AUDIT REPORT

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Audit of NRC's Oversight of Irradiator Security

OIG-10-A-17 September 2, 2010

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

OFFICE OF THE
INSPECTOR GENERAL

September 2, 2010

MEMORANDUM TO: R. William Borchardt
Executive Director for Operations

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

SUBJECT: AUDIT OF NRC'S OVERSIGHT OF IRRADIATOR SECURITY (OIG-10-A-17)

Attached is the Office of the Inspector General's (OIG) audit report titled, *Audit of NRC's Oversight of Irradiator Security.*

The report presents the results of the subject audit. Agency comments provided at the August 2, 2010, exit conference have been incorporated, as appropriate, into this report.

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 Beth Serepca, Team Leader, Security and Information Management Audit Team, at 415-5911.

Attachment: As stated

EXECUTIVE SUMMARY

BACKGROUND

Irradiators are devices that expose products, such as food and medical supplies, to radiation for sterilization and other purposes. Radiation is achieved by the exposure to high-risk radioactive materials, such as Cobalt-60 and Cesium-137. Commercial firms, as well as State-run organizations such as hospitals and universities, operate irradiators and are licensed to possess the radioactive materials used in these devices.

The U.S. Nuclear Regulatory Commission (NRC) and NRC "Agreement States" regulate the safe and secure use of these irradiators and other radioactive materials. NRC's Office of Federal and State Materials and Environmental Management Programs develops and implements rules and guidance for the safe and secure use of source, byproduct, and special nuclear material in industrial, medical, academic, and commercial activities, including irradiators.

In the changed threat environment since the terrorist attacks of September 11, 2001, NRC determined that certain licensed material should be subject to enhanced security requirements and issued several orders to address the security of radioactive materials.

PURPOSE

The purpose of this audit was to determine the adequacy of NRC's oversight of industrial irradiator security. Due to the scope of the security orders and NRC's efforts to combine these security orders into one section of the Code of Federal Regulations, the audit findings and recommendations expand beyond irradiators to address the radioactive materials security program as a whole. See Appendix A for information on the audit scope and methodology.

RESULTS IN BRIEF

While NRC has worked to increase security of irradiators and other radiological materials of concern, enhancements in the materials security program are needed to better ensure the security of these materials.

Specifically, NRC needs to (1) establish security inspection frequencies based on a risk-informed approach, (2) enhance access authorization controls of individuals with unescorted access to materials of concern, and (3) fully develop the security training program for materials inspectors.

Security Inspection Frequency

The frequency of materials security inspections should be based on a risk-informed process that takes into account the security risk associated with the material. Currently, security inspections are based on a licensee's safety inspection schedule rather than the risk that the material will be stolen or exploited for malevolent purposes. The frequency of the security inspections is not risk-informed because the frequencies established in Inspection Manual Chapter 2800 do not consider current security risks. Without a risk-informed approach to the security inspection program, radioactive materials could be at an increased vulnerability to theft or sabotage.

Access Authorization Controls

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Security Training Program

NRC materials inspectors should be provided the tools and training necessary to make risk-informed decisions to address security, health and safety, and environmental aspects of licensee compliance. While these inspectors receive initial training on the security requirements for material licensees, they do not receive any refresher training to address the security aspects of their jobs. Although NRC has acknowledged the need

to incorporate security training into the inspector qualification program, the development of a security refresher course has not been a priority. Without formalized refresher training, NRC might not be able to ensure licensees are adequately protecting materials of concern.

RECOMMENDATIONS

This report makes recommendations to improve the agency's radioactive materials security program. A consolidated list of these recommendations appears in Section IV of this report.

AGENCY COMMENTS

At an exit conference on August 2, 2010, agency management stated their general agreement with the findings and recommendations in this report. Agency management also provided supplemental information that has been incorporated into this report as appropriate. As a result, the agency opted not to provide formal comments for inclusion in this report.

ABBREVIATIONS AND ACRONYMS

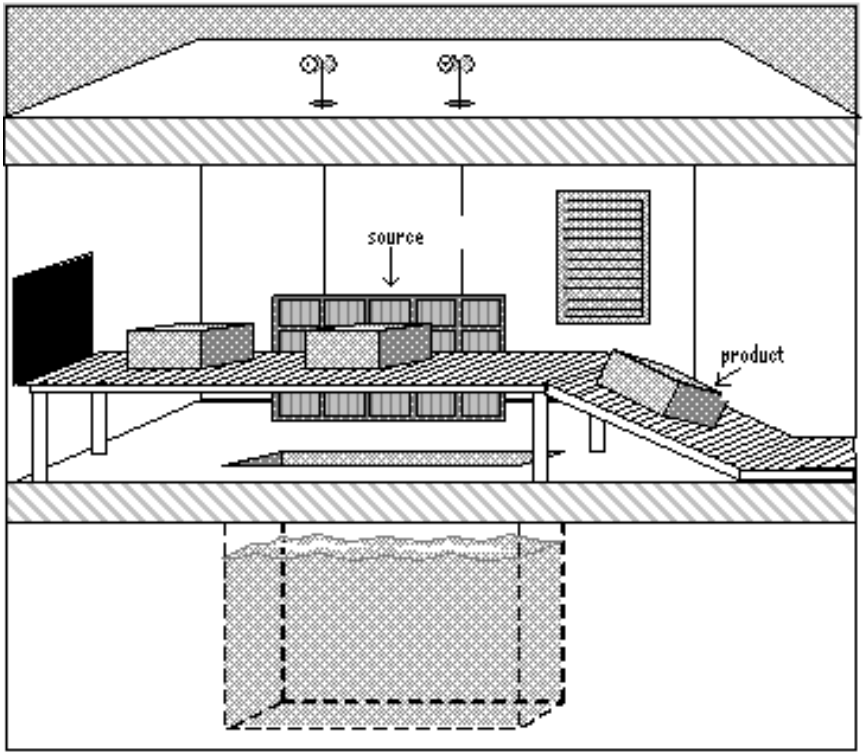
FSME	Office of Federal and State Materials and Environmental Management Programs
IAEA	International Atomic Energy Agency
NRC	U.S. Nuclear Regulatory Commission
OIG	Office of the Inspector General

TABLE OF CONTENTS

I. BACKGROUND

Irradiators are devices that expose products, such as food and medical supplies, to radiation for sterilization and other purposes. Radiation is achieved by the exposure to high-risk radioactive materials, such as Cobalt-60 and Cesium-137. Commercial firms, as well as State-run organizations such as hospitals and universities, operate irradiators and are licensed to possess the radioactive materials used in these devices.

Figure 1: Illustration of Large Irradiator



Source: NRC Public Web Site.

Figure 2:
Small Irradiator

The U.S. Nuclear Regulatory Commission (NRC) and NRC "Agreement States"[1] regulate the safe and secure use of these irradiators and other radioactive materials. NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) develops and implements rules and guidance for the safe and secure use of source, byproduct, and special nuclear material in industrial, medical, academic, and commercial activities, including irradiators. Inspections to ensure compliance with these regulations are conducted by approximately 46 NRC materials inspectors and numerous inspectors within the 37 Agreement States. Nationwide, there are approximately 50 licensees that operate about 50 large irradiators that contain more than 10,000 curies of Cobalt-60. (See Figure 1 for an illustration of a large irradiator.) Additionally, there are approximately 590 licensees that operate about 1,100 smaller type irradiators that use lesser quantities of radioactive materials. (See Figure 2 for a picture of a smaller type irradiator.)

Materials Inspection Program

NRC materials inspectors based in NRC's regional offices[2] are responsible for ensuring licensee compliance with regulatory safety and security requirements. NRC Inspection Manual Chapter 2800, "Materials Inspection Program," outlines NRC's materials inspection program policy. This manual chapter establishes frequencies for routine inspections of all licensees, details when poor performance requires increased inspection oversight, and addresses other areas of materials oversight. NRC Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area," defines training and qualification requirements for personnel working within the nuclear materials inspection program.

[1] An Agreement State is a State that has assumed regulatory responsibility over certain byproduct, source, and small quantities of special nuclear material through an agreement with NRC. As of June 2010, 37 States had signed formal agreements with NRC.

[2] These NRC inspectors are located at NRC Regions I, III, and IV. Region II facilities are inspected by Region I personnel.

History of NRC's Materials Security Oversight

NRC regulations provide requirements for the safe use, transport, and control of licensed radioactive material. A licensee's loss of control over high-risk radioactive material, whether inadvertent or through a deliberate act, has the potential to result in significant harm to public health and safety, the environment, and cause significant economic loss.

In the changed threat environment since the terrorist attacks of September 11, 2001, NRC determined that certain licensed material should be subject to enhanced security requirements.[3] In developing the enhanced security measures, NRC performed vulnerability assessments to identify gaps or vulnerabilities in security, and the effectiveness and cost of certain physical protection enhancements at various licensed facilities. The vulnerability assessment results were used to develop security orders that were issued to licensees based on the relative risk and quantity of material possessed by the licensee.

These security orders specifically address the security of radioactive material possessed in quantities greater than or equal to Category 1 and Category 2 quantities (referred to as "materials of concern" throughout this report).[4] Both large and small irradiators contain radioactive materials within the Category 1 and Category 2 quantity thresholds. In June 2003, NRC issued Safeguards Order EA-02-249 to large irradiator licensees that possessed more than 10,000 curies of radioactive material. In November 2005, NRC issued Increased Control Order EA-05-090 to smaller irradiator licensees and other licensees authorized to possess Category 1 and Category 2 quantities of radioactive material.

The Energy Policy Act of 2005 authorized NRC to require all individuals who are permitted unescorted access to "significant" radioactive material to be fingerprinted and undergo a Federal Bureau of Investigation criminal

[3] NRC adopted the International Atomic Energy Agency (IAEA) "Code of Conduct on the Safety and Security of Radioactive Sources" (Code of Conduct) categorization system for radioactive materials. Specifically, the IAEA characterizes Category 1 and Category 2 as quantities of radiological materials that are deemed to be attractive targets for malevolent use and pose the greatest risk to people and the environment if not safely managed or securely protected. (See Appendix B for information on these materials and associated thresholds).

[4] As of May 2010, there were approximately 1,400 licensees in these two categories.

history records check. NRC determined that Category 1 and Category 2 quantities of radioactive material are "significant," and by December 2007, had issued responsive orders to all licensees possessing Category 1 or Category 2 quantities of radioactive material.

In May 2010, NRC proposed adding a new Part 37 to NRC's regulations in Title 10 of the U.S. Code of Federal Regulations to impose security requirements for the use of Category 1 and Category 2 quantities of radioactive material. The proposed requirements would codify and expand upon the previously issued security orders.

II. PURPOSE

The purpose of this audit was to determine the adequacy of NRC's oversight of industrial irradiator security. Due to the scope of the security orders and NRC's efforts to combine these security orders into one section of the Code of Federal Regulations, the audit findings and recommendations expand beyond irradiators to address the radioactive materials security program as a whole. See Appendix A for information on the audit scope and methodology.

III. FINDINGS

While NRC has worked to increase security of irradiators and other radiological materials of concern, enhancements in the materials security program are needed to better ensure the security of these materials. Specifically, NRC needs to (1) establish security inspection frequencies based on a risk-informed approach, (2) enhance access authorization controls of individuals with unescorted access to materials of concern, and (3) fully develop the security training program for materials inspectors.

A. Reevaluation of Security Inspection Frequency Is Needed

The frequency of materials security inspections should be based on a risk-informed process that takes into account the security risk associated with the material. Currently, security inspections are based on a licensee's safety inspection schedule rather than the risk that the material will be stolen or exploited for malevolent purposes. The frequency of the security inspections is not risk-informed because the frequencies established in Inspection Manual Chapter 2800 do not consider current security risks. Without a risk-informed approach to the security inspection program, radioactive materials could be at an increased vulnerability to theft or sabotage.

Risk-Informed Process

The frequency of materials security inspections should be based on a risk-informed process that takes into account the security risk associated with the material. In 1999, the Commission defined its expectations for risk-informed and performance-based regulation. This process is an approach in which risk insights, engineering analysis, and performance history are used to guide the inspection program. NRC defines risk by asking three questions: (1) What can go wrong? (2) How likely is it to happen? and (3) What are the consequences?

Frequency of Security Inspections Based on Safety Inspection Schedule

Currently, NRC bases security inspections on a licensee's safety inspection schedule rather than the risk that the material will be stolen or exploited for malevolent purposes. When Safeguards Order EA-02-249 was issued in June 2003, initial security inspections were completed within a year; however, there was no established frequency as to how often subsequent inspections should be conducted to verify licensee compliance with this order. After many discussions to try to determine the frequency, FSME, the program owner, decided to use the established frequency for safety inspections as previously outlined in Inspection Manual Chapter 2800.[5] Specifically, "priority codes" are assigned to a particular radioactive material license (e.g., panoramic/large irradiator, self-shielded/small irradiator) based on safety risk. The priority code (i.e., 1, 2, 3, or 5) is the interval, expressed in years, between routine inspections. The priority represents the relative risk of radiation hazard for the type of use. Priority Code 1 presents the greatest risk to the health and safety of workers, members of the public, and the environment. Priority Code 5 presents the least potential risk.

Established Frequency Does Not Include Current Security Risk

The current security inspection frequency is not based on a risk-informed approach because the frequencies established by Inspection Manual Chapter 2800 do not consider current security risks. According to FSME management, NRC used risks to safety, security, and the environment when establishing the priority codes; however, FSME established the codes prior to 2001 when security threats were viewed differently compared to today.

Prior to September 11, 2001, NRC license requirements focused on worker and public safety and preventing inadvertent or accidental exposure to radioactive materials. According to NRC, these requirements also indirectly provided materials security. Specifically, by protecting workers and the public from inappropriate exposure through safety

[5] In November 2005, Increased Control Order EA-05-090 was issued with guidance to conduct inspections at the frequency established in Manual Chapter 2800.

requirements, licensees implemented controls that also provided additional security protection to materials. However, as noted in the Background section of this report, the events of September 11 prompted NRC to reevaluate its requirements and the protections needed to prevent a terrorist from obtaining materials of concern. While NRC subsequently issued a number of security orders to impose additional controls, the agency did not update its inspection frequency requirements to incorporate increased security risks to materials.

Furthermore, in 2007, NRC chartered an independent external review panel to identify vulnerabilities in the NRC's materials licensing program and to validate the agency's ongoing radioactive materials security efforts. The panel's March 2008 report stated that fully integrating security with health, safety, and environmental protection when regulating radioactive material would require a culture change at NRC and in the Agreement States. The report further stated that:

> Security starts with identifying an appropriate level of protection based on the type, form, and quantity of radioactive material. The processes currently used to make risk-informed decisions for health, safety, and environmental protection are identical to those used to determine risk as it applies to security. The strategies for responding to security threats are different from the strategies for responding the [*sic*] health, safety, and environmental concerns in that they must consider malevolent action.

FSME plans to conduct a pilot inspection program for security inspections to help determine the appropriate inspection frequency. However, this pilot program is in its infancy and FSME has yet to define how it will evaluate the inspection frequency and the methodology for this review. The FSME Office Director supports an initiative to reevaluate the materials inspection program taking a risk-informed approach that integrates both safety and security.

Without a risk-informed approach to the security inspection program, radioactive materials could be at an increased vulnerability to theft or sabotage. NRC conducts inspections to ensure licensees are following

the security requirements, and by taking a risk-informed approach to security inspections, NRC can enhance the protection for materials of concern.

Recommendation

The Office of the Inspector General (OIG) recommends that the Executive Director for Operations:

1. Reevaluate and determine the frequency of security inspections based on a risk-informed approach.

B. Process To Regularly Check Individuals With Unescorted Access to Materials of Concern Is Needed

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Recommendation

OIG recommends that the Executive Director for Operations:

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C. Formal Materials Security Refresher Training Program Is Needed

NRC materials inspectors should be provided the tools and training necessary to make risk-informed decisions to address security, health and safety, and environmental aspects of licensee compliance. While these inspectors receive initial training on the security requirements for material licensees, they do not receive any refresher training to address the security aspects of their jobs. Although NRC has acknowledged the need to incorporate security training into the inspector qualification program, the development of a security refresher course has not been a priority. Without formalized refresher training, NRC might not be able to ensure licensees are adequately protecting materials of concern.

Security Training Requirements

NRC materials inspectors should be provided the tools and training necessary to make risk-informed decisions to address security, health and safety, and environmental aspects of licensee compliance. Specifically, initial and refresher security training should be provided to all personnel involved in the security oversight of materials licensees.

No Formal Security Refresher Training

While materials inspectors receive initial training on the materials security requirements, they do not receive formal refresher training to address the security aspects of their jobs. When NRC issued Safeguards Order EA-02-249 to large irradiator licensees, the Commission designed and implemented a training course at Sandia National Labs to provide instruction on a methodology to evaluate physical protection systems associated with the security order. Subsequently, when NRC issued Increased Control Order EA-05-090 to the small irradiator licensees, the training course was modified to focus on the security controls of this order as well. Although Inspection Manual Chapter 1246 does not discuss specific security training requirements, NRC materials inspectors generally take this initial security training course at Sandia National Labs prior to conducting security inspections. However, in the 7 years since NRC introduced the security orders, it has neither provided nor required additional formal security training courses for the materials inspectors.

Since there is not a formal refresher training course, some regions and Agreement States have developed their own methods of communicating information and lessons learned on security aspects. These courses help ensure consistency within the region or the State; however, without FSME involvement, there are no assurances that these self-developed refresher courses meet the intent of the program office.

The regional inspectors conducting materials security inspections have health physics backgrounds, and in-depth security reviews only became part of their job function after the introduction of the security orders. Inspectors interviewed expressed the need for refresher training. OIG interviewed 22 regional-based employees involved with the materials security program. Of these 22 employees, 16 expressed the need to have security refresher training. For example, one inspector stated that refresher training would be helpful since security inspections are not done all the time and it is important to be fresh on the inspection procedures before conducting inspections. Another inspector expressed a desire for refresher training to help ensure consistency between regions and to allow lessons learned to be shared across the materials inspector community.

Development of Security Refresher Training Is Not a Priority

While NRC has acknowledged the need to incorporate security training into the inspector qualification program, the development of a security refresher course has not been a priority. However, FSME has recently established a working group to revise Inspection Manual Chapter 1246. As part of this review, the group will look to make necessary changes to the training program to provide inspection personnel with the tools and training necessary to make risk-informed decisions that address security aspects, as well as health and safety aspects, and to foster a security culture. The group began meeting in April 2010 and the working group charter was approved in July 2010.

Additionally, FSME has worked to provide tools for inspectors and others involved with increased security to discuss concerns and lessons learned. For example, FSME created the Increased Controls Toolbox as a method of sharing updated information and clarification about the Increased Control Order. Individuals can also use this Web portal to ask specific questions to other toolbox members.

Without formalized refresher training, NRC might not be able to ensure licensees are adequately protecting materials of concern. Specifically, inspectors might not be able to conduct adequate security inspections because they may not have a full understanding of the ever-changing security environment and threats. As materials inspectors continue to perform inspections, it is critical that they are knowledgeable in all aspects of security relating to materials of concern, and that NRC implements security refresher training in the near future.

Recommendation

OIG recommends that the Executive Director for Operations:

3. Develop and offer periodic refresher training for all individuals involved in the materials security program.

IV. CONSOLIDATED LIST OF RECOMMENDATIONS

OIG recommends that the Executive Director for Operations:

1. Reevaluate and determine the frequency of security inspections based on a risk-informed approach.

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3. Develop and offer periodic refresher training for all individuals involved in the materials security program.

V. AGENCY COMMENTS

At an exit conference on August 2, 2010, agency management stated their general agreement with the findings and recommendations in this report. Agency management also provided supplemental information that has been incorporated into this report as appropriate. As a result, the agency opted not to provide formal comments for inclusion in this report.

Appendix A

SCOPE AND METHODOLOGY

Auditors evaluated the adequacy of NRC's oversight of industrial irradiator security. However, due to the scope of the security orders and NRC's efforts to combine these security orders into one section of the Code of Federal Regulations, the audit findings and recommendations expand beyond irradiators to address the radioactive materials security program as a whole.

The audit team reviewed relevant criteria, including Safeguards Order EA-08-033, *Compensatory Measures For Panoramic And Underwater Irradiator Licensees*, and Increased Controls Order EA-05-090, *Increased Controls For Licensees That Possess Sources Containing Radioactive Material Quantities Of Concern*. Additionally, auditors reviewed NRC policies, including Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area," and Inspection Manual Chapter 2800, "Materials Inspection Program."

At headquarters in Rockville, MD, auditors interviewed NRC staff and management from FSME and the Office of Nuclear Security and Incident Response to gain an understanding of their roles and responsibilities in the oversight of industrial irradiator security. Auditors also traveled to and interviewed NRC staff and management located in Region I (King of Prussia, PA), Region III (Lisle, IL), and Region IV (Arlington, TX) and Agreement State officials on their roles and involvement in the oversight program.

We conducted this performance audit from January 2010 through June 2010, in accordance with generally accepted Government auditing standards. Those standards require that the audit is planned and performed with the objective of obtaining sufficient, appropriate evidence to provide a reasonable basis for any findings and conclusions based on the stated audit objective. OIG believes that the evidence obtained provides a reasonable basis for the report findings and conclusions based on the audit objective. 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. The work was conducted by Beth Serepca, Team Leader; Rebecca Underhill, Audit Manager; Gail Butler, Management Analyst; Michael Blair, Management Analyst; and Kevin Nietmann, Senior Technical Advisor.

Appendix B

CATEGORY 1 AND CATEGORY 2 QUANTITIES OF CONCERN

The IAEA "Code of Conduct on the Safety and Security of Radioactive Sources" (Code of Conduct) contains a categorization system for radiological sources to allow controls to be applied commensurate with the radiological risks. The Code of Conduct identified 16 radioactive materials that could pose a serious threat to people and the environment and furthermore, identified the different quantities or "thresholds" of materials that could be useful to a terrorist (i.e., Category 1 and Category 2). Table A identifies these materials and the associated thresholds. NRC adopted the IAEA Code of Conduct Category 1 and Category 2 threshold quantities to provide consistency between domestic and international efforts for security of radioactive materials that are deemed to be attractive targets for malevolent use.

Table A. Radionuclides of Concern

Radioactive Material	Category 1 Threshold		Category 2 Threshold	
	Terabecquerels	Curies	Terabecquerels	Curies
Americium-241	60	1,620	0.6	16.2
Americium-241/Beryllium	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Curium-244	50	1,350	0.5	13.5
Cobalt-60	30	810	0.3	8.10
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1000	27,000	10.0	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Beryllium	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2.0	54.0
Strontium-90 (Yttrium-90)	1,000	27,000	10.0	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0