activities**: Applicants who perform low-risk licensed activities are not required to submit operating procedures but should provide emergency procedures for all likely scenarios. **High Risk Activities**: Applicants who perform high-risk licensed activities should submit their operating and emergency procedures for radiological conditions that might be encountered as part of their license application.				❐ ❐
10.2	**Material Receipt and Accountability** Provide the following statement: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times." **AND** Provide the following statement, if applicable: "We will comply with the National Source Tracking System (NSTS) reporting requirements, as described in 10 CFR 20.2207." **AND**	❐ ❐		❐	

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
10.2	**Material Receipt and Accountability** Provide either of the following: A statement that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory." **OR** A description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced.	❒	❒		❒
10.3	**Radiation Monitoring Instruments** **Provide one of the following:** Describe the instrumentation that will be used to perform the required radiological surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.' We reserve the right to upgrade our survey instruments as necessary." **OR** Describe the instrumentation that will be used to perform the required radiological surveys and state, "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.' Additionally, we will implement the model radiation survey meter calibration program published in Appendix F of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.' We reserve the right to upgrade our survey instruments as necessary."	❒ ❒	❒ ❒	❒	❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
	OR				
10.3	**Radiation Monitoring Instruments** Describe alternative equipment and/or procedures for ensuring that appropriate radiation-monitoring equipment will be used during licensed activities, and that proper calibration and calibration frequency of survey equipment will be performed. Include a statement that: "We reserve the right to upgrade our survey instruments as necessary."	❒	❒		❒
10.5	**Leak Tests** Provide one of the following: A statement that: "Leak tests sample collection and analysis will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee using a leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak tesing services."	❒	❒		
	OR				
	A statement that: "Leak testing and analysis will be done by the applicant." Provide the information in Appendix G of this NUREG supporting a request to perform leak testing and sample analysis, and either (1) state that the applicant will follow the model procedures in Appendix G of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses, or (2) submit alternative procedures.	❒	❒		❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
10.6	**Occupational Dose** Provide one of the following: A statement that: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502." **OR** A statement that: "We will monitor individuals in accordance with the criteria in the Section 8.10.6, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."" **OR,** **IN LIEU OF THESE STATEMENTS** Provide a description of an alternative method for demonstrating compliance with the referenced regulations.	❒ ❒	❒ ❒		 ❒
10.9	**Routine Maintenance** Provide either of the following: A statement that: "We will implement and maintain procedures for conducting routine maintenance of devices according to each manufacturer's (or distributor's) written recommendations and instructions." **OR** Provide alternative routine maintenance procedures for NRC's review.	❒		❒	 ❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
10.9	**Nonroutine Maintenance** Provide the following: Obtain prior NRC approval, if OEM replacement parts cannot be used, for sealed source shielding, the source driving unit, or other electrical or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the device or the source	❒		❒	
	AND				
	Nonroutine Maintenance A statement that: "We will have the device manufacturer (or distributor) or other person authorized by NRC or an Agreement State to perform nonroutine maintenance of devices."	❒			
	OR				
	Provide alternative procedures for the NRC's review addressing the information listed in Appendix K of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."				❒
11	**Waste Management** Provide the following: A statement that: "We will use the model waste procedures published in Appendix M of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'"	❒	❒		
	OR				
	Provide procedures for waste management by any of the methods described in Section 8.11, "Waste Management" of this NUREG. Applicants should contact the appropriate regional office of the NRC for guidance as to how to obtain approval of any method(s) of waste disposal other than those discussed in this section.				❒

Information Needed to Support Applicant's Request to Perform Nonroutine Maintenance Checklist

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

Routine maintenance is maintenance that the manufacturer or distributor allows their customers to perform in accordance with instructions in the user manual. Nonroutine maintenance is maintenance that requires specialized training and experience. Nonroutine operations include installation of the sealed source/device, repair or maintenance involving or potentially affecting components, including electronics, related to the radiological safety (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding), relocation, replacement, and disposal of sealed sources, alignment, removal of a sealed source/device from service, and any other activities during which personnel could receive radiation doses exceeding U.S. Nuclear Regulatory Commission (NRC) limits.

The service provider may obtain replacement parts from the manufacturer/distributor or have its customer order the parts from the manufacturer/distributor. If neither the service provider nor the customer can obtain a replacement part from the manufacturer or distributor, the service provider may purchase a part from another vendor or fabricate the part.

It is preferable to use the original equipment manufacturer or distributor (OEM) supplied components or parts. Any non-OEM replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor will need to be evaluated to ensure that they do not degrade the results of the engineering safety analysis performed and accepted as part of the device sealed source and device (SSD) registration. If the service provider uses a part integral to the safe operation of the device that has not been provided by the manufacturer, the service provider will verify that the part will have the commensurate form, fit, and function as the original component. In addition, the service provider will provide the information related to the form, fit, and function of a non-OEM part (as specified in Section 8.10.9 "Maintenance") to the customer, and the customer will provide the technical information to the NRC for a safety review. The use of replacement parts may result in the device being a custom device in accordance with NUREG–1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration." The service provider will not install this part until verifying that its customer has retained the appropriate authorization to proceed. Licensees will also ensure that, after maintenance or repair is completed, the sealed source/device is tested and functions as designed, before the unit is returned to routine use.

For guidance on the use of sources that have not been supplied by the manufacturer and/or distributor, see Regulatory Issue Summary 2013-01, March 12, 2013 (ADAMS Accession No. ML12313A147).

If nonroutine operations are not performed properly with attention to good radiation safety principles, the sealed source/device may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits.

Thus, applicants wishing to perform nonroutine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's or distributor's instructions and recommendations that address radiation safety concerns (e.g., use of radiation

survey meter, shielded container for the source, and personnel dosimetry (if required)). Accordingly, provide the following information.

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

- installation, relocation, or alignment of the sealed source/device
- components, including electronics, related to the radiological safety of the device (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
- replacement and disposal of sealed sources
- removal of a sealed source/device from service
- a potential for any portion of the body to come into contact with the primary radiation beam
- any other activity during which personnel could receive radiation doses exceeding NRC limits

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

- Identify who will perform nonroutine operations and their training and experience. Acceptable training would include manufacturer's or distributor's courses for nonroutine operations or equivalent.
- Verify that the maintenance activities are authorized on the license.
- Submit operating and emergency procedures for nonroutine operations. These procedures will ensure the following:
  - Doses to personnel and members of the public are within regulatory limits and as low as is reasonably achievable (ALARA) (e.g., use of shielded containers or shielding).
  - The source is secured against unauthorized removal or access or under constant surveillance.
  - Appropriate labels and signs are used.
  - Manufacturer's or distributor's instructions and recommendations are followed.
  - Any nonmanufacturer/nondistributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration.

- Before being returned to routine use, the sealed source/device is tested to verify that it functions as designed and source integrity is not compromised.

- Ensure emergency procedures will be developed and reviewed for all likely accident scenarios.

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

- Verify possession of at least one survey instrument that meets the criteria in Appendix F of this document.

- Describe steps to be taken to ensure that radiation levels in areas where nonroutine operations will take place do not exceed the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1301, "Dose limits for individual members of the public." For example, applicants can do the following:

  - Commit to performing surveys with a survey instrument (as described above).

  - Specify where and when surveys will be conducted during nonroutine operations.

  - Commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 10 CFR 20.2103.

- Commit to providing the customer a service report describing the work that was completed, especially replacement parts and/or sources.

INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST TO PERFORM NONROUTINE OPERATIONS

Applicants should review Section 8.10.8, "Maintenance," which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Nonroutine operations, which require specific authorization by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State, include gauge installation; initial radiation survey; repair and maintenance of radiological safety components; gauge relocation; replacement and disposal of sealed sources; gauge alignment; or removal of a gauge from service. See Figure 8-7 in Section 8.10.8.

Any replacement components, parts, or other materials (e.g., lubricants) other than those supplied, specified, or recommended by the manufacturer or distributor need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device's Sealed Source and Device (SSD) registration certificate. Licensees also need to ensure that, after maintenance or repair is completed, the gauge is tested and functions as designed before the unit is returned to routine use.

If nonroutine operations are not performed properly with attention to good radiation safety principles, the gauge may not operate as designed, and personnel performing these tasks could receive radiation doses that exceed the NRC's regulatory limits. Radionuclides and activities in fixed gauges vary widely. For illustrative purposes, in less than 1 minute, an unshielded cesium-137 source with an activity of 3.7 gigabecquerels [100 millicuries] can deliver 0.05 Sv [5 rem] to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. This dose corresponds to the threshold for extremity monitoring. Some gauges may contain sources of even higher activities with correspondingly higher dose rates.

Thus, applicants wishing to perform nonroutine operations must use personnel with specialized training for the activities intended to be performed and follow appropriate procedures consistent with the manufacturer's or distributor's instructions and recommendations that address radiation safety concerns [e.g., use of radiation survey meter, shielded container for the source, and personnel dosimetry (if required)].

Accordingly, applicants wishing to perform nonroutine operations must provide the following information with their license application:

- Describe the types of work, maintenance, cleaning, and/or repair that involve any of the following:
  - installation, relocation, or alignment of the gauge
  - components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
  - replacement and disposal of sealed sources
  - removal of a gauge from service

- a potential for any portion of the body to come into contact with the primary radiation beam

- any other activity during which personnel could receive radiation doses exceeding NRC limits

- Identify who will perform nonroutine operations, and describe their training and experience. Acceptable training includes manufacturers' or distributors' courses for nonroutine operations or an equivalent.

- Submit procedures for nonroutine operations. These procedures should ensure the following:

  - doses to personnel and members of the public are within regulatory limits and are kept as low as is reasonably achievable (ALARA) (e.g., use of shielded containers or shielding)

  - the source is secured against unauthorized removal or access or is under constant surveillance

  - appropriate labels and signs are used (Lock-out procedures are adequate to ensure that no individual or portion of an individual's body can enter the radiation beam.)

  - manufacturer's or distributor's instructions and recommendations are followed

  - replacement components, parts, or other materials (e.g., lubricants) other than those supplied, specified, or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the SSD registration certificate

  - the gauge, before being returned to routine use, is tested to verify that it functions as designed and source integrity is not compromised

- Confirm that individuals performing nonroutine operations on gauges will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing nonroutine operations are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a).

- Confirm possession of at least one survey instrument that is appropriate for measuring the types of radiation and expected dose rates from the fixed gauge(s).

- Describe steps to be taken to ensure that radiation levels in areas where nonroutine operations will take place do not exceed limits set in 10 CFR 20.1301(e.g., surveys, calculations).

Model Waste Disposal Program

General Guidelines (NOTE THAT INAPPLICABLE BULLETS HAVE BEEN REMOVED.)

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary "nonradioactive" waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

- Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material will not be mixed with radioactive waste.

- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

- In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, inflammability), and costs.

- The waste management program should include waste-handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.

- Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

- A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."

Note: Licensees may also provide Appendices D, F, and/or G of this NUREG to customers. Appendices F and G of this NUREG contain information about GL devices in question and answer format. Appendix F of this NUREG may be helpful to a wide range of general licensees, and Appendix G of this NUREG may be helpful to general licensees that use self-luminous exit signs. These appendices may be used as additional ways of informing customers but do not replace the information required by 10 CFR 32.51a and will not satisfy a distributor's obligations under 10 CFR 32.51a. Table C–1 of Appendix C of this NUREG lists all requirements applicable to general licensees under 10 CFR 31.5.

Response From Applicant:

An applicant should provide sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, installation, servicing, leak testing, operating and safety instructions, potential hazards of the devices, and conditions of handling, storage, and use of device(s) to demonstrate that the product will meet the safety criteria set forth in the regulations discussed above. This includes the following:

- all of the specific information required about the device(s) one intends to distribute
- a dose assessment addressing all of the appropriate scenarios to demonstrate that the device meets the safety criteria in 10 CFR 32.51(a)(2)(ii) and (a)(2)(iii), which references the table in 10 CFR 32.24
- information on quality control and information on product labeling (actual example labels are helpful)
- information on the safety instructions that will be provided to recipients
- when seeking longer testing intervals for general licensees, submit sufficient information to demonstrate that such longer interval is justified by performance characteristics and by design features that affect the probability or consequences of leakage from the device or failure of the on-off mechanism and indicator
- when seeking authorization for general licensees to perform certain service activities, as described in 10 CFR 32.51(c), submit the written instructions to be followed by the general licensee, the estimated calendar quarter doses associated with such activities, and the basis for these estimates

To confirm the applicant's understanding of its responsibilities as a licensee, applicants should submit the following statements:

- "We will transfer only devices that are manufactured consistent with all of the statements in the application, as approved by the NRC and referenced in the registration certificate and the license."
- "We will transfer devices only to persons authorized to use such devices, either by the general license in 10 CFR 31.5, or by an equivalent general license if the potential recipient is in an Agreement State."
- "We will provide information to customers prior to purchase, in accordance with 10 CFR 32.51a(a) and (b)."
- "We will provide quarterly transfer reports in accordance with 10 CFR 32.52(a) and (b) and will maintain records in accordance with 10 CFR 32.52(c)."

Additional guidance pertaining to obtaining the registration certificate under 10 CFR 32.210 is provided in NUREG–1556, Volume 3.

NUREG 1556, Volume 16, revision 1, pp. 9-5 to 9-6

Information to be Provided to Customers (General Licensees)

Requirements of 10 CFR 32.51a for Distributors to 10 CFR 31.5 General Licensees

Those licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 32.51 are required to provide information to their generally licensed (GL) customers before transfer of devices in accordance with 10 CFR 32.51a(a) and (b). The intent is for the customer to be aware of this information and make an informed decision before making a commitment to purchase (i.e., so the customer can consider the requirements associated with the GL and the costs of disposal of the device in making a decision to purchase).

Information to be Supplied to Customers in U.S. Nuclear Regulatory Commission (NRC) Jurisdiction

Distributor licensees who transfer generally licensed material to end users in NRC jurisdiction must ensure that the end user receives the following information in accordance with 10 CFR 32.51a(a):

- a copy of 10 CFR 30.51, "Records;" 10 CFR 31.2, "Terms and conditions;" 10 CFR 31.5, 10 CFR 20.2201, "Reports of theft or loss of licensed material;" and 10 CFR 20.2202, "Notification of incidents"
- a list of services that can only be performed by a specific licensee
- information on acceptable disposal options and estimated cost of disposal
- an indication that the NRC's policy is to issue high civil penalties for improper disposal

Information to be Supplied to Customers in Agreement States

If the customer plans to use the device in an Agreement State, the distributor licensee must provide the customer with a copy of the applicable Agreement State's regulations and the name, address, and telephone number of the contact at the relevant Agreement State regulatory agency pursuant to 10 CFR 32.51a(b). A copy of the NRC regulations that are to be provided to customers in NRC jurisdiction (listed above) may be substituted for the Agreement State regulations provided that a note is included explaining that the device is regulated by the Agreement State regulations. Information about NRC's policy for high civil penalties for improper disposal need not be included.

Distributors need to keep informed concerning the applicable regulations in each Agreement State in which they transfer or distribute devices, at least to the extent of determining whether their device is covered by an equivalent general license. As 10 CFR 30.41(c) requires distributors to verify that the recipient is authorized to receive the device, it would be advisable to provide copies of relevant regulations for the particular State.

Note: Licensees can also give Appendix F or G of this NUREG to customers for additional information. These appendices contain useful information about GL devices in a question and answer format. Appendix F of this NUREG may be helpful to a wide range of general licensees, and Appendix G of this NUREG may be helpful to general licensees that use self-luminous exit signs. Appendix C of this NUREG also contains a table listing regulations applicable to these general licensees in NRC jurisdiction (Table C–1).

Requirements of 10 CFR 40.35(d) for Distributors to 10 CFR 40.25 General Licensees

Those licensed under 10 CFR 40.34 are required by 10 CFR 40.35(d) to provide information to their GL customers when transferring devices for use under 10 CFR 40.25 or equivalent Agreement State provisions. The intent is for the customer to be aware of this information (i.e., the requirements associated with the general license) and to be able to complete applicable registration requirements. The licensee must provide the following information:

- a copy of the general license contained in 10 CFR 40.25
- a copy of NRC Form 244 (See Figure D-1).

If the customer plans to use the device in an Agreement State's jurisdiction, the licensee should provide the customer with a copy of the equivalent State general license and any Agreement State certificate. Copies of 10 CFR 40.25 and NRC Form 244 can be substituted with a note explaining that the device is regulated by the Agreement State under regulations substantially the same as 10 CFR 40.25. Although not required by regulation, providing the name, address, and telephone number of the contact at the relevant Agreement State regulatory agency is advisable so that customers will be able to meet registration requirements in a timely manner.

Note: Table C–8 of Appendix C of this NUREG also contains a table listing regulations applicable to these general licensees, which may also be provided to customers for information.

Requirements of 10 CFR 40.55(c) for Distributors to 10 CFR 40.22 General Licensees

Those licensed under 10 CFR 40.54 are required by 10 CFR 40.55(c) to provide information to their GL customers before the first transfer in each calendar year to each particular recipient.

The licensed distributor must provide the following information:

- a copy of 10 CFR 40.22 and 10 CFR 40.51, or relevant equivalent Agreement State provisions

- appropriate radiation safety precautions and instructions relating to the handling, use, storage, and disposal of source material

What is adequate and appropriate safety instruction depends on the amount and type of material the user is obtaining. For dispersible materials, it is particularly important to address means of minimizing the intake of the material. Instructions should include general statements about radiation safety such as the following:

- Minimize exposure by applying the basic radiation safety principles of time, distance, and shielding.[1]

- Prohibit eating, drinking, smoking, and applying cosmetics in areas of use.

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[1]Minimizing the time spent around radioactive material, as well as maximizing the distance and the shielding between persons and the radioactive material.

- Wear gloves and laboratory coats when handling liquid or powdered radioactive material.

- Securely store all radioactive materials when not in use.

Applicants under 10 CFR 40.54 must describe how they will ensure that this information is provided to customers before transfer of the source material, including transactions conducted over the Internet.

Note: Licensees can also give Appendix I of this NUREG to customers for additional information. That appendix contains useful information about the small quantities general license in a question and answer format. Table C–7 of Appendix C of this NUREG also contains a table listing regulations applicable to general licensees under 10 CFR 40.22.

Recordkeeping and Material Transfer Reports for Distributors Licensed Under 10 CFR 32.51, Including NRC Form 653–Transfers of Industrial Devices Report

Quarterly Material Transfer Reports for 10 CFR 32.51 Licensees

Licensed distributors are required to file a report with the U.S. Nuclear Regulatory Commission (NRC) within 30 days of the end of each calendar quarter in accordance with Title 10 of the *Code of Federal Regulation* (10 CFR) 10 CFR 32.52. They may use NRC Form 653 (see copy in this Appendix) to submit these quarterly reports. Alternatively, licensees may use another report format as long as the report includes the following information:

- Name and license number of the specific licensee submitting the report.

- Name and address of *each* general licensee, including intermediate persons, to which a device was transferred.

  This address should be the mailing address for the location of use of the device. For devices that are portable, this address should be the mailing address of the primary place of storage of the device.

  When a customer has multiple locations of use, each location of use should be listed as a separate transfer, with the corresponding mailing address of each location of use (unless the multiple locations are contained within the same business campus or industrial complex). For example, an applicant transfers generally licensed (GL) devices to Company A at two different locations (Plant 1 and Plant 2). Company A is considered as two separate general licensees, one for each location of use. In other words, Company A-Plant 1 is considered a separate general licensee from Company A-Plant 2. The applicant should report both general licensees to which a device was transferred.

  Different facilities at the same industrial complex or business campus are not considered separate locations.

  If there is no mailing address for the location of use, an alternate address for the general licensee should be submitted, along with information on the actual location of use, such as GPS coordinates. (This might be the case if the device is used on a pipeline.)

  Reports to the NRC should only include transfers of devices for which the place of use is within the NRC's jurisdiction or, for portable devices, the primary place of storage of the device is within the NRC's jurisdiction. (See Chapter 2 for details on NRC jurisdiction.)

- Name, title, and telephone number of each general licensee's responsible individual.

  The responsible individual must be an individual designated by the general licensee to be responsible for having knowledge of and the authority to take required actions to ensure the day-to-day compliance with the appropriate regulations and requirements. Each general licensee must designate only one responsible individual per location.

  However, a responsible individual can be assigned to more than one general licensee. This individual is not necessarily someone who works on site at the place of use of the

device and is not necessarily conducting all required actions, but he or she is responsible for ensuring that required actions are taken.

- Date of transfer.

- Type, model number, and serial number of the device transferred.

- Quantity and type of byproduct material contained in the device.

Under 10 CFR 32.52(b), licensees must also submit a report containing the same information outlined above to the responsible Agreement State agency for transfers to or from general licensees in each Agreement State. However, a report of no transfers during the reporting period is only required if an Agreement State requests it.

Important Notes on Transfer Reports

Licensees should note the following information about transfer reports:

- Under 10 CFR 32.52(a)(2), if one or more "intermediate persons" will temporarily possess the device at the intended place of use before the intended end user takes possession, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s). The term "intermediate persons" means a person, company, or corporation that will temporarily possess the device at an intended place of use before its possession by the intended user. Such temporary possession includes a manufacturer transferring devices to a distributor or electrical contractor. For example, if XYZ Building Company owns an office building during its construction and the building contains self-luminous tritium exit signs (GL devices), XYZ Building Company is the intermediate person. When XYZ Building Company sells the office building to Company 123, then Company 123 becomes the general licensee. In accordance with 10 CFR 31.5(c)(15), an intermediate person should not hold a device in storage for longer than 2 years, unless quarterly physical inventories of these devices are performed while they are in standby.

- Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service need not be mentioned on the transfer report to the extent that they transport or store the byproduct material in the regular course of transfer pursuant to 10 CFR 30.13.

- In accordance with 10 CFR 32.52(a)(3), If a GL-distribution licensee receives a device from a 10 CFR 31.5 general licensee, the report must note this and identify the general licensee by name and address; the type, model number, and serial number of the device received; the date of receipt; and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor. If using NRC Form 653, these receipts are to be included on the portion identified as 653A.

- In accordance with 10 CFR 32.52(a)(7) and 10 CFR 32.52(b)(7), if there are no transfers or receipts made during the reporting period, the licensee must file a report of no activity, except that such reports should only be sent to Agreement States that request reports of no activity.

- If a GL-distribution licensee makes a change(s) to a device possessed under 10 CFR 31.5, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the change to information on the device label in accordance with 10 CFR 32.52(a)(4). If the distributor licensee uses NRC Form 653 to report transfers, then they should report the required changes on NRC Form 653B.

Recordkeeping

In accordance with 10 CFR 32.52(c) distributor licensees must maintain the information on all 10 CFR 31.5 (and equivalent Agreement State licensees) transfers and receipts that support the reports described above for 3 years after the recorded event.

In the event the distributor licensee files for bankruptcy or requests termination of the license, the licensee must make available to the various regulatory agencies, upon request, records of the final disposition of devices pursuant to 10 CFR 32.51a(e).

Guidance for 10 CFR 31.5 General Licensees (Questions and Answers)

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

Generally licensed (GL) devices contain source or byproduct material or both and are typically used to detect, measure, or control the density, level, or chemical composition of various items. Examples of such devices are density gauges, fill-level gauges (see Figure F–1), gas chromatographs (see Figure F–2), and static elimination devices. Another type of GL device is a self-luminous exit sign (see Figure F–3).

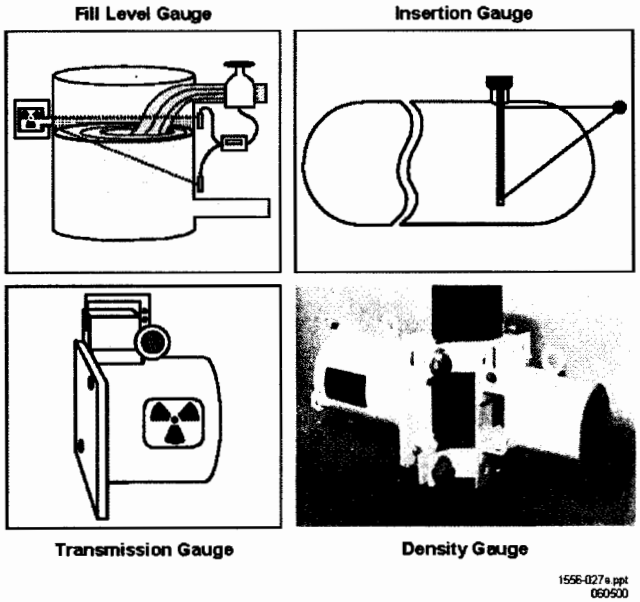

Figure F–1. Fixed Gauges. *Certain fixed nuclear gauges may be possessed and used under the general license in Title 10 of the Code of Federal Regulations (10 CFR) 10 CFR 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere."*

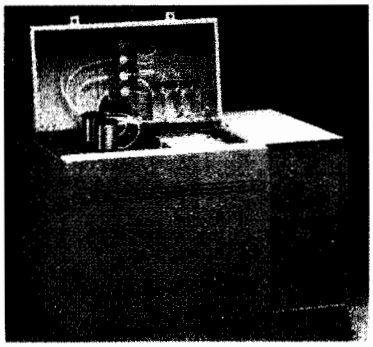

Figure F–2. Gas Chromatograph Unit. *Certain gas chromatograph units (detector cells) used for analysis of chemical composition can be possessed under the general license in 10 CFR 31.5.*

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Figure F–3. Self-Luminous Exit Sign. *Certain self-luminous, tritium exit signs can be possessed under 10 CFR 31.5. (Typical devices initially contain 25 curies of tritium per sign.)*

2. What is a 10 CFR 31.5 general licensee?

A general licensee is a company or person who uses or stores a GL device. The device is obtained through an authorized transfer from the device manufacturer or distributor or by a transfer to another general licensee only if the device remains in use at a particular location. If a device is received through unauthorized means, contact the regulatory authority immediately (see Question 14).

3. What is U.S. Nuclear Regulatory Commission (NRC) annual registration of GL devices?

The NRC requires that certain devices licensed in 10 CFR 31.5 be registered each year. Registration of the device depends upon the type and quantity of radioactive material in the device (see Questions 4 and 6). Registration involves completing NRC Form 664, "General Licensee Registration," when requested and returning it to the NRC.

4. Which GL devices are subject to NRC registration?

Devices used or stored in an NRC jurisdiction that contain, at the time of manufacture, at least 370 megabecquerels (MBq) [10 millicuries (mCi)] of cesium-137, 3.7 MBq [0.1 mCi] of strontium-90 or radium-226, or 37 MBq [1 mCi] of cobalt-60, americium-241, or any other transuranic [i.e., element with an atomic number greater than that of uranium (92)] are subject to NRC registration.

Tritium exit signs and gas chromatographs are not subject to registration.

In accordance with 10 CFR 31.5I(13)(iv), persons generally licensed by an Agreement State who have devices meeting the registration criteria are not subject to NRC registration requirements if the devices are used in areas of NRC jurisdiction for less than 180 days in any calendar year.

See Question 14 for a listing of States where the NRC has jurisdiction (non-Agreement States), as well as a listing of States where the NRC has given the State the authority for regulating use of radioactive material (Agreement States).

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

If you have a device of a type described in Question 1 above, look at the labels on the device, if any. GL devices will have a label containing the words, "The receipt, possession, use, and transfer of this device Model _____ , Serial No. _____ are subject to a general license ...". Radioactive material contained in the devices will be identified as specified in 10 CFR 32.51(a)(3)(iii).

Also, review any paperwork (such as manuals or brochures) that you received with the device. These documents can provide you with information on the radioactivity contained within the device and whether or not the device is subject to NRC regulations. If you are still unsure, contact the manufacturer or distributor of the device for help. If the manufacturer is not available, contact the NRC (see Question 14).

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 NRC or the appropriate Agreement State for a specific license.

6. How do I know if I have a GL device that is subject to annual registration?

The device manufacturer should be able to answer questions about the registration of any devices you have purchased. You can also look at the label on the device for the identification of the radioisotope and quantity of radioactive material. If the device contains the type and quantity of material indicated in Question 4, then it is subject to registration by the NRC.

7. What are the requirements for a GL device?

GL devices used within an NRC jurisdiction are subject to the NRC regulations listed in 10 CFR 31.5. General licensees are required to appoint a responsible individual who knows about the requirements and has the authority to carry out the necessary duties to comply with the regulatory requirements. The five tables below summarize these requirements.

Routine Maintenance

Ensure that all labels affixed to the device stay attached to the device.
Comply with the instructions and precautions provided on the labels, including any referenced documents such as operating and service manuals.
If required, perform leak tests every 6 months, in accordance with the manufacturer's instructions or as required by the regulations (unless the device is in storage or unless otherwise indicated on the label), and maintain leak test records for 3 years.

Routine Maintenance (Continued)

If required, perform shutter tests every 6 months, in accordance with the manufacturer's instructions or regulatory requirements (unless the device is in storage or unless otherwise indicated on the label), and maintain shutter test records for 3 years. Fixed gauges routinely operate in a continuous mode with the shutter open, exposing the radioactive source inside. This increases the chances of corrosion and the buildup of rust or debris to affect the ability of the shutter to close. Therefore, licensees should consider more frequent shutter tests by taking into account such factors as the accessibility of the gauge (e.g., the gauge is mounted 100 feet above the ground), indications that a shutter may have a buildup of debris, whether any components are beginning to corrode, "sticking" or "binding" of the shutter during closure, and the potential for employees to be exposed should a shutter get stuck in the open position.

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, distributor, or other person holding a specific license to repair or dispose of it.
Within 30 days, provide the NRC a brief description of the event and remedial actions taken. If measured contamination is greater than 185 becquerels [0.005 microcuries] or is likely to have resulted from the event, develop and submit a plan to the NRC 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

Notify the person who is responsible for overseeing use of devices containing byproduct material. 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 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 is competent in the use of a radiation survey meter.
In addition to any required notification of the NRC, you may report any incident to the NRC by calling the NRC's Emergency Operations Center at 301-816-5100. The center is staffed 24 hours a day and accepts collect calls. Local authorities may also be able to provide assistance.

Reporting Requirements (Applicable to All 10 CFR 31.5 General Licensees)

Type of Report	Contents of Report	Frequency	Send to
Transfer or disposal report	Identification of device by manufacturer's (or initial transferor's) name; model number and serial number; name, address, and license number of the recipient; and date of transfer	Within 30 days of transfer, disposal, or export	Director of NMSS Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Report of transfer of a device to another general licensee (where the device remains in use at a particular location)	Manufacturer's (or initial transferor's) name; model number and serial number; name and address of the transferee; and name, title, and telephone number of the responsible individual for the transferee	Within 30 days of transfer	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Report if the device becomes damaged or fails a shutter or leak test	Brief description of the event and remedial actions taken and a plan (if contamination is measured or likely) for ensuring that the premises and environs are acceptable for unrestricted use	Within 30 days of occurrence	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Report a change in the name of the licensee	New name of the general licensee	Within 30 days of occurrence	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
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's primary place of storage.)	New mailing address for the location where the device is used or stored	Within 30 days after relocating the device	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001

Reporting Requirements (Applicable to All 10 CFR 31.5 General Licensees) (Continued)

Type of Report	Contents of Report	Frequency	Send to
Report of incidents (*Note:* An NRC licensee that possesses a fixed gauge with a shutter that cannot be closed must notify the NRC within 24 hours of any such incident, in accordance with 10 CFR 30.50(b)(2). In addition, in accordance with 10 CFR 30.50(c)(2), the licensee must follow the initial report within 30 days with a written report describing the circumstances that led to the shutter failure and the corrective actions taken.)	Written report includes the following: • description of the event, including probable cause, and the equipment manufacturer and model number • exact location of the event • isotopes, quantities, and chemical and physical form of the licensed material • date and time of the event • corrective actions and results of evaluations or assessments • radiation exposures to individuals	Telephone report immediately or within 24 hours of occurrence per 10 CFR 30.50; written report within 30 days of the telephone report per 10 CFR 30.50	Administrator of the appropriate NRC regional office
Report of lost or stolen devices	Written report includes the following: • description of the licensed material • description of the circumstances under which the loss or theft occurred • disposition of the licensed material • radiation exposure to individuals • actions to recover the material • actions to prevent recurrence	Telephone report immediately or within 30 days of occurrence per 10 CFR 20.2201(a); written report within 30 days of the telephone report per 10 CFR 20.2201(b)	Administrator of the appropriate NRC regional office

Additional Reporting Requirements for GL Devices Subject to Registration

Type of Report	Contents of Report	Frequency	Send to
Registration	The following information and any other information specifically requested by the NRC: • name and mailing address • information about each device: the manufacturer or initial transferor, model number, serial number, radioisotope, and activity • name, title, and telephone number of the responsible individual • address where the device(s) is used or stored or both • certification that the information concerning the device(s) has been verified through a physical inventory and check of the label • certification by the responsible individual that he or she is aware of the requirements of the general license (***Note:*** This information should be submitted using NRC Form 664.)	Annual	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001, or as otherwise indicated in the request for registration
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	Administrator of the appropriate NRC regional office

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

Some GL devices have been approved for installation and relocation by the general licensee; however, this does not apply to all GL devices. You should contact the manufacturer or distributor to determine whether your device(s) has been approved for relocation and installation by the general licensee.

9. Is there reciprocity for GL devices?

No, there is no reciprocity provision applicable to general licensees. If a general licensee obtains a device in an Agreement State and wishes to use the device within an NRC jurisdiction, it must do so under 10 CFR 31.5. In this case, the general license in 10 CFR 31.5 applies automatically without application for license or other permission as long as the device has been manufactured and distributed appropriately. The general licensee is subject to the provisions of 10 CFR 31.5, including registration requirements. However, NRC registration is not required for a general licensee using a device in NRC jurisdiction for less than 180 days in any calendar year.

The general license in 10 CFR 31.5 only applies within NRC jurisdiction. General licensees intending to move from one jurisdiction to another should contact the applicable regulatory authority (i.e., the NRC or the particular Agreement State) before moving, to determine the applicable regulations in their jurisdictions. Not all jurisdictions have a general license, and specific provisions of the general license may vary among jurisdictions.

10. I am an Agreement State general licensee. Does the NRC allow me to use my GL device at temporary jobsites within an NRC jurisdiction?

Yes. For portable devices, such as devices used for demonstration purposes, which may be transported from an Agreement State to an NRC jurisdiction, use of the device in an NRC jurisdiction is permitted as long as the general licensee follows the requirements of 10 CFR 31.5. As mentioned above, NRC registration is not required for an Agreement State general licensee using a device in NRC jurisdiction for less than 180 days in any calendar year.

11. Would an Agreement State allow me to use my GL device at temporary jobsites within that Agreement State's jurisdiction?

For devices that may be transported from one Agreement State to another, or from an NRC jurisdiction to an Agreement State, use of the device comes under the regulations of the Agreement State where the device is being used. Be sure to know the requirements in the area where you are using the device by contacting the particular Agreement State. Some Agreement States currently require that the device be registered or specifically licensed before it can be used in that State.

12. How can I get rid of a GL device?

GL devices can only be transferred (for disposal or to obtain a replacement device) to (1) a person holding a specific license under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," or equivalent 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. A GL device can be transferred to other specific licensees only with prior written approval of the NRC.

A GL device can only be transferred to another general licensee if the GL device remains at a particular location. The transferor must give the new general licensee copies of 10 CFR 30.51, "Records;" 10 CFR 31.2, "Terms and conditions;" 10 CFR 31.5, 10 CFR 20.2201, "Reports of theft or loss of licensed material;" 10 CFR 20.2202, "Notification of incidents;" and any safety documents identified in the device label.

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

GL devices containing byproduct materials not in use can only be stored for 2 years. After 2 years, the device must be properly transferred. During this period of nonuse, the shutter must be locked in the closed position. Devices kept in standby for future use are excluded from the 2-year time limit if the general licensee performs a quarterly physical inventory of the device while it is in standby status. The general licensee must continue to annually register the device and pay the appropriate fees.

14. Who can answer additional questions?

Call the device manufacturer, who should be able to assist you. If the manufacturer is no longer in business, or if you cannot contact the manufacturer, call the appropriate NRC regional office or Agreement State for assistance. See Figure 2-1 of this NUREG for the telephone numbers for the NRC regional offices.

Note that States where the NRC has jurisdiction are called non-Agreement States. States where the NRC has given the State the authority to regulate the use of radioactive material are called Agreement States.

15. What other requirements apply?

Persons who possess devices listed in 10 CFR 31.5 are exempt from the requirements of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations;" 10 CFR Part 20, "Standards for Protection against Radiation;" and 10 CFR Part 21, "Reporting of Defects and Noncompliance," with the exception of the provisions in 10 CFR 20.2201 and 10 CFR 20.2202. These persons are subject to the following sections of 10 CFR Part 30: 30.1 through 30.10, 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.53, and 30.61 to 30.63.

16. My company has a specific license for the use of radioactive material and also has GL devices. Do I have to include these GL devices on my inventory of radioactive materials?

No, you do not have to include GL devices on the inventory that is required by your specific license. However, many companies have chosen to keep track of their devices, along with their specifically licensed material, through periodic inventory.

Forster, Sara

From: Forster, Sara
Sent: Thursday, April 25, 2019 12:23 PM
To: ben.scher@endress.com
Subject: Additional Information Request re Endress+Hauser, Inc. renewal, NRC Lic. No. 13-32721-01, CN611031
Attachments: 03214.611031.13-32721-01 signed RFAI via NRC 699.pdf

Dear Mr. Scher:

We have reviewed your January 11, 2019 application (NRC Accession No. ML19011A093) requesting renewal of the above-listed radioactive materials license, for use of radioactive material for service provider, manufacturing & distribution, and general license distribution of fixed gauging devices.

Upon review, and as we will discuss, we have noted that the application omits information requested in revision 1 to each of the NRC's NUREG guidance volumes 12 "Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution," 4 "Program-Specific Guidance about Fixed Gauge Licenses," 18 "Program-Specific Guidance about Service Provider Licenses," and 16 "Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees." Please see attached for information needed to complete our review of your request.

To facilitate our continued review of your request, please provide additional information – via a signed and dated cover letter and resubmitted supporting information - as noted in the attached record.

Please provide a response within 28 days (on or before May 24, 2019). Include a signed and dated cover letter transmitting your response. Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. Thank you for your prompt attention to this matter.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
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U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment