AUDIT REPORT

Audit of NRC's 10 CFR Part 31 General Licensing Program

OIG-12-A-21 September 26, 2012

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
INSPECTOR GENERAL

September 26, 2012

MEMORANDUM TO: R. William Borchardt
Executive Director for Operations

FROM: Stephen D. Dingbaum **/RA/**
Assistant Inspector General for Audits

SUBJECT: AUDIT OF NRC'S 10 CFR PART 31 GENERAL LICENSING PROGRAM (OIG-12-A-21)

Attached is the Office of the Inspector General's (OIG) audit report titled, *Audit of NRC's 10 CFR Part 31 General Licensing Program.*

The report presents the results of the subject audit. Agency comments provided at the September 4, 2012, exit conference have been incorporated, as appropriate, into this report. On September 21, 2012, the agency provided a formal response to this report. No changes were made to the report, based on the agency's formal response.

Please provide information on actions taken or planned on each of the recommendations within 30 days of the date of this memorandum. Actions taken or planned are subject to OIG followup as stated in Management Directive 6.1.

We appreciate the cooperation extended to us by members of your staff during the audit. If you have any questions or comments about our report, please contact me at 415-5915 or Sherri Miotla, Team Leader, Nuclear Materials and Waste Safety Audit Team, at 415-5914.

Attachment: As stated

EXECUTIVE SUMMARY

BACKGROUND

The Nuclear Regulatory Commission (NRC) issues two types of domestic licenses to users of nuclear materials. Specific licenses are issued to named individuals who have filed an acceptable application to use certain types or quantities of radioactive materials. In contrast, general licenses are provided by regulations found in Title 10, Code of Federal Regulations, Part 31, *General Domestic Licenses for Byproduct Material*. These regulations allow persons to receive and use a general licensed device containing byproduct or source material if the device has been manufactured and distributed in accordance with a specific license issued by NRC or an Agreement State.

General Licensed Devices

A general licensed device (GLD) consists of radioactive material encased in a capsule within a shielded device. NRC asserts that the GLDs are designed with inherent radiation safety features so that they can be used by persons with no radiation safety training or experience. A few of the more commonly used GLDs include fixed gauges, static elimination devices, x-ray fluorescence analyzers, and luminous (tritium) exit signs.

How NRC Regulates GLDs

NRC's Office of Federal and State Materials and Environmental Management Programs is primarily responsible for the regulation of GLDs. Specifically, the Licensing Branch within the office provides program oversight for the general license program. In addition to developing and implementing technical and policy guidance, the branch is responsible for the following:

- Safety evaluation reviews of sealed sources and devices–The design and use of a device must undergo a technical and safety review prior to distribution as a GLD. Satisfying the review ensures that the device meets NRC's safety requirements.

- General License Tracking System (GLTS)–GLTS facilitates the tracking and accountability of GLDs and general licensees. This database is populated primarily with information provided to NRC from device manufacturers.

- Registration–General licensees in possession of GLDs containing certain isotopes and activity are required to register their devices with NRC annually.

OBJECTIVE

The audit objective was to determine if NRC's general licensing program provides for the necessary accountability and tracking of general licensed devices to protect public health and safety.

RESULTS IN BRIEF

Many General Licensees Are Unaware of NRC Regulatory Requirements

Over the past decade, NRC has made some improvements to its oversight of general licensees and GLDs to facilitate adequate protection of public health and safety and the environment; however, opportunities exist for NRC to further strengthen its oversight of this type of licensee. In order to improve program oversight, NRC has developed and maintains GLTS and the registration program. NRC can further improve oversight of general licensees and GLDs by informing each new general licensee of regulatory requirements, and periodically re-informing general licensees of regulatory requirements.

The Atomic Energy Act, through the Code of Federal Regulations, establishes regulatory requirements for GLDs. However, NRC relies on manufacturers to make general licensees aware of these requirements, thereby delegating some of its responsibilities. When licensees are unaware of their regulatory requirements, there is an increased probability that accountability of GLDs will decrease, placing public health and safety and the environment at risk.

RECOMMENDATIONS

This report makes two recommendations to improve the agency's accountability and tracking of general licensed devices.

AGENCY COMMENTS

An exit conference was held with the agency on September 4, 2012. At this meeting, agency management provided supplemental information that has been incorporated into this report as appropriate.

On September 21, 2012, NRC's Executive Director for Operations provided a formal response to this report (Appendix C). No changes were made to the report, based on the agency's formal response. OIG's response to the agency's formal comments is presented in Appendix D.

ABBREVIATIONS AND ACRONYMS

CFR	Code of Federal Regulations
GLD	general licensed device
GLTS	General License Tracking System
NMED	Nuclear Materials Events Database
NRC	Nuclear Regulatory Commission
OIG	Office of the Inspector General

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I. BACKGROUND

The Nuclear Regulatory Commission's (NRC) mission is to regulate the Nation's civilian use of byproduct, source, and special nuclear materials[1] to ensure adequate protection of public health and safety, to promote the common defense and security, and to protect the environment. NRC issues two types of domestic licenses to users of nuclear materials. Specific licenses[2] are issued to named individuals who have filed an acceptable application to use certain types or quantities of radioactive materials. In contrast, general licenses are provided by regulations found in Title 10, Code of Federal Regulations (10 CFR) Part 31, *General Domestic Licenses for Byproduct Material*. These regulations allow persons to receive and use a general licensed device containing byproduct or source material if the device has been manufactured and distributed in accordance with a specific license issued by NRC or an Agreement State.[3]

General Licensed Devices

A general licensed device (GLD) consists of radioactive material encased in a capsule within a shielded device. The design of a GLD is subject to a regulatory review and safety evaluation to ensure that the device is in compliance with NRC requirements prior to approval for distribution. NRC asserts that the GLDs are designed with inherent radiation safety features so that they can be used by persons with no radiation safety training or experience. A few of the more commonly used GLDs include fixed gauges, static elimination devices, x-ray fluorescence analyzers, and luminous (tritium) exit signs.

[1] Byproduct material includes, but is not limited to, nuclear material (other than special nuclear material) that is produced or made radioactive in a nuclear reactor, discrete sources of radium-226, and accelerator produced radioactive material that is produced, extracted, or converted after extraction for a commercial, medical, or research activity. Source material is either the element thorium or the element uranium, provided that the uranium has not been enriched in the isotope uranium-235. Depleted uranium (left over from uranium enrichment) is also considered source material. Special nuclear material consists of uranium-233 or uranium-235, enriched uranium, or plutonium.

[2] A specific license is a document issued by NRC to a named person who has filed an application. NRC conducts a detailed review of the radioactive materials program proposed by the applicant. A specific licensee is subject to routine inspections and other requirements.

[3] An Agreement State is a U.S. State that has signed an agreement with NRC authorizing the State to regulate certain uses of radioactive materials within the State. NRC relinquishes to such States portions of its regulatory authority to license and regulate byproduct materials, source materials, and certain quantities of special nuclear materials.

How NRC Regulates General Licenses and GLDs

NRC's Office of Federal and State Materials and Environmental Management Programs is primarily responsible for the regulation of GLDs. Specifically, the Licensing Branch within the office provides program oversight for the general licensing program. In addition to developing and implementing technical and policy guidance, the branch is responsible for the following:

- Safety evaluation reviews of sealed sources and devices–The design and use of a device must undergo a technical and safety review prior to distribution as a GLD. This review ensures that the device is designed and built to be used safely by someone without training in radiological protection. Satisfying the review ensures that the device meets NRC's safety requirements. NRC staff monitor reports of events involving nuclear materials in the Nuclear Material Events Database (NMED)[4] to ensure that devices approved for distribution as GLDs continue to meet safety requirements in practice.

- General License Tracking System (GLTS)–GLTS facilitates the tracking and accountability of GLDs and general licensees. This database is populated primarily with information provided to NRC from device manufacturers. GLTS is also updated when a general licensee or a vendor reports a device transfer. The database stores information about NRC's current general licensees, with device and vendor information.

- Registration–General licensees in possession of GLDs containing certain isotopes and activity[5] are required to register their devices with NRC annually. The registration requires licensees to verify and provide NRC the location of the devices and specific information about the licensee and submit an annual fee (currently $400) to NRC.

When needed, inspection support for general license oversight is provided by three NRC regional offices (Region I, King of Prussia, PA; Region III, Lisle, IL; and Region IV, Arlington, TX).[6]

[4] NMED contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees.

[5] Activity is the rate of disintegration or decay of radioactive material per unit of time.

[6] General licensees are not inspected routinely. Failure of a licensee to return NRC's annual registration paperwork or a significant reported event are often causes for an inspection.

Universe of NRC GLDs and General Licensees

The universe of GLDs and general licensees tracked in GLTS is shown below in Table 1:

Table 1: **The Universe of NRC GLDs and General Licensees Tracked in GLTS**[7]

	Number of Active Devices	Number of General Licensees
All General Licensees	147,734	17,115
General Licensees Possessing Only Tritium Exit Signs	96,980	9,667
General Licensees Required to Register	3,055	633

Source: GLTS as of June 2012

In NRC jurisdiction, 147,734 active devices are tracked in GLTS. Tritium exit signs represent the vast majority of the devices tracked in GLTS. Tritium exit signs are considered very low risk to public health and safety and are exempt from regulation in some other industrialized countries. Approximately 3.7 percent of the 17,115 general licensees in NRC jurisdiction are required to register their devices.

Resources Allocated

In fiscal year 2012, NRC dedicated approximately $890,000 in total resources to administering the general licensing program. This includes 2.3 full-time equivalent staff located at NRC headquarters and regional offices.

[7] GLTS tracks only items distributed pursuant to §31.5 and §31.7, which are required to be reported to NRC, therefore, Table 1 represents only these GLDs and general licensees possessing these items in NRC jurisdiction. The majority of general licensees are in Agreement States who oversee approximately 85 percent of materials licensees.

II. OBJECTIVE

The audit objective was to determine if NRC's general licensing program provides for the necessary accountability and tracking of general licensed devices to protect public health and safety. Appendix A provides information on the audit scope and methodology.

III. FINDING

Over the past decade, NRC has made some improvements to its oversight of general licensees and GLDs to facilitate adequate protection of public health and safety and the environment; however, opportunities exist for NRC to further strengthen its oversight of this type of licensee. In order to improve program oversight, NRC has developed and maintains GLTS and the registration program. NRC can further improve oversight of general licensees and GLDs by informing each new general licensee of regulatory requirements, and periodically re-informing general licensees of regulatory requirements.

Many general licensees are unaware of NRC regulatory requirements. The Atomic Energy Act, through the Code of Federal Regulations, establishes regulatory requirements for GLDs. However, NRC relies on manufacturers to make general licensees aware of these requirements, thereby delegating some of its responsibilities. When licensees are unaware of their regulatory requirements, there is an increased probability that accountability of GLDs will decrease, placing public health and safety and the environment at risk.

The Atomic Energy Act and the Code of Federal Regulations

The Atomic Energy Act, as interpreted by NRC in the Code of Federal Regulations, establishes standards which the licensees must meet.

Atomic Energy Act

The Atomic Energy Act of 1954, as amended, establishes the licensing of byproduct material for research or development purposes; for medical therapy, industrial, and agricultural uses; or other applications. General licenses, as well as specific licenses, are authorized in the act. The act also obligates NRC to ensure the capabilities of any licensee, including a general licensee, to use the byproduct material according to regulatory standards, stating NRC:

> shall not permit the distribution of any byproduct material [such as in a GLD] . . . to any licensee, who is not equipped to observe or who fails to observe such safety standards . . . to protect health or who uses such material in violation of law. . . .[8]

To fulfill its mission of ensuring protection of public health and safety when nuclear materials are used, NRC must obtain assurance that its licensees have the necessary resources to perform licensed activities in a manner that protects public health and safety.

Figure 1: **Continuous Gamma Level Gauge**

Source: Thermo Scientific Web site

Code of Federal Regulations

10 CFR defines how NRC will oversee general licenses by providing requirements for the general licensees and for the specific licensees who manufacture and distribute GLDs.

NRC issues and regulates a variety of general licenses under 10 CFR Part 31. The specific requirements vary with the type of device and radioactive material covered in each section of the regulations. Typical general licenses are listed in Table 2. The NRC regulatory requirements for these types of general licenses are enumerated in Appendixes B-1 through B-6 of this report.

[8] Atomic Energy Act of 1954, as amended, §81.a.

Table 2: **Types of Part 31 General Licenses**[9]

10 CFR Section	Type of General License	Regulatory Requirements
§31.5	Certain detecting, measuring, and controlling devices, and certain devices for producing light or an ionized atmosphere (e.g., density gauges, gas chromatographs, and luminous tritium exit signs).	Subject to numerous regulatory requirements for reporting, recordkeeping, transfers, and disposal, among other responsibilities. Requirements presented in greater detail in Appendixes B-1 and B-2.
§31.7	Luminous safety devices for use in aircraft (with not more than 10 curies of tritium or 300 millicuries of promethium-147 per device).	
§31.8	Americium-241 and radium-226 in the form of calibration or reference sources.	Sources not tracked; used in conjunction with specific license.
§31.10	Strontium-90 in ice detection devices (containing not more than 50 microcuries).	No reporting requirements; not tracked.
§31.11	Use of byproduct material for certain *in vitro* clinical or laboratory testing.	Materials not tracked; used with a specific license or registered as practicing *in vitro* testing.
§31.12	Certain items and self-luminous devices containing radium-226.	Not tracked; specific license required above a threshold quantity of items.

Source: Office of the Inspector General (OIG) analysis of NRC regulations

NRC made a risk-informed decision not to track §31.10 and §31.12 items.

- There are no reporting requirements for devices covered by the general license in §31.10. However, devices containing greater amounts of strontium-90 are subject to the requirements in §31.5 and are tracked, and certain devices with higher levels of activity must be registered.

- Items subject to the general license in §31.12 are, for the most part, small timepieces and self-luminous devices in aircraft and marine vehicles. Many are part of museum collections or may be possessed by individual collectors. The general license contains a limit for the number of items that

[9] Regulatory requirements for certain static eliminators and ion generating tubes general licensed under 10 CFR §31.3 are not included in this table. Rulemaking (Federal Register 77:143, pages 43666-43696) effective October 23, 2012, will exempt these devices from licensing.

can be used or stored under a general license; when that number is exceeded, a specific license must be obtained.

NRC's general licensing program focuses on §31.5 and §31.7 devices. These licensees are expected to comply with a range of requirements for the general license. These requirements fall into several broad categories, such as submitting reports to NRC within prescribed time limits, adhering to restrictions on the transfer and disposal of GLDs, and implementing a program to manage the possession and routine use of GLDs. The full requirements for general licensees under 10 CFR §31.5 and §31.7 are listed in Appendixes B-1 and B-2.

NRC's ability to oversee general licensees, and to track GLDs and the radiological material they contain, depends on proper fulfillment of restrictions on servicing and transfers of GLDs and meeting requirements for general licensee recordkeeping and reporting to NRC. General licensees must remain aware of and comply with all of the requirements so that NRC can ensure public health and safety.

NRC regulations assign an important role for GLD manufacturers[10] in ensuring general licensee awareness of regulatory requirements. Manufacturers must hold specific licenses. In addition to ensuring that their devices meet NRC guidelines for safety, manufacturers also have regulatory requirements under 10 CFR Part 32 related to distribution of GLDs. One important requirement for manufacturers is that they must provide specific information to general licensees about regulatory requirements. The regulations state that manufacturers of devices for possession and use under 10 CFR Part 31.5 must provide the following:

- A copy of the general license and safety requirements from NRC regulations or equivalent Agreement State regulations.
- A list of services that can be performed only by a specific licensee, such as transportation or repair of the GLD.
- Information on acceptable disposal options and estimated costs of disposal.
- An explanation of possible penalties for improper disposal.

[10] Although the regulations for providing information to general licensees apply to both manufacturers and distributors of GLDs, to simplify, this report will refer only to manufacturers hereafter.

Manufacturers also must report to NRC, on a quarterly or annual basis, all transfers of devices to general licensees. The reports must include information about the device and about the general licensee receiving the device, such as address and name of responsible person. Accurate and timely reports enable NRC to track individual GLDs.

General Licensees Lack Awareness of NRC Regulatory Requirements

Many general licensees are unaware of NRC regulatory requirements despite provisions requiring manufacturers to provide this information to general licensees at the time of device distribution. Through NMED and NRC inspection reports, staff have identified many cases in which general licensees are unaware of NRC regulatory requirements. These cases show that throughout the last decade, general licensees have failed to fulfill every applicable requirement in 10 CFR Part 31. Several recent examples of licensees failing to fulfill NRC's regulatory requirements follow.

Device Transfer Reporting Requirement

A Federal agency laboratory possessing specifically licensed devices and GLDs did not leak test its GLDs as required by regulations and also transferred GLDs to another licensee without proper reporting to NRC. The laboratory program management was not aware that there were different requirements for the GLDs than for the materials and devices under the specific license.

Appointment of Responsible Person Requirement

One large general licensee lost numerous GLDs. NRC inspectors found that the corporate office centrally purchased the devices and received all technical information about regulatory requirements for the GLDs. Local managers should have been appointed as the "responsible persons," but they did not receive the information, were not aware of the requirements for the devices installed in their facilities, and did not maintain accountability for the devices.

Recordkeeping Requirement

An NRC inspector visited a facility and found a GLD in use at the location on record but could not verify that the required tests had been conducted on the GLD. A personnel change at the facility led to a loss of records related to the required leak tests and shutter tests for the GLD.

Bankruptcy Notification Requirement

A company possessing GLDs had been acquired by another firm, which then became the general licensee. The new general licensee did not notify NRC, as required by regulations, when it later went bankrupt. NRC discovered the bankruptcy when it attempted to verify the location of the device for registration.

NRC headquarters and regional office staff described lack of awareness as a significant challenge with general licensees. Some observed it is a common occurrence, especially among smaller firms, that the person initially responsible for the devices will leave, as in the bankruptcy example where the business changed hands. Although some NRC staff asserted that larger firms are aware of the regulatory requirements, this is not always the case. Other examples show that Federal agencies and large corporations also can lack awareness of the regulatory requirements for GLDs.

Manufacturers Provide NRC's Regulatory Requirements to General Licensees

Manufacturers meet the regulatory requirement[11] of providing information prior to distribution of devices to general licensees. In some cases, however, the information provided to general licensees regarding regulatory requirements for GLDs is unclear and potentially confusing. The following examples of guidance supplied by manufacturers illustrate the challenges:

- One manufacturer's safety manual places important information regarding general licenses and GLD safety in the specific license section, where it could be overlooked by a general licensee.

- Another manufacturer's manual conveys the required regulations to the general licensee but adds the incorrect and confusing statement that because the device has been distributed under the manufacturer's specific license, the user is "a 'General Licensee' under the [manufacturer's] license."

- A third manufacturer provides the essential requirements to the general licensee in two separate booklets. The operating manual has the regulations reprinted in full, and the safety manual contains specific descriptions of what the general licensee is required to do and how to do it. The separation of material in this way could make it more likely that

[11] 10 CFR 32.51a(a)

important information will be overlooked or lost, preventing a general licensee's complete understanding of the regulatory requirements.

Such diverse styles of presenting regulatory requirements may not provide a clear and consistent understanding of the requirements among all general licensees. NRC staff questioned whether manufacturers supply all the information general licensees need and stated that NRC should ensure GLD manufacturers provide the proper information to device recipients.

NRC Approach to Problems with NRC's General Licensing Program

The challenges facing the general licensing program are not new, and NRC has been working to address them since the 1980s. An NRC study in 1987 first summarized general licensee incognizance of regulatory requirements, stating that:

- General licensees did not know the location of their devices.
- General licensees frequently misplaced or did not read material supplied by the device manufacturer and did not realize they had any responsibility to comply with NRC requirements.
- Many general licensees were unaware of particular NRC requirements for disposal, transfer, reporting, leak tests, or shutter testing.

While considering how to address such lack of awareness, NRC conducted another study, published in 1996. This study found that awareness of general license requirements declines over time while a device is in a general licensee's possession. A GLD may be in use for many years, during which personnel who have knowledge of the device or applicable regulations leave, or labels with general license information become lost or illegible.

NRC developed the annual registration program and GLTS in 2000-2001 to address some issues identified by the agency studies.

Figure 2: **Static Eliminator**

Source: Amstat Web site

Registration Program

NRC's general licensee annual registration program was intended to obtain an annual inventory report from those general licensees possessing risk-significant devices. Registration is currently functioning as designed in that NRC has a 99-percent response rate from the subset of general licensees required to register their devices annually. However, the information provided annually by NRC to general licensees (the registration package) does not include any safety- or program management-related reminders to licensees. Instead, NRC's registration package explains the requirement to register and how to file the form confirming their inventory of GLDs. In addition, registration focuses on only about 4 percent of general licensees; therefore, NRC tracks the remaining 96 percent only through GLTS.

General License Tracking System

GLTS was designed to be an information system to track GLDs. Currently, the system supports the registration program, but contains errors that may hamper broad oversight of general licensees. NRC staff report problems when they attempt to use information from GLTS to locate missing general licensees and GLDs. A general licensee's failure to return the registration form triggers NRC staff attempts to verify the location of the devices required to be registered. Examples of errors in GLTS information that surface during verification include the following:

- A company had changed hands and the GLD was in use in the same location but the information had not been reported to NRC as required.

- Devices had been placed on a company's specific license but the NRC general licensing program did not receive a report from the general licensee or from the NRC regional office.

- Although GLTS contained correct contact information for one registered device, the information supplied to the inspector was from a different, incorrect field of the GLTS record, and the inspector was unable to locate the general licensee or the device.

- A facility was closed for 15 years and the devices returned to the manufacturer, but the general licensee had failed to report this to NRC.

Failure of the general licensee to report as required was a problem in three of these examples. General licensees that are unaware of NRC's regulatory requirements frequently have lapses in compliance.

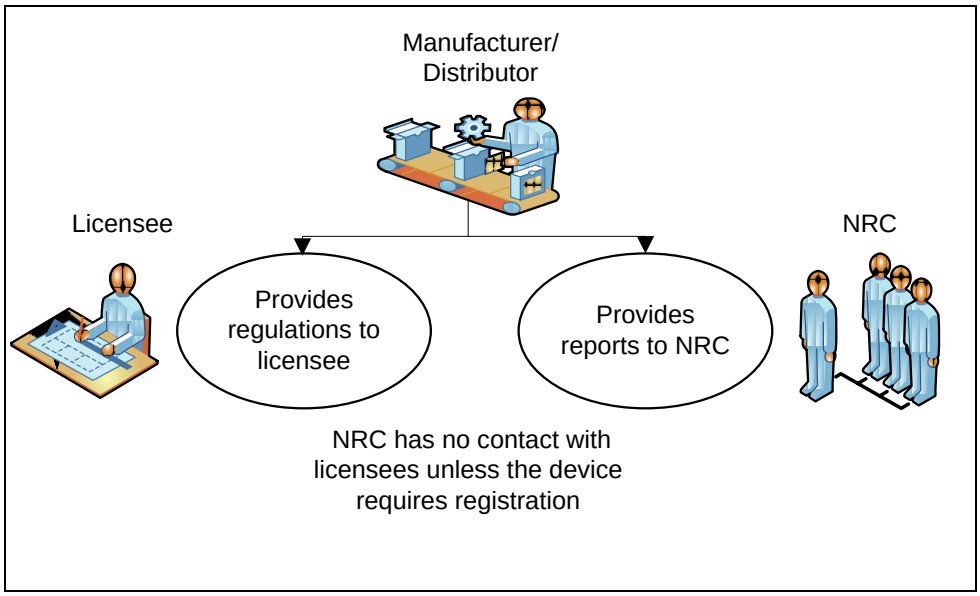
NRC Relies on Manufacturers and Does Not Routinely Communicate With General Licensees

General licensees lack awareness of NRC's regulatory requirements because NRC relies on manufacturers to communicate with general licensees. NRC does not routinely communicate with all of its general licensees.

NRC Relies on Manufacturers

NRC relies on manufacturers to make general licensees aware of NRC's regulatory requirements, delegating some of its oversight responsibilities. Manufacturers provide NRC regulatory information to the general licensee and report general licensee information to NRC, thus acting as the intermediary between NRC and the general licensees at the time of device distribution.

Table 3: **Communication From Manufacturers**



Source: OIG

However, NRC requires general licensees to be familiar with and abide by more regulations than manufacturers are required to deliver with the device. NRC requires general licensees to comply with numerous regulations. (See Appendix B for a complete listing of the regulations.) However, manufacturers are not required to include all of these regulations in the information they provide with devices. Upon distribution of GLDs, manufacturers are required to provide general licensees with copies of certain NRC regulations. The specific regulations that 10 CFR Part 31.5 device manufacturers are required to distribute are:

- 10 CFR 31.5, the general license.
- 10 CFR 31.2, general terms and conditions for general licenses.
- 10 CFR 30.51, recordkeeping for transfers and disposal.
- 10 CFR 20.2201 and 10 CFR 20.2202, reporting loss or theft and radiation overexposure incidents.

A challenge to general licensees arises from 10 CFR 31.2, which incorporates by reference several sections of other regulations, "unless indicated otherwise in the specific provision of the general license." Specific provisions of the general license in 10 CFR 31.5 preempt several of the general terms and

conditions in 10 CFR 31.2. Other referenced regulations relate to what it means to be an NRC licensee, such as limits to licensed activities, submitting to inspections, and the possibility of civil penalties for violations. These significant requirements still apply to general licenses under 10 CFR 31.5, but manufacturers are not required by NRC regulations to provide the full text of all the applicable regulations. Although general licensees do not submit an application and most do not pay an annual fee, they remain NRC licensees and need to be fully informed of all requirements.

Some manufacturers may provide NRC's Internet address for general licensees to look up the regulations. However, it may be difficult for general licensees unfamiliar with Federal regulations to locate and understand the numerous regulatory requirements from NRC's home page.

NRC Does Not Routinely Communicate With the Vast Majority of General Licensees

NRC does not routinely communicate with most general licensees. Unless devices require registration, NRC has no contact with general licensees and takes a hands-off approach for GLDs. An NRC working group[12] report stated the following:

> . . . a major contributing factor to licensees losing control and accountability is the lack of adequate oversight by regulatory authorities. Specifically, many users do not have routine contact with the regulatory authorities. . . . For almost all general licensees, the only connection between the licensee and the regulatory authority is through the vendor of the device.

Because most general licensees are not required to register their devices, those possessing about 98 percent of GLDs do not receive any regular contact with or followup from NRC. According to NRC staff, lack of contact with the agency contributes to general licensees' lack of awareness and misunderstanding of regulatory requirements.

[12] Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices, October 1996 (NUREG-1551).

NRC has made some non-routine efforts to provide general licensees with important information, but the effectiveness of the efforts may be limited. For example:

- NRC has a Web page that contains a toolkit for general licensees. This is a passive approach to communication and assumes general licensees will know there is a need to look for information and have access to the Web site.

- Although NRC staff lack confidence that Information Notices[13] change behavior of materials licensees, NRC issued Information Notices to general licensees because not all regulatory requirements were being met. However, the Information Notices required no specific licensee action or response.

NRC took a more direct approach when it published a Regulatory Issue Summary[14] in 2006 about disposal of tritium exit signs. This mailing, to both general licensees possessing tritium exit signs and to the specific licensees that manufacture and distribute them, reiterated NRC's regulatory requirements with the intent of minimizing chances that the devices would be disposed of incorrectly. The use of the Regulatory Issue Summary was a reaction to concerns about general licensees' lack of awareness regarding their responsibilities. However, NRC's approach remains based on a regulatory structure that tightly controls manufacturers. By contrast, unless a general licensee is required to register a device, NRC's monitoring of GLDs is limited.

Decreased Accountability of General Licensed Devices Poses a Potential Risk to Public Health and Safety and the Environment

When licensees are unaware of their regulatory requirements, there is an increased probability that accountability for GLDs will decrease. Decreased accountability for GLDs can place public health and safety and the environment at risk.

[13] NRC uses Information Notices to provide significant recently identified operational information about safety, safeguards, or environmental issues. Addressees are expected to review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems.

[14] NRC uses Regulatory Issue Summaries to announce technical or policy positions not previously communicated to industry or not broadly understood.

Figure 3: **Continuous Level Detector**

Source: Ohmart/Vega Web site

Lost, Abandoned, and Improperly Disposed Devices

General licensees continue to lose, abandon, and improperly dispose of GLDs containing radioactive material, just as they did when NRC first studied the problem in the 1980s. NRC tracks events and monitors nuclear material trends across the country through NMED. A search of NMED identified that over a 5-year period,[15] there were 341 reports[16] of lost, abandoned, and improperly disposed GLDs reported across the United States. As would be expected, approximately 80 percent of the event reports came from Agreement States. However, such events also commonly occurred in NRC jurisdiction throughout the 5-year period.

Members of the public who encounter GLDs after they have been lost, abandoned, or improperly disposed can be exposed to low doses of radiation.

There is also ongoing concern with the environmental impact resulting from inadequate control of products containing radioactive materials. In the past, improper disposal has led to the contamination of metal scrap process recycling streams, resulting in significant environmental cleanup costs and potential worker exposure. Many metal recycling facilities have installed detectors to screen incoming loads for radioactive materials and, as a result, lost GLDs are sometimes discovered in scrap metal. However, not all lost radioactive devices

[15] July 1, 2007, through June 30, 2012.

[16] Of the 341 reports, 253 were related to lost or improperly disposed luminous (tritium) exit signs.

are recovered; some improperly disposed devices are exported in scrap metal shipments.

NRC Staff Concerns

NRC staff note the continued problems from loss of accountability and control of GLDs. One staff member stated that the "lack of awareness by general licensees is the reason NRC finds general licensed devices on the auction block or in the scrapyard." Another staff member agreed with the statement, adding that GLDs "are not recognized as radioactive and are sold or sent to scrapyards." A stakeholder pointed out that NRC cannot know what is not reported.

Reporting Reliability

When general licensees are unaware of regulations and fail to report as required by NRC, the agency lacks the best information to support effective long-term oversight of the program. For NRC to ensure that general licensees are conducting their activities in a manner that protects public health and safety and the environment, NRC must have reliable information to track general licensees and GLDs.

Recommendations

OIG recommends that the Executive Director for Operations:

1. Develop and implement procedures for NRC to provide information clearly describing all applicable regulatory requirements each time an NRC general licensed device is distributed to an NRC general licensee.

2. Develop and implement procedures for NRC to periodically reinform existing general licensees of applicable regulatory requirements.

IV. AGENCY COMMENTS

An exit conference was held with the agency on September 4, 2012. At this meeting, agency management provided supplemental information that has been incorporated into this report as appropriate.

On September 21, 2012, NRC's Executive Director for Operations provided a formal response to this report (Appendix C). No changes were made to the report, based on the agency's formal response. OIG's response to the agency's formal comments is presented as Appendix D.

APPENDIX A

OBJECTIVE, SCOPE, AND METHODOLOGY

OBJECTIVE

The audit objective was to determine if NRC's general licensing program provides for the necessary accountability and tracking of general licensed devices to protect public health and safety.

SCOPE

We conducted this performance audit at NRC headquarters (Rockville, MD) and three NRC regional offices (Region I, King of Prussia, PA; Region III, Lisle, IL; and Region IV, Arlington, TX) from November 2011 through June 2012. OIG also interviewed staff in the Agreement States of Maryland (Baltimore) and Pennsylvania (Harrisburg), during this timeframe. Internal controls related to the audit objectives were reviewed and analyzed. Throughout the audit, auditors were aware of the possibility or existence of fraud, waste, or misuse in the program.

METHODOLOGY

The audit team reviewed relevant criteria, including the *Atomic Energy Act of 1954, as amended*; 10 CFR Part 31, *General Domestic Licenses for Byproduct Material*, and Part 32, *Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material*; and NRC's *Principles of Good Regulation.* The team also reviewed NRC Information Notices, Commission Papers, and Staff Requirements Memoranda.

The audit team reviewed NMED and inspection reports to determine whether general licensees comply with NRC requirements. The team also reviewed the reporting and tracking of general licensed devices in GLTS.

At NRC headquarters, auditors interviewed Office of Federal and State Materials and Environmental Management Programs staff and management to gain an understanding of their roles and responsibilities related to the oversight of general licenses. Auditors interviewed staff and management from NRC Regions I, III, and IV to gain an understanding of how each region oversees

general licenses. Auditors also interviewed staff in the Agreement States to gain an understanding of the State general licensing programs.

We conducted this performance audit in accordance with generally accepted Government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The audit work was conducted by Sherri Miotla, Team Leader; Robert Woodward, Audit Manager; Kevin Nietmann, Senior Technical Advisor; Maxinne Lorette, Senior Auditor; and Amy Hardin, Auditor.

APPENDIX B-1

Regulatory requirements for certain detecting, measuring, and controlling devices, and certain devices for producing light or an ionized atmosphere generally licensed under 10 CFR Part 31.5			
	Requirement Name	Description of Requirement	Regulation
1	Report theft or loss of licensed radioactive material	Describes when licensee must report by telephone or in writing a theft or loss; certain reports must be made within 24 hours, others within 30 days; specifies content of reports.	10 CFR 20.2201
2	Report exposure incidents	Describes exposure thresholds where licensee must report radiation incidents to NRC.	10 CFR 20.2202
3	Exempt quantities and products	Transfer to an exempt person must be under a specific license.	10 CFR 30.14(d)
4	License terms and conditions	Licensee shall confine his possession and use to the locations and purposes authorized in the license; Commission can change terms by rule or order.	10 CFR 30.34(a)-(e)
5	Transfers of licensed radioactive material	Transfer permitted to a specific licensee or a general licensee; transferring licensee must verify that recipient is authorized to possess the material.	10 CFR 30.41
6	Reporting requirements	Describes when licensee must report incidents by telephone or in writing; certain reports must be made immediately, within 24 hours, others within 30 days; specifies content of reports.	10 CFR 30.50
7	Records	Receipt/transfer/disposal of material; transfer records to NRC when license terminated; retention periods specified elsewhere in regulations or as license condition.	10 CFR 30.51
8	Inspections	General licensees not normally inspected but if NRC wishes to inspect a general licensee, material, facility, and records must be available for inspection.	10 CFR 30.52
9	Tests as required	Licensee shall perform such tests of byproduct material, facilities, radiation detection devices as the Commission deems necessary to administer the regulations.	10 CFR 30.53
10	Modify license conditions by rule change	License conditions can be modified by amendment of laws or regulations; license can be revoked for false statements or for violations.	10 CFR 30.61
11	Withholding materials	Commission may withhold byproduct material from a licensee not equipped to observe or who fails to observe safety standards or protect health.	10 CFR 30.62
12	Violations and civil penalties	Commission may obtain a court order to prevent violation of the Commission's regulations; Commission may impose a civil penalty for violations.	10 CFR 30.63
13	General license terms and conditions	Licensee shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license; in addition, general licensees subject to 30.14(d), 30.34(a)-(e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, unless otherwise specified.	10 CFR 31.2
14	Types of devices	General licensee is permitted to acquire, receive, possess, use or transfer byproduct material contained in devices designed and manufactured by a specific licensee under §32.51 for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.	10 CFR 31.5
15	Labels	Labels must remain attached and general licensee must comply with instructions of label.	10 CFR 31.5(c)(1)
16	Leak testing	Leak test at least every 6 months (tritium exit signs exempt).	10 CFR 31.5(c)(2)
17	Testing and service by a specific licensee	Must have a specific licensee perform these tasks.	10 CFR 31.5(c)(3)

APPENDIX B-1 continued

18	Records of leak testing	Maintain records showing compliance with leak testing requirement.	10 CFR 31.5(c)(4)
19	Stop use if device fails	Suspend operation if failure of shielding or on/off mechanism, report to NRC, repair by specific licensee.	10 CFR 31.5(c)(5)
20	Do not abandon device	Shall not abandon the device containing byproduct material.	10 CFR 31.5(c)(6)
21	Do not export the device	Shall not export the device containing byproduct material.	10 CFR 31.5(c)(7)
22	Report Transfers	Shall transfer only to a specific licensee, and within 30 days after the transfer of a device to a specific licensee or export, furnish a report to NRC.	10 CFR 31.5(c)(8)
23	Transfer device to general licensee	Shall transfer the device to another general licensee only if the device remains in use at a particular location.	10 CFR 31.5(c)(9)
24	Reporting radiation incidents, theft or loss	Shall comply with the provisions of §§ 20.2201 and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, otherwise exempt from Part 19, 20, 21.	10 CFR 31.5(c)(10)
25	Respond to written requests from NRC	Shall respond to written requests from the Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request.	10 CFR 31.5(c)(11)
26	Appoint a responsible person	Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements.	10 CFR 31.5(c)(12)
27	Register appropriate devices	Shall register, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label.	10 CFR 31.5(c)(13)
28	Report changes in mailing address	Shall report changes to the mailing address for the location of use to NRC within 30 days of the effective date of the change.	10 CFR 31.5(c)(14)
29	Do not hold devices not in use more than 2 years	May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only.	10 CFR 31.5(c)(15)

APPENDIX B-2

Regulatory requirements for luminous safety devices for use in aircraft (with not more than 10 curies of tritium or 300 millicuries of promethium-147 per device) licensed under 10 CFR Part 31.7			
	Requirement Name	Description of Requirement	Regulation
1	Report theft or loss of licensed radioactive material	Describes when licensee must report by telephone or in writing a theft or loss; certain reports must be made within 24 hours, others within 30 days; specifies content of reports.	10 CFR 20.2201
2	Report exposure incidents	Describes exposure thresholds where licensee must report radiation incidents to NRC.	10 CFR 20.2202
3	Exempt quantities and products	Transfer to an exempt person must be under a specific license.	10 CFR 30.14(d)
4	License terms and conditions	Licensee shall confine his possession and use to the locations and purposes authorized in the license; Commission can change terms by rule or order.	10 CFR 30.34(a)-(e)
5	Transfers of licensed radioactive material	Transfer permitted to a specific licensee or a general licensee; transferring licensee must verify that recipient is authorized to possess the material.	10 CFR 30.41
6	Reporting requirements	Describes when licensee must report incidents by telephone or in writing; certain reports must be made immediately, within 24 hours, others within 30 days; specifies content of reports.	10 CFR 30.50
7	Records	Receipt/transfer/disposal of material; transfer records to NRC when license terminated; retention periods specified elsewhere in regulations or as license condition.	10 CFR 30.51
8	Inspections	General licensees not normally inspected but if NRC wishes to inspect a general licensee, material, facility, and records must be available for inspection.	10 CFR 30.52
9	Tests as required	Licensee shall perform such tests of byproduct material, facilities, radiation detection devices as the Commission deems necessary to administer the regulations.	10 CFR 30.53
10	Modify license conditions by rule change	License conditions can be modified by amendment of laws or regulations; license can be revoked for false statements or for violations.	10 CFR 30.61
11	Withholding materials	Commission may withhold byproduct material from a licensee not equipped to observe or who fails to observe safety standards or protect health.	10 CFR 30.62
12	Violations and civil penalties	Commission may obtain a court order to prevent violation of the Commission's regulations; Commission may impose a civil penalty for violations.	10 CFR 30.63
13	General license terms and conditions	Licensee shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license; in addition, general licensees subject to 30.14(d), 30.34(a)-(e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, unless otherwise specified.	10 CFR 31.2
14	Type of device and material threshold	Permits the ownership, receipt, acquisition, possession, and use of tritium or promethium-147 contained in luminous safety devices for use in aircraft provided that each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147; devices must be manufactured by a specific licensee under §32.53; General licensees exempt for requirements of parts 19, 20, and 21 except for except for the provisions in §20.2201 and 20.2202.	10 CFR 31.7

APPENDIX B-3

Regulatory requirements for americium-241 and radium-226 in the form of calibration or reference sources generally licensed under 10 CFR Part 31.8			
	Requirement Name	Description of Requirement	Regulation
1	Training for workers in radiation safety	Describes the notices (including postings of regulations) and instructions to workers. Information that must be given to individuals who in the course of employment are likely to receive a one year occupational dose in excess of 100 millirem.	10 CFR 19
2	Radiation protection standards and programs	Dose limits for workers and for members of the public; the features of radiation safety programs to protect workers and the public; recordkeeping; reporting (e.g., theft or loss and incidents); and enforcement of the requirements.	10 CFR 20
3	Device defect reporting	Specific requirements for identifying and reporting defects with substantial safety hazards to NRC within specific time limits.	10 CFR 21
4	Exempt quantities and products	Transfer to an exempt person must be under a specific license.	10 CFR 30.14(d)
5	License terms and conditions	Licensee shall confine his possession and use to the locations and purposes authorized in the license; Commission can change terms by rule or order.	10 CFR 30.34(a)-(e)
6	Reporting requirements	Describes when licensee must report incidents by telephone or in writing; certain reports must be made immediately, within 24 hours, others within 30 days; specifies content of reports.	10 CFR 30.50
7	Records	Receipt/transfer/disposal of material; transfer records to NRC when license terminated; retention periods specified elsewhere in regulations or as license condition.	10 CFR 30.51
8	Inspections	General licensees not normally inspected but if NRC wishes to inspect a general licensee, material, facility, and records must be available for inspection.	10 CFR 30.52
9	Tests as required	Licensee shall perform such tests of byproduct material, facilities, radiation detection devices as the Commission deems necessary to administer the regulations.	10 CFR 30.53
10	Modify license conditions by rule change	License conditions can be modified by amendment of laws or regulations; license can be revoked for false statements or for violations.	10 CFR 30.61
11	Withholding materials	Commission may withhold byproduct material from a licensee not equipped to observe or who fails to observe safety standards or protect health.	10 CFR 30.62
12	Violations and civil penalties	Commission may obtain a court order to prevent violation of the Commission's regulations; Commission may impose a civil penalty for violations.	10 CFR 30.63
13	General license terms and conditions	Licensee shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license; in addition, general licensees subject to 30.14(d), 30.34(a)-(e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, unless otherwise specified.	10 CFR 31.2
14	Must have specific license to use this general license.	General license to possess calibration and reference sources containing Am-241 and Ra-226 is granted to persons or government agencies that hold specific licenses to possess, use, or transfer other byproduct material; source must have been manufactured under a specific license under §32.57.	10 CFR 31.8(a)-(b)
15	Requirements for these sources	General licensee is subject to §§30.14, 30.34(a)-(e), and 30.50 to 30.63; also subject to 10 CFR Parts 19, 20, 21; limits for use, storage, transfer and disposal, prohibits abandonment, export, or import.	10 CFR 31.8(c)-(e)

APPENDIX B-4

Regulatory requirements for a general license for strontium-90 in ice detection devices under 10 CFR Part 31.10			
	Requirement Name	Description of Requirement	Regulation
1	Disposal requirements	A licensee shall dispose of licensed material only by transfer to an authorized recipient, by decay in storage, by release in effluents, or as otherwise authorized.	10 CFR 20.2001
2	Report theft or loss of licensed radioactive material	Describes when licensee must report by telephone or in writing a theft or loss; certain reports must be made within 24 hours, others within 30 days; specifies content of reports.	10 CFR 20.2201
3	Report exposure incidents	Describes exposure thresholds where licensee must report radiation incidents to NRC.	10 CFR 20.2202
4	Exempt quantities and products	Transfer to an exempt person must be under a specific licens	10 CFR 30.14(d)
5	License terms and conditions	Licensee shall confine his possession and use to the locations and purposes authorized in the license; Commission can change terms by rule or order.	10 CFR 30.34(a)-(e)
6	Transfers of licensed radioactive material	Transfer permitted to a specific licensee or a general licensee; transferring licensee must verify that recipient is authorized to possess the material.	10 CFR 30.41
7	Reporting requirements	Describes when licensee must report incidents by telephone or in writing; certain reports must be made immediately, within 24 hours, others within 30 days; specifies content of reports.	10 CFR 30.50
8	Records	Receipt/transfer/disposal of material; transfer records to NRC when license terminated; retention periods specified elsewhere in regulations or as license condition.	10 CFR 30.51
9	Inspections	General licensees not normally inspected but if NRC wishes to inspect a general licensee, material, facility, and records must be available for inspection.	10 CFR 30.52
10	Tests as required	Licensee shall perform such tests of byproduct material, facilities, radiation detection devices as the Commission deems necessary to administer the regulations.	10 CFR 30.53
11	Modify license conditions by rule change	License conditions can be modified by amendment of laws or regulations; license can be revoked for false statements or for violations.	10 CFR 30.61
12	Withholding materials	Commission may withhold byproduct material from a licensee not equipped to observe or who fails to observe safety standards or protect health.	10 CFR 30.62
13	Violations and civil penalties	Commission may obtain a court order to prevent violation of the Commission's regulations; Commission may impose a civil penalty for violations.	10 CFR 30.63
14	General license terms and conditions	Licensee shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license; in addition, general licensees subject to 30.14(d), 30.34(a)-(e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, unless otherwise specified.	10 CFR 31.2
15	Ice detection devices containing strontium-90	General license to own, use, transfer Sr-90 in ice detection devices as long as activity not greater than 50 microcuries and device is manufactured by a specific licensee under §32.61; discontinue use in case of observable damage, service should be provided by a specific licensee; label must be maintained. Exempt from 19,20,21 except for 20.2001, 20.2201, 20.2202.	10 CFR 31.10

APPENDIX B-5

Regulatory requirements for byproduct material for certain *in vitro* clinical or laboratory testing generally licensed under 10 CFR Part 31.11			
	Requirement Name	Description of Requirement	Regulation
1	Disposal of waste containing licensed material	Licensee shall dispose of licensed material only by transfer to an authorized recipient under §20.2006 or as authorized in §§20.2002, 20.2003, 20.2004, 20.2005, 20.2008 (applicable only to users of Mock-Iodine-125).	10 CFR 20.2001
2	Report theft or loss of licensed radioactive material	Describes when licensee must report by telephone or in writing a theft or loss; certain reports must be made within 24 hours, others within 30 days; specifies content of reports (applicable only to users of Mock-Iodine-125)..	10 CFR 20.2201
3	Report exposure incidents	Describes exposure thresholds where licensee must report radiation incidents to NRC (applicable only to users of Mock-Iodine-125).	10 CFR 20.2202
4	Exempt quantities and products	Transfer to an exempt person must be under a specific license.	10 CFR 30.14(d)
5	License terms and conditions	Licensee shall confine his possession and use to the locations and purposes authorized in the license; Commission can change terms by rule or order.	10 CFR 30.34(a)-(e)
6	Reporting requirements	Describes when licensee must report incidents by telephone or in writing; certain reports must be made immediately, within 24 hours, others within 30 days; specifies content of reports.	10 CFR 30.50
7	Records	Receipt/transfer/disposal of material; transfer records to NRC when license terminated; retention periods specified elsewhere in regulations or as license condition.	10 CFR 30.51
8	Inspections	General licensees not normally inspected but if NRC wishes to inspect a general licensee, material, facility, and records must be available for inspection.	10 CFR 30.52
9	Tests as required	Licensee shall perform such tests of byproduct material, facilities, radiation detection devices as the Commission deems necessary to administer the regulations.	10 CFR 30.53
10	Modify license conditions by rule change	License conditions can be modified by amendment of laws or regulations; license can be revoked for false statements or for violations.	10 CFR 30.61
11	Withholding materials	Commission may withhold byproduct material from a licensee not equipped to observe or who fails to observe safety standards or protect health.	10 CFR 30.62
12	Violations and civil penalties	Commission may obtain a court order to prevent violation of the Commission's regulations; Commission may impose a civil penalty for violations.	10 CFR 30.63
13	General license terms and conditions	Licensee shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license; in addition, general licensees subject to 30.14(d), 30.34(a)-(e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, unless otherwise specified.	10 CFR 31.2
14	General license for limited quantities	General license to possess limited quantities of specified isotopes is granted to physicians, veterinarians, clinical laboratories, or hospitals; material must be in the form of a pre-packaged units manufactured under a specific license under §32.71 and affixed with a required label.	10 CFR 31.11(a)(1)-(8), (d)(1)-(2)
15	Must register or have a specific license to use this general license.	Persons possessing and using byproduct material under this general license must: register with NRC as practicing *in vitro* testing; or hold specific licenses under 10 CFR Part 35, Medical Use of Byproduct Material.	10 CFR 31.11(b)(1)-(2)
16	Requirements for receiving, acquiring, possessing, and use under this general license.	General licensee is subject to §§30.14, 30.34(a)-(e), and 30.50 to 30.63; with respect to the byproduct material under general license, exempt from 10 CFR Parts 19, 20, 21, except for users of Mock-Iodine-125, who are subject to §§20.2001, 20.2201, 20.2202; limits for use, storage, and transfer.	10 CFR 31.11(c)(1)-(5), (e), (f)

APPENDIX B-6

Regulatory requirements for a general license for certain items and self-luminous devices containing radium-226 under 10 CFR Part 31.12			
	Requirement Name	Description of Requirement	Regulation
1	Disposal of certain byproduct material	A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in § 20.1003 [discrete sources of Ra-226], at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law.	10 CFR 20.2008
2	Exempt quantities and products	Transfer to an exempt person must be under a specific license.	10 CFR 30.14(d)
3	License terms and conditions	Licensee shall confine his possession and use to the locations and purposes authorized in the license; Commission can change terms by rule or order.	10 CFR 30.34(a)-(e)
4	Transfers of licensed radioactive material	Transfer permitted to a specific licensee or a general licensee; transferring licensee must verify that recipient is authorized to possess the material.	10 CFR 30.41
5	Inspections	General licensees not normally inspected but if NRC wishes to inspect a general licensee, material, facility, and records must be available for inspection.	10 CFR 30.52
6	Tests as required	Licensee shall perform such tests of byproduct material, facilities, radiation detection devices as the Commission deems necessary to administer the regulations.	10 CFR 30.53
7	Modify license conditions by rule change	License conditions can be modified by amendment of laws or regulations; license can be revoked for false statements or for violations.	10 CFR 30.61
8	Withholding materials	Commission may withhold byproduct material from a licensee not equipped to observe or who fails to observe safety standards or protect health.	10 CFR 30.62
9	Violations and civil penalties	Commission may obtain a court order to prevent violation of the Commission's regulations; Commission may impose a civil penalty for violations.	10 CFR 30.63
10	General license terms and conditions	Licensee shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license; in addition, general licensees subject to 30.14(d), 30.34(a)-(e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, unless otherwise specified.	10 CFR 31.2
11	General license issued for particular items (including antiques) in limited uses	Antique items originally intended for use by the public, intact timepieces, luminous items installed in land, air, or marine vehicles, all other luminous products so long as no more than 100 items are used or stored at the same location at any one time, small radium sources such as are used in educational demonstration items; report damage to NRC, do not abandon or export, shall dispose only as specified in §20.2008, shall respond to NRC request for information, only timepieces may be disassembled; general licensees exempt from Parts 19,20, and 21 except for §20.2008, and from §30.50 and 30.51.	10 CFR 31.12

APPENDIX C

FORMAL AGENCY COMMENTS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 21, 2012

MEMORANDUM TO: Stephen D. Dingbaum
Assistant Inspector General for Audits

FROM: /for/ R. W. Borchardt
Executive Director for Operations

SUBJECT: FORMAL COMMENTS ON DRAFT REPORT: "AUDIT OF NRC'S 10 CFR PART 31 GENERAL LICENSING PROGRAM"

This memorandum is in response to your September 18, 2012, e-mail transmitting the Office of the Inspector General's (OIG) Draft Audit Report, "Audit of NRC's 10 CFR Part 31 General Licensing Program." I appreciate the time spent by the OIG in observing and evaluating the NRC's general licensing program.

The staff agrees that additional communication with general licensees regarding the applicable regulatory requirements may aid in improving the awareness of these requirements, and subsequently enhance the control of generally licensed devices over time.

In reviewing the OIG report, the staff noted that some descriptions regarding general license requirements were very broad in nature. While this type of description may be suitable for illustrating an issue, the regulations in Title 10, *Code of Federal Regulations* (CFR), Part 31 provide very specific requirements which are dependent on the device and radioactive material. The general descriptions in the OIG report are not necessarily reflective of the staff's view regarding the applicability of the regulations in all cases.

Again, I appreciate your efforts to improve the general licensing program and for the opportunity for us to comment on your draft report. In addition, staff review concluded that the draft report does not contain any sensitive unclassified information.

CONTACT: Brian McDermott, FSME/MSSA
(301) 415-3340

APPENDIX D

OIG RESPONSE TO FORMAL AGENCY COMMENTS

On September 21, 2012, NRC's Executive Director for Operations provided a formal response to this report which expressed agreement that the report's recommendations may aid in improving general licensees' awareness of regulatory requirements and, subsequently, enhance the control of generally licensed devices over time.

OIG will review the adequacy of agency corrective actions taken to address the report's recommendations during the audit followup process.