



United States Nuclear Regulatory Commission

*Protecting People and the Environment*

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**OFFICE OF NUCLEAR MATERIAL SAFETY AND  
SAFEGUARDS  
INTERIM STAFF GUIDANCE  
NMSS-ISG-04**

**GUIDANCE FOR THE IMPLEMENTATION OF  
10 CFR PART 31 SUBPART C STANDARD GENERAL  
LICENSES**

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## TABLE OF CONTENTS

TABLE OF CONTENTS .....	ii
PAPERWORK REDUCTION ACT .....	iv
PUBLIC PROTECTION NOTIFICATION .....	iv
ABBREVIATIONS .....	v
1.0 PURPOSE .....	1
2.0 APPLICABILITY AND USE .....	2
3.0 BACKGROUND .....	3
4.0 GUIDELINES .....	4
4.1 Standard General License Framework .....	4
4.1.1 10 CFR 31.13 Standard General License Requirements .....	5
4.1.2 10 CFR 31.14 Standard General License for Certain Fixed Gauging Devices .....	6
4.1.3 10 CFR 31.15 Standard General License for Portable Gauging .....	7
4.1.4 10 CFR 31.16 Standard General License for Certain Medical Uses .....	9
4.1.5 10 CFR 31.17 Standard General License for Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators .....	10
4.1.6 10 CFR 31.18 Standard General License for Certain In Vitro Testing .....	11
4.2 Standard General License Resources .....	12
4.2.1 Radiation Safety Program Resources .....	12
4.2.2 SGL Considerations and Limitations .....	15
4.3 Management Responsibility .....	16
4.3.1 Notifications .....	18
4.3.2 Reports .....	18
4.3.3 Safety Culture .....	18
4.3.4 Inspection and Enforcement .....	19
4.4 Submittals .....	20
4.4.1 Initials .....	20
4.4.2 Changes .....	20
4.4.3 Location Removals .....	21
4.4.4 Terminations .....	21
4.4.5 Where to File .....	21
4.4.6 Acceptable Means to File .....	22
4.5 Fees .....	23
4.6 General Instructions for Completing the NRC Form 1003 .....	24
4.6.1 Item 1: Name of Licensee .....	24
4.6.3 Section A – Registration Information .....	25
4.6.3.2 Item 2: Management Contact .....	25
4.6.3.3 Item 3: RSO Contact .....	25
4.6.3.4 Item 4: Actual physical address for locations of use and storage .....	25
4.6.3.5 Item 5: Activities to be conducted .....	26
4.6.3.6 Item 6: List of Radioactive Materials .....	26
4.6.3.7 Item 7: License Fees .....	27
4.6.3.9 Item 8: Previous work .....	27
4.6.3.9 Item 9: Certification .....	28
4.6.4 Section B – Disposition of Materials .....	28

4.6.4.1 Item 1: Location status .....	28
4.6.4.2 Item 2: Actual physical addresses.....	28
4.6.4.3 Item 3: Disposal Of Radioactive Material .....	28
4.6.4.4 Item 4: Surveys Performed And Reported .....	30
4.6.5 Section C – Validation .....	30
4.7 Identifying and Protecting Sensitive Information .....	31
5.0 Questions and Answers about SGLs .....	33
REFERENCES .....	38

## **PAPERWORK REDUCTION ACT**

This interim staff guidance contains voluntary guidance for implementing the mandatory information collections in 10 CFR Part 31 and NRC Form 1003 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), under control numbers 3150-0016 and 3150-xxxx respectively. Send comments regarding these information collections to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to [Infocollects.Resource@nrc.gov](mailto:Infocollects.Resource@nrc.gov), and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0016 and 3150-xxxx), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503.

## **PUBLIC PROTECTION NOTIFICATION**

The U.S. Nuclear Regulatory Commission (NRC) may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

## ABBREVIATIONS

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
AEA	Atomic Energy Act of 1954, as amended
DOT	U.S. Department of Transportation
EO	Executive Order
GL	General License
IMC	Inspection Manual Chapter
ISG	Interim Staff Guidance
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget
PII	Personally identifiable information
PET	Positron Emission Tomography
RIS	Regulatory Issue Summary
RSO	Radiation Safety Officer
SGL	Standard General License
SSDR	Sealed Source and Device Registry
U.S.C.	United States Code

## 1.0 PURPOSE

This document provides guidance for implementing Standard General License (SGL) requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 31, “General Domestic Licenses for Byproduct Material.” This interim staff guidance (ISG) is intended for use by licensees that are seeking to use an SGL for certain activities with byproduct material.

This ISG also provides criteria for the NRC staff and Agreement State regulators to implement an SGL program and evaluate SGL registrations. This ISG explains the regulatory framework, provides direction on developing a radiation safety program for an SGL, and outlines the information needed to register an SGL.

This ISG does the following:

- Discusses SGL requirements and regulations.
- Identifies the responsibilities of a licensee.
- Provides additional resources that may be helpful to licensees.
- Details limitations of SGLs and topics for persons to consider when determining which type of license is most appropriate for their needs.
- Identifies the information and supporting documentation needed to complete the NRC FORM 1003 and describes step-by-step instructions for various situations.

## **2.0 APPLICABILITY AND USE**

This ISG provides guidance on a newly developed licensing pathway for some byproduct materials to be used for certain industrial, commercial, and medical applications. The ISG states expectations for implementing an SGL program and the associated requirements. Additionally, it provides references to additional guidance that may be helpful to licensees.

The NRC issues guidance to describe methods that the staff considers acceptable for implementing and complying with specific parts of the agency's regulations. This ISG is not a substitute for NRC or Agreement State regulations. Therefore, licensees are free to demonstrate approaches and solutions that differ from those described in this guidance that may also be deemed acceptable if they satisfy 10 CFR 31 Subpart C requirements and provide a suitable basis for the NRC staff to make the necessary determinations.

Licensees and staff should use this ISG until it is superseded by or incorporated in other guidance. Currently, the NRC staff intends to develop a new Volume of NUREG-1556 "Consolidated Guidance About Materials Licenses" in the future to address SGLs. The NRC staff intends to further review the guidance and make necessary revisions to enhance the program efficiencies in the future. This will involve a thorough evaluation of comments received outside the scope of this ISG development, incorporating feedback and lessons learned, and further public engagement.

Certain States, called Agreement States, have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any licensee, other than a Federal or Tribal entity, that wishes to possess or use licensed material in one of these Agreement States, should contact the responsible officials in that State for guidance on implementing these regulations. Refer to NUREG 1556, "Consolidated Guidance About Materials Licenses" or Section 4.4.5 of this ISG for additional information.

A licensee may seek the NRC staff input for clarification on what is required under existing regulations and for the basis for the regulations. The NRC staff will not draft or develop text for submittals or advise on decisions by the licensee related to submittals.

### **3.0 BACKGROUND**

The NRC's regulations require that persons obtain a license to use byproduct material greater than exempt quantities. The NRC issues two types of byproduct material licenses: (i) general and (ii) specific.

Specific licenses are issued to a named person who has filed an application for the license. Applications for specific licenses require significant effort by applicants to prepare and significant effort by the NRC to review. Additionally, amendments to specific licenses are required when a variety of changes occur. The level of effort for an amendment can range from low effort to high effort for both licensees and the NRC. Specific licenses cover a wide range of activities with byproduct material and have a variety of associated risk profiles. Some activities are conducted in a standard method across the industry, while others are conducted in a non-uniform manner. The specific licenses for standard operations use consistent license authorizations and conditions, such that, these specific licenses appear almost identical across the industry with the exception of individuals named on the license and the locations authorized by the license. For example, the majority of specifically licensed portable gauge licensees operate under the same license conditions and have the same license commitments. The same can be said for some specifically licensed medical activities, fixed gauge activities, users of analytical equipment, and users of in vitro and laboratory tests. The burden associated with applying for a specific license and maintaining a specific license can be high for low-risk, standard operations when the specific license follows the standard format.

By contrast, a general license (GL), which is provided by regulation, grants authority to a person for certain activities involving licensed material and is effective without the need for a person to file an application with the NRC or the issuance of a licensing document to a particular person. However, certain GLs may require registration with the NRC. Under 10 CFR Part 31, the NRC grants GLs for the use of certain items containing byproduct material and provides the primary requirements associated with these GLs. This regulatory framework has proven to be effective and low burden for many low-risk standard activities.

On May 23, 2025, President Trump signed Executive Order (EO) 14300, "Ordering the Reform of the Nuclear Regulatory Commission." EO 14300 required the NRC to undertake a review and wholesale revision of its regulations and guidance documents. In accordance with EO 14300 the NRC identified changes across 10 CFR intended to yield significant efficiencies and reduce regulatory burden for licensees, the NRC, and Agreement States while upholding shared commitment to public safety. As result of EO 14300, the NRC established a new class of GLs, called SGLs. The regulatory framework was codified in 10 CFR 31 Subpart C.

## **4.0 GUIDELINES**

The new class of GLs, codified in 10 CFR 31 Subpart C, allows some low risk standardized operations that are currently specifically licensed to be licensed through an SGL. The SGL framework allows eligible persons to select between an SGL and a specific license. An SGL provides a low burden licensing option while maintaining adequate safety, security, and oversight of the licensed activities.

The SGL framework found in 10 CFR 31 Subpart C supplements the current generally licensed framework by permitting additional fixed gauges, analytical instruments, and in vitro testing as well as adding GLs for portable gauges and certain diagnostic medical uses. The SGLs are granted by regulation upon submission of a registration, fee, and certification of understanding. SGLs are required to pay an annual fee that is established in 10 CFR 171.

The sections below discuss the SGL regulatory framework, the registration process, available resources, management responsibilities, and protections of sensitive information.

### **4.1 Standard General License Framework**

The SGL framework grants SGLs by regulation upon submission of a registration, fee, and certification of understanding for five authorized uses. Rule language, found in 10 CFR 31.13 - 31.18, was developed based on standard license conditions and essential standard commitments related to programs necessary for radiological safety and security.

Requirements for the registration process, decommissioning, and termination are found in § 31.13. In addition, requirements in § 31.13 provide possession limits.

Each of the five authorized uses has an SGL that is specific to the use as follows:

- Requirements for a Standard General License for Certain Fixed Gauging activities are found in § 31.14.
- Requirements for a Standard General License for Portable Gauging activities are found in § 31.15.
- Requirements for a Standard General License for Certain Medical Uses are found in § 31.16.
- Requirements for a Standard General License for Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators are found in § 31.17.
- Requirements for a Standard General License for Certain In Vitro Testing activities are found in § 31.18.

The contents of each SGL are structured similarly. However, the content is specific to the activities being conducted under the SGL. For example, paragraph (a) of each section grants the SGL to applicable persons, describes the authorized materials, and specifies the authorized activities. Meanwhile, paragraph (b) provides additional requirements that the SGLs are subject to in other parts of 10 CFR, as well as applicable exceptions. Finally, paragraph (c) provides the technical requirements related to the radiation safety program. The elements in paragraph (c) of each SGL were derived from standard license conditions and essential standard commitments from risk significant elements in the applicable NUREG-1556 Volume. The SGLs impose the

same basic requirements upon licensees that would be imposed on a specific licensee for the same activity which ensures equivalent assurance of public health and safety.

To support the new class of SGLs, the NRC made changes in other parts of 10 CFR to ensure radioactive materials can be distributed to and from the SGLs. Changes included: the definition of principal activities in § 30.4, the addition of SGLs to § 30.6, the addition of SGLs in § 30.34(h)(1), the addition of SGLs to § 30.35(g), the addition of SGLs to § 30.41(d)(1), the addition of SGLs for certain medical uses to § 32.72(a), the addition of SGLs for certain medical uses to § 32.74(a), and the addition of SGLs to § 150.20.

The following sections summarize the requirements in each section of 10 CFR 31 Subpart C. All standard general licensees are required to comply with requirements in § 31.13 and the applicable SGL for their authorized use(s).

#### 4.1.1 10 CFR 31.13 Standard General License Requirements

The administrative requirements for registering and maintaining an SGL are contained in § 31.13. The requirements in § 31.13 are applicable to all SGLs. These requirements ensure that licensees maintain regulatory compliance, protect public health and safety, and manage radioactive materials responsibly.

To register for an SGL, NRC Form 1003 must be submitted to the NRC at least 30 days before acquiring or commencing activities with byproduct material. The NRC must validate the form and assign a registration number before the licensee can proceed with activities licensed under the SGL. A copy of the validated NRC Form 1003 will be returned to the licensee. Without a validated NRC Form 1003, licensees will not be able to receive byproduct material. Additionally, the licensee must pay the appropriate fee as described in Section 4.5 of this ISG. SGLs can authorize up to five locations of use or storage, not including temporary job sites. Temporary job sites are only permitted for activities authorized under § 31.15 and § 31.17.

The licensee must notify the NRC of any significant changes at least 30 days in advance by submitting an updated NRC Form 1003. Significant changes include change in ownership, licensee name, mailing address, locations of use, Radiation Safety Officer (RSO), or the byproduct materials used. In cases where licensed activities are transferred to a new owner, the current licensee must transfer certain records, such as those related to material disposal and radiation surveys, to the new license holder. No fee is required when submitting an NRC Form 1003 for changes, location removals, or terminations. However, licensees are required to pay an annual fee as described in Section 4.5 of this ISG.

SGLs do not authorize exporting byproduct material. SGLs are prohibited from abandoning byproduct material. SGLs do not authorize byproduct materials that require implementation of 10 CFR Part 37 requirements, financial assurance for decommissioning, or an emergency response plan. All SGLs must restrict the possession of licensed material to the following limits:

- A total quantity below unity for the radionuclides listed in 10 CFR Part 37 Appendix A, calculated using the Category 2 activity thresholds specified in the table, according to 10 CFR Part 37 Appendix A;
- Quantities below the minimum limits for unsealed and/or sealed material as specified in § 30.35(d) for which decommissioning financial assurance is required; and

- Quantities below the limits specified in § 30.72, in the form of unsealed material and foil or plated sources, above which, consideration of the need for an emergency plan for responding to a release of licensed material is required.

When a licensee decides to permanently stop using radioactive materials at a location, or if no licensed activities have occurred for a specified period, they must notify the NRC within 60 days by submitting an NRC Form 1003. Within the same timeframe, the licensee must either begin decommissioning the site or submit a decommissioning plan. Decommissioning must be completed as soon as possible, but no later than 24 months after it begins. If all the licensee's facilities are being decommissioned, the licensee must request the SGL termination no later than 24 months following the initiation of decommissioning. As part of the final steps, the licensee must certify the disposal of all radioactive materials and may need to conduct a radiation survey of the site.

It is not expected that many SGLs will use a decommissioning plan. However, the framework is in place in the event that unexpected radiological hazards arise during a licensee's operations that would prompt more detailed decommissioning. A plan is required if the decommissioning process involves unusual procedures that could increase risks to workers or the public. The plan must include detailed descriptions of the site, planned activities, safety measures, final radiation surveys, and financial provisions for completing the work. The NRC will review and approve the plan as described in § 31.13(f)(3). If a licensee needs more time to complete decommissioning, they may request an extension from the NRC. This request must be submitted at least 30 days before the required notification and will only be granted if it does not pose a risk to public health or safety and is in the public's best interest.

Finally, to terminate the SGL, the licensee must submit NRC Form 1003. The NRC will provide written notice of termination once the NRC determines that all byproduct materials have been properly disposed of, reasonable effort has been made to eliminate residual radioactive contamination, and the site meets the criteria for release under the NRC's decommissioning standards.

#### 4.1.2 10 CFR 31.14 Standard General License for Certain Fixed Gauging Devices

The fixed gauging SGL allows a wide range of persons — including commercial and industrial firms, research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local governments — to acquire, receive, possess, use, or transfer, byproduct material contained in fixed gauging devices. The devices must be designed to detect, measure, gauge, or control physical properties such as thickness, density, level, interface location, or qualitative or quantitative or chemical composition. The license applies only if the devices are registered in the Sealed Source and Device Registry (SSDR) with prescribed principle use codes D – gamma gauges or E – beta gauges. The SGL permits the use of devices distributed as specifically licensed devices and used as specifically licensed devices under this SGL at specific locations. This means temporary job sites are not permitted by this SGL. The SGL does not authorize the manufacture, initial transfer or distribution, or import of such devices containing byproduct material.

The licensee is subject to all applicable provisions of the Atomic Energy Act of 1954, as amended (AEA), and the NRC regulations, including those in 10 CFR Parts 19, 20, 21, and 71. Within 10 CFR Parts 30 and 31, licensees are subject to §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64, 31.1 through 31.4, 31.13, and 31.21 through 31.23. These licensees are excepted from the requirements of § 30.34(b).

The technical requirements in paragraph (c) of this section include the minimum elements to safely conduct fixed gauging operations with byproduct material. Embedded within each technical requirement are recordkeeping requirements. Licensees should thoroughly review each requirement in paragraph (c) of the SGL. The SGL requires compliance with each element in paragraph (c). The technical requirements are summarized as follows:

- Licensees must ensure that only sealed sources registered in the SDDR are used, that these sources are incorporated into compatible devices by manufacturer and model, and that they are used within the activity limits specified in the registry.
- A RSO must be appointed in writing, and their qualifications and appointment must be documented.
- Authorized users must be designated in writing and trained.
- Only designated authorized users may use or supervise the use of licensed materials.
- Devices must be operated within the limits specified by the manufacturer, sealed sources may not be opened or removed from holders, and nonroutine maintenance may only be performed by the gauge manufacturer, distributor, or other persons authorized by the Commission or an Agreement State.
- This SGL does not authorize nonroutine maintenance such as installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources.
- Licensees must either evaluate radiation exposure to ensure unmonitored individuals remain below regulatory limits or implement a monitoring program.
- Radiation detection instruments must be appropriate for the isotopes used and calibrated annually.
- Physical inventories must be conducted every six months.
- Leak testing of sealed sources is required at intervals identified in the SDDR, or at intervals not to exceed six months if not specified in the SDDR, with the expectation of sources emitting alpha particles which must not exceed an interval of three months. SGLs may collect leak test samples but may not analyze the leak test samples. Analysis must be performed by an entity licensed to perform leak test analysis. Exemptions from leak testing apply to certain low-activity or gaseous sources.
- Shutter mechanisms must be tested every six months, unless the device is in storage with the shutter in the locked position.
- Licensees must develop, implement, and maintain procedures for:
  - Routine maintenance of gauges according to each manufacturers or distributor's written recommendations and instructions.
  - Operations, emergencies, and security that meet the requirements of §§ 20.1101, 20.1801 through 1802, 20.2201 through 2203, and 30.50.

#### 4.1.3 10 CFR 31.15 Standard General License for Portable Gauging

The portable gauging SGL allows a wide range of persons — including commercial and industrial firms, research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local governments — to acquire, receive, possess, use, or transfer, byproduct material contained in portable gauging devices. The devices must be designed to measure the physical properties of materials. The license applies only if the devices are registered in the SSDR with prescribed principle use code G – Portable Moisture Density Gauges. The SGL permits the use of devices distributed as specifically licensed devices and used as specifically licensed devices under the SGL. Additionally, the SGL authorizes the use, possession, and storage of licensed materials at specified locations and temporary job sites within NRC jurisdiction. The SGL does not authorize the manufacture, initial transfer or distribution, or import of such devices containing byproduct material.

The licensee is subject to all applicable provisions of the AEA and the NRC regulations, including those in Parts 19, 20, 21, and 71. Within 10 CFR Parts 30 and 31, licensees are subject to §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64, 31.1 through 31.4, 31.13, and 31.21 through 31.23. These licensees are excepted from the requirements of § 30.34(b).

The technical requirements in paragraph (c) of this section include the minimum elements to safely conduct portable gauging operations with byproduct material. Embedded within each technical requirement are recordkeeping requirements. Licensees should thoroughly review each requirement in paragraph (c) of the SGL. The SGL requires compliance with each element in paragraph (c). The technical requirements are summarized as follows:

- Licensees must ensure that only sealed sources registered in the SSDR are used, that these sources are incorporated into compatible devices by the manufacturer and model, and that they are used within the activity limits specified in the registry.
- A RSO must be appointed in writing, and their qualifications and appointment must be documented.
- Authorized users must be designated in writing and trained.
- Only designated authorized users may use or supervise the use of licensed materials.
- Licensees must evaluate radiation exposure to ensure unmonitored individuals remain below regulatory limits or implement a monitoring program.
- Licensees must possess and use, or have access to and use, a radiation detection instrument for required surveys.
- Licensees must conduct physical inventories every six months.
- Leak testing of sealed sources is required at intervals identified in the SSDR, or at intervals not to exceed six months if not specified in the SSDR, with the expectation of sources emitting alpha particles which must not exceed an interval of three months. SGLs may collect leak test samples but may not analyze the leak test samples. Analysis must be performed by an entity licensed to perform leak test analysis. Exemptions from leak testing apply to certain low-activity or gaseous sources.
- Licensees must develop, implement, and maintain procedures for:
  - Ensuring accountability of licensed materials at all times.
  - Routine maintenance of gauges according to each manufacturer's or distributor's written recommendations and instructions.

- Operations, emergencies, and security that meet the requirements of §§ 20.1101, 20.1801 through 1802, 20.2201 through 2203, 30.34, and 30.50.

Of special note, SGLs for Portable Gauging require compliance with § 30.34(i). For additional guidance on implementing these requirements, refer to Appendix G of NUREG-1556, Volume 1, Rev. 2.

#### 4.1.4 10 CFR 31.16 Standard General License for Certain Medical Uses

The medical use SGL allows a wide range of persons — including commercial and industrial firms, research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local governments —to manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for certain medical purposes. The medical uses are limited to uptake, dilution, excretion, imaging, and localization studies for which a written directive is not required for medical uses as described in §§ 35.100 and 35.200. The SGL authorizes the use of gallium-67, indium-111, iodine-123, iodine-125, iodine-131, technetium-99m, thallium-201, and xenon-133. The SGL authorizes the use of molybdenum-99/technetium-99m generators to prepare radiopharmaceuticals for medical uses as described in §§ 35.100 and 35.200. The SGL authorizes the use of calibration, transmission, and reference sources for uses described in § 35.65. The SGL does not authorize mobile medical services or the medical use of sealed sources.

The licensee is subject to all applicable provisions of the AEA and the NRC regulations, including those in Parts 19, 20, 21, and 71. Within 10 CFR Parts 30 and 31, licensees are subject to §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64, 31.1 through 31.4, 31.13, and 31.21 through 31.23. The licensee is subject to the NRC requirements in 10 CFR Part 35, except for §§ 35.11, 35.12, 35.13, 35.14, 35.18, 35.24(a)-(b), 35.24(d), and 35.24(f). These licensees are excepted from the requirements of § 30.34(b).

The technical requirements in paragraph (c) of this section include the minimum elements to safely conduct the limited set of medical uses with byproduct material. Embedded within each technical requirement are recordkeeping requirements. Licensees should thoroughly review each requirement in paragraph (c) of the SGL. The SGL requires compliance with each element in paragraph (c). The technical requirements are summarized as follows:

- A RSO must be appointed in writing, and their qualifications and appointment must be documented. The RSO must meet the training and experience requirements of §§ 35.50 and 35.59.
- Temporary RSOs may be used under specific circumstances.
- Authorized users must be designated in writing and trained. Authorized users must meet the criteria in § 35.190 or § 35.290, as appropriate for the type of use, and § 35.59.
- Only designated authorized users may use or supervise the use of licensed materials.
- Licensees must either evaluate radiation exposure to ensure unmonitored individuals remain below regulatory limits or implement a monitoring program.
- Radiation detection instruments must be appropriate for the isotopes used and calibrated annually.

- Licensees must conduct leak tests in accordance with § 35.67 or ensure samples are collected and analyzed by an authorized entity or use a leak test sample collection kit that is analyzed by an authorized entity.
- Licensees must develop, implement, and maintain procedures for:
  - Safe use of unsealed byproduct material that meet the requirements of §§ 20.1101 and 20.1201.
  - Safe response to spills of licensed material in accordance with § 20.1101.
  - Area surveys in accordance with § 20.1101 that meet the requirements of §§ 20.1501 and 35.70.
  - Licensed material accountability and control to ensure that: license possession limits are not exceeded; licensed material in storage is secured from unauthorized access or removal; licensed material not in storage is maintained under constant surveillance and control; records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.
  - A program for training required under § 19.12 for each group of workers, including: (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.
  - Waste disposal of licensed material in accordance with § 20.1101, that also meet the requirements of the applicable sections of 10 CFR Part 20, Subpart K, and of § 35.92.

#### 4.1.5 10 CFR 31.17 Standard General License for Certain Analytical Equipment Including Electron Capture Detectors, X-Ray Fluorescence Devices, and Ion Generators

The analytical equipment SGL allows a wide range of persons — including commercial and industrial firms, research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local governments — to acquire, receive, possess, use, or transfer, byproduct material contained in analytical equipment. The devices must be designed to detect, measure, or qualitatively or quantitatively assess chemical composition, or to produce an ionized atmosphere. The license applies only if the devices are registered in the SDDR with prescribed principle use codes N – Ion Generators, Chromatography, or U – X-Ray Fluorescence. The SGL permits the use of devices distributed as specifically licensed devices and used as specifically licensed devices under the SGL. Additionally, the SGL authorizes the use, possession, and storage of licensed materials at specified locations and temporary job sites within NRC jurisdiction. The SGL does not authorize the manufacture, initial transfer or distribution, or import of such devices containing byproduct material.

The licensee is subject to all applicable provisions of the AEA and the NRC regulations, including those in Parts 19, 20, 21, and 71. Within 10 CFR Parts 30 and 31, licensees are subject to §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64, 31.1 through 31.4, 31.13, and 31.21 through 31.23. Licensees are excepted from the requirements of § 30.34(b).

The technical requirements in paragraph (c) of this section include the minimum elements to safely use analytical equipment containing byproduct material. Embedded within each technical

requirement are recordkeeping requirements. Licensees should thoroughly review each requirement in paragraph (c) of the SGL. The SGL requires compliance with each element in paragraph (c). The technical requirements are summarized as follows:

- Licensees must ensure that only sealed sources registered in the SDDR are used, that these sources are incorporated into compatible devices by the manufacturer and model, and that they are used within the activity limits specified in the registry.
- A RSO must be appointed in writing, and their qualifications and appointment must be documented.
- Devices must be operated within the limits specified by the manufacturer. Licensees must ensure sealed sources, source rods, foil sources, or detector cells containing licensed material are not opened or that sources are not removed from source holders, detached from source rods, or foil sources are not removed from detector cells. Additional specific requirements exist for titanium tritide foils or scandium tritide foils.
- Nonroutine maintenance may only be performed by the equipment manufacturer, distributor, or other person authorized by the Commission or an Agreement State.
- This SGL does not authorize nonroutine maintenance such as installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources.
- Physical inventories must be conducted every six months.
- Leak testing of sealed sources is required at intervals identified in the SDDR, or at intervals not to exceed six months if not specified in the SDDR, with the expectation of sources emitting alpha particles which must not exceed an interval of three months. SGLs may collect leak test samples but may not analyze the leak test samples. Exemptions from leak testing apply to certain low-activity or gaseous sources.
- As applicable, licensees must test each analytical instrument for the shutter mechanism every six months, unless the device is in storage with the shutter in the locked position.

#### 4.1.6 10 CFR 31.18 Standard General License for Certain In Vitro Testing

The in vitro testing SGL allows a wide range of persons — including commercial and industrial firms, research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local governments — to acquire, receive, possess, use, or transfer byproduct material for certain in vitro clinical or laboratory testing. The SGL authorizes the use of materials listed in § 31.11(a)(1)-(8). The SGL does not permit the use of materials in or on humans, nor does it authorize the use of materials in field applications where radioactivity is released.

The licensee is subject to all applicable provisions of the AEA and the NRC regulations, including those in Parts 19, 20, 21, and 71. Within 10 CFR Parts 30 and 31, licensees are subject to §§ 30.7, 30.8, 30.9, 30.10, 30.11, 30.31, 30.34, 30.35, 30.41, 30.50 through 30.64, 31.1 through 31.4, 31.13, and 31.21 through 31.23. These licensees are excepted from the requirements of § 30.34(b) and § 31.11.

The technical requirements in paragraph (c) of this section include the minimum elements to safely conduct the in vitro or laboratory tests with byproduct material. Embedded within each technical requirement are recordkeeping requirements. Licensees should thoroughly review

each requirement in paragraph (c) of the SGL. The SGL requires compliance with each element in paragraph (c). The technical requirements are summarized as follows:

- A RSO must be appointed in writing, and their qualifications and appointment must be documented.
- Authorized users must be designated in writing and trained.
- Only designated authorized users may use or supervise the use of licensed materials.
- Licensees must either evaluate radiation exposure to ensure unmonitored individuals remain below regulatory limits or implement a monitoring program.
- Radiation detection instruments must be appropriate for the isotopes used and calibrated annually.
- Waste must be properly disposed of as described through decay-in-storage or methods described in 10 CFR Part 20. Certain exceptions apply for waste from in vitro kits that are exempt by 10 CFR 31.11(f)
- Licensees must develop, implement, and maintain written procedures for:
  - Safe use of unsealed byproduct material that meet the requirements of § 20.1101 and § 20.1201.
  - Safe response to spills of licensed material in accordance with § 20.1101.
  - Area surveys in accordance with § 20.1101 that meet the requirements of § 20.1501.
  - Licensed material accountability and control to ensure that: license possession limits are not exceeded; licensed material in storage is secured from unauthorized access or removal; licensed material not in storage is maintained under constant surveillance and control; records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material are maintained.
  - A program for training required under § 19.12 for each group of workers, including: (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.
  - Waste disposal of licensed material in accordance with § 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K.

## **4.2 Standard General License Resources**

This ISG is intended to explain the regulatory framework, provide direction on developing a radiation safety program for an SGL, and outline how to register an SGL. While the administrative processing differs drastically from the processing of a specific license, the basic technical requirements that standard general licensees are subject to remain the same as the technical requirements that specific licensees are subject to. As such, entities may wish to use this ISG in addition to the guidance that was previously developed for specific licensees. The following sections highlight guidance that may be helpful while also describing considerations for licensees when determining the most appropriate type of license for their operations.

### **4.2.1 Radiation Safety Program Resources**

The SGL program requires licensees to comply with various NRC requirements as well as develop certain programs that are essential to radiation safety.

It is the licensee’s responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of 10 CFR contain regulations applicable to standard general licensees and regulations that may be helpful in understanding limitations of SGLs. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

The current versions of the following parts can be found online using the links provided below:

- [10 CFR Part 2 “Agency Rules of Practice and Procedure”](#)
- [10 CFR Part 19 “Notices, Instructions and Reports to Workers: Inspection and Investigations”](#)
- [10 CFR Part 20 “Standards for Protection Against Radiation”](#)
- [10 CFR Part 21 “Reporting of Defects and Noncompliance”](#)
- [10 CFR Part 30 “Rules of General Applicability to Domestic Licensing of Byproduct Material”](#)
- [10 CFR Part 31 “General Domestic Licenses for Byproduct Material”](#)
- [10 CFR Part 32 “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material”](#)
- [10 CFR Part 35 “Medical Use of Byproduct Material”](#)
- [10 CFR Part 37 “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material”](#)
- [10 CFR Part 71 “Packaging and Transportation of Radioactive Material”](#)
- [10 CFR Part 150 “Exemptions And Continued Regulatory Authority In Agreement States And In Offshore Waters Under Section 274”](#)
- [10 CFR Part 170 “Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended”](#)
- [10 CFR Part 171 “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC”](#)

Copies of these documents may be obtained by calling the Government Publishing Office Customer Contact Center toll-free at 866-512-1800, in Washington, DC; calling 202-512-1800; or ordering online at the U.S. Government Bookstore. In addition, 10 CFR Parts 1 through 199 can be found on the National Archives and Records Administration website at: <https://www.ecfr.gov/current/title-10/chapter-I>. Regulations are periodically amended, and the NRC (as well as all other Federal agencies) is required to publish notice of such amendments in the *Federal Register*.

Because entities can select an SGL or specific license for activities that are authorized by the SGL framework, the basic safety requirements are the same. As such, licensees may use the program specific guidance found in the NUREG-1556 series for guidance in developing the required programs and procedures. The following table provides a crosswalk between SGL requirements and applicable guidance that may be helpful to licensees. The NRC notes that licensees are not required to follow the guidance, however, the guidance is intended to provide one option that the staff finds acceptable to meet the radiation safety program requirements of an SGL.

Regulation	Topic	Guidance Location
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§ 31.14(c)(2)	RSO training and experience	<a href="#">Volume 4, Rev. 1</a> , Appendix D
§ 31.14(c)(3)	User training and experience	<a href="#">Volume 4, Rev. 1</a> , Appendix D
§ 31.14(c)(6)	Occupational monitoring	<a href="#">Volume 4, Rev. 1</a> , Appendix G
§ 31.14(c)(9)	Leak testing	<a href="#">Volume 4, Rev. 1</a> , Appendix I
§ 31.14(c)(11)	Routine maintenance	<a href="#">Volume 4, Rev. 1</a> , Section 8.10.8, Discussion
§ 31.14(c)(12)	Operating, Emergency, And Security Procedures	<a href="#">Volume 4, Rev. 1</a> , Appendix H
§ 31.15(c)(2)	RSO training and experience	<a href="#">Volume 1, Rev. 2</a> , Section 8.7.1, Discussion
§ 31.15(c)(3)	User training and experience	<a href="#">Volume 1, Rev. 2</a> , Appendix C
§ 31.15(c)(4)	Occupational monitoring	<a href="#">Volume 1, Rev. 2</a> , Appendix H
§ 31.15(c)(6)	Radiation detection instruments	<a href="#">Volume 1, Rev. 2</a> , Section 8.10.2, Discussion
§ 31.15(c)(7)	Material control and accountability	<a href="#">Volume 1, Rev. 2</a> , Section 8.10.3, Discussion
§ 31.15(c)(8)	Leak testing	<a href="#">Volume 1, Rev. 2</a> , Appendix I
§ 31.15(c)(9)	Routine maintenance	<a href="#">Volume 1, Rev. 2</a> , Section 8.10.8, Discussion
§ 31.15(c)(10)	Operating, Emergency, And Security Procedures	<a href="#">Volume 1, Rev. 2</a> , Appendix G
§ 31.16(c)(1)	RSO training and experience	<a href="#">Volume 9, Rev. 3</a> , Appendix D
§ 31.16(c)(2)	Authorized User training and experience	<a href="#">Volume 9, Rev. 3</a> , Appendix D
§ 31.16(c)(4)	Occupational monitoring	<a href="#">Volume 9, Rev. 3</a> , Appendix M
§ 31.16(c)(5)	Surveys	<a href="#">Volume 9, Rev. 3</a> , Appendix R
§ 31.16(c)(6)	Leak testing	<a href="#">Volume 9, Rev. 3</a> , Appendix Q
§ 31.16(c)(7)	Safe use	<a href="#">Volume 9, Rev. 3</a> , Appendix T
§ 31.16(c)(8)	Spills	<a href="#">Volume 9, Rev. 3</a> , Appendix N
§ 31.16(c)(9)	Area surveys	<a href="#">Volume 9, Rev. 3</a> , Appendix R
§ 31.16(c)(10)	Material control and accountability	<a href="#">Volume 9, Rev. 3</a> , Section 8.10.10, Discussion
§ 31.16(c)(11)	Training	<a href="#">Volume 9, Rev. 3</a> , Appendix J
§ 31.16(c)(12)	Waste	<a href="#">Volume 9, Rev. 3</a> , Appendix W
§ 31.17(c)(2)	RSO training and experience	<a href="#">Volume 7, Rev. 1</a> , Section 8.7.1, Discussion
§ 31.17(c)(5)	Leak testing	<a href="#">Volume 7, Rev. 1</a> , Appendix N
§ 31.18(c)(1)	RSO training and experience	<a href="#">Volume 7, Rev. 1</a> , Section 8.7.1, Discussion
§ 31.18(c)(2)	User training and experience	<a href="#">Volume 7, Rev. 1</a> , Section 8.7.2, Discussion
§ 31.18(c)(4)	Occupational monitoring	<a href="#">Volume 7, Rev. 1</a> , Section 8.10.4, Discussion
§ 31.18(c)(7)	Safe use	<a href="#">Volume 7, Rev. 1</a> , Appendix L
§ 31.18(c)(8)	Spills	<a href="#">Volume 7, Rev. 1</a> , Appendix L
§ 31.18(c)(9)	Area surveys	<a href="#">Volume 7, Rev. 1</a> , Appendix M

§ 31.18(c)(10)	Material control and accountability	<a href="#">Volume 7, Rev. 1</a> , Appendix J
§ 31.18(c)(11)	Training	<a href="#">Volume 7, Rev. 1</a> , Appendix F
§ 31.18(c)(12)	Waste	<a href="#">Volume 7, Rev. 1</a> , Appendix P

Medical use SGLs can refer to [“Office Of Nuclear Material Safety And Safeguards Interim Staff Guidance NMSS-ISG-03 Guidance For The Implementation Of 10 CFR Part 35 Training And Experience Requirements”](#) for additional guidance in documenting RSO and Authorized User training an experience as required by §§ 31.16(c)(1) and 31.16(c)(2).

#### 4.2.2 SGL Considerations and Limitations

The SGL framework in 10 CFR 31 Subpart C creates an alternate option for licensing certain activities and does not eliminate the current specific licensing process. This allows licensees to select between an SGL or a specific license for certain activities such as use, storage, and possession of byproduct materials for fixed gauging, portable gauging, and some medical uses. Several factors will determine the most appropriate licensing pathway for an entity’s operations. Entities wishing to conduct activities in a non-standard manner or outside of the normal conditions of an SGL will need to have a specific license. Licensees should carefully review SGL requirements to ensure they pursue the most appropriate type of license. An SGL may apply for a specific license at any time should the need arise. SGLs are subject to an inspection program that is equivalent to the inspection program for the same specifically licensed activities. SGLs are not subject to requirements beyond what is currently required to obtain a specific license.

The NRC notes specific considerations for SGLs:

- The SGL framework in 10 CFR 31 Subpart C creates SGLs for gauges and analytical equipment. This is not intended to be duplicative of GLs that are currently permitted by § 31.5. The SGL framework authorizes use of devices registered in the SSDR as with license code “S” for specific licensees or license code “B” for both specific and general licensees that are distributed as specifically licensed devices. This means, an entity may have a GL under § 31.5 for devices that are distributed as generally licensed devices and an SGL under 10 CFR 31 Subpart C for devices that are distributed as specifically licensed devices. If a licensee wishes to possess a device with a license code “B” under an SGL, they will need to have them distributed as specifically licensed devices and maintain compliance with the requirements in 10 CFR 31 Subpart C. This would alleviate the need to comply with § 31.5 for the devices that are authorized and regulated under the SGL. This may or may not be permissible depending on the license code listed on the SSDR. For example, only devices with the license code “S” or “B” are authorized by an SGL based on the type of distribution. This license code distinction is in addition to the use code limitations listed in the SGL for the different technologies.
- The SGL framework in 10 CFR 31 Subpart C creates SGLs for in vitro testing. This is not intended to be duplicative of GLs that are currently permitted by § 31.11. The SGL for in vitro testing is permitted to authorize in vitro testing with the radionuclides and activities listed in § 31.11 if the activities are conducted in accordance with the requirements of 10 CFR 31 Subpart C. This eliminates the need to register under § 31.11 if the activities are registered under 10 CFR 31 Subpart C. This is meant to allow entities conducting certain

medical activities under an SGL to also be authorized for in vitro testing under the SGL without filing a second registration.

- The medical use SGL in § 31.16 does not authorize mobile medical services or the use of Positron Emission Tomography (PET) radionuclides.

An SGL may be appropriate for:

- Licensees working with certain fixed gauges, certain portable gauges, some medical uses, certain analytical equipment, or performing certain in vitro testing.
- Licensees that conduct work in a standard format and do not perform non-routine activities.
- Licensees that will not aggregate 10 CFR Part 37 Category 2 quantities of material.
- Licensees that will not aggregate quantities of material requiring decommissioning financial assurance.
- Licensees that will not aggregate quantities of material requiring an emergency plan.
- Licensees will not operate more than 5 locations of use or storage at one time.

Of special note, an entity may only maintain a single SGL at a time. This means that an entity may not obtain more than one SGL from a single regulatory authority. Multiple SGLs within the same jurisdiction may not be used to circumvent the 5 locations limitation imposed by the SGL regulatory framework. A specific license may be appropriate for an entity with more than 5 locations.

In general, the benefits of an SGL include a lower burden licensing pathway for activities within the framework of the SGL. The burden is reduced by:

- Replacing the application fee with a lower registration fee.
- Reducing the annual fee.
- Streamlining the process by eliminating the need for amendments and the time associated with awaiting approval of an amendment. Instead of amendments, a notification process is used for certain program changes as listed in § 31.13(b)(2).
- Increasing efficiency by allowing work to commence 30 days after submission of NRC Form 1003 as compared to the typical 90 days it takes to issue a specific license.
- Increased clarity since all license requirements are present in regulation.

#### **4.3 Management Responsibility**

The NRC recognizes that effective management of radiation safety programs is vital to achieving safe, secure, and compliant operations. Consistent compliance with NRC regulations provides reasonable assurance that licensed activities will be conducted safely and that effective management will result in increased safety, security, and compliance.

“Management,” as used in this ISG, refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance. In general, this refers to the chief executive officer or other individual(s) having the authority to administer the licensee’s activities.

Generally, licensee management has a responsibility for all aspects of the radiation safety program, including, but not limited to, the following:

- Radiation safety, security, and control of radioactive materials, and compliance with regulations.
- Completeness and accuracy of radiation safety records and all information provided to the NRC (§ 30.9, “Completeness and accuracy of information”).
- Knowledge of the contents of the current NRC Form 1003.
- Compliance with current NRC and U.S. Department of Transportation (DOT) regulations and the licensee’s operating, emergency, and security procedures, and NRC requirements.
- Commitment to provide adequate financial and other resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and that compliance with regulations is maintained.
- Commitment to report defects, noncompliances, or reportable events in accordance with regulations.
- Selection and assignment of a qualified individual to serve as the RSO for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities.
- Commitment to ensure that radiation workers have adequate training.
- Prevention of discrimination of employees engaged in protected activities and commitment to provide information to employees about employee protection provisions (§ 30.7, “Employee protection”).
- Commitment to provide information to employees about deliberate misconduct provisions (§ 30.10, “Deliberate misconduct”).

The RSO is responsible for the day-to-day oversight of the entire radiation safety program and has independent authority to stop operations that the RSO considers unsafe. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO duties and responsibilities include ensuring radiological safety, security, and compliance with both the NRC and the DOT regulations and the conditions of the license. Typically, these duties and responsibilities include, but are not limited to, the following:

- Stop unsafe activities involving licensed material.
- Ensure radiation exposures are within regulatory limits.
- Properly secure radioactive material from unauthorized use or access.
- Oversee all activities involving radioactive material.
- Perform/oversee the routine radiation safety tasks related to sealed sources, inventories, transport of radioactive material, radioactive waste, surveys, monitoring, and training.
- Ensure that up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed, as appropriate.
- Notify the proper authorities of incidents and events involving licensed material.
- Serve as the point of contact for the NRC and licensee’s management during routine operations, emergencies, or incidents.
- Perform and document periodic audits, 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.

- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- Ensure corrective actions are developed, implemented, and documented when the licensee identifies violations of regulations or program weaknesses.
- Maintain up-to-date copies of the NRC regulations, the SGL, and the revised licensee procedures.

#### 4.3.1 Notifications

It is the licensee's obligation to keep the SGL registration, as required by 10 CFR 31 Subpart C, current. Therefore, after the initial submittal, licensee management is responsible for providing pertinent updates to the NRC by submitting NRC Form 1003, as needed, in accordance with § 31.13(b)(2).

#### 4.3.2 Reports

In accordance with § 20.2201, "Reports of theft or loss of license material," licensees are required to report the theft or loss of radioactive material. In accordance with § 20.2202, "Notification of incidents," licensees are required to notify the NRC of certain events involving specified dose-based conditions. In accordance with § 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," licensees are required to report occurrences involving exceedances of regulatory limits. In addition, licensees, in accordance with § 30.50, "Reporting Requirements," are required to report instances that could lead to exposures to radiation or radioactive materials. This includes failures of safety components, unplanned contamination, etc. Furthermore, licensees may be required to notify the NRC if:

- A sealed source is determined to be leaking, in accordance with 10 CFR 31 Subpart C.
- A medical event occurs, in accordance with § 35.3045.
- A dose to an embryo/fetus or nursing child occurs, in accordance with § 35.3047.
- An eluate from a radionuclide generator exceeds limits, in accordance with § 35.3204.

For immediate notifications, licensees can contact the NRC Operations Center at 301-816-5100. The Center is staffed 24 hours a day and accepts collect calls.

#### 4.3.3 Safety Culture

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees.

The NRC's Safety Culture Policy Statement (76 FR 34773; June 14, 2011) defines "Nuclear safety culture" as "the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has

shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety).

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment process. However, the NRC's Safety Culture Policy Statement and traits are not incorporated into the regulations. Safety culture traits may be inherent to an organization's existing radiation-safety practices and programs. Licensees should be aware of the NRC's Safety Culture Policy Statement and should consider reviewing their radiation safety programs in order to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

More information, including the traits of a positive safety culture and the NRC's Safety Culture Policy Statement can be found at:

<https://www.nrc.gov/about-nrc/safety-culture/sc-policy-statement#traits>.

#### 4.3.4 Inspection and Enforcement

The SGLs provided in 10 CFR 31 Subpart C are subject to all provisions of the AEA, now or hereafter in effect, and to all applicable rules, regulations, and orders of the NRC. Therefore, licensees are required to notify the NRC of a change that affects the information provided in the initial NRC Form 1003 in a timely manner, allowing the NRC adequate time to inspect the activity and carry out its statutory mandate of ensuring that licensed materials are adequately safeguarded and that the public health and safety are protected.

Standard general licensees may be subject to an NRC enforcement action, should they fail to register the SGL before working in NRC jurisdiction. In addition, persons operating under an SGL within NRC jurisdiction are subject to NRC inspection and to NRC enforcement actions when violations are identified.

SGLs are subject to the NRC's inspection program established in Inspection Manual Chapter (IMC) 2800 "Materials Inspection Program." Therefore, all SGLs will be subject to initial, routine, and nonroutine inspections of byproduct material and the premises and facilities wherein byproduct material is used or stored under the SGL. For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of the NRC Enforcement Policy and Guidance and the appropriate NRC IMCs. The current version of the NRC Enforcement Policy and Guidance is available electronically at <http://www.nrc.gov/about-nrc/regulatory/enforcement.html>.

## 4.4 Submittals

Persons registering an SGL should do the following:

- Determine their eligibility and ability to work within the SGL framework.
- Complete the NRC Form 1003 as described in Section 4.4.1 through Section 4.4.4 based on the purpose of the submittal. A link to the form may be found at <http://www.nrc.gov/reading-rm/doc-collections/forms/>.
- NRC Form 1003 may not have sufficient space for licensees to provide full responses. Therefore, pertinent information to any Item may be provided separately and submitted with the completed NRC Form 1003.
- For separate information submitted with NRC Form 1003, identify and cross reference submitted information to the Item number on the form or the topic to which it refers.
- Protect sensitive information by properly marking the submittal. Section 4.7 of this ISG provides information for properly protecting proprietary information submitted to the NRC along with NRC Form 1003.
- Retain a copy of the validated NRC Form 1003 for future reference.

Paper registrations received by the NRC are scanned through an optical character reader and converted to an electronic format. To ensure an accurate transfer to an electronic format, licensees should do the following:

- Submit all documents, typed, on 8½ × 11-inch or legal-sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura (the text of this document is in the Arial font).
- Use 11-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

The following sections outline specific types of submittals that licensees may encounter.

### 4.4.1 Initials

New submittals occur once for each SGL; this type of submittal is only applicable for the first time a licensee registers with the NRC. Prior to using an SGL for the first time, a licensee must file an NRC Form 1003, and pay the appropriate fee, with the appropriate NRC regional office where the licensee is located, at least 30 calendar days before beginning activities. The appropriate NRC regional office can be found in Section 4.4.5 of this ISG. Initial submittals should include a completed Item 1 and Item 2. Within Item 2, the initial box should be selected. Next, Section A should be completed in its entirety. Section B need not be completed for initial registrations. Specific directions on completing each Item can be found in Section 4.6 of this ISG.

### 4.4.2 Changes

Change submittals occur as often as needed for each SGL. This type of submittal may occur multiple times per year, or every few years depending on the frequency in which operations change for the licensee. Changes are required when certain criteria, as listed in § 31.13(b)(2), are met. Changes include changes to the licensee's direct ownership, controlling ownership of the licensed activities, name of the licensee, location of use addresses, mailing address, RSO, byproduct materials, quantities of materials, or devices containing byproduct material. Prior to implementing one of the prescribed changes, a licensee must file an NRC Form 1003, with the appropriate NRC regional office where the licensee is located, at least 30 calendar days before implementing the change. The appropriate NRC regional office can be found in Section 4.4.5 of this ISG. Change submittals should include a completed Item 1 and Item 2. Within Item 2, the change box should be selected. Next, Section A should be completed in its entirety. Section B need not be completed for changes, unless a location is being removed. Guidance on location removal is described in Section 4.4.3 of this ISG. Specific directions on completing each Item can be found in Section 4.6 of this ISG.

#### 4.4.3 Location Removals

Location removals occur as often as needed for each SGL. This type of submittal may occur multiple times per year, every few years, or only upon termination of the SGL. Location removals are decommissioning of a location of use and removal of the location from the SGL. Location removals are required when certain criteria, as listed in § 31.13(f) are met. To remove a location of use, a licensee must file an NRC Form 1003 with the appropriate NRC regional office where the licensee is located and provide applicable supporting documentation. The appropriate NRC regional office can be found in Section 4.4.5 of this ISG. For this type of submittal, licensees should complete Item 1 and Item 2. Within Item 2, the location removal box should be selected. Next, Sections A and B should be completed in their entirety. Specific directions on completing each Item can be found in Section 4.6 of this ISG.

Please note, each SGL may only authorize up to five locations per use at a time. If a licensee's SGL has five locations of use listed and requests a sixth, the NRC would expect one location of use to be decommissioned and removed prior to the new location being used.

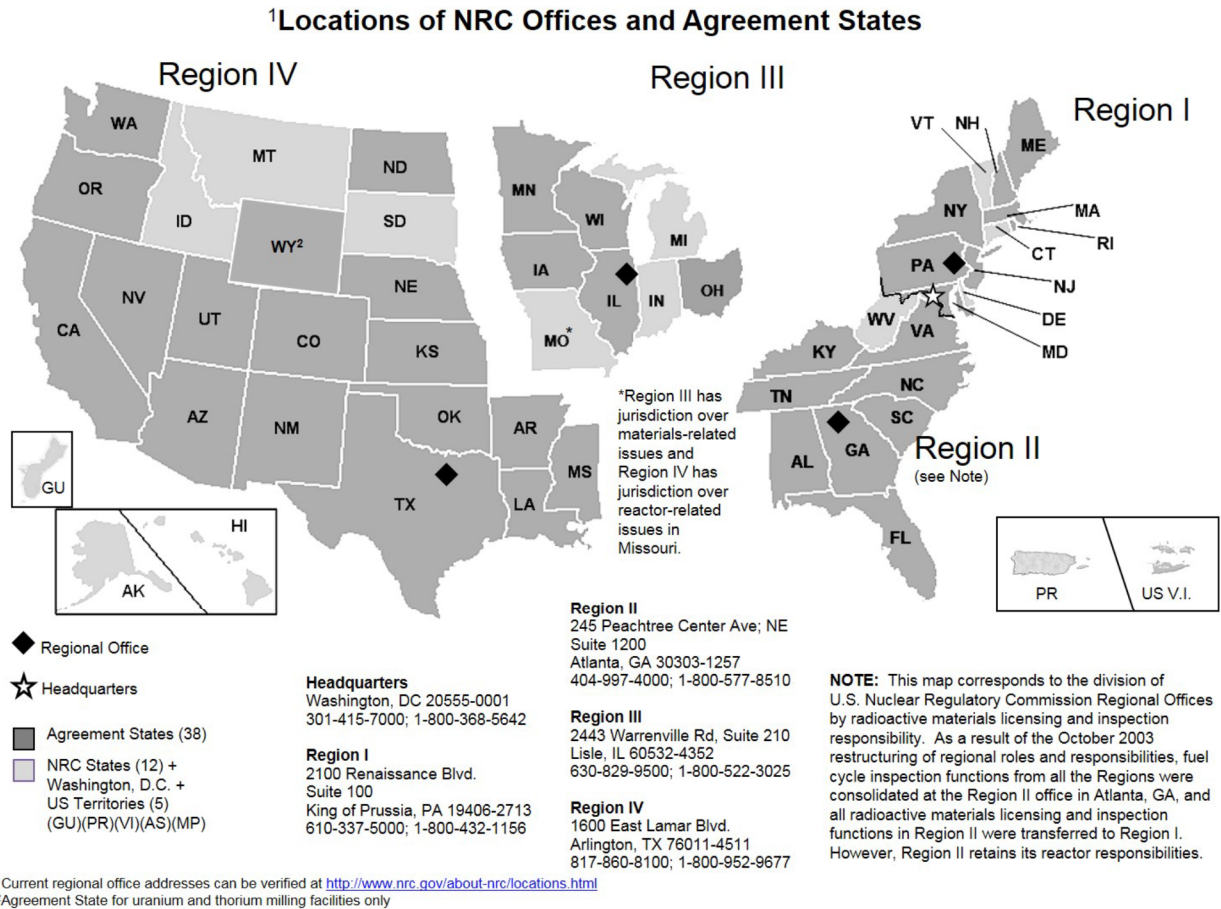
#### 4.4.4 Terminations

Terminations occur for each SGL when the licensee no longer wishes to conduct licensed activities under the SGL. Terminations require that each location of use is decommissioned. Terminations are required when certain criteria, as listed in § 31.13(h), are met. To terminate an SGL, a licensee must file an original NRC Form 1003 with the appropriate NRC regional office where the licensee is located and provide applicable supporting documentation. The appropriate NRC regional office can be found in Section 4.4.5 of this ISG. For this type of submittal, licensees should complete Item 1 and Item 2. Within Item 2, the termination box should be selected. Next, Sections A and B should be completed in their entirety. Specific directions on completing each Item can be found in Section 4.6 of this ISG.

#### 4.4.5 Where to File

Licensees wishing to use an SGL in any state, U.S. territory, or U.S. possession subject to NRC jurisdiction must file a NRC Form 1003 with the NRC regional office for the location in which the material will be possessed or used. If a licensee will conduct operations in more than one region, then the licensee should register with the regional office in which their headquarters is located. Figure 4-1 identifies the NRC's four regional offices and their respective areas for

licensing purposes. Note that all SGL registration certificates should be submitted to Regions I, III, or IV. All materials licenses located in the Region II geographical area should send their registrations to Region I.



**Figure 4-1. U.S. Map: Locations of NRC Offices and Agreement States**

In general, licensees wishing to possess or use licensed material in Agreement States must file with the Agreement State and not with the NRC. Persons should contact the applicable Agreement State to discuss their implementation of the SGL program. An Agreement State may require use of its own forms that are equivalent to the NRC Form 1003. Licensees should contact the responsible officials in the Agreement State for guidance on the required form. Additionally, some Agreement States may not adopt SGLs as a licensing option. However, if work will be conducted at federally controlled sites, or federally recognized Indian Tribal lands in Agreement States, licensees must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. Refer to NUREG 1556, “Consolidated Guidance About Materials Licenses” for additional information.

#### 4.4.6 Acceptable Means to File

In addition to direct mail, submittals of NRC Form 1003 by facsimile or e-mail are acceptable, provided that:

- The facsimile or e-mail contains, in addition to the completed NRC Form 1003, proof of fee payment to meet fee requirements, as appropriate.
- The licensee confirms that the NRC has received the electronic submittal (confirmation of receipt by NRC may be made by telephoning or emailing the NRC office to which the submittal was sent).
- The NRC receives, within at least 30 calendar days before beginning activities, NRC Form 1003 and the appropriate fee, if applicable.

Changes to NRC Form 1003, removal of locations, or termination requests should be submitted to the NRC Regional Office, either by facsimile or by e-mail to the electronic mailbox established by each office as listed on the NRC Form 1003.

Note: Avoid submitting proprietary information and personally identifiable information (PII) (such as home address, home telephone number, social security number, and date of birth) unless it is absolutely necessary or requested by the NRC. If it is necessary to submit proprietary information, follow the procedure in § 2.390, “Public inspections, exemptions, requests for withholding.” Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the form. Additional information on proprietary information is provided in Section 4.7, “Identifying and Protecting Sensitive Information,” of this ISG.

The NRC will provide additional instructions, as the agency implements new mechanisms for electronic license registration filing. **At this time, the preferred communication method for submittals of NRC Form 1003 is email.** Region 1’s electronic mailbox is: [R1DRSSMail.Resource@nrc.gov](mailto:R1DRSSMail.Resource@nrc.gov); Region 3’s electronic mailbox is: [R3-DRSSMAIL.Resource@nrc.gov](mailto:R3-DRSSMAIL.Resource@nrc.gov); and Region 4’s electronic mailbox is: [R4licensing@nrc.gov](mailto:R4licensing@nrc.gov).

#### 4.5 Fees

Each new registration for which a fee is specified must be accompanied by the appropriate fee. Refer to § 170.31, “Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses,” to determine the amount of the fee. The NRC will not validate the registration certification until the fee is received. Consult § 170.11, “Exemptions,” for information on exemptions from these fees. Once the technical review of the submittal has begun, no fees will be refunded. Registration fees will be charged regardless of the NRC’s validation of the registration certificate or the withdrawal of a submittal.

Most standard general licensees are also subject to annual fees; refer to § 171.16, “Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC,” to determine the amount of the fee. Consult § 171.11 for information on exemptions from annual fees and § 171.16(c) on reduced annual fees for licensees that qualify as “small entities.” Note that in order to pay reduced fees, a licensee that qualifies as a “small entity” must provide proper certification of this status to the NRC each year, along with its annual fee payment.

Payments should be made electronically on pay.gov. Direct all questions about the NRC’s fees or completion of Item 7 of NRC Form 1003 to the Office of the Chief Financial Officer at NRC

Headquarters in Rockville, Maryland, 301-415-7554. Information about fees may also be obtained by calling NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address is [Fees.Resource@nrc.gov](mailto:Fees.Resource@nrc.gov).

#### **4.6 General Instructions for Completing the NRC Form 1003**

SGLs are required to complete the NRC Form 1003 to communicate registration of their generally licensed activities in NRC jurisdiction. Licensees should file the completed NRC Form 1003 with the NRC regional office provided in Section 4.4.5 of this ISG.

In completing NRC Form 1003, the licensee must provide sufficient information to enable the NRC to validate the registration, plan and conduct inspections, remove a location based on decommissioned status, or terminate the registration. If NRC Form 1003 contains omissions or errors, the NRC staff will first try to resolve them by telephone with the registrant. If the discrepancies can be resolved by telephone, the NRC staff will mark the form with the corrections and continue processing the form. The NRC staff will sign the form and return a copy to the licensee when its review is completed. The signed form becomes the validated NRC Form 1003 for the licensee.

If the deficiencies cannot be resolved by telephone, the NRC staff will verbally request that the registrant provide the deficient information or send a letter requesting the necessary information, identifying the deficiencies and informing the licensee that the NRC will continue its review upon receipt of the requested information. The licensee will also be informed that licensed activities may not commence until the NRC receives the required information and completes its review.

Entities that do not meet the requirements of 10 CFR 31 Subpart C will be informed that they do not qualify for the SGL and may not conduct licensed activities in NRC jurisdiction under the SGL program.

The following sections provide directions on information that should be provided in each Item of NRC Form 1003.

##### **4.6.1 Item 1: Name of Licensee**

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

##### **4.6.2 Item 2: Type of Submittal**

Select one option. When submitting NRC Form 1003, licensees are required to mark the appropriate box: "initial" or "change" or "location removal and/or registration termination."

Sections 4.4.1 – 4.4.4 describe the different types of submittals in detail. More than one box can be selected. For example, a licensee may be making a change to their RSO at the same time as removing a location. In this case, the licensee would select "change" and "location removal and/or registration termination."

#### 4.6.3 Section A – Registration Information

Section A is intended to communicate the current persons, activities, and locations of activities being conducted under the SGL. Section A requests the necessary information for performing oversight of the SGL. It is essential that this section is accurate at all times. Furthermore, this section requires certification by the licensee to ensure understanding of SGL requirements.

##### 4.6.3.1 Item 1: Address of Licensee

Provide the mailing address for correspondence to be mailed. A post office box number is an acceptable mailing address.

##### 4.6.3.2 Item 2: Management Contact

Provide the name, title, business telephone number, and business email address for the individual serving as the management representative for the license. In general, this person will not be the same person as the RSO. However, they will likely be within the RSO's chain of command at the executive or principal level within their organization. Further guidance on the meaning of "Management" can be found in Section 4.3 of this ISG.

##### 4.6.3.3 Item 3: RSO Contact

Provide the name, title, business telephone number, and business email address for the individual serving as the RSO for the license. The NRC will contact this individual if there are questions about NRC Form 1003. While licensees are required to document RSO training and experience, it should not be submitted to the NRC as part of the registration. These records may be reviewed during inspection of the license. Guidance on determining if an RSO is qualified can be found in Section 4.2.2 of this ISG.

##### 4.6.3.4 Item 4: Actual Physical Address for Locations of Use and Storage

An SGL can authorize up to five locations of storage or use at a time. If byproduct material is to be used at more than one location under the license, excluding temporary job sites, the specific address (e.g., street and building) must be provided for each facility so that the NRC can conduct inspections.

In Item 2, specify the street address, city, and state or a descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility at which licensed material will be used or stored, excluding temporary job sites. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. If known, provide the global positioning system (GPS) coordinates. A post office box address or general area locations are not acceptable.

Notify the NRC of any facilities on NRC Form 1003. Notification is required 30 days before receiving, using, or storing licensed material at an address or location not already listed on the NRC Form 1003. As a reminder, temporary job sites are only permitted for SGLs under §§ 31.15 and 31.17.

#### 4.6.3.5 Item 5: Activities to Be Conducted

Select the box for the type of SGL to be registered. One SGL can authorize multiple uses; therefore more than one box may be selected. For example, a medical office wishing to be authorized for medical uses under § 31.16 may also wish to be authorized for in vitro testing under § 31.18; this licensee would need to select the boxes for both SGLs. As another example, a refinery may need an SGL for fixed gauges under § 31.14 and an SGL for laboratory equipment under § 31.17, this licensee would therefore need to select the boxes for both SGLs.

#### 4.6.3.6 Item 6: List of Radioactive Materials

The licensee should indicate the byproduct material that will be used for licensed activities. This may be one line or multiple lines depending on the variety of byproduct material to be used by the licensee. If additional space is needed, supplemental information may be submitted as described in Section 4.4 of this ISG.

On NRC Form 1003 provide the radionuclide, chemical and/or physical form, and the maximum amount that will be possessed at any one time. Additionally, for sealed sources, the sealed source model and device model should be provided. For unsealed materials, "N/A" is an appropriate entry in the sealed source model and device model columns. The table below shows example entries for some of the most common SGL uses.

<b>SGL type</b>	<b>Radionuclide</b>	<b>Form</b>	<b>Maximum quantity which will be possessed at any sealed one time</b>	<b>source model</b>	<b>device model</b>
Fixed gauge	Specify the Isotope	Sealed	Specify the total activity (activity per source multiplied by the total number of gauges)	Specify the source manufacturer and model number as listed on the SSSR	Specify the Device manufacturer and model number as listed on the SSSR
Portable gauge	Specify the Isotope	Sealed	Specify the total activity (activity per source multiplied by the total number of gauges)	Specify the source manufacturer and model number as listed on the SSSR	Specify the Device manufacturer and model number as listed on the SSSR
Medical – § 35.100 uses	Any byproduct material permitted by § 35.100 limited	Any	As needed	N/A	N/A

	to radionuclides listed in § 31.16(a)(2)(i)				
Medical – § 35.200 uses	Any byproduct material permitted by § 35.200 limited to radionuclides listed in § 31.16(a)(2)(i)	Any	As needed	N/A	N/A
Medical – § 35.65 uses	Byproduct material permitted by § 35.65	Sealed	Limited by 10 CFR 35.65	N/A	N/A
Analytical equipment – (e.g. X-ray Fluorescence Devices)	Specify the Isotope	Sealed	Specify the total activity (activity per source multiplied by the total number of gauges)	Specify the source manufacturer and model number as listed on the SSDR	Specify the Device manufacturer and model number as listed on the SSDR
In-vitro testing – (e.g. I-131)	Specify the Isotope	unsealed	Specify the total activity (activity per vial multiplied by the total number of vials)	N/A	N/A

#### 4.6.3.7 Item 7: License Fees

Enter the appropriate fee category from § 170.31 and provide proof of the fee payment with the registration certificate.

#### 4.6.3.9 Item 8: Previous work

Select one option. If the license holder has previously worked with byproduct materials under an NRC or Agreement State license, select “yes” and provide the name of the license name or license number for which work was conducted. Select “no” if the license holder has not previously worked with byproduct materials. The response to this question will provide the NRC the information to understand the registrant’s experience in handling the type and quantity of licensed materials to be possessed and used and to determine if the licensee is a known entity. The information will be used to establish the initial inspection window. In the context of this question, “license holder” refers to the licensee as provided in Item 1.

#### 4.6.3.9 Item 9: Certification

A management representative from the corporation or legal entity filing the registration must sign and date NRC Form 1003. The representative signing the form must be authorized to make binding commitments and to sign official documents on behalf of the licensee. As discussed previously in Section 4.3, management must acknowledge their commitment to and responsibility for the radiation protection program. The NRC will return all unsigned forms for proper signature.

#### 4.6.4 Section B – Disposition of Materials

Section B is intended to only be used when one or more location is being removed from the SGL or during termination of the SGL. Section B requests the necessary information needed for the NRC to determine that a licensee has adequately decommissioned their location(s) of use or storage.

##### 4.6.4.1 Item 1: Location status

Select one option. Item 1 provides two choices: (1) all locations are decommissioned, please terminate the registration, and (2) some locations are decommissioned, do not terminate the registration. If all locations are decommissioned and the licensee will no longer be conducting licensed activities, option (1) would be appropriate. If the licensee is removing a location of use but plans to continue operations at other locations of use, then option (2) would be appropriate.

##### 4.6.4.2 Item 2: Actual physical addresses

An SGL can authorize up to five locations of storage or use at a time. When removing one or more locations of use from the SGL, list each location's physical address in Section B, Item 2. Note, only locations that have previously been authorized by a prior NRC Form 1003 can be removed through this process.

In Item 2, specify the street address, city, and state or other descriptive address (e.g., nearest intersection, site name, building name or number, project name) for each location. If known, provide GPS coordinates. A post office box address or general area locations are not acceptable.

##### 4.6.4.3 Item 3: Disposal of Radioactive Material

Select the appropriate combination of options.

Disposal of radioactive material is an essential element for removing a location of use from an SGL. Item 3 is intended to collect the information that demonstrates all radioactive material from the locations listed in Item 2 have been properly disposed of. Licensees should describe the specific radioactive material transfer actions. If radioactive wastes were generated in terminating this license, the licensee should describe the disposal actions taken, including the disposition of low-level radioactive waste, mixed waste, greater-than-Class-C waste, and sealed sources.

Number 1 should be selected if no radioactive materials have been procured or possessed by the licensee at the specified location. This box should only be checked if no radioactive material was present at the location of use during operations of the SGL.

Number 2 should be selected once all authorized activities have ceased and all radioactive material procured and/or possessed by the licensee under the registration number has been properly disposed of. Typically, Number 2 will be selected. Following number 2 there are four options (a) – (d). One or more of these options may be appropriate to select.

- When radioactive materials have been transferred to another entity, select (a) and provide the name of the recipient. The information provided for the transfer of radioactive material to another licensee should specify the date of the transfer, the name of the licensee recipient, an individual contact name and telephone number for the licensee recipient, and the recipient's NRC or Agreement State license number. This would be appropriate when, for example, a portable gauge SGL transfers their gauge to another engineering firm that is licensed to possess the portable gauge.
- When radioactive materials have been disposed of properly, select (b) and then identify the disposal method that was used. Supporting documentation for the disposal should be provided.
  - When disposal by the licensee is selected, licensees should describe the specific disposal method or procedure. Decay in storage or disposal in the sanitary sewer are examples of disposal directly by the licensee.
  - When radioactive materials are disposed of by a licensed disposal site, the licensee should specify the name, address, and telephone number of the licensed disposal site operator or waste contractor. Burial disposal by a licensed entity is an example of disposal by a licensed disposal site.
  - When radioactive materials are disposed of by a waste contractor, the licensee should specify the name, address, and telephone number of the licensed waste contractor. Transfer to a waste contractor who will ultimately transfer the waste to a licensed disposal site is an example of disposal by a waste contractor.
- When all radioactive materials have been removed and any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, select (c) and provide supporting documentation demonstrating the removal of the radioactivity and that the levels of residual radioactivity are within the limits. "Residual radioactivity," is defined in § 20.1003.
- When radioactive material is transferred or disposed through a disposal site under (a) or (b), provide supporting documentation demonstrating the material has been received by the other party. For example, after transfer of radioactive materials licensees should attach a record of receipt from the recipient that contains information regarding what was received.

When multiple locations of use or storage are being removed, each location should be addressed in Item 3. If the radioactive material at each location was disposed of in the same manner, sufficient room may be present on NRC Form 1003. However, supplemental pages may be submitted as described in Section 4.4.6 of this ISG if additional space is needed to convey information.

#### 4.6.4.4 Item 4: Surveys Performed and Reported

Select the appropriate combination of options and fill in the blanks as appropriate.

Surveys are an essential element for removing a location of use. Item 4 is intended to collect information that demonstrates that the locations listed in Item 2 meet the requirements listed in § 31.13(f)-(h). Licensees should describe the specific surveys that were completed and the conclusions of the survey. In general, licensees handling unsealed byproduct material should perform surveys of their facility to demonstrate compliance. This is generally applicable to medical use and in vitro testing SGLs. Licensees are generally not required to conduct surveys of their facilities if they have only possessed sealed sources that have not leaked. This generally includes fixed gauge, portable gauge, and analytical equipment SGLs. If sealed sources have leaked, licensees should provide surveys of their facilities. Additional guidance on decommissioning can be found in NUREG-1757.

Number 1 should be selected if radiation surveys were conducted by the licensee at the specified location. If surveys were performed, the conclusion of the survey should also be selected following Number 1.

Number 2 provides further information on the statements made in Number 1. Number 2 is intended to prompt the licensee to provide supporting information for the statements made in Number 2. Generally, the NRC prefers that licensees provide a copy of the surveys as an attachment to NRC Form 1003. This survey should include detailed measurements and documentation of the instruments used. However, licensees may choose to provide an explanation of why a copy of surveys are not attached to the form, or they may choose to forward them to the NRC through other means.

Number 3 is intended for licensees that have only possessed sealed sources under their SGL. Licensees should provide the most recent leak test for each sealed source that was possessed by the licensee at the location specified in Item 2. The second box should be selected if no sealed sources leaked. The licensee should provide supporting information demonstrating that only sealed sources that were exempt from leak testing were possessed by the licensee at the specified location if the licensee's sealed sources were exempt from leak testing requirements.

#### 4.6.5 Section C – Validation

Section C is for use by the NRC. The NRC staff member reviewing NRC Form 1003 should print their name and title, sign the form signifying validation of the NRC Form 1003, provide the date of validation, and list the SGL's unique registration number. Validation can be done by hand or electronically using a digital signature.

As part of the validation, the NRC staff member should perform a limited, in-office, review of the licensee's history. Specifically, the NRC should seek to understand whether the entity is known or unknown to the NRC. Information provided by the licensee in Section A, Item 9, should be used to help determine if the licensee is a known entity. The NRC may perform a review of the licensee online by searching for business registrations, business webpages, or other related documents. Additionally, the NRC may contact the licensing entity such as an Agreement State for which the licensee states they have previously worked. The determination of whether a

licensee is known or unknown will be used to establish the window for the initial inspection to be conducted.

#### **4.7 Identifying and Protecting Sensitive Information**

Registration certificates, except for portions containing sensitive information, will be made available for review in the NRC Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit [www.nrc.gov](http://www.nrc.gov).

The registration certificates should identify, mark, and protect sensitive information against unauthorized disclosure to the public. Registrations that contain sensitive information should be marked as indicated below, in accordance with § 2.390, before the information is submitted to the NRC. Key examples are as follows:

- **Proprietary Information and Trade Secrets:** If it is necessary to submit proprietary information or trade secrets, follow the procedure in § 2.390(b). Failure to follow this procedure could result in disclosure of proprietary information to the public or substantial delays in processing.
- **Personally Identifiable Information:** PII about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security numbers, home addresses, home telephone numbers, date of births, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII and the top of every page of the documents containing PII should be marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications website under "Regulatory Issue Summaries" and "Information Notices" at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC updated its procedures to avoid the release of information that terrorists could use to plan or execute an attack against U.S. facilities or citizens. As a result, certain types of information are no longer routinely released and are they treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities and associated security measures are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information, and the top of every page of the documents containing such information should be clearly marked: "Security Related Information—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source,

Byproduct, and Special Nuclear Material,” dated December 22, 2005, which can be found on the NRC’s Generic Communications website under “Regulatory Issue Summaries” at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional information on procedures and any updates are available at <http://www.nrc.gov/readingrm/sensitive-info.html> .

The NRC recognizes that certain information reported on NRC Form 1003 may be sensitive and that the public release of such information may have an adverse impact on the licensee. Licensees requesting NRC to withhold from public disclosure, as proprietary, the information contained on the NRC Form 1003 should submit an application for withholding, accompanied by an affidavit. The application and affidavit must be submitted in accordance with 10 CFR 2.390(b). Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing NRC Form 1003. The regulations list various forms of information that can be protected from public disclosure. These include:

- Trade secrets and commercial or financial information.
- Interagency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with NRC.
- Certain records or information compiled for law enforcement purposes.
- Geological and geophysical information and data, including maps, or information concerning wells.
- Personnel, medical, or other information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The NRC specifies the procedures and requirements for submitting sensitive information so that it may be properly protected from disclosure in § 2.390. This regulation is available electronically on the National Archives and Records Administration website at: <https://www.ecfr.gov/current/title-10/chapter-I/part-2?toc=1>.

Except for PII, which is not subject to the affidavit requirement, if the NRC determines that the application or affidavit is deficient (i.e., does not contain the required information as outlined in § 2.390), the applicant will be notified that additional information is required and the review will continue when the information is received.

If the request is denied, in whole or in part, the NRC will give the applicant the option of withdrawing the information or application, as permitted in § 2.390. If the applicant decides not to withdraw the information or application, the NRC will notify the applicant in writing that the request for withholding has been denied and the NRC will disregard any references concerning the proprietary status of the information.

Any part of NRC Form 1003 that the NRC has determined should be withheld from public disclosure will be handled in accordance with Management Directive 12.6, “NRC Sensitive Unclassified Information Security Program,” and the applicant will be notified in writing that the NRC plans to honor the request. Management Directive 12.6 is available electronically on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/management-directives/>.

Anyone submitting a request to withhold information from public disclosure should thoroughly review § 2.390 and be familiar with its requirements and limitations.

Withholding information from public inspection does not affect the right of any person who is properly and directly concerned to inspect the documents. The NRC may send copies of this information to the NRC consultants working in that area, if the need arises. The NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future, such that the information could then be made available for public inspection, the licensee should promptly notify the NRC. The licensee also should understand that the NRC may have cause to review this determination in the future; for example, if the scope of a Freedom of Information Act request includes the information in question. If the NRC makes a determination adverse to the above, the licensee will be notified in advance of any public disclosure in all review situations. Anyone submitting commercial or financial information they believe to be privileged, confidential, or a trade secret must remember that the NRC's policy is to achieve an effective balance between legitimate concerns for the protection of competitive positions and the right of the public to be fully appraised of the basis for, and the effects of, licensing or rulemaking actions. It is within the NRC's discretion to withhold such information from public disclosure.

## **5.0 Questions and Answers about SGLs**

The NRC amended its regulations in 10 CFR Part 31 to create a new licensing framework for SGLs. The rule is intended to provide the licensees with a low burden licensing pathway for certain activities previously described in this ISG. This rule affects a large number of licensees and regulatory authorities. The "Question and Answer" format of this section is intended to provide a simplified means for applicants to understand the requirements of this recent addition to the NRC regulations.

Q1. Who is the contact for questions on the SGL framework and registration process?

A1. Contact the appropriate Region for your license. The appropriate Region can be found in Section 4.4.5 of this ISG.

Q2. Can a licensee possess more than one SGL?

A2. No, each licensee can only possess one SGL at a time. However, the SGL can authorize multiple activities. For example, one SGL could authorize activities under § 31.14 for fixed gauging and activities under § 31.17 for analytical equipment. Additionally, one SGL can authorize up to five locations.

Q3. Can standard general licensees apply for a specific license?

A3. Yes, if a licensee determines they cannot work within the framework of an SGL, they may apply for a specific license at any time.

Q4. Can a licensee have an SGL and a specific license?

A4. Yes, a licensee can have an SGL and one or more specific licenses. In this case, they would be subject to the applicable fees for the SGL as well as the applicable fees for the specific license(s).

Q5. Can a licensee have a GL and an SGL?

A5. Yes, a licensee can have a GL and an SGL. The types of materials and uses authorized by a GL are distinctly different than the types of materials and uses authorized by an SGL. See Section 4.2.2 of this ISG for more information on differences between SGLs and §§ 31.5 and 31.11 GLs.

Q6. Are SGLs subject to inspections?

A6. Yes, SGLs are subject to inspections in accordance with IMC 2800 "Materials Inspection Program." More information on inspections can be found in Section 4.3.4 of this ISG. Of special note, the NRC may conduct initial inspections at a reduced periodicity for new standard general licensees.

Q7. Will inspections be announced or unannounced?

A7. In general, initial inspections are announced but routine inspections are unannounced. More information in circumstances that may lead to the NRC announcing an inspection can be found in IMC 2800 "Materials Inspection Program".

Q8. Are SGLs subject to pre-licensing site visits?

A8. No, SGLs are not subject to pre-licensing site visits. The NRC will attempt to establish whether an entity is known during an in-office review of NRC Form 1003. If an entity's status cannot be established, or concerns arise, the NRC may conduct an initial inspection soon after authorized activities commence. If issues with an entity are identified, the NRC may take enforcement action against the entity, including a potential revocation of the SGL. More information on the NRC's inspection and enforcement programs can be found in section 4.3.4 of this ISG.

Q9. Do SGLs have to report events or incidents to the NRC like specific licensees?

A9. Yes, in general, SGLs and specific licensees are subject to the same reporting requirements. More information can be found in section 4.3.2 of this ISG and the regulation for each standard general license in §§ 31.14 through 31.18.

Q10. Can I apply for reciprocity using an SGL?

A10. Yes, § 150.20 requires a specific license from an Agreement State or a validated SGL from an Agreement State to be recognized.

Q11. Can standard general licensees apply for exemptions to the requirements?

A11. Licensees may request exemptions from the NRC regulations. The licensee must demonstrate that the exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public's best interest. Licensees may also use existing specific exemptions outlined in 10 CFR regulations if they meet the established criteria. Various sections of the NRC's regulations address requests for exemptions (e.g., § 19.31, "Applications for exemptions;" § 20.2301, "Applications for exemptions;" and § 30.11, "Specific exemptions"). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person. Exemptions are not intended to revise regulations or to apply to large classes of licensees and are generally limited to unique situations. Requests for exemptions submitted to the NRC must identify the regulation for which the exemption is being requested and include a justification for the requested exemption.

Q12. Do standard general licensees have to notify the NRC of change of control or change of ownership?

A12. Yes, licensees must file a submittal containing NRC Form 1003, with the Commission using a communication method defined in § 30.6(a), at least 30 calendar days prior to the effective date a change to the licensee's direct ownership, controlling ownership of the licensed activities, or name of the licensee.

Q13. What if an SGL files for bankruptcy?

A13. SGLs are subject to the requirements in § 30.34(h)(1) and would be required to notify the NRC of a filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.) by or against: (1) the licensee, (2) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the licensee as property of the estate; or (3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

Q14. What fees are standard general licensees subject to?

A14. Standard general licensees are subject to a one-time registration fee and an annual fee. For more information see section 4.5 of this ISG.

Q15. Do manufacturers of devices or distributors of radioactive material need to verify that an individual/entity is authorized to receive radioactive material under an SGL?

A15. Yes, manufacturers or distributors of licensed material must verify that an individual/entity has a validated NRC Form 1003 prior to transferring radioactive material to them. Other options may exist under certain circumstances. For additional information, refer to § 30.41.

Q16. Can SGL's transfer licensed material?

A16. Yes, SGLs are permitted to transfer material to entities that are licensed to possess the material.

Q17. How can licensed material be disposed of by SGLs?

A17. Licensed material can be disposed of in accordance with 10 CFR Part 20 requirements, or it can be transferred to an entity that is licensed to possess the material, or in some circumstances, it can be decayed-in-storage as described in §§ 31.16 and 31.18.

Q18. Do SGL's authorize activities in any state or territory in the U.S.?

A18. No, an SGL only authorized activities in the jurisdiction of the issuing authority. For SGL's issued by the NRC, they may only be used in areas of NRC jurisdiction such as non-agreement states or areas of exclusive federal jurisdiction.

Q19. What is the difference between a GL for a fixed gauge vs an SGL for fixed gauging?

A19. Fundamentally, the devices authorized by a GL versus an SGL are different. GLs, as authorized by § 31.5, allow the use of generally licensed devices that have a SSDR license code "G" or "B" and are distributed as generally licensed devices. GLs under § 31.5 have minimal training requirements and the devices have been found to be low risk. SGLs, as authorized by § 31.14, allow the use of specifically licensed devices that have a SSDR license code "S" or "B" and are distributed as specifically licensed devices. SGLs under § 31.14 require compliance with the essential elements of a radiation safety program, including training. In general, devices that are distributed as specifically licensed have different labeling and pose higher risk. A single device cannot be authorized by a GL and SGL.

Q20. Can standard general licensees possess a device that has an SSDR license code of "G"?

A20. No, devices with SSDR license code "G" or "B" that are distributed as generally licensed devices must be registered and used under the GL framework in § 31.5.

Q21. Can I use a device that is distributed as a generally licensed device under an SGL?

A21. No, devices registered to be used by general licensee are, in part, labeled in accordance with § 32.51(3)(iii). Therefore, labeling must be updated to differentiate between devices that are distributed as generally licensed devices and specifically licensed devices. In order to have a device under an SGL, it must meet all the requirements under § 31.14, 31.15, or 31.18, as applicable for the authorization. One requirement is that the device is distributed as a specifically licensed device which will ensure appropriate labeling. The radiation safety program requirements are more intensive for SGLs compared to § 31.5 GLs, therefore, if the device is distributed appropriately then the SGL radiation safety program requirements will provide reasonable assurance that the device will be used safely and the requirements in § 31.5 are no longer necessary.

Q22. I have a fixed gauge that has an SSDR with a license code "B" meaning the device is registered for both general licensees and specific licensees. Can this device be used under the new SGL framework?

A22. Yes, if the device is distributed as a specifically licensed device, it can be used under an SGL, otherwise it will remain as a generally licensed device under § 31.5. If it's used under an SGL, it is subject to the requirements of 10 CFR 31 Subpart C, but not § 31.5.

Q23. Will the SSDRs need to be updated to have a new designation SGL, similar to "S" for specific licensees or "G" for general licensees in the registry?

A23. No, the SGL framework authorizes devices that are distributed as specifically licensed devices (with SSDR license code "S" or "B") and are to be possessed and used under the SGL framework. SSDRs do not need to be amended to create a new license code. Devices that are distributed as generally licensed devices shall meet the requirements in § 31.5 .

Q24. I am a device manufacturer. Can I request an amendment to the SSD to have all my devices registered as specifically licensed device to be able to use an SGL?

A24. Yes, registration certificate with license code "G" or "B" can be amended to have the designation "S." Please refer to NUREG 1556, Volume 3 for information on this process.

Q25. PET radiopharmaceuticals are authorized under § 35.200. Why are they excluded from SGL authorizations?

A25. PET radiopharmaceuticals require special shielding considerations due to the high energy of PET radionuclides. As such, shielding is reviewed by the NRC during licensing to ensure compliance with 10 CFR Part 20 requirements. Since SGLs do not have a licensing process, there is no opportunity for the NRC to provide oversight of the shielding designs under the SGL framework. Therefore, PET radionuclides are not authorized under SGL framework.

Q26. Why are mobile medical services excluded from the SGL framework?

A26. Mobile medical services may require special shielding or administrative controls. As such, shielding and other controls may be reviewed by the NRC during licensing to ensure compliance with 10 CFR Part 20 requirements. Since SGLs do not have a licensing process, there is no opportunity for the NRC to provide oversight of the shielding or controls under the SGL framework. Therefore, mobile medical services are not authorized under SGL framework.

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*U.S. Code of Federal Regulations*, “Standards for Protection Against Radiation,” Part 20, Chapter I, Title 10, “Energy.”

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*U.S. Code of Federal Regulations*, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” Part 30, Chapter I, Title 10, “Energy.”

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