AUDIT REPORT

Audit of NRC's Issuance of General Licenses

OIG-12-A-14 June 28, 2012

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EXECUTIVE SUMMARY

BACKGROUND

The U.S. Nuclear Regulatory Commission's (NRC) regulations provide a general license for the use of byproduct material contained in certain products. This general license allows persons to receive and use a device containing byproduct or source material (a general licensed device) if the device has been manufactured and initially distributed in accordance with a specific license issued by NRC or an Agreement State.

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 to ensure that the device meets NRC or Agreement State regulatory requirements prior to approval for distribution. NRC asserts that the GLD is designed with inherent radiation safety features so that it can be used by persons with no radiation safety training or experience. A few of the more commonly used GLDs include fixed gauges, x-ray fluorescence analyzers, static elimination devices, and 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:

- **Sealed Source and Device Registry Review** – A device must undergo this review and safety evaluation prior to distribution as a GLD. Satisfying the review ensures that the device meets NRC's or an Agreement State's regulatory requirements.

- **General License Tracking System** – This database facilitates the tracking and accountability of general licensees and GLDs. The database stores information about NRC's current general licensees located in NRC's jurisdiction.

- **Registration** – Certain general licensees (approximately 600) are required to register their devices with NRC annually. The registration requires licensees to provide NRC the location of the devices and specific information about the licensee.

OBJECTIVE

The audit objective was to determine if NRC issues general licenses for only inherently safe nuclear materials.

RESULTS IN BRIEF

General Licensed Devices Can Contain Dangerous Sources

Although GLDs can contain dangerous radioactive sources, NRC considers GLDs to be inherently safe, allowing persons with no radiation training or experience to operate these devices. Existing regulations do not specify an activity threshold for byproduct material allowed in general licensed fixed gauges. When exposed to a dangerous source, a person can receive a radioactive dose that exceeds the regulatory limits for radiation exposure.

RECOMMENDATIONS

This report makes four recommendations to improve the agency's oversight of general licensed devices.

AGENCY COMMENTS

An exit conference was held with the agency on June 7, 2012. At this meeting, agency management provided supplemental information that has been incorporated into this report as appropriate. As a result, agency management stated their general agreement with the findings and recommendations in this report and opted not to provide formal comments for inclusion in this report.

ABBREVIATIONS AND ACRONYMS

CFR	Code of Federal Regulations
GLD	general licensed device
IAEA	International Atomic Energy Agency
mrem	millirem
NMED	Nuclear Material Events Database
NRC	Nuclear Regulatory Commission
OIG	Office of the Inspector General

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I. BACKGROUND

The U.S. 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, promote the common defense and security, and protect the environment. NRC's regulations provide a general license for the use of byproduct material contained in certain products. This general license allows persons to receive and use a device containing byproduct or source material (a general licensed device) if the device has been manufactured and initially distributed in accordance with a specific license issued by NRC or an Agreement State.[2]

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 to ensure that the device meets NRC or Agreement State regulatory requirements prior to approval for distribution. NRC asserts that the GLD is designed with inherent radiation safety features so that it can be used by persons with no radiation safety training or experience. A few of the more commonly used GLDs include fixed gauges, x-ray fluorescence analyzers, static elimination devices, and tritium exit signs. As the safety of general licensed fixed gauges is the primary focus of this report, a brief explanation of the uses and design of fixed gauges follows.

[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 natural uranium or thorium or depleted uranium that is not suitable for use as reactor fuel. Special nuclear material consists of uranium-233 or uranium-235, enriched uranium, or plutonium.

[2] 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.

Fixed Gauges

Fixed gauges are typically used to monitor a production process and ensure quality control. There are many types of fixed gauges, including those that measure thickness, density, level, and volumetric flow. Americium-241, cesium-137, and cobalt-60 are the radioactive sources commonly used in fixed gauges. When the shutter on a fixed gauge is opened, the radiation passes through the material and a detector, which is mounted opposite the source, measures the radiation that passes through the material. A readout, either on the gauge or on a connected computer terminal, captures the required information. The passage of radiation through the material does not cause any physical or chemical change, and the material itself does not become radioactive.

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:

Figure 1. **Cutaway View of Density Gauge**

Source: Vega Controls UK Web site

- **Sealed Source and Device Registry Review** – A device must undergo this review and safety evaluation prior to distribution as a GLD.[3] Satisfying the review ensures that the device meets NRC's or an Agreement State's regulatory requirements.

[3] The certificate issued upon completion of the Sealed Source and Device Registry Review indicates whether the device is approved for distribution under a general license, under a specific license, or under both specific and general licenses.

- **General License Tracking System** – This database facilitates the tracking and accountability of general licensees and GLDs. The database stores information about NRC's current general licensees located in NRC's jurisdiction, along with device information and vendor information.

- **Registration** – Certain general licensees (approximately 600) are required to register their devices with NRC annually. The registration requires licensees to provide NRC the location of the devices and specific information about the licensee. General licensees required to register are also required to submit an annual fee (currently $400) to NRC. General licensees that possess at least one device containing one of the following isotopes at or above the activity shown are required to register (see Table 1).

Table 1. **Isotopes Subject to Registration**

Isotope	Minimum activity in millicuries[4]
Americium-241	1
Cesium-137	10
Cobalt-60	1
Curium-244	1
Radium-226	0.1
Strontium-90	0.1
Plutonium-238	1
Plutonium-239	1
Californium-252	1

Source: Title 10 Code of Federal Regulations (CFR) 31.5(c)(13)(i)

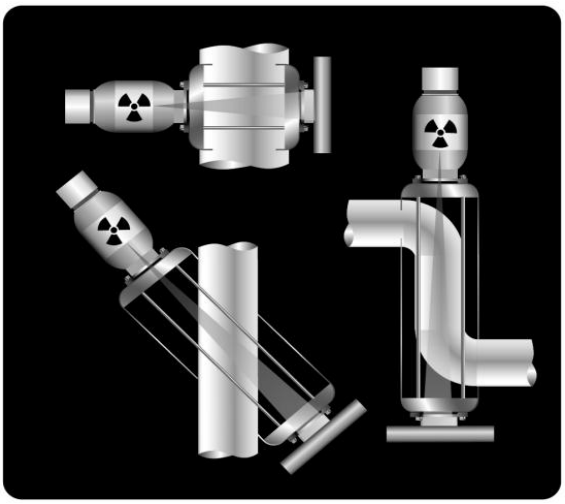
[4] Activity is the rate of disintegration or decay of radioactive material per unit of time. The minimum activity for GLDs subject to annual registration is shown in millicuries. A curie is a unit used to measure the intensity of radioactivity. It refers to the amount of ionizing radiation released when an element spontaneously emits energy as a result of the radioactive decay (or disintegration) of an unstable atom. A millicurie is one thousandth of a curie and a microcurie is one millionth of a curie.

General Licenses Versus Specific Licenses

NRC ensures public health and safety differently for general licensed and specific licensed devices. For general licenses, NRC asserts that safety concerns are generically addressed by extensive regulatory review of the device design and the practices of the device manufacturer so that, even in accident scenarios, there is no unacceptable risk to public health and safety. General license requirements and fees are substantially less than for a specific license. Consequently, the general license simplifies the licensing process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

By contrast, NRC may issue a specific license to a named person who has filed an application for a license to use a fixed gauge that contains a sealed source or sealed sources. An application for a specific license provides NRC an opportunity to conduct a detailed review of the radioactive materials program proposed by the applicant. NRC is able to interact with the applicant during the licensing process prior to making a regulatory decision as to whether to grant the license as requested or with modifications. The following table highlights the primary distinctions between general licenses and specific licenses.

Figure 2. **Fixed Gauges Attached to Pipes**



Source: Canadian Nuclear Safety Commission Web site

Table 2. **General License Versus Specific License Comparison**

Regulatory Area	General License	Specific License
Application	Not required	Required
Licensing	By rule, no license document issued	License document issued
Expiration	No expiration	Specific expiration date
Inspections	Not normally inspected	Routine inspections
Worker Training	Not required	Required
Radiation Protection Program	Not required	Required
Fees to NRC	Annual Registration (certain Part 31 devices only) $400	Annual license fees: Small manufacturing entities with fewer than 35 employees $500, 35-500 employees $2,300; Byproduct material uses ("All other" including fixed & portable gauges, gas chromatographs, and other analyzing and measuring equipment) $4,800

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

II. OBJECTIVE

The audit objective was to determine if NRC issues general licenses for only inherently safe nuclear materials. The report Appendix contains information on the audit scope and methodology.

III. FINDING

Although GLDs can contain dangerous radioactive sources, NRC considers GLDs to be inherently safe, allowing persons with no radiation training or experience to operate these devices. Existing regulations do not specify an activity threshold for byproduct material allowed in general licensed fixed gauges. When exposed to a dangerous source, a person can receive a radioactive dose that exceeds the regulatory limits for radiation exposure.

Safety Is NRC's Number One Priority

The aim of NRC's safety goal strategies is to focus attention on safety matters and individual accountability of those engaged in regulated activities. During a public speech, NRC's Chairman said that safety is always NRC's number one priority. The agency's commitment to safety is through its oversight of licensee performance through inspections, investigations, enforcement, and performance assessment activities.

Inherently Safe

An inherently safe device should amount to a low level of danger even when the device is not operating as designed. NRC's experience with GLDs indicates that if users follow basic safety procedures, and the devices operate as designed, radiation exposures to users are generally low. As such, NRC does not require users to have radiation training or experience prior to operating a GLD because NRC considers the devices to be inherently safe.

General Licensed Devices Can Contain Dangerous Sources

NRC's regulation of GLDs allows certain devices to contain radioactive sources that, if not used properly, could be dangerous.

IAEA Code of Conduct

In 2004, the International Atomic Energy Agency (IAEA) issued the *Code of Conduct on the Safety and Security of Radioactive Sources*, in part, to protect individuals, society, and the environment from the harmful effects of possible accidents and malicious acts involving radioactive sources. In 2005, the United States made a commitment to fully support and endorse the IAEA Code of Conduct. IAEA developed a categorization system that provides a relative ranking and grouping of sources and practices on which regulatory decisions can be based. The categorization is based on a definition of a dangerous source. Such a source could, if not under control, give rise to exposure sufficient to cause severe deterministic effects (i.e., fatal or life threatening) or a permanent injury. The IAEA Code of Conduct identifies specific radioactive materials and categorizes them by activity level.

The IAEA categories are:

Category 1: **Extremely Dangerous**. These sources could cause permanent injury within a few minutes if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from a few minutes to an hour.

Category 2: **Very Dangerous**. These sources could cause permanent injury within minutes to hours if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from hours to days.

Category 3: **Dangerous**. These sources could cause permanent injury within hours if handled. Doses could possibly (but unlikely) be fatal to someone in close proximity to an unshielded source for periods ranging from days to weeks.

Category 4: **Unlikely to be Dangerous**. These sources would not cause permanent injury, although delayed health effects are possible. Doses could possibly (but unlikely) cause temporary injury to someone in close proximity to an unshielded source for a period of many weeks.

Category 5: **Most Unlikely to be Dangerous**. These sources would not cause permanent injury.

Fixed Gauges Contain Dangerous Sources

Licensees in NRC's jurisdiction possess GLDs that contain dangerous sources as defined by IAEA. As of February 16, 2012, OIG confirmed through a search of the General License Tracking System that 32 GLDs, containing single Category 3 sources, exist in NRC jurisdiction. The devices are fixed gauges primarily in steel, paper, coal, oil, and chemical facilities. Currently, there are no Category 1 or 2 GLDs in NRC jurisdiction.[5] Although there were some Category 2 GLDs several years ago, they have all been converted to specific licenses. The following table details the locations within NRC jurisdiction with licensees possessing GLDs containing Category 3 sources.

Table 3. **GLDs in NRC Jurisdiction**

State	Number of GLDs with Category 3 Sources
Montana	2
Indiana	20
Michigan	7
West Virginia	2
Wyoming	1
Total	**32**

Source: NRC's General License Tracking System as of February 2012

[5] While NRC regulations do not specifically preclude the use of a Category 1 source in a general licensed fixed gauge, the weight and size of the shielding required to reduce the radiation levels outside such a device would make the device impractical.

Agreement State Regulation of GLDs

Although Agreement States regulate more than 85 percent of the material licenses in the United States, only a small percentage of GLDs in Agreement States contain IAEA defined dangerous sources. OIG interviewed a representative from each of the 37 Agreement States and found that some States do not issue general licenses and only issue specific licenses for devices with Category 1, 2, or 3 sources. Several other Agreement States are considering transferring all GLDs with Category 1, 2, or 3 sources to specific licenses. OIG also learned that some Agreement States routinely inspect their general licensees. Only 7 of the 37 Agreement States[6] have licensees with GLDs containing Category 3 sources in their jurisdiction. In contrast, 5 of the 13 States in NRC jurisdiction have licensees with GLDs containing Category 3 sources. The following table details the Agreement States with licensees possessing GLDs containing Category 3 sources.

Table 4. **GLDs in Agreement State Jurisdiction[7]**

State	Number of GLDs with Category 3 Sources
California	2
Illinois	4
New Jersey	1
New Mexico	4
Ohio	11
Oklahoma	6
Texas	2
Total	**30**

Source: OIG

[6] Due to their tracking methods, two additional States were unable to readily provide the number, if any, of Category 1, 2, or 3 sources in GLDs in their jurisdictional areas.

[7] In addition to the GLDs with Category 3 sources, a licensee in California is in possession of a GLD with a Category 2 source.

Fixed Gauge Regulation

NRC regulations[8] for fixed gauges require that the applicant (the manufacturer requesting to produce a GLD) submit sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that the following design criteria are met:

A. The device is designed and built to be used safely by someone without training in radiological protection.

B. Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive an annual dose greater than 500 millirem (mrem)[9] to the whole body.

C. Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external or internal radiation dose greater than 15,000 mrem to the whole body.

These device safety regulations point to an apparent inconsistency in allowable exposures for GLD users. The following table compares dose limits for members of the public, GLD users, and radiation workers.

[8] 10 CFR 32.51, *Byproduct material contained in devices for use under 10 CFR 31.5 requirements for license to manufacture or initially transfer.*

[9] A rem is a unit used to measure the amount of energy (from any type of ionizing radiation) that is deposited in human tissue, along with the medical effects of the given type of radiation. One millirem is one thousandth of a rem.

Table 5. **Comparison of Dose Limits or Maximum Exposures for Members of the Public, GLD Users, and Radiation Workers**

Regulation For	Annual Dose Limit (Whole Body) or Maximum Exposure	NRC Regulation
Public	100 mrem	10 CFR 20.1301(a)
Untrained individuals using a GLD under ordinary conditions (members of the public)	500 mrem	10 CFR 32.51(a)(2)(ii)
Untrained individuals using a GLD under accident conditions (members of the public)	15,000 mrem	10 CFR 32.51(a)(2)(iii)
Radiation worker (occupational)	5,000 mrem	10 CFR 20.1201(a)

Source: OIG analysis of NRC regulations

The discrepancy between dose limits for the public and those for untrained individuals using GLDs occurred when NRC's dose criteria for the safety of GLDs were not updated to reflect guidelines published by the International Commission on Radiological Protection. Although NRC revised 10 CFR 20 (*Standards for Protection Against Radiation*) in 1991, the agency did not also update 10 CFR 32 (*Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material*) to match. Therefore, manufacturers are currently allowed to design gauges that could expose general licensees (members of the public), using their devices under ordinary conditions of handling, storage, and use, to radiation doses up to 500 mrem per year (whole body) with no training in radiological protection. If a specific licensee's workers are expected to exceed 100 mrem (whole body) in a year, they are required under 10 CFR 19.12, *Instructions to Workers*, to receive training in radiological protection. However, because

general licensees under 10 CFR 31.5, *Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere,* are exempt from Parts 19 and 20, they are not required to receive this training or wear radiation exposure monitoring apparatus under a radiation protection program. NRC considers GLD users to be members of the public.

Shutters on Fixed Gauges Fail

The shutter on a fixed gauge is a safety feature designed to eliminate or significantly reduce the radiation levels at the opening of a fixed gauge when the device is not in use and the shutter is in the closed position. Fixed gauges routinely operate in a continuous mode with the shutter open; this increases the chances of corrosion or the buildup of debris to affect the ability of the shutter to close. Shutter failures are not uncommon. NRC tracks events through its Nuclear Material Events Database (NMED)[10] to monitor nuclear material trends across the country, and to identify issues that require followup. For example, recent NMED reports for fiscal year 2011 (October 2010 through September 2011) identified 50 events involving stuck shutters, failures of shutter mechanisms, and related shutter problems in fixed gauges. Additionally, Agreement State representatives confirmed that stuck shutters on fixed gauges is an ongoing problem. The inability to close the shutter, due to the presence of corrosion or foreign materials, breakage of the closure mechanism, or some other cause, is considered by NRC to be a failure of equipment to operate as designed.

No Threshold Limiting Byproduct Material Activity in Fixed Gauges

NRC regulations do not specify a threshold limiting the activity of byproduct material allowed in general licensed fixed gauges. However, NRC regulations do specify limiting thresholds for certain devices and equipment that are also general licensed (see Table 6).

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

Table 6. **Limiting Thresholds by Device Type**

Type of Device or Equipment	Limiting Threshold	NRC Regulation
Static elimination device	Not more than 500 microcuries of polonium-210	10 CFR 31.3
Ion generating tube	Not more than 500 microcuries of polonium-210 or not more than 50 millicuries of hydrogen-3 (tritium)	10 CFR 31.3
Luminous safety devices for use in aircraft	Not more than 10 curies of tritium or 300 millicuries of promethium-147	10 CFR 31.7
Ice detection devices	Not more than 50 microcuries of strontium-90	10 CFR 31.10

Source: 10 CFR 31

Limiting thresholds also exist for certain calibration or reference sources, in vitro clinical or laboratory tests, and certain self-luminous products containing radium-226.

Commission Involvement

NRC's Commission has frequently considered issues related to NRC's general licensing program. Most recently, in 2010 NRC staff presented a final rule to the Commission that would establish a threshold limiting the activity of byproduct material allowed in general licensed devices.[11] The Commission disapproved publication of the final rule, citing various concerns such as an undue economic burden on the affected entities and the adequacy of current requirements. During interviews with

[11] The rule was to limit the quantity of byproduct material in GLDs to not exceed 1/10th of IAEA Category 3 threshold values.

OIG, several Commission members stated that they had not been presented with safety concerns regarding the GLD rulemaking, only security issues related to the aggregation of sources.

Potential for Radiation Exposure Exceeding Regulatory Limits

A person exposed to radiation from an unshielded fixed gauge can receive a dose that exceeds NRC's regulatory limits. Exposure to radiation can occur to non-radiation workers during routine operations or in accident conditions. Furthermore, members of the public who encounter fixed gauges after they have been lost, stolen, or improperly disposed can also be exposed.

Figure 3. **Fixed Gauge To Measure Paper Density**

Source: Thermo Scientific Web site

Device Failures and Incidents

Devices do not always operate as designed. Because of this, NRC recently issued Information Notices[12] to alert fixed gauge licensees about the potential for the failure of shutter closure mechanisms due to fixed gauges operating in harsh working environments. One Information Notice states that "the concern with shutters that are stuck in the open position is that when the process or line is stopped workers performing maintenance or other work in the area could receive exposures." The Information Notice also states that "for workers considered non-radiation workers [members of the public], under certain

[12] NRC *Information Notice 2011-09, Fixed Gauge Shutter Failures Due to Operating in Harsh Working Environments*, dated May 18, 2011, and NRC *Information Notice 2009-18, Performance of Required Shutter Checks and Reporting of Gauge Shutter Failures*, dated September 18, 2009.

circumstances it would not take long to exceed the applicable regulatory limits for radiation exposure." Several examples of safety related incidents occurring with fixed gauges are noted below. The incidents include both device failures and human errors involving general licensed and specific licensed devices.

Device Failures

- In 2011, the shutter on a fixed gauge containing 8 curies of cesium-137 (IAEA Category 3) failed, exposing a total of 10 workers (members of the public) to radiation. During the weekend, the workers locked out[13] two gauges while performing maintenance on equipment. The following Monday morning it was discovered that the shutter on one gauge had failed, leaving the source unshielded. Of the 10 workers exposed in the event, officials believe that 4 received a dose in excess of 1 rem each while others received lesser doses. The gauge in this event is the same model as two GLDs in NRC jurisdiction containing Category 3 sources.

- In 2012, the shutter on a fixed gauge containing 5 curies of cesium-137 (IAEA Category 3) became stuck in the open position because of rust buildup from high humidity in the facility. Although the device manufacturer recommended a cover to protect the device in such conditions, the cover had not been available at the time of installation. The gauge in this event is the same model as one GLD in NRC jurisdiction containing a Category 3 source.

Human Error

Additionally, GLD users may fail to observe procedures or may be unaware that specific procedures even exist. Also, because GLD users are non-radiation workers (members of the public), they may not realize the dangers associated with radioactive materials. Devices may be abandoned when a property is sold

[13] Typical lock-out procedures include locking the shutter into the "off" position and tagging the shutter control mechanism to indicate the gauge is locked out.

or may be improperly disposed. During a 10-year period across the United States, 42 Category 2 sources and 27 Category 3 sources were lost.[14]

- In 2008, non-radiation workers were exposed to radiation from two installed gauges, one containing 5 curies of cesium-137 (IAEA Category 3), over 3 days. Of the four exposed contract workers (reported by the licensee as members of the public), two received doses greater than the regulatory limit of 100 mrem per year. Failure of staff to follow proper lock-out procedures, which would have established safe boundaries for the contractors, was identified as the cause for the exposure. The gauge in this event is the same model as one GLD in NRC jurisdiction containing a Category 3 source.

- In 2010, four general licensed fixed gauges containing cesium-137 were located at a facility that had changed hands multiple times. The current owner was unaware of the presence of the gauges or that the company possessed radiological material. One of the four gauges was found to have a shutter stuck open. The gauge in this event is the same model as eight GLDs in NRC jurisdiction containing Category 3 sources.

- In 2010, a general licensed fixed gauge containing cesium-137 was discovered in a load of scrap metal. The licensee had properly transferred three of four general licensed gauges in the 1990s, but a fourth gauge was reported as "whereabouts unknown" on a 2001 registration questionnaire. After being discovered in the scrap metal shipment, the fourth device was disposed of properly.

[14] The 10-year period is for the timeframe 2002 through 2011. Two Category 2 and three Category 3 sources have yet to be recovered.

Dose Can Exceed NRC's Regulatory Limits

Figure 4. **Fixed Density Gauge**

Source: Vega Australia Web site

When a fixed gauge containing a dangerous source fails, exceeding the applicable regulatory limits for radiation exposure can occur in a relatively short period of time. A fixed gauge is continually emitting an invisible beam of radiation when its shutter is stuck in the open position. GLDs are typically positioned so it is difficult for workers (members of the public) to be in the beam of radiation. However, workers at a facility where fixed gauges are in use must perform periodic maintenance on the facility's other equipment. When this occurs, workers are required to follow typical lock-out procedures prior to performing the maintenance. If a gauge shutter is stuck open, depending on the workers' positions, they may be unknowingly exposed to radiation.

Although typically shielded, radioactive sources used in fixed gauges can be dangerous if the shielding fails or the source becomes exposed. A radioactive source commonly used in fixed gauges is cesium-137. If a person was 1 foot away and exposed to the radiation from an 8 curie cesium-137 source, they would be subjected to a dose rate of around 25 rem per hour. Moving to 1 inch away from the source increases the dose rate to more than 3,500 rem per hour. Therefore, a person could receive a lethal dose[15] from exposure to an 8 curie cesium-137 source.

[15] The dose of radiation expected to cause death to 50 percent of an exposed population within 30 days. Typically, a lethal dose is in the range from 400 to 450 rem received over a very short period.

Reporting Reliability

While licensees report some events, it is not known how many members of the public may have been harmed in some way from GLDs. Although general licensees are required to report incidents that occur involving their GLDs, they may not know when such incidents occur or be aware of applicable reporting requirements. The general licensees may not know of incidents because the users do not typically have monitoring devices to alert them of danger or track the amount of radiation they receive. During an interview with OIG, a Commissioner stated that there is a lack of data on exposures to support effective decisionmaking on the issue, precisely because general licensees and their employees are not required to wear dosimetry or conduct surveys. An Agreement State investigation in 2008 found that many events involving fixed gauges had occurred, but were not reported as required. Therefore, it is reasonable to conclude that general licensees may be unknowingly exposed to harmful amounts of radiation and NRC is unaware of the actual number of overexposures that occur.

Recommendations

OIG recommends that the Executive Director for Operations:

1. Contact current general licensees with general licensed devices containing IAEA Code of Conduct Category 1, 2, or 3 sources, within 180 days, to encourage the general licensee to transfer the device(s) to a specific license(s).

2. Visit all general licensees currently in possession of general licensed devices containing IAEA Category 1, 2, or 3 sources within 2 years. Focus such visits on:

    - Reviewing records of leak testing and proper operations of open-close mechanisms and indicators.

- Device use, installations, maintenance and repair to determine that the devices are being used within authorized parameters.

3. Monitor agency records for 2 years to identify new general licensees entering the marketplace and visit those in possession of IAEA Category 1, 2, or 3 general licensed devices to ensure that devices are properly installed and that general licensees have adequate understanding of relevant regulations and their responsibilities.

4. Analyze information retrieved from recommendations 1, 2, and 3 and take additional regulatory action, if needed, within 6 months after completion of data collection.

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IV. AGENCY COMMENTS

An exit conference was held with the agency on June 7, 2012. At this meeting, agency management provided supplemental information that has been incorporated into this report as appropriate. As a result, agency management stated their general agreement with the findings and recommendations in this report and opted not to provide formal comments for inclusion in this report.

Appendix

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to determine if NRC issues general licenses for only inherently safe nuclear materials.

Scope

This audit focused on determining if GLDs can contain dangerous radioactive sources. This report focused primarily on the safety of fixed gauges. We conducted this performance audit at NRC headquarters (Rockville, Maryland) from February 2012 through April 2012. Internal controls related to the audit objective 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 IAEA *Code of Conduct on the Safety and Security of Radioactive Sources*; 10 CFR Part 31, *General Domestic Licenses for Byproduct Material*; and 10 CFR Part 32, *Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material*. The team reviewed NRC Information Notices, Commission Papers, and Staff Requirements Memoranda.

The audit team reviewed NMED to identify events associated with fixed gauges. The team reviewed the General License Tracking System to identify the number of active GLDs that contain IAEA Code of Conduct Category 1, 2, and 3 sources.

At NRC headquarters, in Rockville, Maryland, 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 issuance of general licenses. Auditors also interviewed

the NRC Chairman and each NRC Commissioner to gain their perspectives on the licensing of GLDs. Auditors conducted telephone interviews with representatives from each of the 37 Agreement States to determine if the Agreement States issue general licenses for devices containing Category 1, 2, or 3 sources.

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 objective. We believe that the evidence obtained provides a reasonable basis for our finding and conclusions based on our audit objective.

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