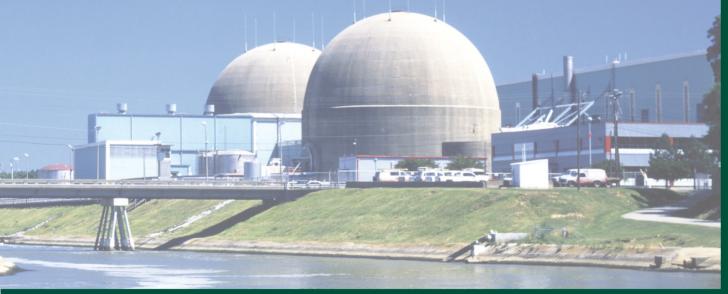


Office of the Inspector General

U.S. Nuclear Regulatory Commission
Defense Nuclear Facilities Safety Board

Audit of NRC's Process for Ensuring Integrity in Scientific Research

OIG-15-A-08 February 10, 2015





All publicly available OIG reports (including this report) are accessible through NRC's Web site at

http://www.nrc.gov/reading-rm/doc-collections/insp-gen

OFFICE OF THE INSPECTOR GENERAL

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

February 10, 2015

MEMORANDUM TO: Mark A. Satorius

Executive Director for Operations

FROM: Stephen D. Dingbaum /RA/

Assistant Inspector General for Audits

SUBJECT: AUDIT OF NRC'S PROCESS FOR ENSURING INTEGRITY

IN SCIENTIFIC RESEARCH (OIG-15-A-08)

Attached is the Office of the Inspector General's (OIG) audit report titled *Audit of NRC's Process for Ensuring Integrity in Scientific Research*.

The report presents the results of the subject audit. Following the January 23, 2015, exit conference, agency staff indicated that they had no formal comments for inclusion in 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 (301) 415-5915 or Sherri Miotla, Team Leader, at (301) 415-5914.

Attachment: As stated



Office of the Inspector General

U.S. Nuclear Regulatory Commission Defense Nuclear Facilities Safety Board

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Results in Brief

Why We Did This Review

This was a planned audit as noted in the 2014 OIG Annual Plan. This audit aligned with NRC's identified management challenges regarding managing regulatory processes to meet a changing environment in the oversight of nuclear materials and facilities.

The audit objective was to determine whether the **Nuclear Regulatory** Commission (NRC) has controls in place to assure that scientific research is objective, credible, and transparent. As such, we examined NRC's Information Quality Program and peer review guidance to determine whether NRC had followed applicable Federal requirements when establishing the program and instituting guidance. We also assessed the oversight of NRC's Information Quality Program to determine if there is consistent understanding and communication of the associated roles and responsibilities assigned to involved management and staff.

Audit of NRC's Process for Ensuring Integrity in Scientific Research

What We Found

Although NRC has established an Information Quality Program that contains the administrative mechanisms required by the Office of Management and Budget (OMB), there is room for improvement. NRC's Information Quality Program is ineffective because of a lack of program management and communication regarding program requirements to involved staff and management. As a result, NRC's commitment to public participation and transparency is compromised. Moreover, NRC is at risk of providing inaccurate information to OMB and Congress regarding a Federally mandated program.

What We Recommend

We recommend that the Executive Director for Operations take steps to strengthen the agency's Information Quality Program, including designating an Information Quality Program owner and clearly delineating roles and responsibilities among involved offices; assigning responsibility for routinely checking, responding to, and tracking the resolution of information correction requests submitted via vehicles identified on NRC's public Web pages regarding Information Quality Guidelines; holding an annual meeting with involved NRC staff and management to discuss the requirements and responsibilities associated with the identification and reporting of Influential Scientific Information and Highly Influential Scientific Assessment information products; developing a schedule to ensure that the Office of Nuclear Regulatory Research's internal office instructions are regularly reviewed and revised, as appropriate; and directing all offices to review and revise office guidance on peer review to align with requirements established by OMB and the National Academy of Sciences.

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ABBREVIATIONS AND ACRONYMS

MD Management Directive

NRC U.S. Nuclear Regulatory Commission

OMB Office of Management and Budget

RES Office of Nuclear Regulatory Research

I. BACKGROUND

Scientific Integrity in the Federal Government

The Federal Government disseminates a variety of scientific information, including statistical information; information about health, safety, and environmental risks; and technical information it creates or obtains in the course of developing regulations. Scientific information is based on scientific research, analyses, and data performed to support the agency's work.

Scientific information is defined as factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. Often, regulations are based on scientific, engineering, and economic analyses. Therefore, it is crucial that information disseminated by Federal agencies be objective, and have utility, quality, and integrity.

Requirements for Federal Agencies

To ensure information integrity, Federal agencies are required to adopt standards for information quality. These standards are set by the Office of Management and Budget (OMB). OMB requires agencies to

- Designate influential¹ information.
- Implement an administrative mechanism allowing affected persons to seek and obtain correction of information disseminated by the agency.

¹ "Influential," when used in the phrase "influential scientific or statistical information," means the agency expects that information in the form of analytical results will likely have an important effect on the development of domestic or international government or private sector policies or will likely have important consequences for specific technologies, substances, products, or firms.

- Provide a publicly available annual report that provides information on information correction requests, designated influential information, and peer reviews.
- Follow peer review requirements for designated influential scientific information.

Information Integrity at the U.S. Nuclear Regulatory Commission (NRC)

NRC has an Information Quality Program that involves many offices, including the Office of Information Services, the Office of Nuclear Regulatory Research (RES), and the Office of the Executive Director for Operations. These three offices have a central role in implementing NRC's Information Quality Program. Additionally, other offices support the Office of Information Services, RES, and the Office of the Executive Director for Operations in ensuring information integrity. These offices include the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of New Reactors, and the Office of Nuclear Security and Incident Response.

Areas of NRC Research

NRC's regulatory research program addresses issues in nuclear reactors, nuclear materials, and radioactive waste. RES is a technical support office that supplies technical tools, analytical models, analyses, experimental data, and technical guidance to support NRC's regulatory programs and decisions. See Table 1 for examples of NRC research areas.

Table 1: Examples of NRC Research Areas

Area of Research	Description		
Nuclear Reactor Safety Research	Research in this area includes reactor fuel behavior, plant aging, digital instrument and control, and operational data assessment.		
Radiation Protection	The radiation protection research program collects, analyzes, and disseminates information on occupational exposures reported to NRC by licensees.		
Radiation Safety Research	Research in this area includes a state-of-the-art study on cancer risk for populations surrounding NRC-licensed facilities and estimates of the offsite radiological health consequences for severe nuclear power reactor accidents.		
Waste Safety Research	Research in this area includes spent nuclear fuel and assessing decommissioning and waste management options.		
Computer Codes	NRC uses computer codes to model and evaluate fuel behavior, reactor kinetics, thermal-hydraulic conditions, severe accident progression, time-dependent dose for design-basis accidents, emergency preparedness and response, health effects, and radionuclide transport during various operating and postulated accident conditions.		

Source: NRC.

Peer Review

Peer review is an important procedure used by the scientific community to ensure the quality of published information and increase the quality and credibility of the scientific information generated across the Federal Government. Peer review is a form of deliberation involving an exchange of judgments about the appropriateness of methods and the strength of the author's inferences. It involves the review of a draft product for quality

by specialists in the field who were not involved in producing the draft. NRC conducts peer review of some of its scientific products.

II. OBJECTIVE

The audit objective was to determine whether NRC has controls in place to assure that scientific research is objective, credible, and transparent. Appendix A contains information on the audit scope and methodology.

III. FINDINGS

While NRC has controls in place, there is room for improvement. Specifically, NRC needs to strengthen its Information Quality Program and adopt OMB guidelines on peer review.

A. NRC's Information Quality Program Is Ineffective

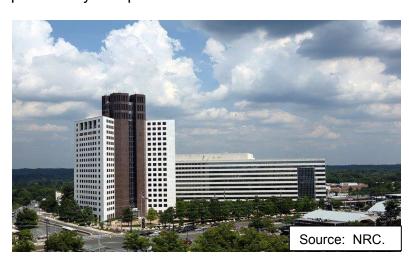
Although NRC has established an Information Quality Program that contains the administrative mechanisms required by OMB, the program is largely ineffective. NRC's Information Quality Program is ineffective because of a lack of program management and communication regarding program requirements to involved staff and management. As a result, NRC's commitment to public participation and transparency is compromised. Moreover, NRC is at risk of providing inaccurate information to OMB and Congress regarding a federally mandated program.

What Is Required

Federal Guidance

In October 2001, OMB issued the Guidelines for Ensuring and

Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2001 OMB Bulletin). These guidelines provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information they disseminate. Within 1 year after the guidelines' issuance, Federal agencies were required to implement their own guidelines that include "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency." Pursuant to the guidelines, agencies are also required periodically to report to OMB the number and nature of complaints



received
regarding the
accuracy of
information
disseminated by
the agency and
how the
complaints were
handled.
Agencies are
also required to
provide an

annual report on the number of information products that met the criteria for Influential Scientific Information or Highly Influential Scientific Assessment. Table 2 contains the definitions of Influential Scientific Information and Highly Influential Scientific Assessment. Information product refers to any book, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD-ROM, or Web page.

Table 2: Definitions of Influential Scientific Information and Highly Influential Scientific Assessment

Term	Definition	
Influential Scientific Information	Influential scientific information is information that an agency reasonably can determine will have or does have a clear and substantial impact on important public policies or the private sector. Influential information, as defined in the NRC Information Quality Guidelines, is information that forms the technical basis for a substantive rulemaking that has substantial impact on an industry.	
Highly Influential Scientific Assessment	A highly influential scientific assessment is utilized as the basis of a rulemaking or regulatory action that NRC determines could have a potential impact of more than \$500 million in any single year on either the public or private sector or that the action represents a novel, controversial, or precedent setting approach, or has significant interagency interest. These assessments are considered a subset of Influential Scientific Information.	

Source: NRC Management Directive 3.17.

Agency Guidance

In 2009, NRC implemented Management Directive (MD) 3.17, *NRC Information Quality Program,* which established policy and quality standards for information disseminated by the agency and delineated organizational roles and responsibilities among offices. In accordance with the 2001 OMB Bulletin, MD 3.17 specifically addresses the administrative process for handling and reporting on information correction requests and provides instructions for reviewing information dissemination products to determine if they meet the criteria for Influential Scientific Information or Highly Influential Scientific Assessment. MD 3.17 provides guidance for processing information correction requests to ensure an opportunity for public involvement in the agency's Information Quality Program. Specific roles and responsibilities for overseeing the processing

of information correction requests are identified within MD 3.17 and are specific to designated individuals; however, primary accountability for ensuring the effectiveness of information correction requests lies with the Office of Information Services. It is important that information correction requests receive appropriate consideration in a timely manner. For example, MD 3.17 states, "The Information Quality Coordinator must review the information correction request within five days of receipt, and forward it to the responsible NRC office." MD 3.17 also addresses the review of NRC information to identify Influential Scientific Information and Highly Influential Scientific Assessments and assigns specific roles and responsibilities to the Office of the Executive Director for Operations, the Office of Information Services, RES, and other offices. It also identifies the criteria for designating information as Influential Scientific Information or a Highly Influential Scientific Assessment.

To ensure that the agency's information products are appropriately reviewed and identified as Influential Scientific Information or a Highly Influential Scientific Assessment, it is imperative that involved offices fulfill their assigned roles and responsibilities. It is also important that the criteria associated with Influential Scientific Information and Highly Influential Scientific Assessment are consistently understood and applied by involved staff and management.

What We Found

NRC has established an Information Quality Program governed by MD 3.17. Although the agency's program meets OMB requirements, it is largely ineffective.

Specifically, the public's ability to seek correction to agency information or access annual reports on the resolution of previously submitted information correction requests is limited. Additionally, agency staff and management are not consistently reviewing information products against the Influential Scientific Information and Highly Influential Scientific Assessment criteria.

Information Correction Requests

As it is currently administered, NRC's Information Quality Program does not ensure effective or efficient processing of information correction requests in accordance with OMB and NRC requirements. The administrative mechanisms identified by NRC on the public Web page titled "How to Submit a Request for Correction" include mail, fax, e-mail, and Internet submission. Beginning in August 2014, OIG submitted multiple inquiries, following the agency's instructions using each of the identified mechanisms, to test their functionality and determine whether



the agency followed the identified process for reviewing each submission. Three of the four mechanisms were functional and the inquiries were successfully sent; however, the fax number was invalid. To date, NRC has not responded to any of the three successfully sent

inquiries, thereby significantly exceeding the designated 5-day timeliness metric in MD 3.17. Program management agreed that there is no consistent monitoring of incoming information correction requests to ensure each is acknowledged and reviewed in a timely manner even though MD 3.17 assigns this responsibility to an Information Quality Coordinator.

To comply with Federal requirements, NRC has developed two public Web pages dedicated to making information publicly available on the processing of individual information correction requests. The Web page titled "Information Quality: Information Quality Correction Request, Responses, and Appeals" is intended to provide information on each information correction request received, the agency's formal response(s), and any communications regarding appeals. However, the information contained on the Web page is incomplete as there is no reference to years

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² http://www.nrc.gov/public-involve/info-quality/req-resp-appls.html

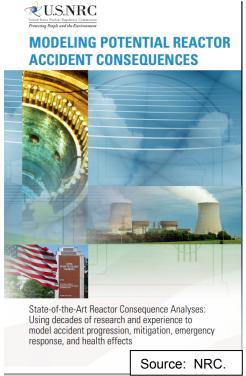
2009 through 2014. In fact, this Web page was last reviewed/updated in March 2012. The Web page titled "Information Quality: Annual Reports" is intended to list annual reports submitted by NRC to OMB regarding information correction requests received and processed under the 2001 OMB Bulletin. The information contained on this Web page is also incomplete because there is no annual report listed for 2012.

Essentially, NRC is noncompliant with both OMB and its own requirements pertaining to facilitating public participation in the agency's Information Quality Program. In its current state, NRC's Information Quality Program does not provide the public with reliable administrative mechanisms to seek correction of information maintained by NRC or obtain information on the resolution of all information correction requests for a given year.

Review and Identification of Influential Scientific Information/Highly Influential Scientific Assessment

In accordance with OMB requirements to report Influential Scientific Information and Highly Influential Scientific Assessments annually, the Office of Information Services sends out a data call to involved program offices to determine if any information products produced each year are

identified as Influential Scientific Information or Highly Influential Scientific Assessments, Information collected through the data call should be collated by the Office of Information Services and forwarded to OMB in a report. Both OMB and NRC officials corroborated that NRC has never reported producing an information product that met the criteria of Influential Scientific Information or Highly Influential Scientific Assessment since the OMB requirement was enacted in 2004. It is common for NRC staff and management to automatically respond to the annual data call that



³ http://www.nrc.gov/public-involve/info quality/annual-reports.html

their respective office has not produced any Influential Scientific Information or Highly Influential Scientific Assessments without consistently reviewing each information product against the identified criteria. An Office of Information Services official stated that some NRC offices base their response on the prior year's response, which, to date, have always been negative. As such, NRC has consistently reported that it does not produce information that is subject to OMB's Bulletin.

In some instances, staff and management do perform the required Influential Scientific Information and Highly Influential Scientific Assessment review but may be misapplying the criteria. For example, although the criteria are not mutually exclusive, staff and management apply them as such. Specifically, some staff and management have based their determination that an information product does not meet the Highly Influential Scientific Assessment criteria simply based on the fact that its impact is not judged to be more than \$500 million in any single year. Meanwhile, equal consideration is not given to the remaining criteria that states, "[T]he action represents a novel, controversial, or precedent setting approach, or has significant interagency interest."

NRC further defines Influential Scientific Information as any "information that forms the technical basis for a substantive rulemaking that has substantial impact on an industry." Given that NRC is a science based agency that has initiated several rulemakings and participated in or sponsored significant research studies that have impacted its stakeholders, it is questionable to think that none of the resulting information products met Influential Scientific Information or Highly Influential Scientific Assessment criteria. This occurrence has been noted both by OMB and by NRC senior management who agree with OIG's assertion that it is likely a result of a misunderstanding and/or misapplication of the Influential Scientific Information and Highly Influential Scientific Assessment criteria.

NRC's Information Quality Program does not provide adequate assurance that NRC information products are being appropriately reviewed to determine if they meet Influential Scientific Information or Highly Influential Scientific Assessment criteria. MD 3.17 defines Influential Scientific Information and Highly Influential Scientific Assessment and the associated criteria. It also assigns involved staff and management specific roles and responsibilities for the review and identification of NRC

information products. However, staff and management do not consistently perform the required reviews or correctly apply the associated criteria to determine if an NRC information product should be designated and reported as Influential Scientific Information or as a Highly Influential Scientific Assessment.

Why This Occurred

Although the agency has met Federal requirements to establish an Information Quality Program, it is largely ineffective because of a lack of program oversight. OIG concludes that staff and management view the program as a formality without a clear purpose. This conclusion has been

corroborated by involved management who have referred to the program "as decorative," while the associated activities are viewed as an "administrative annoyance," "not mission critical" and "not important." Consequently, information correction requests go



unanswered and information products are not being consistently reviewed and identified as Influential Scientific Information or as Highly Influential Scientific Assessments, thereby signaling the ineffectiveness of the agency's Information Quality Program. NRC's Information Quality Program is ineffective because of a lack of program management and communication to involved staff and management regarding program requirements. This is demonstrated by the inherent confusion among staff and management in the Office of the Executive Director for Operations, the Office of Information Services, and RES regarding aspects of the agency's Information Quality Program, including respective roles and responsibilities. For example, staff and management in the Office of Information Services stated that it was unclear as to who has responsibility for routinely monitoring the receipt of and response to information correction requests. There is also confusion among involved offices regarding assigned and perceived roles and responsibilities. For example, Office of Information Services' management sees its role as a "liaison" that collects, collates, and disseminates information but does not have a responsibility to designate information products as Influential Scientific Information or Highly Influential Scientific Assessment. In contrast, RES does not see itself as having any "special role in the Information Quality Program," but rather views the Office of Information Services as the lead for designating information products as Influential Scientific Information or Highly Influential Scientific Assessment. As such, it is evident that the staff and management in the involved offices are unclear on their respective roles and responsibilities despite the guidance provided in MD 3.17. This includes a shared obligation among staff and management in implementing MD 3.17.

A general lack of communication among staff and management on the requirements, assigned roles, and associated responsibilities of the Information Quality Program has also contributed to its ineffective implementation. This was confirmed when OIG contacted involved staff and management to determine (1) if they had evaluated their respective information product against OMB and NRC guidance and (2) the basis for deciding if it met Influential Scientific Information or Highly Influential Scientific Assessment criteria. OIG contacted staff and management involved in key NRC rules, research activities, analyses, and studies.⁴ Table 3 lists those selected by OIG. Half of the staff and management contacted did not evaluate their respective information product against OMB/NRC guidance to determine if it met Influential Scientific Information or Highly Influential Scientific Assessment criteria.

Of the information products that staff evaluated, staff determined that none met the Influential Scientific Information or Highly Influential Scientific Assessment criteria based either on a misapplication or misunderstanding of OMB and NRC guidance. For example, reasons for not identifying an information product included that it was ordered by the Commission, had a "quick turnaround," or "did not result in a regulatory action." Furthermore, at least one of these products would have reasonably met either the Influential Scientific Information or Highly Influential Scientific Assessment criteria.

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⁴ See Appendix B for description of methodology OIG used to select key research activities including analyses, reports, and rulemakings.

Table 3: Sample of NRC Rules, Research Activities, Analyses, and Studies⁵

Activity	Evaluation Against OMB & NRC Criteria	Criteria Met	Agency Reasoning
2009 Security Rule	No	No	Orders were issued prior to OMB Bulletin ⁶ ; Orders were classified
10 CFR Part 37	Yes	No	Did not meet monetary threshold of Highly Influential Scientific Assessment criteria
Continued Storage Rule	Yes	No	Did not meet monetary threshold of Highly Influential Scientific Assessment criteria
Fatigue Management Rule	No	N/A	Update occurred prior to OMB Bulletin ⁷
SOARCA	Yes	No	Did not meet monetary threshold of Highly Influential Scientific Assessment criteria
Cancer Study	Yes	No	"Study is primarily for public confidence reasons and not driven by rulemaking"
Fukushima Task Force Report	No	N/A	A "unique product" that was Commission ordered; quick turnaround; report did not "impose regulatory requirements"
GSI-191	No	N/A	"Study was for public confidence reasons and not driven by rulemaking"

Source: NRC staff and management.

 $^{\rm 5}$ For the full title of the rules, research activities, analyses, and studies, see Appendix B.

⁶ Although the Orders were published in 2001, prior to the OMB Peer Review Bulletin, the resulting rule was published in 2009 and any information products supporting the final rule should have been evaluated for Influential Scientific Information or Highly Influential Scientific Assessment.

⁷ Although the update was published prior to the OMB Peer Review Bulletin, the final Rule was published in 2009, after the OMB Bulletin.

Why This Is Important

To improve the quality of Government information, agencies have a responsibility to ensure that the information they produce conforms to OMB guidance on information quality. This requires that adequate systems are in place to foster openness and transparency that facilitate public participation in the agency's Information Quality Program.

In its current state, NRC's Information Quality Program does not meet the intent of Federal law and does not fully ensure and maximize the quality, objectivity, utility, and integrity of information it disseminates. Stakeholder participation allows the public to contribute ideas and expertise, thereby further enhancing the quality, objectivity, utility, and integrity of an agency's information products while promoting the concepts of transparency and openness. However, the opportunity for the public to seek and obtain correction to NRC information is severely limited. As a result, an opportunity to maximize the quality, objectivity, utility, and integrity of NRC information products through public review is being missed.

Additionally, because the agency's information products are not being consistently reviewed and identified as Influential Scientific Information or Highly Influential Scientific Assessments in accordance with Federal requirements, NRC may be reporting inaccurate data to OMB. As a result, NRC's regulatory work may not be accurately represented to the public and Congress. Consequently, in both instances, stakeholder perception of the agency's commitment to openness and transparency is compromised.

Recommendations

OIG recommends that the Executive Director for Operations

- 1. Designate an Information Quality Program owner and clearly delineate roles and responsibilities among involved offices.
- 2. Assign responsibility for routinely checking, responding to, and tracking the resolution of information correction requests submitted

- via vehicles identified on NRC's public Web pages regarding Information Quality Guidelines.
- Hold an annual meeting with involved NRC staff and management to discuss the requirements and responsibilities associated with the identification and reporting of Influential Scientific Information and Highly Influential Scientific Assessment information products.

B. NRC Has Not Adopted OMB Guidelines on Peer Review

NRC has not adopted OMB requirements on peer review as its official guidelines. The OMB requirements have not been adopted because NRC lacks an effective mechanism to ensure that internal office guidance that may be impacted by new or revised Federal guidance is regularly reviewed to determine if revisions are necessary. As a result, offices involved in the peer review process, such as RES, have outdated office guidance on the peer review process that is not aligned with OMB requirements. Consequently, the potential exists for NRC to inappropriately assess the need for and/or conduct a peer review, which could subsequently lead to the public questioning the credibility of NRC's research products.

What Is Required

Federal law requires integrity in the information disseminated by the Government. The Information Quality Act of 2001 directed OMB to issue Governmentwide guidelines that provide guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information. OMB issued a 2004 Bulletin titled "Final Information Quality Bulletin for Peer Review" (2004 OMB Bulletin) that

- 1. Defines peer review and explains its importance and purpose.
- 2. Requires that important scientific information be peer reviewed,

including influential scientific information and highly influential scientific assessment.

3. Requires agencies to adopt the committee selection policies of the National Academy of Sciences⁸ when selecting peer reviewers who are not Government employees.

One way a Federal agency can ensure the integrity of its information is through a peer review. Peer review is an important procedure used to ensure that information meets the standards of the scientific and technical community. Peer review involves the review of a draft by a specialist in the field who was not involved in producing the draft. The critique provided by peer review often suggests ways to clarify assumptions, findings, and conclusions. Peer review may take a variety of forms, depending upon the nature, importance, and categorization of the product.

OMB requires that for peer review of influential scientific information, an agency must consider the following:

- Individual versus panel review.
- 2. Timing of peer review.
- 3. Scope of the review.
- 4. Selection of the reviewers, including conflicts of interest.
- 5. Public participation.
- 6. Disposition of the reviewer comments.
- 7. Adequacy of prior peer review.

OMB requirements for a Highly Influential Scientific Assessment are stricter than those for Influential Scientific Information. For example, agencies must ensure that reviewers are independent of the agency

⁸ The National Academy of Sciences is a private, non-profit society established by Congress, charged with providing independent and objective advice on matters related to science and technology.

sponsoring the review. Additionally, agencies must avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential and cannot be obtained elsewhere.

Moreover, NRC must adopt the National Academy of Sciences policy for selection of peer reviewers who are not Government employees, with respect to evaluating for the potential of conflicts of interest. For example, when selecting a non-Government peer reviewer, NRC must use the Academy's policies for evaluating conflicts arising from investments, affiliations, and income.

What We Found

NRC has not adopted the OMB requirements as its official guidelines for peer review. Specifically, offices that have a central role in the agency's peer review process, such as RES, have outdated office guidance on the peer review process.

RES has internal office guidance on peer review – PRM-010: Peer Review of RES Projects (PRM-010). However, PRM-010 is not in full alignment with OMB requirements. For example, NRC must adhere to the 2004 OMB Bulletin in conducting a peer review of Influential Scientific Information or a Highly Influential Scientific Assessment, but PRM-010 does not clearly articulate the criteria associated with identifying Influential Scientific Information, or address the specific requirements associated with peer reviewing such products. For example, PRM-010 does not mention the adoption of the committee selection policies of the National Academy of Sciences when selecting peer reviewers who are not Government employees. PRM-010 does not provide correct reference to MD 3.17, a document that serves as the agency's primary guidance document on Information Quality including review of Influential Scientific Information and Highly Influential Scientific Assessment products. However, PRM-010 does say that NRC is in the process of adopting OMB's guidelines on peer review as its official guideline for peer review.

Although NRC has not officially adopted OMB peer review guidelines, NRC has a fairly robust peer review program, whereby its products are

peer reviewed and the agency receives independent feedback in other forums. For example, the State-of-the-Art Reactor Consequence Analyses (SOARCA), the Spent Fuel Pool Study, ⁹ and the Cancer Study were all peer reviewed. Additionally, NRC receives independent feedback in other forums outside the traditional peer review context. For example, NRC partners with other countries to exchange information on complex computer codes. ¹⁰ NRC benefits from these partnerships because the countries share their code assessment and experimental results, which helps NRC's validation of the codes. Also, NRC runs cooperative testing with Federal and international partners. For example, NRC ran tests on spent fuel pools at a national laboratory with the Committee of the Safety of Nuclear Installations and the Nuclear Energy Agency. As a result of this cooperative experiment, NRC will benefit from other countries' review and analysis of the testing.

Why This Occurred

NRC has not adopted OMB's peer review requirements because there is not an effective control to ensure that internal office guidance is reviewed upon issuance or revision against Federal requirements. RES requires a biennial review of its office instructions, set forth in Office Instruction ADM-001, *Preparing and Maintaining RES Office Instructions*. However, the requirement was not followed for updating PRM-010. PRM-010 was published in 2007 for interim use and has not been updated. Consequently, ADM-001 is not an effective control to ensure that internal RES guidance is updated.

⁹ The full title of the study is "Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for A U.S. Mark-I Boiling-Water Reactor."

¹⁰ Partnerships include: (i) CSARP [The Cooperative Severe Accident Research Program], which facilitates joint information exchange, periodic analysis, and data for additional code validation and verification; and (ii) CAMP [Code Applications and Maintenance Program], which exchanges information on thermal-hydraulic safety issues related to reactor and plant systems.

Why This Is Important

Since RES internal office instruction is not aligned with OMB guidance, the potential exists for NRC to inappropriately assess the need for and/or conduct a peer review. For example, an NRC product that qualifies as Influential Scientific Information or as a Highly Influential Scientific Assessment may not be peer reviewed in accordance with required OMB standards. Additionally, when NRC selects a peer reviewer who is not a Government employee, the required National Academy of Sciences selection criteria may not be followed.

Subsequently, the potential exists for stakeholders to question the credibility of information disseminated by NRC. The public must be able to have confidence in the Government's scientific products. This is why OMB issued the 2004 Bulletin on peer review – to enhance the quality and credibility of the Government's scientific information. To have public confidence in the quality and credibility of its research products, NRC must follow OMB requirements.

Recommendations

OIG recommends that the Executive Director for Operations

- 4. Develop a schedule to ensure that RES' internal office instructions are regularly reviewed and revised, as appropriate.
- 5. Direct all offices to review and revise office guidance on peer review to align with requirements established by OMB and the National Academy of Sciences.

IV. SUMMARY/CONCLUSION

It is imperative for NRC to have effective controls in place to ensure that its information products are objective, credible, and transparent. Not only do such controls help ensure that NRC is compliant with Federal requirements, but it also strengthens the stakeholder confidence in the agency's ability to regulate in an unbiased, trustworthy, and open manner. At the highest level, the public and other stakeholders want and expect that there is scientific integrity behind the regulatory decisions the agency is making.

V. CONSOLIDATED LIST OF RECOMMENDATIONS

OIG recommends that the Executive Director for Operations

- 1. Designate an Information Quality Program owner and clearly delineate roles and responsibilities among involved offices.
- Assign responsibility for routinely checking, responding to, and tracking the resolution of information correction requests submitted via vehicles identified on NRC's public Web pages regarding Information Quality Guidelines.
- Hold an annual meeting with involved NRC staff and management to discuss the requirements and responsibilities associated with the identification and reporting of Influential Scientific Information and Highly Influential Scientific Assessment information products.
- 4. Develop a schedule to ensure that RES' internal office instructions are regularly reviewed and revised, as appropriate.
- 5. Direct all offices to review and revise office guidance on peer review to align with requirements established by OMB and the National Academy of Sciences.

V. AGENCY COMMENTS

An exit conference was held with the agency on January 23, 2015. Prior to the exit conference, after reviewing a discussion draft, agency management provided comments that have been incorporated into this report, as appropriate. As a result, agency management stated their general agreement with the findings and recommendations and opted not to provide formal comments.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to determine whether NRC has controls in place to assure that scientific research is objective, credible, and transparent.

Scope

The scope of the audit focused on identifying and analyzing NRC's current controls to determine if they are aligned with Federal guidance and ensure that its scientific research is objective, credible, and transparent. We conducted this performance audit at NRC headquarters (Rockville, MD) from June 2014 to December 2014. Internal controls related to the audit objective were reviewed and analyzed. Throughout the audit, auditors were aware of the possibility of fraud, waste, or abuse in the program.

Methodology

OIG reviewed OMB requirements, NRC Management Directives, and NRC Office Instructions, including, but not limited to:

- Memorandum for the Heads of Executive Departments and Agencies (2009).
- OMB Guidelines for Ensuring and Maximizing Quality, Objectivity, Utility, and Integrity (2001).
- OMB's Final Information Quality Bulletin for Peer Review (2004).
- MD 3.17: NRC's Information Quality Management Program (2009).
- MD 10.158: NRC Non-Concurrence Process (2014).
- MD 10.159: The NRC Differing Professional Opinions Program.

- PRM 001, Rev 0: Process for New Work Requests: Responding to Informal Assistance, Research Assistance and User Need Requests (2009).
- PRM 010, Revision 0: Peer Review RES Projects (2007).
- COM 100: Office Instruction Office of Nuclear Reactor Regulation (NRR) interfaces with RES (2006).
- COM 106: Office of New Reactors (NRO) interfaces with RES Rev. 2 (2013).

OIG interviewed NRC staff and management to gain an understanding of the roles and responsibilities related to assurance that scientific research is objective, credible, and transparent. Auditors interviewed staff and management from the Office of Information Services, the Office of the Executive Director for Operations, the Office of Nuclear Regulatory Research, the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of New Reactors, and the Advisory Committee on Reactor Safeguards. Additionally, OIG contacted representatives from OMB.

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

This audit was conducted by Sherri Miotla, Team Leader; Kristen Lipuma, Audit Manager; Kevin Nietmann, Senior Technical Advisor; Jaclyn Storch, Senior Management Analyst; Ashley Gerwitz, Management Analyst; and Anna Boyle, Student Intern.

Rules, Analyses, and Studies Reviewed by OIG

OIG analyzed multiple NRC rules, analyses, and studies performed since the 2004 OMB Bulletin was issued. These items were selected because of significant public interest, interagency cooperation, and potential for substantial impact. These items are named in Table 3 and are referred to by their commonly known name, rather than their official title. The official title of the items is listed below:

- Power Reactor Security Requirements (10 CFR Part 73) [2009 Security Rule].
- NUREG 2155 Implementation Guidance for Title 10 of the CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material" [10 CFR Part 37].
- Continued Storage of Spent Nuclear Fuel Rule (10 CFR 51.23)
 [Continued Storage Rule].
- Final Rulemaking to Amend the Fitness-for-Duty Rule (10 CFR Part 26) [Fatigue Management Rule].
- SOARCA [State-of-the-art Reactor Consequence Analysis].
- Analysis of Cancer Risks in Populations Near Nuclear Facilities: Phase I [Cancer Study].
- Recommendations for Enhancing Reactor Safety in the 21st Century: The Near-Term Task Force Review of Insights From the Fukushima Dai-ichi Accident [Fukushima Take Force Report].
- GSI-191: Experimental Studies of Loss-of-Coolant-Accident-Generated Debris Accumulation and Head Loss with Emphasis on the Effects of Calcium Silicate Insulation [GSI-191].

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COMMENTS AND SUGGESTIONS

If you wish to provide comments on this report, please email OIG using this link.

In addition, if you have suggestions for future OIG audits, please provide them using this <u>link</u>.