AUDIT REPORT

Audit of NRC's Oversight of Master Materials Licensees

OIG-11-A-14 June 22, 2011

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

OFFICE OF THE
INSPECTOR GENERAL

June 22, 2011

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 MASTER MATERIALS LICENSEES (OIG-11-A-14)

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

The report presents the results of the subject audit. Agency comments provided during a May 2, 2011, exit conference and an additional meeting with staff from the Office of the General Counsel on May 5, 2011, 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 Sherri Miotla, Team Leader, Nuclear Materials & Waste Safety Audit Team, at 415-5914.

Attachment: As stated

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EXECUTIVE SUMMARY

BACKGROUND

The Nuclear Regulatory Commission's (NRC) mission is to regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. NRC regulates medical, industrial, and academic uses of nuclear materials through a combination of regulatory requirements, including licensing, inspection, and enforcement. NRC also issues Master Materials Licenses (MMLs) to Federal agencies.

An MML is a materials license issued to a Federal agency authorizing use of material at multiple sites that fall under the jurisdiction of the Federal agency. The MML allows the Federal agency to conduct some activities as a regulator, such as issuing permits for radioactive materials use at the sites that use materials (referred to as permittees), conducting inspections, handling allegations, following up on incidents and events, and taking enforcement actions. NRC, in turn, provides oversight of MML licensees and permittees through various means.

MMLs incorporate by reference a Letter of Understanding (LOU) that defines the licensee's responsibilities for the radiation control program and NRC's role supporting the MML licensee. The MMLs also incorporate by reference "tie downs," which are documents such as MML licensee procedures for permitting and inspections that become license conditions and are considered part of the license.

As of April 2011, NRC had issued MMLs to three Federal agencies: the Department of the Air Force, the Department of the Navy, and the Department of Veterans Affairs. For each MML, the responsible Federal agency has established a master radiation safety committee and an MML licensee staff organization that reports to the committee. The licensee staff organizations conduct the day-to-day management of the MML licensee's program. The three MML licensee organizations vary based on the numbers and types of permits.

Each MML licensee has a corresponding project manager in an NRC region assigned to monitor the MML licensee's activities. NRC oversight of MML licensees is coordinated by the project managers and is conducted through biennial reviews of the MML licensee program, independent inspections of the MML permittees, accompaniments of MML licensee inspections of the permittees, enforcement, and allegations followup.

PURPOSE

The audit objective was to determine whether NRC's oversight of MML licensees adequately protects public health and safety and the environment.

RESULTS IN BRIEF

Over the past decade, NRC has made some improvements to its oversight of MML licensees to facilitate adequate protection of public health and safety and the environment; however, opportunities exist for NRC to further strengthen its oversight of this unique type of materials licensee. NRC has developed guidance to oversee MML licensees, and the agency has taken steps to improve its implementation of its guidance.

NRC management could strengthen MML licensee oversight by:

- Improving the guidance for NRC staff providing technical assistance and training to MML licensees.
- Improving the guidance for the selection of MML permittees for NRC independent inspection.
- Clarifying MML licensee regulatory oversight roles, responsibilities, and accountabilities.

NRC Could Improve Guidance for NRC Staff Providing Technical Assistance and Training to MML Licensees

MML licensees have difficulty obtaining support they need to successfully implement their programs. The LOUs state that NRC will provide guidance and assistance in areas pertinent to the administration of the

MML license, including technical assistance and training where NRC has special capabilities. NRC management has not provided adequate guidance or a consistent process for supporting MML licensee staff. Without this support, MML licensee staff may lack the knowledge and skills necessary to effectively implement their oversight programs and, consequently, they might not adequately protect public health and safety and the environment.

Guidance on Selection of MML Permittees for Inspection Could Be Improved

NRC selection of MML permittees for independent inspection varies. NRC monitors MML licensees' performance primarily through independent inspections of MML permittees, and NRC principles regarding regulatory transparency and predictability should guide these monitoring actions. Regional variation in selecting MML permittees for inspection is a result of unclear and vague guidance. Without a clear definition of inspection parameters, MML permittee inspections are at risk of becoming a lower priority than deadline-driven activities, which could impair the effectiveness of monitoring MML licensee and permittee performance.

NRC Should Clarify MML Licensee Regulatory Oversight Roles, Responsibilities, and Accountabilities

NRC's regulatory oversight expectations for MML licensees are not enforced. To ensure adequate protection of public health and safety and the environment, NRC expects MML licensees to perform regulatory oversight functions. However, these expectations are not clearly defined or explicitly enumerated in NRC regulations, the MMLs, the LOUs, or licensee "tie downs." As a result, MML licensees and NRC may have different understandings of MML licensee staff and the master radiation safety committee accountabilities and regulatory oversight roles and responsibilities. Consequently, MML licensees may not fully perform these regulatory oversight functions in a manner NRC expects, which could result in inadequate protection of public health, safety, and the environment.

RECOMMENDATIONS

This report makes five recommendations to help NRC improve its oversight of MML licensees. A consolidated list of these recommendations appears in Section IV of this report.

AGENCY COMMENTS

Agency comments provided during a May 2, 2011, exit conference and an additional meeting with staff from the Office of the General Counsel on May 5, 2011, have been incorporated, as appropriate, into this report. The agency declined to provide formal comments.

ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
CFR	Code of Federal Regulations
DNMS	Division of Nuclear Materials Safety
FSME	Office of Federal and State Materials and Environmental Management Programs
FTE	full-time equivalent
IMC	Inspection Manual Chapter
IP	Inspection Procedure
LOU	Letter of Understanding
MML	Master Materials License
NRC	Nuclear Regulatory Commission
OIG	Office of the Inspector General
TAR	technical assistance request
TTC	Technical Training Center

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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, promote the common defense and security, and protect the environment. NRC regulates medical, industrial, and academic uses of nuclear materials through a combination of regulatory requirements, including licensing, inspection, and enforcement. NRC also issues Master Materials Licenses (MMLs) to Federal agencies.

What is a Master Materials License?

An MML is a material (byproduct, source, and/or special nuclear material) license issued to a Federal agency authorizing use of material at multiple sites that fall under the jurisdiction of the Federal agency. The MML allows the Federal agency to conduct some activities as a regulator, such as issuing permits for radioactive materials use at the sites that use materials (referred to as permittees), conducting inspections, handling allegations, following up on incidents and events, and taking enforcement actions. NRC, in turn, provides oversight of MML licensees primarily through biennial reviews and permittees through independent inspections conducted by NRC staff. According to NRC managers, the issuance of MMLs saves NRC resources. For example, MMLs save NRC from having to monitor about 500 individual specific materials licenses. Also, MML licensee staff are closer to the users of the materials and can respond more quickly than NRC. MML licensees each pay an annual fee of $234,000 to NRC.

MMLs incorporate by reference a Letter of Understanding (LOU) that defines the licensee's responsibilities for the radiation control program. The MMLs also incorporate by reference "tie downs," which are documents such as MML licensee procedures for permitting and inspections that become license conditions and are considered part of the

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

license. The LOUs lay out areas of separate and shared responsibility between NRC and the licensee. For example, the MML licensee assumes responsibility for issuing permits for the use of nuclear materials and inspects those permittees. NRC reviews the permitting actions of the licensee, accompanies licensee inspections of a few permittees each year, and independently inspects the permittees. Enforcement is another area of divided responsibility. The MML licensee identifies violations at permittee facilities and must report escalated enforcement to NRC.[2] NRC reviews MML licensee escalated enforcement actions to determine whether the MML licensee made the correct determination as to the violation's severity level. For escalated enforcement, NRC retains sole authority to issue civil penalties.

Three Current MMLs

As of April 2011, NRC had issued MMLs to three Federal agencies: the Department of the Air Force (Air Force), the Department of the Navy (Navy), and the Department of Veterans Affairs (Veterans Affairs). For each MML, the responsible Federal agency has established a master radiation safety committee and an MML licensee staff organization that reports to the committee. The licensee staff organizations conduct the day-to-day management of the MML licensee's program. The MML licensee staff organization issues the permits for nuclear materials use, conducts the inspections of the permittees, and decommissions sites no longer needed for nuclear materials use. Each master radiation safety committee holds its own quarterly meetings to discuss issues related to their respective MML licensee staff organization's activities and the performance of the MML permittees. The current MML licensees and features of their oversight programs are outlined in Table 1.

[2] Under NRC's Enforcement Policy there are three primary enforcement sanctions: orders, civil penalties, and violations. A violation formalizes how a regulatory requirement was violated and normally requires a written response. Violations are assigned a severity level, ranging from Severity Level IV, for those of more than minor concern, to Severity Level I for the most significant. Severity Level I, II, and III violations are considered to be "escalated enforcement actions."

Table 1: MML Licensees as of March 2011

Federal Agency Licensee	Date of MML Issuance	Number of Permits	Master Radiation Safety Committee	MML Licensee Staff Organization(s)	MML Permitted Uses
Air Force	June 1985	269	Radioisotope Committee	Radioisotope Committee Secretariat	Chemical agent monitors and detectors, nuclear medicine, waste disposal, decommissioning, among others
Navy	March 1987	79	Naval Radiation Safety Committee	Radiological Affairs Support Office, and Naval and Marine Corps Public Health Center	Radiography, nuclear medicine, research and development, decommissioning, among others
Veterans Affairs	March 2003	116	National Radiation Safety Committee	National Health Physics Program	Primarily nuclear medicine, also research and development

Source: OIG analysis of NRC and licensee documents.

The three MML licensee organizations vary based on the numbers and types of permits. The Air Force has 269 permits, but more than half are for chemical agent detectors and portable gauges, which are normally considered low risk. Air Force permits also cover some research and development and medical activities. Although the Navy and Veterans Affairs have more comparable numbers of permits, the activities the permits cover differ. The Navy has 15 medical permits and the balance is for various industrial uses. The Navy also has a large number of existing and potential decommissioning sites for which permits will have to be issued. Additionally, the Navy maintains thousands of chemical agent detectors and monitors, but those are not tracked as individual permits. The permits issued under the Veterans Affairs MML are primarily for medical uses, but there are also some permits for research activities.

Structure for MML Oversight

NRC oversight of MML licensees is outlined in NRC Inspection Manual Chapter (IMC) 2810, "Master Material License Inspection Program." Each MML licensee has a corresponding project manager in an NRC region. The project managers are the primary points-of-contact between the MML licensees and NRC. The project managers are located in branches within the Divisions of Nuclear Materials Safety (DNMS) in each region. Working with their responsible branch chief, the project managers coordinate NRC oversight of the MML licensee that their region is assigned to monitor. Table 2 shows the NRC regions and branches responsible for oversight of the MML licensees.

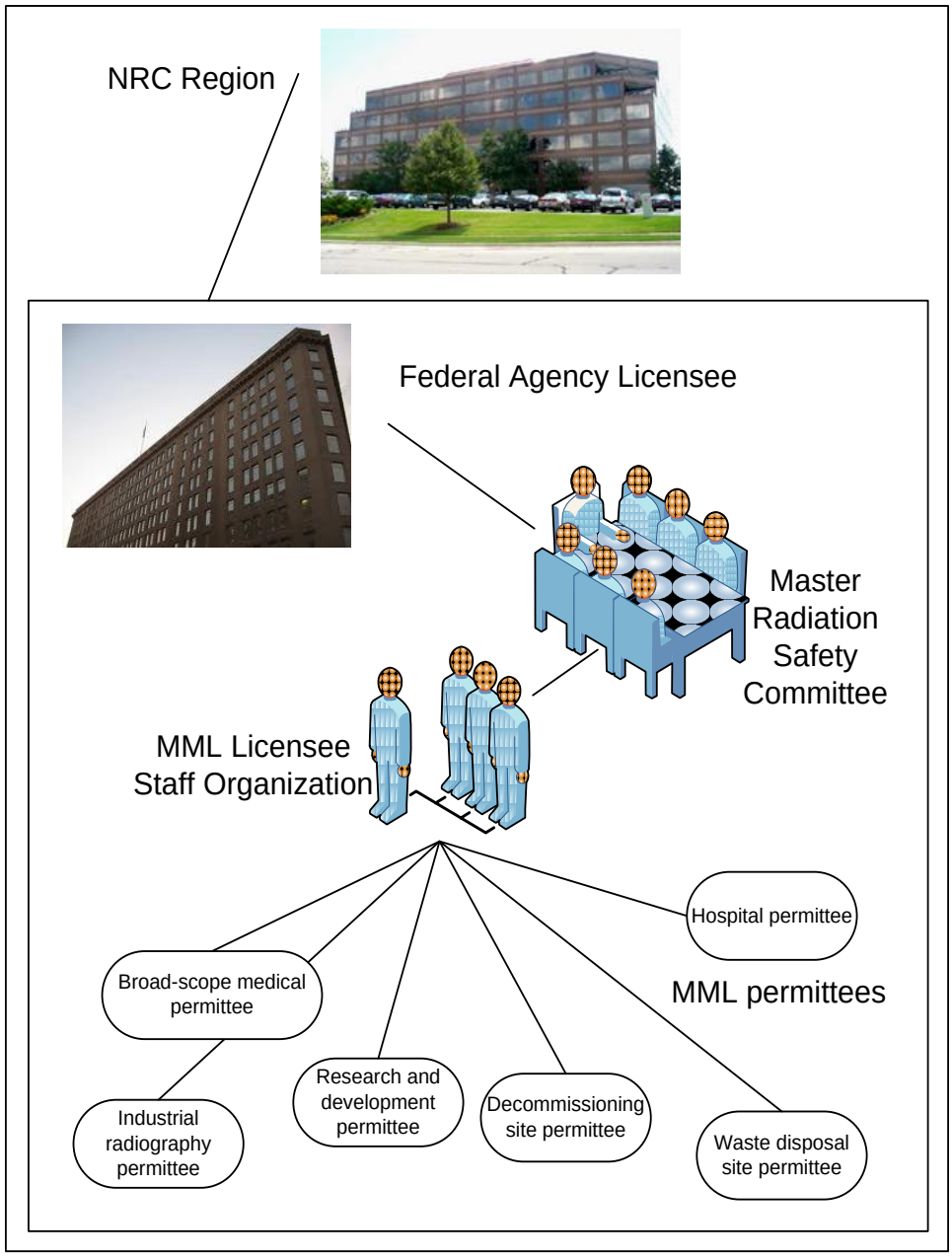
Table 2: NRC Regions, Divisions, and Branches Responsible for MML Oversight

Responsible NRC Region, Division, and Branch	Federal Agency Licensee
Region IV, DNMS, Nuclear Materials Safety Branch B	Air Force
Region I, DNMS, Decommissioning Branch	Navy
Region III, DNMS, Materials Licensing Branch	Veterans Affairs

Source: OIG interviews with NRC staff.

Additionally, there is an MML project manager at headquarters, in the Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environment Management Programs (FSME). The headquarters project manager's activities include communicating with all the regional project managers on a regular basis and distributing information to the MML licensees. NRC has allocated 1.5 full-time equivalents (FTE) for fiscal year 2011 for routine oversight of MML licensees as follows: FSME - 0.2 FTE, Region I - 0.4 FTE, Region III - 0.5 FTE, and Region IV - 0.4 FTE. Figure 1 shows the general oversight relationship of NRC regions to the internal structure of the MML organizations.

Figure 1: Generic NRC Oversight of MML Licensees



Source: OIG analysis of NRC and licensee documents and OIG interviews with NRC and licensee staff.

NRC oversight of MML licensees is conducted through biennial reviews, independent inspections, accompaniment inspections, enforcement, and allegations followup.

- Biennial reviews: Comprehensive NRC team reviews that focus on licensee and permittee compliance with NRC requirements and specific focus elements associated with the MML licensee's management oversight, staffing, training, permitting, inspection, and response to events or allegations.

- Independent inspections: NRC inspections of MML licensees' permittees, including both routine and any reactive inspections performed in response to incidents, events, or allegations. Violations identified by NRC during these independent inspections are issued in accordance with NRC's Enforcement Policy.

- Accompaniment inspections: NRC's observation of an MML licensee inspector conducting an inspection of a permittee to evaluate the performance of the MML inspector and the implementation of the MML licensee's inspection program.

- Enforcement: If an MML licensee identifies a violation at a permittee location that leads to escalated enforcement, the region responsible for that MML will evaluate the MML licensee's enforcement in accordance with NRC's Enforcement Policy and issue violations and levy civil penalties as appropriate.

- Allegations followup: All allegations concerning the MML licensee brought to the attention of the regional NRC project manager and the regional allegations coordinator are processed according to NRC Management Directive 8.8, *Management of Allegations*. The regional allegations review board may refer the allegation back to the MML licensee or recommend independent followup by NRC.

II. PURPOSE

The audit objective was to determine whether NRC's oversight of MML licensees adequately protects public health and safety and the environment.[3] The report appendix contains information on the audit scope and methodology.

III. FINDINGS

Over the past decade, NRC has made some improvements to its oversight of MML licensees to facilitate adequate protection of public health and safety and the environment; however, opportunities exist for NRC to further strengthen its oversight of this unique type of materials licensee. NRC has developed guidance to oversee MML licensees, and the agency has taken steps to improve its implementation of its guidance. For example, NRC — in response to issues associated with the Veterans Affairs MML licensee — established a lessons-learned task group to review NRC licensing and inspection policies, procedures, and practices related to prostate implant brachytherapy and NRC's oversight of the MML. NRC is taking actions to implement recommendations from the task group's final report. The agency has established counterpart meetings and working groups to better communicate with MML licensee staff. NRC has started to offer training in enforcement and allegations for MML licensee staff. Finally, NRC is revising its guidance for MML oversight, such as NUREG 1556, Volume 10, "Program-Specific Guidance About Master Materials Licenses."

NRC management could strengthen MML licensee oversight by:

- Improving the guidance for NRC staff providing technical assistance and training to MML licensees.
- Improving the guidance for the selection of MML permittees for NRC independent inspection.
- Clarifying MML licensee regulatory oversight roles, responsibilities, and accountabilities.

[3] The original objective of this audit, as noted in OIG's fiscal year 2011 *Annual Plan*, was to determine the extent to which NRC is providing effective oversight of MMLs. The objective was revised during fieldwork to tie the audit objective to NRC's mission of protection of public health and safety and the environment.

A. NRC Could Improve Guidance for NRC Staff Providing Technical Assistance and Training to MML Licensees

MML licensees have difficulty obtaining support they need to successfully implement their programs. The LOUs state that NRC will provide guidance and assistance in areas pertinent to the administration of the MML license, including technical assistance and training where NRC has special capabilities. NRC management has not provided adequate guidance or a consistent process for supporting MML licensee staff. Without this support, MML licensee staff may lack the knowledge and skills necessary to effectively implement their oversight programs and, consequently, they might not adequately protect public health and safety and the environment.

NRC Obligations To Support Licensee Execution of MML

An LOU between NRC and an MML licensee is incorporated by reference in the MML and enumerates assurances and obligations of both NRC and the licensee. These letters also describe activities that NRC will undertake to assist the MML licensee in fully executing its regulatory responsibilities under the license to adequately protect public health and safety and the environment. Two important NRC obligations to MML licensees are (1) support the licensee by providing guidance and technical assistance and (2) make training available to licensee staff. Specifically, the LOU incorporated by reference in the Navy's MML states the following in regard to NRC support:

> The NRC will provide guidance and assistance in areas pertinent to the administration of this license, to include technical assistance in those matters where the NRC has special capabilities and technical ability, or where the NRC determines that such assistance is in the best interests of its regulatory program or responsibility.

The Navy LOU also states the following in regard to NRC providing training to MML licensees:

> The NRC and USN [Navy] will mutually arrange for Navy inspectors to attend appropriate NRC training courses….

The Air Force and Veterans Affairs LOUs are similar to the Navy's LOU.

NRC's Current Approach to MML Licensee Support Could Be Improved

MML licensees have difficulty obtaining the support they need to successfully implement their programs in accordance with their licenses. MML licensees often do not receive timely or clear responses to their requests for technical assistance. Additionally, the MML licensees have difficulty getting into NRC-sponsored training courses.

MML Licensees Do Not Receive All the Support They Need From NRC

MML licensee staff rely on NRC staff to provide information on enforcing NRC regulations and for ensuring permittee compliance with regulations, but NRC staff do not always provide timely or clear answers. MML licensee requests pertain to topics such as increased controls[4] requirements, decommissioning,[5] and the applicability of medical event[6] reporting to prostate implant brachytherapy. Staff from all three MML licensees stated that NRC does not always respond to requests for guidance and technical assistance, and when NRC does respond, the response is not always timely or clear. Although the NRC MML regional project managers provide support by answering phone calls or e-mails, responding to questions at meetings, and while accompanying or conducting inspections of permittees, some requests for technical

[4] NRC issued the "Order Imposing Increased Controls" to NRC licensees, including MML licensees, authorized to possess radioactive material in quantities of concern. The radionuclides and associated threshold quantities were based on the Category 1 and Category 2 quantities described in the International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources. The order requires licensees to implement enhanced security to control access to radioactive materials quantities of concern and to protect sensitive security-related information. The order was issued to applicable material licensees under the NRC's public health and safety authority.

[5] Decommissioning is the process of safely closing a facility where nuclear materials are handled to retire it from service after its useful life has ended. This process primarily involves decontaminating the facility to reduce residual radioactivity and then releasing the property for unrestricted or (under certain conditions) restricted use. This often includes dismantling the facility or dedicating it to other purposes.

[6] A "medical event" occurs if one or more of several incidents occur such as the dose administered to a patient differs from the prescribed dose by at least 20 percent, either too high or too low; or the wrong radioactive drug is administered; and the difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in 10 Code of Federal Regulations (CFR) 35.3045.

assistance go unanswered. For example, an MML licensee official explained that when the licensee asks a question, the need for information is immediate, but the responses are delayed or never provided. This official added this is a special cause for concern because NRC expects the licensee to enforce NRC regulations and ensure permittees comply with regulations.

NRC does not have controls in place to ensure that the MML licensee staff receive an official answer from NRC. For example, a particular project manager may be an expert in licensing but unable to provide an answer to an MML licensee staff question about NRC decommissioning requirements. As such, the project manager is not able to immediately respond to the MML licensee staff question. An NRC staff member acknowledged that MML licensees often receive either a quick response to their questions or none at all. An MML official said that it is difficult to get information from NRC and that the biggest issue is getting NRC to answer questions that would help the MML licensee perform its regulatory role. For example, when NRC issued the increased controls order, it established an e-mail address to take questions. An MML official sent an e-mail with 12 questions, but NRC never answered the questions. In another example, NRC staff told MML licensee staff that the licensee could not use permittee-owned radiation survey equipment for inspections. MML licensee staff asked for an explanation and requested that the requirement be put in writing, but NRC did not provide an answer.

While a few of the MML licensee requests may be answered formally through NRC's Technical Assistance Request (TAR)[7] process, MML licensee staff in all three regions expressed timeliness concerns with the TAR process. For example, MML licensee staff in one region made a request that was routed through the TAR process, and the licensee has been waiting well over a year for NRC's response.

MML licensee staff and NRC regional project managers also rely on the headquarters project manager for guidance and technical support. However, the level of support depends on the resources available and the

[7] A TAR response is a formal NRC document that NRC staff develop to address licensee requests for clarification. NRC's goal for completing a TAR response, which includes coordination throughout NRC, is 60 working days after the assigned branch has conducted an initial review.

individual who holds the position at any given time. For example, the current headquarters project manager has taken the initiative to set up meetings to discuss MML oversight and provide information to MML licensees. MML licensee staff members expressed appreciation for the current project manager's initiative to forward Federal Register notices and updated NRC guidance affecting their license and for providing a headquarters perspective of MML licensee performance during biennial reviews. Regional project managers counted on the headquarters project manager to assist during two recent biennial reviews. However, due to resource constraints, the headquarters project manager was only able to attend part of one review and none of the other, which left the NRC team conducting the biennial without headquarters participation. NRC regional managers and staff supporting MML oversight have contended that headquarters support of MML oversight has waxed and waned over the past decade or more and that the previous headquarters project managers did little or nothing to coordinate MML oversight and support. Although the attention and initiative given by the current headquarters MML project manager is encouraging and helpful, there is nothing in place to ensure that such support will continue.

MML Licensee Staff Have Difficulty Obtaining NRC Training

MML licensee staff have experienced trouble getting into NRC-hosted training courses that they need to successfully implement their programs. NRC offers specialized technical training encompassing such topics as health physics, risk assessment, and regulatory skills for NRC, Agreement State,[8] and MML licensee staff. However, MML licensee staff often do not learn of course offerings in time to register. An MML licensee staff member complained that MML licensee staff do not find out about course offerings when Agreement State officials are notified. An NRC Technical Training Center (TTC) staff member agreed that MML licensees are notified of available courses differently and might become aware of courses only after the course is full. When MML licensees are aware of course offerings, they have trouble registering. For example, one region has a three-step process for course registration while another allows MML licensee staff to register directly with TTC staff.

[8] 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.

NRC Management Has Not Provided Adequate Guidance or a Consistent Process for Supporting MML Licensee Staff

MML licensees do not receive all the support they need from NRC because NRC guidance for regional and headquarters project managers is inadequate. While NRC has inspection guidance, there is no agencywide guidance on how MML project managers should support licensees by providing guidance and technical assistance. Two regions have developed region-specific guidance for project managers, but NRC does not have agencywide guidance that would ensure consistent oversight of MMLs by regional and headquarters project managers. Furthermore, there is no guidance addressing the role and responsibilities of the headquarters project manager.

MML licensee staff have difficulty obtaining NRC-hosted training because there is no clear or consistent process for notification of, or registration for, NRC-hosted training. The processes vary among the regions.

MML Licensee Staff May Lack Some Knowledge and Skills Required To Fully Execute Regulatory Responsibilities

When MML licensee staff are required to wait months for NRC to respond to requests for guidance or technical assistance, licensee staff might not be able to fully execute their regulatory responsibilities. Additionally, as long as NRC headquarters relies solely on the personal dedication of the individual serving as the headquarters project manager without the benefit of clearly defined roles and responsibilities, NRC risks losing knowledge and awareness of MML-related activities as headquarters project managers turn over. Also, when MML licensee staff do not obtain training through NRC-hosted courses, they may violate the terms of the LOU and not have the technical expertise to successfully execute their regulatory responsibilities under the MML and adequately protect public health and safety and the environment.

Recommendations

OIG recommends that the Executive Director for Operations:

1. Define regional and headquarters MML project managers' roles in responding to requests for guidance and assistance from MML licensee staff.

2. Develop and implement a consistent and timely process for notifying MML licensee staff of NRC-hosted training courses.

3. Develop and implement a consistent process for registering MML licensee staff for NRC-hosted training courses.

B. Guidance on Selection of MML Permittees for Inspection Could Be Improved

NRC selection of MML permittees for independent inspection varies. NRC monitors MML licensees' performance primarily through independent inspections of MML permittees, and NRC principles regarding regulatory transparency and predictability should guide these monitoring actions. Regional variation in selecting MML permittees for inspection is a result of unclear and vague guidance. Without a clear definition of inspection parameters, MML permittee inspections are at risk of becoming a lower priority than deadline-driven activities, which could impair the effectiveness of monitoring MML licensee and permittee performance.

Principles of Good Regulation Guide MML Oversight Activities

The Commission established guiding principles to promote the transparency and predictability of NRC regulatory activities such as the independent inspections of MML permittees. The principle of openness states that nuclear regulation must be transacted candidly and requires open communication with licensees as well as Congress, other agencies, and the public. The principle of clarity states that regulation must be coherent, with a clear connection to NRC objectives, and readily understood. The principle of reliability states that regulatory actions should be consistent with written regulations and administered in a manner that will lend stability to operations and planning. As NRC monitors MML permittee performance, it should be apparent that the program is clearly communicated, connected to goals, and fairly administered.

An example of guidance for NRC staff that serves these principles is Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program."[9] The primary objective of IMC 2800 is to establish a policy for the NRC materials inspection program that will achieve a consistent process of inspection for all licensees. A key way in which IMC 2800 establishes a consistent and reliable program is through the inclusion of specific intervals for routine inspections based on priority codes tied to the inherent risk of the licensed activity or material. For example, industrial

[9] NRC uses IMC 2800 to guide inspections of all materials licensees, but not for MML permittees. NRC follows IMC 2810 for inspections of MML permittees. MML licensees follow IMC 2800 for MML licensee inspections of their permittees.

radiography at a temporary jobsite is assigned priority code 1, and those activities are inspected every year. Measuring systems with fixed gauges are assigned priority code 5 and are inspected every 5 years. Decommissioning activities are assigned priority code D, and NRC conducts a special inspection as decommissioning activities occur.

Selection of MML Permittees for Independent Inspection Varies

Selection of MML permittees for independent inspections is shaped by wide-ranging interpretations of the guidance for MML licensee oversight, IMC 2810, "Master Material License Inspection Program." In contrast to the consistent and reliable approach contained in IMC 2800, IMC 2810 directs NRC staff to select a "sufficient number" and to choose a "representative sample" of MML permittees in order to adequately monitor MML licensee and permittee performance. NRC's basis for selection of MML permittees for inspection does not serve the NRC Principles of Good Regulation such as clarity and reliability. The number of independent inspections varies from year to year. In addition, NRC does not conduct independent inspections of MML permittees located in foreign countries.

Guidance for NRC Independent Inspections of MML Permittees

IMC 2810 describes activities that MML project managers are required to perform, including implementing a program of independent inspections of MML permittees. To implement the independent inspection program, the MML project manager is required to:

- Annually request a sufficient number of independent inspections to adequately monitor MML licensee and permittee regulatory performance.
- Choose a representative sample of the MML permittees to be inspected, placing less emphasis where permitted activities have less potential for health and safety problems.
- Avoid re-inspecting recently inspected permittees, unless a repeat inspection is warranted because of safety issues.

IMC 2810 is silent on whether and how MML project managers should incorporate decommissioning inspections into their selection of MML permittees for independent inspection.

Reasons for Selection Are Inconsistent

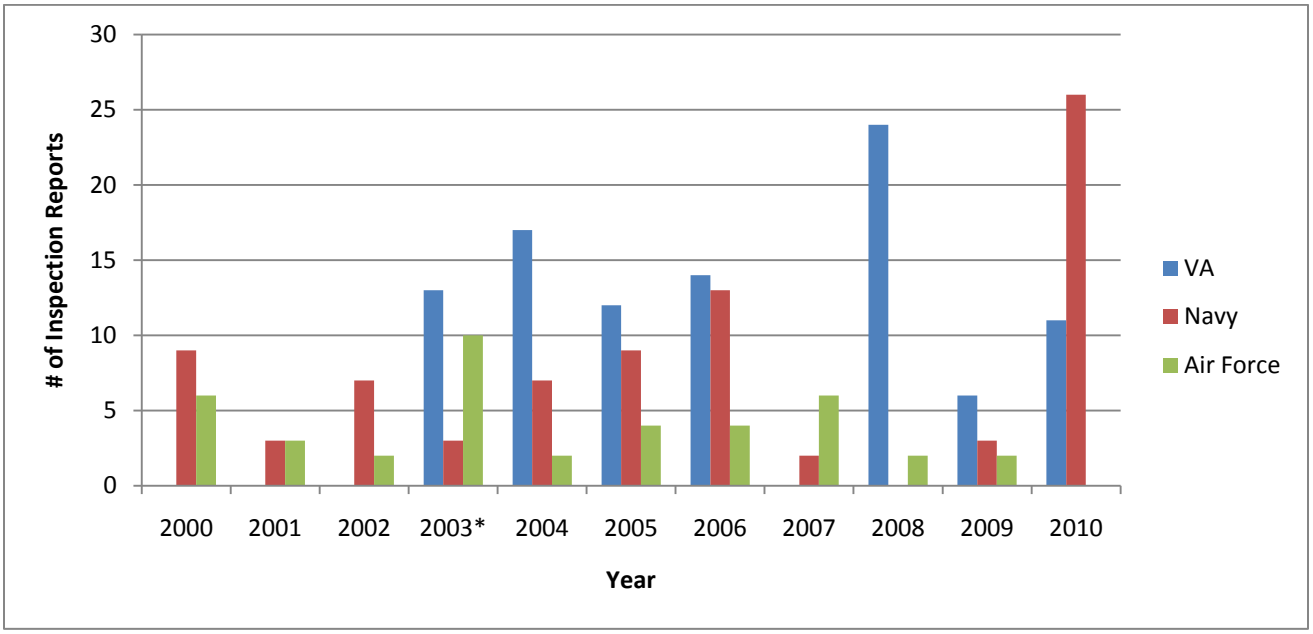
NRC management and staff refer to IMC 2810 when discussing selection of permittees for inspection, yet they expressed a range of reasons for selection that were inconsistent and sometimes conflicting. NRC staff members stated there appears to be "no rhyme or reason" underlying how permittees are selected for independent inspection and "it's a shot in the dark." There is no single perspective on what constitutes "a sufficient number" of independent inspections or "a representative sample" of the MML permittees to be inspected. Management and staff articulated some common themes, such as giving greater scrutiny to higher risk activities, Increased Controls requirements, and MML permittee sites undergoing decommissioning. However, there were also conflicting ideas. For example, one NRC staff member stated that it is important not to overlap with the MML licensee inspection staff, while other NRC staff pointed to MML inspection findings as drivers for selecting MML permittees for inspection. One regional project manager selected exactly 13 permittees for inspections because the MML licensee identified violations at those 13 sites even though the project manager believed the violations were not serious. A different NRC manager stated that 10 percent of the permittees should be inspected, while another manager in the same region said there is no set number.

Some inspection selections are made for reasons that are inconsistent with the risks associated with the activity, materials, or permit amendments. For example, a permittee may be selected for inspection because of its geographic proximity to another permittee, solely to conserve resources and not because of risk- or performance-based criteria. Similarly, while some NRC managers said that the project manager's experience with the MML will contribute to judgments about selection, other NRC staff said selection may be made to train not only a new project manager, but possibly other staff as well, again not because of risk-based criteria. At the same time, one area of risk may be overlooked. Although amendments in permits can signal a potential increase in risk, only one NRC manager mentioned permit amendment as a consideration in selection.

Inconsistency in Inspections

The number of permittees selected for inspection using this range of interpretations is inconsistent and varies from year to year as shown in Figure 2.

Figure 2: Independent Inspection Reports (2000-2010)



* Note: The Veterans Affairs MML was not issued until March 17, 2003.
Source: OIG analysis of NRC documents.

Figure 2 reflects the number of NRC independent inspection reports located in the Agencywide Documents Access and Management System (ADAMS)[10] for each MML docket number for calendar years 2000 to 2010. The number of inspections performed annually for a given MML, as indicated by the inspection reports identified, varies from year to year. There is the least variation in the number of inspections of Air Force permittees; however, the Air Force program receives the fewest NRC inspections overall. For each MML licensee, there is 1 year in which no independent inspections were initiated: 2007 for Veterans Affairs, 2008 for

[10] ADAMS is the official recordkeeping system through which NRC provides access to libraries or collections of documents related to the agency's regulatory activities.

Navy, and 2010 for Air Force. The variation does not elucidate how NRC staff defines "sufficient" or "representative," particularly when existing practice occasionally produces zero annual independent inspections of MML permittees.

MML Permittees Located at U.S. Military Bases in Foreign Countries

NRC does not inspect MML permittees in foreign countries although the Navy and Air Force issue permits for overseas facilities or activities under their MMLs.

Existing Guidance for NRC Staff Overseeing MMLs Is Not Clear

The variation in selection of permittees for independent inspections is the result of unclear and vague guidance for MML project managers. IMC 2810 directs NRC staff to select "a sufficient number" and "a representative sample" of permittees while avoiding duplicating the inspections of the MML inspection staff. While the existing guidance is intended to allow flexibility to develop a performance-based and risk-informed inspection program, the guidance does not serve NRC's Principles of Good Regulation because it lacks clarity in key areas. NRC staff mentioned areas in which greater direction would be helpful in setting priorities and planning for inspections:

- A process to sample the various types of permittees within each MML licensee organization.
- A method to assess relative risk that incorporates performance history, changes to or termination of permits, newly permitted high-risk activities, as well as priority code.
- A minimum frequency for which the independent inspections should be planned.

Consistency and Effectiveness of Independent Inspections Are At Risk

The differing approaches to selecting MML permittees for independent inspections could limit the impact of NRC's oversight. Without clearer guidance for MML permittees selection and in the absence of quantitative or timeliness goals, the inspections can become a lower priority than

deadline-driven activities, and management may have difficulty tracking whether NRC's oversight is commensurate with current MML licensee activities. Moreover, MML licensee staff members expressed frustration with the inconsistency because they perceive that NRC independent inspections are neither connected to clear objectives nor administered in a manner that lends stability to their own operations, as suggested by the Principles of Good Regulation.

The varying approaches to selecting MML permittees for independent inspections could also overlook areas of non-compliance within an MML licensee program or omit inspecting activities with a significant impact on public health, safety, and the environment. Also, if MML licensee decommissioning activities increase, NRC would need to conduct more decommissioning inspections that could divert further resources away from NRC routine inspections of other MML permittees. The lessons-learned task group report noted that NRC staff consensus is that if MML licensee performance is "acceptable," then fewer inspections constitute "sufficient." If some permittees are inspected repeatedly while the overall number of independent inspections declines, then the potential for risk brought about by changes at other permittees may not be evaluated. Because NRC does not inspect the MML permittees as often as the MML licensee staff does, a deliberate selection process that enhances MML oversight becomes more important.

Recommendation

OIG recommends that the Executive Director for Operations:

4. Modify guidance to include a risk-informed methodology with requirements on sample size, selection criteria, and inspection frequency for selecting MML permittees for NRC independent inspection.

C. NRC Should Clarify MML Licensee Regulatory Oversight Roles, Responsibilities, and Accountabilities

NRC's regulatory oversight expectations for MML licensees are not enforced. To ensure adequate protection of public health and safety and the environment, NRC expects MML licensees to perform regulatory oversight functions. However, these expectations are not clearly defined or explicitly enumerated in NRC regulations, the MMLs, the LOUs, or licensee "tie downs." As a result, MML licensees and NRC may have different understandings of MML licensee staff and the master radiation safety committee accountabilities and regulatory oversight roles and responsibilities. Consequently, MML licensees may not fully perform these regulatory oversight functions in a manner NRC expects, which could result in inadequate protection of public health, safety, and the environment.

NRC Expects MML Licensees To Act As Regulators Similar To NRC

NRC has regulatory oversight expectations for MML licensees. To ensure that MML licensees adequately protect public health and safety and the environment, NRC expects MML licensees to conduct regulatory oversight activities, such as identifying the "extent of condition"[11] of events at MML permittee locations and communicating relevant information to permittees. NRC's mission is to ensure adequate protection of public health and safety and the environment. NRC uses licensing, inspections, and enforcement, among other regulatory activities, to provide for this assurance. An MML licensee, under its MML, assumes some authority as a regulator, but remains a licensee. NRC managers and staff have varying views on the nature of MML licensees. While they all agree that an MML licensee is first and foremost a licensee, they also expect the MML licensees to perform regulatory functions. For example, NRC managers and staff expressed the view that MML licensees should embrace their role as a regulator, calling them "quasi-licensees" and "self regulating."

[11] "Extent of condition" is a term used in NRC oversight of nuclear power plants. Under 10 CFR Part 50, nuclear power plant licensees are required to have a quality assurance program that identifies significant conditions adverse to quality, determines the cause of the condition, and takes corrective action to preclude repetition of the condition.

NRC's Expectations for MML Licensee Regulatory Oversight Are Not Enforced

NRC does not enforce its regulatory oversight expectations of MML licensees. NRC has never issued a finding or violation for an MML licensee's lack of adequate regulatory oversight during any of its biennial reviews of the MML licensee's implementation of the MMLs. Since about 2004, approximately every 2 years, NRC has conducted biennial reviews to evaluate the effectiveness of MML licensees' centralized control of nuclear materials use. Inspection Procedure (IP) 87129, "Master Materials Program," contains the guidance for these biennial inspections. IP 87129 directs NRC staff to review several focus elements of the program. One of these elements is management oversight. This review is to verify whether the MML licensees have centralized control over their nuclear materials use programs. For example, under management oversight, IP 87129 requires NRC to determine if the MML licensee's master radiation safety committee is proactive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Another IP 87129 requirement is for NRC to review and assess the MML licensee's efforts to receive and resolve technical questions from permittees and how generic safety and health issues are addressed.

During a special inspection of the Veterans Affairs MML licensee to determine the "extent of condition" of problems related to prostate implant brachytherapy, NRC identified several concerns regarding the MML licensee's regulatory oversight activities, but there were no violations as a result of these concerns. For example, one concern NRC raised in its report was that the MML licensee's master radiation safety committee meetings appeared to focus on "one-way" communication from the MML licensee staff to the committee, with no direction from the committee members or discussion of safety issues among the committee members. Also, NRC raised concerns about this MML licensee's master radiation safety committee not fulfilling its role in providing oversight and direction for event response and not executing its authority in the enforcement process under the MML. Additionally, NRC concluded that the MML licensee did not have a formal process to address technical assistance

requests from MML permittees. Despite all of these concerns, NRC did not issue any violations related to regulatory oversight.[12]

NRC's Regulatory Oversight Expectations Are Not Enumerated in Licensing Documents or NRC Regulations

NRC does not hold MML licensees accountable for all of the regulatory oversight functions that NRC expects the MML licensees to perform because some of those functions are not clearly defined or enumerated in NRC regulations, the MMLs, the LOUs, or the tie downs.

NRC's regulations governing materials licensees do not contemplate a licensee such as an MML licensee that is expected to perform regulatory oversight functions. Rather, NRC's materials regulations are written with a licensee in mind that actually uses nuclear material, as opposed to an entity like the MML licensee staff organization that is issuing permits and conducting inspections but not actually using nuclear materials. An MML licensee official said that NRC inspectors raise concerns about MML licensee performance that have no regulatory basis. One NRC staff member explained that there are no regulations for the MML licensees' management oversight, and there is nothing for NRC to cite against.

MMLs are not defined in NRC regulations or NRC's governing legislation. None of the parts of the CFR that are applicable to materials licensees (specifically Parts 19, 20, 21, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 110) contains a definition or description of MMLs, or any requirements for the performance of regulatory oversight duties by MML licensee staff or master radiation safety committee members. In contrast, there is a regulation describing broad scope licenses[13] – to which MML licensees have been compared – and the role of the broad scope radiation safety committee in managing large broad scope licenses. Furthermore, the Atomic Energy Act, as amended, does not contain any definition of MMLs.

[12] In March 2010, NRC issued a notice of violation and imposition of a $227,500 civil penalty to the Veterans Affairs MML licensee for violations of various NRC regulations. The most serious violations were issued to the licensee for not having adequate procedures for prostate brachytherapy treatments to ensure that the treatments were administered in accordance with the physician directive describing the treatment as required in 10 CFR Part 35 (Medical Use of Byproduct Material). None of the violations issued to the Veterans Affairs MML licensee related to regulatory oversight expectations that NRC expects MML licensees to perform.

[13] While broad scope licensees are NRC licensees that are authorized to use nuclear materials at multiple sites, broad scope licensees do not, for example, conduct inspections and issue violations according to NRC regulations as MML licensees do.

In contrast, the act describes when NRC may enter into agreements with States to assume regulatory authority over certain nuclear materials. Such States are called Agreement States – another entity that has been likened to MML licensees.[14]

Many of the regulatory oversight functions that NRC expects MML licensees to perform are not enumerated in the MMLs, the LOUs, or the tie downs. Without clear requirements in regulation, NRC's only mechanism to clearly communicate its expectations in a manner that is enforceable is by enumerating those expectations in the MML, the LOU, and/or the tie downs. The MMLs, the LOUs, and the tie downs establish that the MML licensee is authorized to permit radioactive materials use at the particular Federal agency's facilities. They also provide that the MML licensee shall conduct inspections and enforcement consistent with NRC's inspection and enforcement guidance. However, these documents do not establish that the MML licensee or the master radiation safety committee is required to perform such regulatory oversight functions such as identifying the "extent of condition" of events or incidents and taking corrective action to prevent recurrence. As one NRC staff member explained, identifying the "extent of condition" of problems is a term borrowed from nuclear reactor oversight and is not regularly used in NRC oversight of materials licensees. This NRC staff member added that these requirements should have been clearly communicated when the MMLs, the LOUs, and the tie downs were established. Also, the MMLs, the LOUs, and the tie downs do not clearly establish the roles and responsibilities of the MML licensee and master radiation safety committee in answering and providing technical assistance to MML permittees.

[14] There are differences between MML licensees and Agreement States. Agreements States are not NRC licensees, while MML licensees are. NRC relinquishes regulatory authority to Agreement States, while MML licensees remain NRC licensees.

Without Clearly Enumerated Regulatory Oversight Requirements, Roles and Responsibilities May Be Confused

Because NRC's regulatory oversight expectations for MML licensees are not clearly defined or enumerated in licensing documents or NRC regulations, MML licensees and NRC may not have the same understanding of the MML licensees' roles and responsibilities as they relate to oversight of the MML permittees. As one MML licensee official said, it is difficult for the MML licensee staff to know when they are the regulator policing MML permittees and when the MML licensee is a licensee accountable for the activities at a particular MML permittee. This official maintains that the MML licensee and the master radiation safety committee are not accountable for the activities that occur at a particular permittee location. This official added that the MML licensee staff and the master radiation safety committee are not the broad scope radiation safety officer[15] for the permittees; rather, the MML licensee staff and the master radiation safety committee are the regulator. There is confusion as to the MML licensees' role specifically when the MML licensee is a licensee, a regulator, or a radiation safety officer.

This lack of clarity could lead to assumptions by NRC staff and MML licensee staff as to who has responsibility for oversight of the safe use of nuclear materials at MML permittees. As one NRC staff member said, the licensee might think it is doing the right thing but if NRC says it is not, this could lead to disagreement between NRC and the MML licensee as to the MML licensee's responsibilities. NRC is unable to issue violations to MML licensees that are not meeting certain NRC regulatory oversight expectations, such as identifying the extent of condition of events or incidents at permittee locations or communicating certain information to permittees. As a result, these expectations may not be met by MML licensees, which could lead to inadequate protection of public health, safety, and the environment.

[15] A material licensee's management appoints a radiation safety officer to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, is responsible for ensuring that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Each MML permittee has a radiation safety officer.

Recommendation

OIG recommends that the Executive Director for Operations:

5. Clearly define all MML licensee staff and master radiation safety committee regulatory oversight responsibilities (e.g., requirements and roles and accountabilities) in NRC regulations, the MMLs, the LOUs, or some combination thereof.

IV. CONSOLIDATED LIST OF RECOMMENDATIONS

OIG recommends that the Executive Director for Operations:

1. Define regional and headquarters MML project managers' roles in responding to requests for guidance and assistance from MML licensee staff.

2. Develop and implement a consistent and timely process for notifying MML licensee staff of NRC-hosted training courses.

3. Develop and implement a consistent process for registering MML licensee staff for NRC-hosted training courses.

4. Modify guidance to include a risk-informed methodology with requirements on sample size, selection criteria, and inspection frequency for selecting MML permittees for NRC independent inspection.

5. Clearly define all MML licensee staff and master radiation safety committee regulatory oversight responsibilities (e.g., requirements and roles and accountabilities) in NRC regulations, the MMLs, the LOUs, or some combination thereof.

V. AGENCY COMMENTS

On April 19, 2011, OIG issued a discussion draft to the Executive Director for Operations. OIG subsequently met with NRC management during a May 2, 2011, exit conference during which agency management stated their general agreement with the findings and recommendations in this report. Agency staff provided informal comments to the draft report. Also, on May 5, 2011, OIG held an additional meeting with staff from the Office of the General Counsel to discuss the agency's informal comments. On May 11, 2011, OIG provided the agency a revised discussion draft and on May 27, 2011, the agency declined to provide formal comments. The final report incorporates revisions made, as appropriate, as a result of meetings with NRC staff.

Appendix

SCOPE AND METHODOLOGY

The audit objective was to determine whether NRC's oversight of MML licensees adequately protects public health and safety and the environment. The audit focused on reviewing the oversight of the MMLs through documentation reviews, observation of NRC oversight activities, and interviews with NRC management and staff involved in MML oversight and with representatives of the MML licensees.

OIG reviewed documents related to the Air Force, Navy, and Veterans Affairs MML licenses, including:

- The licenses.
- The Letters of Understanding, which lay out areas of separate and shared responsibility between the NRC and the licensee.
- Associated tie downs, which are licensee commitments to NRC which become part of the license.

OIG also reviewed applicable sections of the CFR pertaining to materials licensees and NRC guidance relevant to MML oversight. Some of the key documents reviewed include:

- Atomic Energy Act of 1954, as amended.
- CFR Title 10.
- NUREG 1556, Volume 10, Program-Specific Guidance About Master Materials Licenses.
- NUREG 1556, Volume 20, Guidance About Administrative Licensing Procedures.
- NUREG 1757, Volume 1, Revision 2, Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees.
- Final Report of NRC's Department of Veterans Affairs Lessons-Learned Task Group.
- IMC 1246, Qualifications Program in Nuclear Safety and Safeguards Program.
- IMC 2800, Materials Inspection Program.
- IMC 2810, Master Materials License Inspection Program.
- IP 87129, Master Materials Program.

To determine the scope of NRC's independent inspections of MML permittees, OIG reviewed 220 NRC inspection reports from independent inspections conducted between 2000 and 2010. OIG identified the inspection reports through searches of ADAMS. OIG also accompanied NRC inspectors on two independent inspections of MML permittees, one at China Lake Naval Air Warfare Center, California, and the other at Veterans Affairs San Diego Health Care System, California.

Additionally, OIG observed two biennial reviews of MML licensees conducted by NRC teams during OIG's fieldwork. One biennial review was of the Veterans Affairs radiation safety program in Little Rock, Arkansas, and the other was of the Navy radiation safety program in Yorktown, Virginia, and Portsmouth, Virginia. OIG observed quarterly meetings of the master radiation safety committees for the Air Force (Rosslyn, Virginia), Navy (Arlington, Virginia), and Veterans Affairs (Washington, DC). OIG reviewed reports of past biennial and annual reviews of the MML licensees ranging from 1999 through 2009. These reports were located in ADAMS.

The OIG audit team conducted interviews with managers and staff of NRC and of the Air Force, Navy, and Veterans Affairs radiation safety programs. Interviews with NRC staff and managers took place in the regions that oversee the Master Materials Licenses—Region I (King of Prussia, Pennsylvania), Region III (Lisle, Illinois), and Region IV (Arlington, Texas). The audit team interviewed FSME managers and staff. OIG interviewed representatives of all three MML licensees.

We conducted this performance audit at NRC headquarters and regional offices from June 2010 through February 2011 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 audit work was conducted by Sherri Miotla, Team Leader; Kevin Nietmann, Senior Technical Advisor;

Michael Zeitler, Audit Manager; Levar Cole, Senior Management Analyst; Amy Hardin, Auditor; Dana Furstenau, Management Analyst; and Steven Galeski, Management Analyst.