

AUDIT REPORT

Audit of NRC's Agreement State Program

OIG-09-A-08 March 16, 2009



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

OFFICE OF THE
INSPECTOR GENERAL

March 16, 2009

MEMORANDUM TO: R. William Borchardt
Executive Director for Operations

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

SUBJECT: AUDIT OF NRC'S AGREEMENT STATE PROGRAM
(OIG-09-A-08)

Attached is the Office of the Inspector General's (OIG) audit report titled, *Audit of NRC's Agreement State Program*.

The report presents the results of the subject audit. Agency comments provided at the December 16, 2008, exit conference, a subsequent January 9, 2009, meeting, and submitted formally on February 26, 2009, 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 Safety Audit Team, at 415-5914.

Attachment: As stated

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EXECUTIVE SUMMARY

BACKGROUND

In accordance with section 274 of the Atomic Energy Act, as amended, the Nuclear Regulatory Commission (NRC) may relinquish its authority to regulate byproduct, source, and limited quantities of special nuclear material to States (Agreement materials). These States must first demonstrate that their regulatory programs are adequate to protect public health and safety and compatible with NRC's program. States that have entered into an agreement assuming this regulatory authority from NRC are called Agreement States. There are currently 35 Agreement States.

NRC has programmatic responsibility to periodically review the actions of the Agreement States to comply with the requirements of the Atomic Energy Act. NRC's policy is to evaluate Agreement State radiation control programs using performance indicators to ensure that public health and safety is being adequately protected and that Agreement State programs are compatible with NRC's program. In order to accomplish this task, NRC periodically reviews Agreement States using the Integrated Materials Performance Evaluation Program (IMPEP).

PURPOSE

The audit objective was to assess NRC's oversight of the adequacy and effectiveness of Agreement State programs. The Office of the Inspector General (OIG) focused its review on the IMPEP process as well as other elements of the Agreement State program.

RESULTS IN BRIEF

The purpose of the Agreement State program is to ensure the adequate protection of public health and safety in the uses of Agreement materials. Although NRC maintains oversight of Agreement States, there are program adequacy and effectiveness issues that require management's attention. Specifically,

- NRC does not effectively monitor IMPEP operational issues.

- Agreement State program managers are unaware of several operational issues because there is no systematic mechanism for conducting self-assessments and capturing lessons learned for IMPEP. Consequently, IMPEP may not be as effective as it could be for assessing the adequacy and compatibility of Agreement State programs.
- NRC could be challenged to re-exert authority over an Agreement State program in the event of an emergency.
 - Under the Atomic Energy Act, NRC can temporarily suspend its agreement with a State during an emergency situation. However, NRC has not identified all of the information necessary for re-exerting authority and lacks the formal procedural guidance about what information is needed about Agreement State programs and materials licensees. Without this valuable planning information, NRC could lose oversight and awareness of licensees and materials.
- NRC lacks standardization in communications with, and collection of information from, the Agreement States.
 - NRC lacks (1) standardization in communication procedures, and (2) a standardized data collection process that can be used as a basis for developing a national information sharing tool. As a result, some States may be unaware of important issues, and NRC does not have a full and accurate picture of Agreement State regulatory activities.
- Weaknesses exist in NRC's review of Agreement State event reporting.
 - NRC's reviews of whether an Agreement State has appropriately reported all events to the Nuclear Material Events Database (NMED) may not be consistently performed. NRC's IMPEP reviews do not require an analysis of unreported events to determine whether such events are being appropriately identified for and included in NMED. Consequently, NRC and the public may have an inaccurate accounting of material events in some States, which could also hamper events data trend analysis efforts.

RECOMMENDATIONS

This report makes five recommendations to help NRC improve its partnership with, and oversight of, Agreement States. A Consolidated List of Recommendations appears in Section IV.

OIG ANALYSIS OF AGENCY COMMENTS

On December 3, 2008, OIG provided a draft report to the Executive Director of Operations. On February 26, 2009, the Executive Director for Operations provided a formal response to this report. The agency's transmittal letter and specific comments on this report are included in their entirety as Appendix B.

The final report incorporates revisions made, where applicable, as a result of meetings with NRC staff and the agency's written comments. Appendix C contains OIG's analysis of the agency's formal response.

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ABBREVIATIONS AND ACRONYMS

FSME	Office of Federal and State Materials and Environmental Management Programs
IMPEP	Integrated Materials Performance Evaluation Program
MRB	Management Review Board
NMED	Nuclear Material Events Database
NRC	Nuclear Regulatory Commission
NSIR	Office of Nuclear Security and Incident Response
OIG	Office of the Inspector General
OMB	Office of Management and Budget
PM	Project Manager
RSAO	Regional State Agreements Officer
SA	State Agreement

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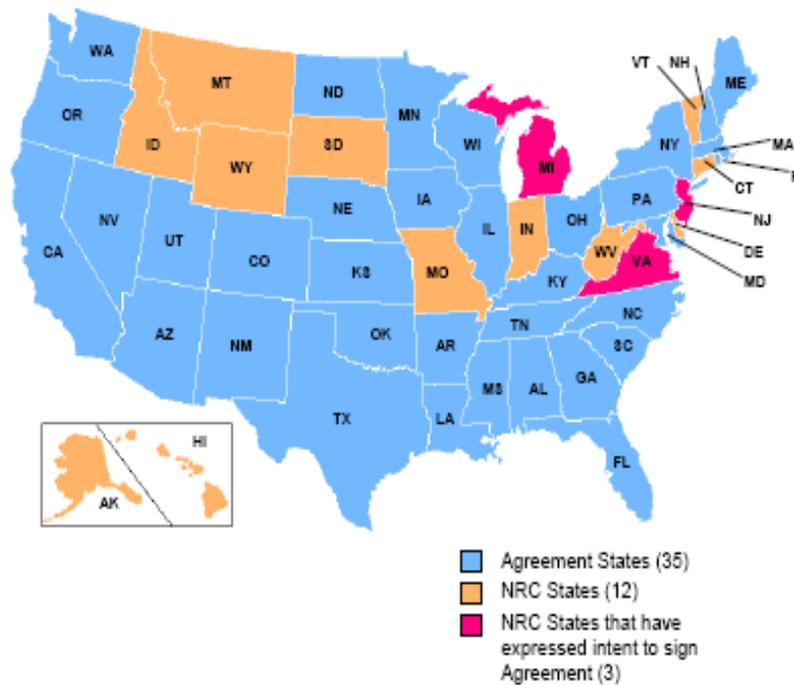
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I. BACKGROUND

In accordance with Section 274 of the Atomic Energy Act, as amended, "Cooperation with States," the Nuclear Regulatory Commission (NRC) may relinquish¹ its authority to regulate byproduct, source, and limited quantities of special nuclear material² to States, hereafter collectively referred to as "Agreement materials." These States must first demonstrate that their regulatory programs are adequate to protect public health and safety and compatible with NRC's program. States that have entered into an agreement assuming this regulatory authority from NRC are called Agreement States. There are currently 35 Agreement States, and 3 States that have submitted a letter of intent to become Agreement States (see Figure 1).

Figure 1: Map of the Agreement States



Source: Information depicted based on NRC Web site as of September 9, 2008.

¹ Under Section 274j, the Commission retains authority to terminate or suspend the agreement and re-exert licensing and regulatory authority.

² The Atomic Energy Act of 1954, as amended, defines byproduct material, in part, as any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

NRC and the Agreement States are responsible for ensuring the adequate protection of public health and safety in the uses of Agreement materials. Accordingly, NRC and the Agreement States must have supporting legislative authority, an implementing organizational structure and procedures, and financial and human resources to effectively administer a radiation control program.

The Office of Federal and State Materials and Environmental Management Programs (FSME) administers the Agreement State program. For fiscal year 2008, the agency budgeted \$57.4 million, including 270 full-time equivalent staff, for activities to regulate nuclear material users. Of the budgeted full-time equivalent staff, approximately 10 percent was dedicated to the Agreement State program. FSME activities include reviewing State requests to assume authority to regulate certain Agreement materials, reviewing Agreement State performance, monitoring State activities, and providing advice and guidance to Agreement States. Most of the NRC regions also have one or two Regional State Agreements Officers (RSAO) that serve as the regional focal point to implement the Agreement State program. Each RSAO is assigned a number of Agreement States for which they serve as NRC's primary point-of-contact.

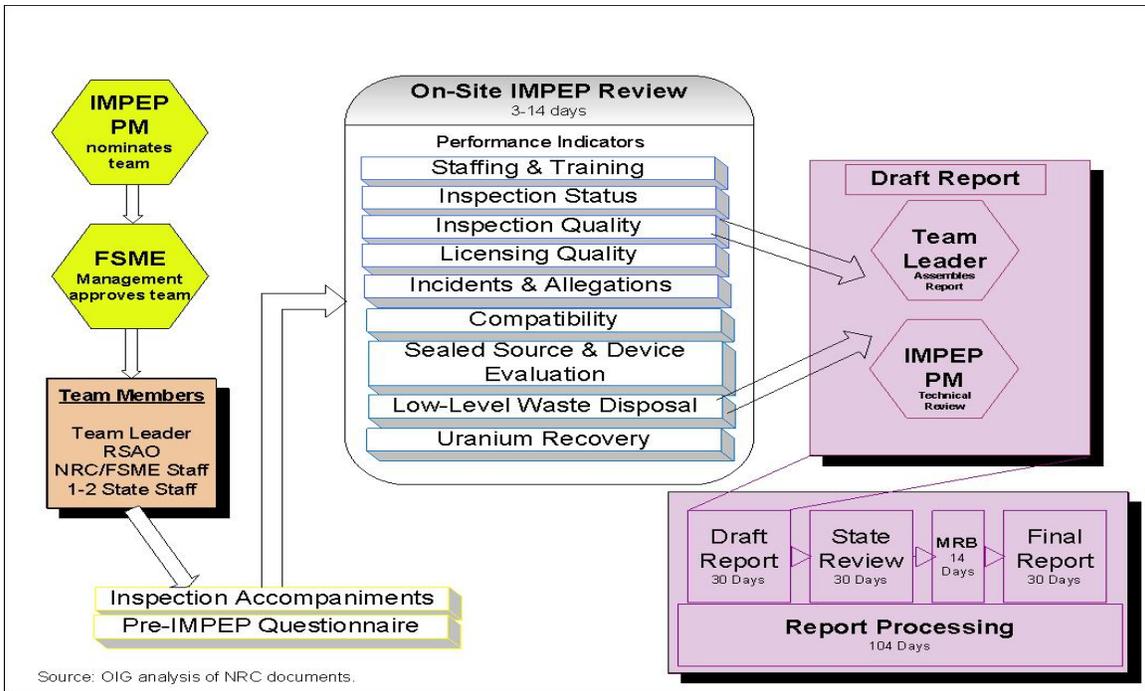
NRC has programmatic responsibility to periodically review the actions of the Agreement States to comply with the requirements of the Atomic Energy Act. NRC's policy is to evaluate Agreement State radiation control programs using performance indicators to ensure that public health and safety is being adequately protected and that Agreement State programs are compatible with NRC's program. In order to accomplish this task, NRC periodically reviews Agreement States. In 1994, the agency revised its program for reviewing Agreement States and created the Integrated Materials Performance Evaluation Program (IMPEP).

IMPEP Review Process

NRC uses IMPEP to evaluate each Agreement State radiation control program generally every 4 years in order to provide an overall assessment of a State's adequacy to protect public health and safety and compatibility with NRC's program. Management Directive 5.6, *Integrated Materials Performance Evaluation Program*, establishes the process and defines the performance criteria by which NRC conducts such periodic IMPEP assessments to determine the adequacy and compatibility of Agreement State programs.

As shown in Figure 2 below, the IMPEP review process begins when the IMPEP project manager (PM)—an individual assigned by FSME to oversee the program's operations—prepares a schedule of the upcoming reviews and appoints members to an IMPEP review team. IMPEP teams are composed of three to eight State and NRC employees, including a team leader and the RSAO to the State under review. Team members are required to attend a 1 1/2 - day training session and periodic refresher training on IMPEP, which emphasizes the value of IMPEP guidance and procedures and the importance of being prepared.

Figure 2: Integrated Materials Performance Evaluation Program (IMPEP) Review Process



Prior to the start of the onsite IMPEP review, the IMPEP PM provides the teams with compact discs that contain program-specific information, IMPEP procedures and guidance, and templates of model IMPEP reports. Accordingly, IMPEP team members review State responses to a pre-IMPEP questionnaire and perform inspection accompaniments before the onsite review. The pre-IMPEP questionnaire is a form with a series of questions that States complete prior to the IMPEP review, and IMPEP team members are responsible for evaluating the State's responses prior to the start of the onsite review. Inspection accompaniments are

performed by selected IMPEP team members and/or NRC staff who accompany Agreement State inspectors at different types of licensed facilities to evaluate their knowledge and capabilities.

During the onsite review, the IMPEP team evaluates the State's program against a set of performance indicators. IMPEP reviews should identify the underlying cause of performance weaknesses related to the performance indicator. Such performance weaknesses are referred to as findings, and the IMPEP team will typically propose recommendations for issues that need to be addressed. Throughout the onsite review, the IMPEP team briefs the State's program management on the status and preliminary findings of the review. At the end of the onsite review, the IMPEP team assesses whether the State's program is adequate to protect public health and safety and is compatible with NRC's program.

Within 30 days of conclusion of the onsite review, the IMPEP team leader assembles the report, submits it to the IMPEP project manager for a technical review, and then issues the draft report to the State for factual review. The IMPEP team next incorporates the State's comments and then presents the report containing preliminary findings to the Management Review Board (MRB) during a meeting that includes State representatives and the IMPEP team.

The MRB is composed of NRC senior management and a non-voting State member. It is responsible for making a final overall assessment of a State's adequacy to protect the public health and safety and compatibility with NRC's program. At the MRB meeting, the State under review has an opportunity to comment on NRC's review of its program. Within 104 days of the end of the onsite review, the IMPEP report is finalized and issued.

Other Agreement State Activities

The collective framework within which NRC and the Agreement States function in carrying out their respective radiation safety regulatory programs is called the National Materials Program. The term "National Materials Program" was conceptualized in late 1990, and focuses on the shared program activities between NRC and the Agreement States as well as the ability of the Agreement States to assume a greater proportional responsibility for shared program activities. The program is also intended to reflect the evolving relationship among NRC and the Agreement States.

NRC serves as the Federal-level presence for radioactive materials safety and security under the National Materials Program, which includes coordinating activities between NRC and the Agreement States. One example of a coordinating activity is Agreement State letters. An Agreement State letter is a document prepared by NRC to, among other things, convey programmatic information to the States and request comments on policy changes. Another example is NRC's coordination of Agreement State data submissions to the Nuclear Material Events Database (NMED), which contains information on the occurrence, description, and resolution of events involving the use of radioactive materials.

II. PURPOSE

The audit objective was to assess NRC's oversight of the adequacy and effectiveness of Agreement State programs. The Office of the Inspector General (OIG) focused its review on the IMPEP process as well as other elements of the Agreement State program. Appendix A provides information on the audit scope and methodology.

III. FINDINGS

The purpose of the Agreement State program is to ensure the adequate protection of public health and safety in the uses of Agreement materials. Although NRC maintains oversight of Agreement States, there are program adequacy and effectiveness issues that require management's attention. Specifically:

- A. Management does not effectively monitor IMPEP operational issues.
- B. NRC could be challenged to re-exert authority over an Agreement State program in the event of an emergency.
- C. NRC lacks standardization in communications with, and collection of information from, the Agreement States.
- D. Weaknesses exist in NRC's review of Agreement State event reporting.

A. Management Does Not Effectively Monitor IMPEP Operational Issues

FSME management does not effectively monitor operational issues related to the IMPEP program. Office of Management and Budget (OMB) internal control guidance states that a systematic process for monitoring the effectiveness of a program should be in place for addressing deficiencies. However, FSME management is unaware of several operational issues because there is no systematic mechanism for conducting self-assessments and capturing lessons learned for IMPEP. Consequently, IMPEP may not be as effective as it could be for assessing the adequacy and compatibility of Agreement State programs.

Guidance for Monitoring the Effectiveness of a Program

OMB Circular A-123, *Management's Responsibility for Internal Control*, states that a systematic process for monitoring the effectiveness of a program should be in place for addressing deficiencies. This circular introduces several objectives for developing and maintaining internal control activities. One of those objectives, "Monitoring," states that periodic assessments should be integrated as part of management's continuous oversight of

internal control. In addition, management should evaluate the internal control deficiencies that are reported and take proper action to correct them.

Management Unaware of Operational Issues

During OIG's review, FSME management was unaware of several IMPEP operational issues, including:

- A lack of underlying cause analysis during IMPEP reviews and in reports.
- An inconsistent use of the pre-IMPEP questionnaire.
- IMPEP team leaders underprepared to conduct reviews.
- Selected IMPEP team members and/or NRC staff accompanying State inspectors unaware of associated guidance.

FSME management was unaware that the underlying cause of a performance weakness in an Agreement State program is rarely discussed during IMPEP reviews and stated in reports. Identifying the underlying cause is important in order to focus IMPEP review recommendations towards State program weaknesses.³ However, OIG attended four onsite reviews and the underlying cause for the performance weaknesses identified was not consistently mentioned in the IMPEP teams' finding discussions. OIG also reviewed recently issued IMPEP reports,⁴ and determined that the majority of the recommendations in these reports were not directly supported with a discussion of the underlying, rather than the apparent, cause. FSME managers contend that the IMPEP reports have sufficient discussions to support the recommendations.

FSME management was also unaware of the inconsistent use of the pre-IMPEP questionnaire responses. The questionnaire responses are provided to the IMPEP team members during the weeks prior to the onsite IMPEP review. However, OIG observed that there were IMPEP team members, including a team leader, who had not thoroughly analyzed the questionnaire responses prior to the onsite review. For example, during one IMPEP review, OIG observed that the State had only partially answered certain questions, yet the IMPEP team members asserted that the State

³ An underlying cause is the fundamental reason—rather than the apparent reason or symptom—that explains a program weakness or performance issue.

⁴ OIG reviewed IMPEP reports issued from January 19, 2007, to August 27, 2008.

had thoroughly answered all of the questions. In another IMPEP review, a team member spent part of the review looking for an answer that was already provided in the State's questionnaire response.

Another issue lacking FSME management awareness pertains to team leader preparation. OIG observed that some team leaders were not thoroughly prepared for their respective IMPEP reviews. During one IMPEP review, the team leader was not aware of how many outstanding recommendations the State had from the previous IMPEP review. During another review, the team leader did not understand that particular State's management structure and spent a considerable amount of time during the review trying to discern it. Also, during the IMPEP reviews that OIG observed, only one team leader prompted the team to discuss the underlying cause of the team members' findings.

FSME management was also unaware that selected IMPEP team members and/or NRC staff who accompanied State inspectors are not aware of associated inspection guidance. State Agreement (SA)-102,⁵ *Reviewing the Common Performance Indicator, Technical Quality of Inspections*, provides guidance on the accompaniment role of the IMPEP team member, including guidance to observe the State inspector's work rather than help with the inspection effort. Yet some accompaniment participants were unaware of this guidance. OIG interviewed nine State and NRC employees who had performed accompaniment inspections during the past 2 years, and one-third of them were not aware of SA-102. Moreover, nearly half of these accompaniment participants were unaware that SA-102 also provides, as a convenience, a checklist of items to review while performing these inspections.

No Systematic Mechanism for Conducting Self-Assessments

FSME has not established a systematic mechanism for conducting self-assessments and capturing IMPEP lessons learned. In 2001, after the first round of IMPEP reviews,⁶ NRC appointed a working group to assess the IMPEP program for lessons learned. However, this group issued only one report and no further assessments were conducted. The working group's report, dated April 2002, examined several program areas, such as the IMPEP questionnaire, guidance for conducting IMPEP reviews, and the

⁵ SAs are Agreement State program procedures issued by FSME.

⁶ The first round of IMPEP reviews consisted of the first review for each Agreement State and was concluded in 1999.

effectiveness of the performance indicators. Although this review examined some structural issues of the IMPEP review process and offered subsequent improvements, the working group did not address IMPEP program operational issues. FSME management confirmed that after this working group, there has not been another formal IMPEP assessment.

Nonetheless, FSME does seek opportunities to continuously improve the IMPEP program on a review-to-review basis, for example, by seeking feedback from managers of programs that have been reviewed and through the IMPEP PM's participation on IMPEP reviews. FSME management has delegated authority of IMPEP operations to the IMPEP PM and contends that IMPEP team member performance issues are brought to FSME management's attention.

However, FSME management is still reliant on staff to self-identify and communicate such issues, mostly on an informal basis. For example, one manager said that operational issues are communicated from staff to management on a case-by-case basis. Another manager stated that FSME management wants to know how well the teams are performing, but this communication is done informally.

IMPEP May Not Be As Effective As It Could Be

Without a systematic mechanism for capturing lessons learned, IMPEP will not be as effective as it could be for assessing the adequacy and compatibility of Agreement States. FSME management may be unaware of a variety of IMPEP operational issues because it attends to these issues on an informal basis. Consequently, operational issues that may hinder the effectiveness of the program are not being captured using a methodical approach. Improving the communication and documentation of operational issues to FSME management would help identify and correct issues in a timely manner and enhance the effectiveness of IMPEP. Moreover, having a systematic mechanism for conducting self-assessments would complement FSME's ongoing efforts at program self-improvement and help IMPEP better adapt to a dynamic regulatory environment.

Recommendation:

1. Develop a mechanism for conducting self-assessments and capturing lessons learned for IMPEP on a regular basis.

B. NRC Could Be Challenged To Re-exert Authority Over an Agreement State Program in the Event of an Emergency

In the event of an emergency in an Agreement State whereby the State regulators are partially or fully incapacitated, NRC could be challenged to re-exert authority over an Agreement State program due to a lack of access to certain program and materials licensee information. Under the Atomic Energy Act, NRC can temporarily suspend its agreement with a State during an emergency situation. However, NRC has not identified all of the information necessary for re-exercising authority and lacks the formal procedural guidance about what information is needed about Agreement State programs and materials licensees. Without this valuable planning information, NRC could lose oversight and awareness of licensees and materials.

Emergency Suspension of Agreement

NRC's authority to suspend an Agreement State program stems from Section 274j of the Atomic Energy Act, "Termination of Agreement," which specifically states that the Commission may temporarily suspend its agreement with a State if an emergency situation exists.⁷ FSME has issued an implementing procedure associated with Section 274j. This procedure, SA-112, *Emergency Suspension of a Section 274b Agreement*, describes the process to be used by the Commission to temporarily suspend an Agreement State program when an emergency situation exists. According to SA-112, the appropriate NRC region is responsible for coordinating with the State to make sure that necessary information is gathered and action is taken to notify the affected licensee, or groups of licensees, that NRC is taking over the State's program.

NRC Lacks Certain Agreement State Information

Although NRC has a procedure in place to suspend an Agreement State program in the event of an emergency, NRC could be challenged to re-exert authority over an Agreement State program. This challenge stems from the agency's lack of information that the

⁷ Section 274j specifically states that "the Commission, upon its own motion or upon request of the Governor of any State, may, after notifying the Governor, temporarily suspend all or part of its agreement with the State without notice or hearing if, in the judgment of the Commission: (A) an emergency situation exists with respect to any material covered by such an agreement creating danger which requires immediate action to protect the health or safety of persons either within or outside of the State, and (B) the State has failed to take steps necessary to contain or eliminate the cause of the danger within a reasonable time after the situation arose."

Agreement States have regarding materials licensees in their plans and programs that would be necessary for NRC to effectively manage an Agreement State's program during the emergency conditions.

Such information might also include the Agreement States' own continuity of operations planning that could help Federal and State regulators in the event of a major disaster. For example, one Agreement State has various types of program contingency plans addressing such topics as emergency operations support at the State level, business continuity for critical services, and disaster recovery for critical technology systems. To prepare for emergencies, this Agreement State has geographically dispersed offices that can assume duties in support of each other to minimize the impact of a major disaster in any one location. Managers in this Agreement State said that it would be difficult for NRC to assume control of the State's program if a natural disaster occurred because NRC does not understand the State's continuity planning. Therefore, this State's program managers hypothesized that, in the event of an emergency, NRC would not be able to help effectively and could potentially get in the way of the State's post-crisis actions.

OIG requested documentation for the agency's plan for re-exerting authority in Agreement States from both FSME and the Office of Nuclear Security and Incident Response (NSIR), and neither office could provide a formal plan. One FSME manager stated that he had never thought about a situation in which NRC would need to immediately re-exert authority over an Agreement State program. Another manager believed that NRC would have enough time to coordinate with State officials in the event of an emergency. This perspective was echoed by an NSIR official, who stated that in the event of an emergency, NRC would contact the State and, together, NRC and the State would discern how to handle the situation. However, it may be unrealistic to assume that there would be adequate time to coordinate with State officials or that State officials would even be available for such coordination.

Agency Lacks Guidance To Identify Needed Information

NRC's lack of Agreement State information that would be necessary for the agency to temporarily re-exert authority over Agreement State programs stems from the following:

- NRC has not formally identified all of the information necessary for re-exerting authority.

- NRC lacks the formal procedural guidance about what information is needed about Agreement State programs and materials licensees.

NRC does not routinely request from Agreement States program and licensee information that would be necessary for NRC to re-exert authority in a State. Neither FSME nor NSIR collects this kind of information. Furthermore, OIG observed that State continuity planning was not examined during IMPEP reviews. An IMPEP team member stated that IMPEP reviews do not collect this information because NRC does not classify State continuity of operations planning as an adequacy or compatibility issue.

Furthermore, NRC lacks formal procedural guidance about what information is needed about Agreement State programs and materials licensees. For example, while SA-112 describes the process to temporarily suspend an Agreement State program when an emergency situation exists, it does not describe the Agreement State program and materials licensee information needed for re-exercising authority over a State.

NRC Could Lose Agreement State Oversight and Awareness

NRC could be challenged to re-exert authority over Agreement State programs because the agency does not have access to certain program and materials licensee information that the Agreement States have. Thus, there is a greater potential for NRC to lose oversight and awareness of Agreement State licensees and materials. It is especially important now, in the post-9/11 and post-Hurricane Katrina environment, that NRC maintain awareness of Agreement States' programs and materials licensee information because this lack of preparation could have potential health, safety, and security implications, and lead to public embarrassment for NRC and Agreement State regulators.

Recommendation:

2. Develop formal procedural guidance for identifying what information is needed about Agreement State programs and materials licensees in the event that an Agreement State is no longer capable of adequately performing its function of protecting public health and safety for an indeterminate period of time.

C. NRC Lacks Standardization in Communications With, and Collection of Information From, the Agreement States

NRC's communications with, and collection of information from, the Agreement States is not standardized even though NRC serves as the Federal-level presence for materials safety and security under the National Materials Program. Both the Atomic Energy Act and the agreements between NRC and the Agreement States emphasize the importance of cooperation between the agency and the States. Also, the National Materials Program focuses on the shared program activities between NRC and the Agreement States as well as the Agreement States' abilities to assume a greater proportional responsibility for shared program activities. However, NRC's information exchange efforts, while better now than in previous years, need additional improvement. This is due to a lack of (1) standardization in NRC's communication procedures, and (2) a standardized data collection process that can be used as a basis for developing a national information sharing tool. As a result, some States may be unaware of important issues, and NRC does not have a full and accurate picture of Agreement State regulatory activities.

The Importance of Cooperation Between NRC and the Agreement States

Both the Atomic Energy Act and the agreements between NRC and the Agreement States emphasize the importance of cooperation between the agency and the States. Section 274a of the Atomic Energy Act, "Cooperation With States," emphasizes the need to establish programs for cooperation between the States and the Commission with respect to control of radiation hazards associated with the use of Agreement materials. Furthermore, a typical signed agreement between NRC and an Agreement State includes a clause about NRC using best efforts to cooperate with the States in the formulation of standards and regulatory programs to protect against hazards of radiation and to ensure the State's program will continue to be compatible with the agency's program.

NRC's agreements with States include language about how NRC and the States will use best efforts to keep each other informed of proposed changes in their respective rules and regulations, and to obtain comments and assistance from each other. The two most recent State agreements—with Minnesota and Pennsylvania—also include a statement that NRC and the State "agree to keep each

other informed of events, accidents, and licensee performance that may have generic implications or otherwise be of regulatory interest.”

As the Federal authority in a National Materials Program, NRC has the responsibility to communicate regulatory and other program changes to its Agreement State partners, such as changes in licensing procedures. NRC is also responsible for collecting information from the Agreement States for different purposes, such as obtaining State responses to the pre-IMPEP questionnaire or information about the status of certain types of licensees operating in the States.

Information Exchange Efforts Could Be Improved

Agreement State officials have stated and OIG analysis shows that NRC's communications with, and collection of data from, the Agreement States could be improved. NRC employs several methods to exchange information with the Agreement States, including the use of formal letters, e-mail messages, telephone calls, working groups, and meetings, and through the IMPEP review process, which provides an opportunity for NRC and Agreement State staffs to share information and best practices. However, NRC's communications to the Agreement States through the RSAOs and via e-mail could be improved. Furthermore, NRC does not systematically collect important program data from the Agreement States outside of IMPEP.

Communications

Some Agreement State officials said that communications with NRC have improved over the years. The States are particularly appreciative of having NRC technical staff available for consultation. However, NRC's communications to the Agreement States through the RSAOs and via e-mail need additional improvement.

A primary means of communicating with the Agreement States is through one of the five agency RSAOs, who are located in three of the four NRC regions. The RSAOs are afforded flexibility in developing rapport with their assigned States, and much of their communications are informal. However, this flexibility does not guarantee that important information exchanges between NRC and the Agreement States take place. For example, in February 2008, the RSAOs were asked by Region I to e-mail their Agreement State contacts and request that the States check with all manufacturer

and distributor licensees. The purpose was to alert these licensees about an unusual purchase inquiry that was received by an NRC licensee from an unidentified suspicious buyer. However, two of the five RSAOs were not familiar with the unusual purchase inquiry, and OIG has not been able to confirm whether all of their Agreement States were ever contacted. OIG is aware of at least two Agreement States that were not contacted by NRC about the unusual order, and officials in one of these States said they had a number of manufacturer and distributor licensees in the State.

Another way NRC communicates with the Agreement States is via e-mail, which several Agreement States have described as overwhelming. Some State personnel reported getting the same e-mail several times from NRC sources as well as from other State staff. State officials have also said that, given the volume of information coming from NRC, it can be difficult to separate the truly important from the “nice-to-know” information. For example, an Agreement State official said that he does not always have time to read everything and determine that a response or some action is required of him. Another Agreement State official said he received almost 1,400 e-mails from NRC during a 1- to 2-year period.

Data Collection

NRC does not systematically collect program data from the Agreement States outside of IMPEP. While NRC periodically collects a large amount of information from the Agreement States through the IMPEP process, such information is limited to those items that NRC deems necessary to assess an Agreement State's program adequacy and compatibility. Other types of information—such as State notices of suspended or revoked licensees, and enforcement and allegations data—are not routinely collected for the purposes of trending, analysis, and data sharing.

One type of data-sharing that a number of Agreement States suggested NRC could enhance is the collection and sharing of information on licensee revocations and suspensions. The concern is that a licensee with a revoked or suspended license in one State could simply apply for a license in another State. The agency currently maintains a list of NRC licensees that have been suspended or revoked, and the agency sometimes shares this information with Agreement States. NRC encourages voluntary sharing amongst the Agreement States of this information and some Agreement States already share information about revoked or suspended licensees with neighboring States, but NRC does not collect this kind of data from the Agreement States.

NRC also does not routinely and systematically collect Agreement State allegations and enforcement data. FSME officials are reluctant to do so, citing a lack of any need to know of or use such information. FSME managers also pointed out that there is no regulatory requirement or other Federal mandate that requires Agreement States to submit or NRC to collect this information. Nonetheless, an FSME manager stated that NRC has programmatic oversight responsibility for the program and, as the Federal regulator, NRC should not relinquish that responsibility. The manager also stated that if there were a serious event in an Agreement State and Congress became interested in that event, Congress would turn to NRC to testify, not the Agreement State.

Agency Lacks Standardized Communications Procedures and Data Collection and Sharing Tools

NRC lacks standardized procedures and tools to facilitate both communications with and data collection from the Agreement States. For communications with the Agreement States, the agency lacks formal standardized procedures or guidance for RSAOs, including for communicating significant events through the RSAOs or other means. With regard to data collection from the Agreement States, NRC lacks a standardized data collection process that can be used as the basis for a national information sharing tool.

Communications Procedures Needed

NRC lacks formal standardized procedures or guidance for RSAOs to communicate with the Agreement States. Furthermore, the agency has not developed a procedure for prioritizing the types of communications provided to the Agreement States.

The RSAOs are not aware of any formal standardized procedures or guidance for how they are utilized by the agency to communicate with the Agreement States. An NRC manager cautioned that adding a procedure may result in inefficiencies if it required RSAOs to get permission for every communication with the States. However, the manager did not make a distinction between the RSAOs' typical day-to-day communications activities and those communications efforts that are in response to an unusual or significant event.

Had such processes been in place, NRC's Agreement State partners would have had adequate notification to check with the manufacturer and distributor licensees in their respective States

about the unusual purchase inquiry from a suspicious buyer discussed in the earlier example. As one Agreement State official observed, NRC does not have any clear method for releasing this kind of information to the States. The State official considered this peculiar because NRC always wants the States to have a record of every incident that occurs.

NRC management has also acknowledged problems with the way the agency communicates to Agreement States via letters and e-mail. The lack of a procedure has recently prompted FSME managers to begin implementing ways to disseminate information to the States.

Data Collection Process Needed

NRC lacks a standardized data collection process that can be used as the basis for sharing information on a national level. Such a process would include documented procedures and guidance—along with some information management tools—to facilitate the collection and/or sharing of “bad actor” licensee information, and allegation and enforcement data.

NRC managers indicated that there is a need for a process to capture suspended/revoked licensee and enforcement data. For example, a few years ago, an applicant was banned from getting a radiography license in multiple States. As one manager said, this type of information is important and there should be a system for capturing it. Another manager said that the idea of a national database that keeps track of this kind of information has been considered before, but these efforts have not progressed.

FSME managers cautioned that it would be difficult to implement a data collection process because it would require consensus among all 35 Agreement State regulators. One manager said that some States might be resistant to change because of budgeting constraints. Furthermore, Agreement State officials point out that such a database could be inappropriately used to blacklist potential licensees. Still, as one State official said, if another State has “bad actors” then the other jurisdictions need to know about them as well. OIG contends that NRC could establish a data collection standard via new rulemaking.

A process to support systematic enforcement data collection is also needed. An NRC manager stated that an enforcement database would benefit reciprocity⁸ because a State would be able to look up a licensee and identify any violations that occurred in another State.

Impacts on NRC and State Regulatory Efforts

Lacking standardized procedures and tools to facilitate both communications with and data collection from the Agreement States, NRC and State regulators are denying themselves benefits of information sharing. Moreover, the consequences of not collecting information, such as licensing and inspection practices, incidents, and other technical and statistical information, could potentially impact the American public health and safety and also hamper the identification and evaluation of issues and options for the development of program responses to national problems.

NRC also assumes risks in not having standardized communications, prioritization, and data collection procedures. Ultimately, this increases the likelihood that States are not cognizant of some important issues and “bad actors,” and NRC not having a full and accurate awareness of Agreement State regulatory activities. By improving communication and data sharing activities, coordination and cooperation between NRC and Agreement States should be enhanced.

Recommendations:

3. Develop a set of procedures that standardizes communications from NRC to the Agreement States.
4. Develop a standardized data collection process that can be used as the basis of an information sharing tool on a national level.

⁸ Reciprocity is the notion that a licensee from one Agreement or non-Agreement State can operate in another Agreement or non-Agreement State, which can accept the license at face value as long as the licensee follows the rules of the State in which it wishes to operate.

D. Weaknesses Exist in NRC's Review of Agreement State Event Reporting

NRC's reviews of whether an Agreement State has appropriately reported all events to the Nuclear Material Events Database (NMED) may not be consistently performed. While IMPEP reviews do look at NMED data submitted by Agreement States, the relevant IMPEP procedure does not require an analysis of unreported events to determine whether such events are being appropriately identified for and included in NMED. Consequently, NRC and the public may have an inaccurate accounting of material events in some States, which could also hamper events data trend analysis efforts.

The Purpose of NMED

Agreement State licensees are required to report the occurrence of incidents and events involving the use of nuclear materials to the appropriate regulatory agency. NRC also requires Agreement States to report some of these events to NMED. Under the authority of the Atomic Energy Act and the Energy Reorganization Act of 1974, as amended, NRC evaluates material event reports for both NRC and Agreement State licensees. NRC compiles materials event data through NMED and the agency's Event Notification system.⁹ NMED contains a historical collection of information on the occurrence, description, and resolution of events involving the use of radioactive materials in the United States and is intended to accommodate the sharing of material event data submitted by Agreement States and non-Agreement States. FSME uses the data collected in NMED for trending analysis.

The FSME procedure which establishes a process for the collection, control, and preliminary review of material events that have been reported to NRC by the Agreement States is SA-300, *Reporting Material Events*. This procedure also provides U.S. Code of Federal Regulations regulatory reporting requirements for material events. Moreover, it encourages States to voluntarily report an event that might be of safety significance or of generic interest or concern, even though it does not meet the regulatory reporting requirement.

⁹ The Event Notification system is an NRC automated event tracking system used by the NRC Operations Center to track information on incoming notifications of the occurrence of significant material events that have affected or may affect public health and safety.

The IMPEP teams are tasked with reviewing Agreement State data submissions to NMED. According to SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*, IMPEP teams should examine a sample of program incident response and allegation activities. This analysis is done to confirm that appropriate followup measures to the reported events are taken, whether NMED notification is performed in a timely manner, and that the number and type of event reports and technical quality of information recorded in NMED and on record at the Agreement States are consistent.

NRC has responsibility for performing analysis on the information contained in NMED for each major event type to identify any statistically significant trends. FSME is the NRC office responsible for NMED, and uses Idaho National Laboratory for coding and quality control of the data. Idaho National Laboratory primarily obtains the data for NMED from the agency's daily reports (event notifications, preliminary notifications, and morning reports), NRC inspection reports, and Agreement State event notifications. Though Idaho National Laboratory maintains the database, NRC staff conduct a weekly review of all new material event notifications received by the NRC Operations Center and followup reports entered into NMED.¹⁰

IMPEP Reviews of NMED May Be Inconsistent

IMPEP reviews include an evaluation of whether the subject Agreement State has appropriately reported all events to NMED, but this effort may not be consistently performed. OIG's analysis of data in NMED indicates that some Agreement States may have underreported events to NMED. For example, the number of events submitted by one State that OIG reviewed was not commensurate with the number of events reported by other States when adjusting for the size of the State programs. However, the reasons for this State's relatively low number of submittals to NMED was not addressed in the last full IMPEP report for the State. Nor is it clear from the report whether the IMPEP team specifically reviewed incidents that were not reported to NMED for potential inclusion in the database.

¹⁰ The objective of the review is to identify any events that may involve generic safety concerns or could have significant impact on public health, safety, or security.

Relevant IMPEP Procedure Does Not Require Analysis of Unreported Events

The FSME procedure SA-105 does not require the IMPEP team to review the States' events in order to determine whether events not reported to NMED were appropriately not reported. The procedure states the overall objective to verify that the information provided by the Agreement States on incidents for inclusion in NMED is complete and accurate. However, the review guidance in SA-105 does not specifically guide the IMPEP team to sample events that were not reported to NMED and confirm that they were appropriately not reported.

For example, SA-105 guides the IMPEP team to determine that the number of events, type of event reports, and technical quality of information recorded in NMED is consistent with the information on record at an Agreement State. But SA-105 does not specifically address those events that are not recorded in NMED for an analysis of whether they should have been included in NMED.

Potentially Inaccurate Accounting of Events in Agreement States

Given the lack of IMPEP guidance to review events that were not reported to NMED and confirm that they were appropriately not reported, NRC and the public may have an inaccurate accounting of material events in some States. Furthermore, this could also hamper trend analysis efforts that have occurred involving the licensed and unlicensed use of nuclear materials, identification of generic issues, and recognition of any inadequacies or unreliability of specific equipment or procedures.

Recommendation:

5. Revise the applicable IMPEP procedure(s) to include a review of Agreement State events that are not recorded in NMED for an analysis of whether they should have been included in NMED.

IV. CONSOLIDATED LIST OF RECOMMENDATIONS

OIG recommends that the Executive Director for Operations:

1. Develop a mechanism for conducting self-assessments and capturing lessons learned for IMPEP on a regular basis.
2. Develop formal procedural guidance for identifying what information is needed about Agreement State programs and materials licensees in the event that an Agreement State is no longer capable of adequately performing its function of protecting public health and safety for an indeterminate period of time.
3. Develop a set of procedures that standardizes communications from NRC to the Agreement States.
4. Develop a standardized data collection process that can be used as the basis of an information sharing tool on a national level.
5. Revise the applicable IMPEP procedure(s) to include a review of Agreement State events that are not recorded in NMED for an analysis of whether they should have been included in NMED.

SCOPE AND METHODOLOGY

The audit objective was to assess NRC's oversight of the adequacy and effectiveness of Agreement State programs. OIG focused its review on the IMPEP process as well as other elements of the Agreement State program. To address the audit objective, OIG reviewed IMPEP guidance, attended IMPEP reviews, reviewed Federal guidance related to emergency preparedness planning, and analyzed the process for collecting and disseminating information to Agreement States. Additionally, OIG analyzed program documents, reviewed relevant management controls, and reviewed documentation from internal and external sources. Some of the key documents reviewed include:

- Section 274 of the Atomic Energy Act, "Cooperation with States."
- Management Directive 5.6, *Integrated Materials Performance Evaluation Program*.
- Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*.
- OMB Circular A-123, *Management's Responsibility for Internal Control*.
- SA-102, *Reviewing the Common Performance Indicator, Technical Quality of Inspections*.
- SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*.
- SA-112, *Emergency Suspension of a Section 274b Agreement*.
- Federal Continuity Directive 1, *Federal Executive Branch National Continuity Program and Requirements*.
- NRC's agreements with States.
- Letters issued to Agreement States by FSME.
- Material events reported to NMED by Agreement States from January 1, 2007, to June 30, 2008.

- IMPEP review reports issued from January 19, 2007, to August 27, 2008.

Auditors also conducted interviews with more than 60 agency and Agreement State employees, including NRC managers and staff at Headquarters and the regions, and Agreement State managers and staff members from 15 States.

OIG conducted this audit at NRC Headquarters, one region, and selected Agreement States nationwide between February 2008 and August 2008 in accordance with generally accepted Government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Major contributors to this report were Sherri Miotla, Team Leader; R.K. Wild, Audit Manager; Eric Rivera, Senior Auditor; David Ditto, Senior Management Analyst; and Rebecca Ryan, Management Analyst.

FORMAL AGENCY COMMENTS



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

February 26, 2009

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

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

SUBJECT: COMMENTS ON OFFICE OF THE INSPECTOR GENERAL'S
DRAFT AUDIT REPORT, "AUDIT OF NRC'S AGREEMENT
STATE PROGRAM"

This memorandum and its enclosure transmits our comments on the Office of the Inspector General's draft audit report, "Audit of NRC's Agreement State Program," transmitted via memorandum on February 13, 2009. We appreciate the opportunity to comment on the draft audit report.

Enclosure:
Comments on Draft Audit Report

CONTACT: Andy Imboden, FSME
301-415-2327

**COMMENTS ON OFFICE OF INSPECTOR GENERAL'S (OIG)
DRAFT AUDIT REPORT: AUDIT OF NRC'S AGREEMENT STATE PROGRAM**

1. The U.S. Nuclear Regulatory Commission (NRC) staff appreciates the recommendations resulting from the audit, and views these recommendations as enhancements to an already strong program that is a model for Federal and State government relations. The NRC's Agreement State Program and the Integrated Materials Performance Evaluation Program (IMPEP) have been recognized domestically and internationally for its effectiveness. NRC has designated IMPEP as the program used to periodically evaluate the Agreement States to ensure adequate protection of public health and safety, as required by Section 274j of the Atomic Energy Act of 1954, as amended. The International Atomic Energy Agency used IMPEP as a basis when developing its program to review member countries. In 2004, IMPEP was recognized by Harvard University as a Top 50 Finalist for the Innovations in Government Award. The staff does not consider any of the OIG findings as indicative that the Agreement State Program and IMPEP fail to continue to adequately fulfill their respective statutory requirements. The staff believes that the resolution of OIG's recommendations will continue the improvement of both of these model programs.
2. Some of the audit findings and observations in this report are more indicative of a program where regulatory authority is delegated, rather than where regulatory authority is discontinued. The NRC's Agreement State Program is a relinquishment, or discontinuance, of NRC's regulatory authority where the State assumes that regulatory authority. The statute governing the Agreement State program requires that NRC maintain an oversight role to ensure that public health and safety is adequately protected across the nation. The audit report recognizes this unique transfer of Federal responsibility to the States that sign Agreements with NRC in the Background Section; however, some of the findings in the draft report reflect a program where regulatory authority is delegated. For example, on page 23, starting on line 19, the report implies that NRC should routinely and systematically collect information, such as allegation and enforcement information, from the Agreement States. Under a relinquishment of authority, the need to routinely collect this information is difficult to justify, and may not be warranted. As appropriate, such information is evaluated during IMPEP reviews.
3. The Agreement States did not have an opportunity to review and comment on the draft audit report, even though many of the findings and recommendations are based upon discussions with Agreement State personnel. The staff suggests OIG consider finding a method of sharing their predecisional information with the Agreement States, and otherwise let them take a meaningful role in the development process, especially regarding audit reports that so closely audit their programs in the future.
4. With regard to OIG Recommendation 4, the staff believes that the legal and policy ramifications of such information collection by NRC need further review. In addition, the staff has efforts underway for improvements to the materials program that may result in achieving the same objectives. For example, pre-licensing visits, background checks, and changes to NRC's "good faith presumption," if adopted, would provide opportunities to identify individuals with questionable backgrounds prior to their approval.

Enclosure

OIG ANALYSIS OF AGENCY COMMENTS

On December 3, 2008, OIG provided a draft report to the Executive Director of Operations. OIG subsequently met with managers from the Office of Federal and State Materials and Environmental Management Programs and the Office of Nuclear Security and Incident Response on December 16, 2008, and again on January 9, 2009, to address agency concerns with the draft report. OIG modified the report as appropriate in response to comments made by agency officials. On February 26, 2009, the Executive Director for Operations provided a formal response to this report. OIG's analysis of those comments are provided below.

NRC Comments

The U.S. Nuclear Regulatory Commission (NRC) staff appreciates the recommendations resulting from the audit, and views these recommendations as enhancements to an already strong program that is a model for Federal and State government relations. The NRC's Agreement State Program and the Integrated Materials Performance Evaluation Program (IMPEP) have been recognized domestically and internationally for its effectiveness. NRC has designated IMPEP as the program used to periodically evaluate the Agreement States to ensure adequate protection of public health and safety, as required by Section 274j of the Atomic Energy Act of 1954, as amended. The International Atomic Energy Agency used IMPEP as a basis when developing its program to review member countries. In 2004, IMPEP was recognized by Harvard University as a Top 50 Finalist for the Innovations in Government Award. The staff does not consider any of the OIG findings as indicative that the Agreement State Program and IMPEP fail to continue to adequately fulfill their respective statutory requirements. The staff believes that the resolution of OIG's recommendations will continue the improvement of both of these model programs.

OIG Response

OIG agrees that the recommendations will enhance the Agreement State and IMPEP programs.

Some of the audit findings and observations in this report are more indicative of a program where regulatory authority is delegated, rather than where regulatory authority is discontinued. The NRC's Agreement State Program is a relinquishment, or discontinuance, of NRC's regulatory authority where the State assumes that

regulatory authority. The statute governing the Agreement State program requires that NRC maintain an oversight role to ensure that public health and safety is adequately protected across the nation. The audit report recognizes this unique transfer of Federal responsibility to the States that sign Agreements with NRC in the Background Section; however, some of the findings in the draft report reflect a program where regulatory authority is delegated. For example, on page 23, starting on line 19,¹¹ the report implies that NRC should routinely and systematically collect information, such as allegation and enforcement information, from the Agreement States. Under a relinquishment of authority, the need to routinely collect this information is difficult to justify, and may not be warranted. As appropriate, such information is evaluated during IMPEP reviews.

OIG Response

OIG holds the view that (1) there should be a balance between the agency's relinquishment of regulatory authority to the Agreement States and NRC's responsibilities to oversee the program and (2) NRC's oversight responsibilities should not be limited to determinations of State program adequacy and compatibility only through IMPEP reviews. The OIG report documents instances where additional types of Agreement State licensee information would be warranted to fulfill NRC's role as a Federal-level partner in the Nationwide regulation of materials. In particular, allegation and enforcement data are precisely the types of information that would meet the requirement in recent NRC agreements with States that the regulatory partners "keep each other informed of events, accidents, and licensee performance that may have generic implications."

The Agreement States did not have an opportunity to review and comment on the draft audit report, even though many of the findings and recommendations are based upon discussions with Agreement State personnel. The staff suggests OIG consider finding a method of sharing their predecisional information with the Agreement States, and otherwise let them take a meaningful role in the development process, especially regarding audit reports that so closely audit their programs in the future.

¹¹ The page number cited in the formal agency comments refers to an earlier draft of this report. The relevant citation in the final report is the section titled "Data Collection" on page 15.

OIG Response

OIG's policy is to share draft reports with the responsible NRC organization or office of the program under review, which, in this case, were two offices. However, OIG also appreciates the importance of NRC's coordinating with its Agreement States partners. OIG encourages NRC to incorporate the various perspectives of the Agreement States in developing a plan to address the OIG recommendations.

With regard to OIG Recommendation 4, the staff believes that the legal and policy ramifications of such information collection by NRC need further review. In addition, the staff has efforts underway for improvements to the materials program that may result in achieving the same objectives. For example, pre-licensing visits, background checks, and changes to NRC's "good faith presumption," if adopted, would provide opportunities to identify individuals with questionable backgrounds prior to their approval.

OIG Response

As discussed in the report, NRC serves as the Federal-level partner in the National Materials Program and provides a coordinating role for all materials regulators. This helps ensure that the safety and security of radioactive materials is consistently regulated nationwide, rather than piecemeal among 36 different regulators, specifically 35 Agreement States and NRC. In simple terms, OIG observed that there are some types of information that NRC does not currently collect, that some of the Agreement State program managers stated would be of value to them if NRC had collected it, and for which there is no mechanism in place for collecting and sharing such information. Recommendation 4 is designed to address these shortcomings.