



April 2017

NUCLEAR REGULATORY COMMISSION

Efforts Intended to Improve Procedures for Requesting Additional Information for Licensing Actions Are Under Way

Accessible Version

GAO Highlights

Highlights of [GAO-17-344](#), a report to congressional requesters

Why GAO Did This Study

NRC issues RAIs to obtain information in licensing requests to ensure that officials can make a fully informed, technically correct, and legally defensible regulatory decision. RAIs are necessary when the information was not included in an applicant's initial submission, is not contained in any other docketed correspondence, or cannot reasonably be inferred from the information available to agency staff. NRC's use of RAIs has come under scrutiny in the past. For example, NRC's Inspector General, in a 2015 report, cited concerns about RAIs, including the amount of time it took to complete the RAI process and the resources required to do so.

GAO was asked to review how NRC uses RAIs. This report examines (1) NRC's guidance for developing and issuing RAIs and how it differs across offices; (2) how many RAIs NRC has issued over the past 5 years and the kinds of activities that elicit RAIs; and (3) strengths and weaknesses of NRC's processes to develop RAIs identified by NRC and licensees and the actions NRC is taking to address concerns. GAO examined agency guidance documents and selected licensing actions containing RAIs. GAO interviewed NRC officials and selected licensees. GAO randomly selected licensing actions and licensees from a sample of recent licensing actions that included cases from each of NRC's RAI-issuing offices.

What GAO Recommends

GAO is not making any recommendations. NRC generally agreed with GAO's findings.

View [GAO-17-344](#). For more information, contact Frank Rusco at (202) 512-3841 or ruscof@gao.gov.

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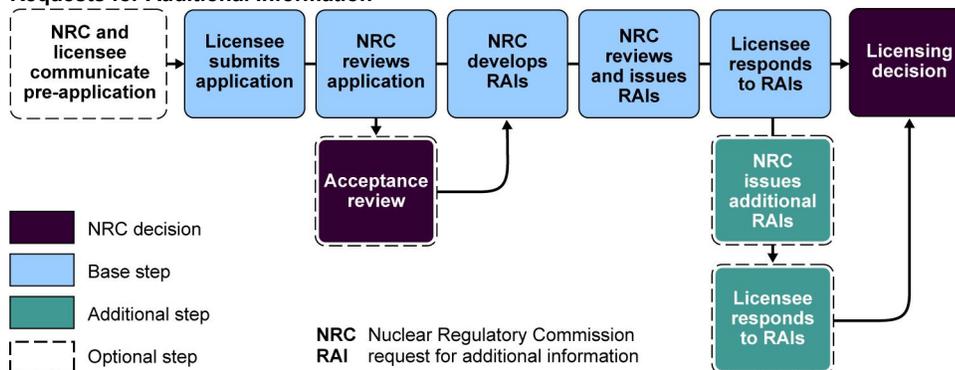
NUCLEAR REGULATORY COMMISSION

Efforts Intended to Improve Procedures for Requesting Additional Information for Licensing Actions Are Under Way

What GAO Found

At the Nuclear Regulatory Commission (NRC), individual offices that issue requests for additional information (RAI) each have their own guidance that is generally the same across the offices. NRC offices have some efforts underway to update their guidance. These efforts are intended to improve oversight of RAIs and include an increased focus on oversight of RAIs and on staff compliance through managerial review. For example, one of the offices that issues RAIs calls for management to discuss the need to send a licensee additional questions on the same topic before doing so.

Summary of Process Used by Nuclear Regulatory Commission Offices to Develop and Issue Requests for Additional Information



Source: GAO analysis of Nuclear Regulatory Commission information. | GAO-17-344

NRC offices that issue RAIs do not specifically track the number of RAIs that they have issued and do not have a comprehensive accounting for the last 5 years, although one office has a system capable of tracking the number of RAIs. Information from NRC officials and licensees GAO interviewed suggests that certain activities and circumstances often elicit RAIs. There is no legal requirement for the agency to track the number of RAIs; however, offices are updating their internal tracking systems in order to improve information on their licensing activities. Receiving RAIs is not unusual, particularly for certain activities such as complex licensing actions and activities for which regulations are unclear, according to officials. In such cases, increased coordination between NRC and the licensee may be required to resolve certain issues.

Licensees GAO interviewed were generally satisfied with the RAI process, identifying strengths and two common weaknesses, and NRC has made recent efforts intended to address these weaknesses. Some licensees noted that they see RAIs as a natural part of interacting with a regulator and identified NRC's openness to communication and engagement as a strength of the RAI process. Two common weaknesses that licensees cited are a gap between NRC's expectations and licensees' understanding of what to include in their applications, and staff departure from guidance. NRC offices have made recent efforts to address these issues. For example, to address inconsistencies between NRC's expectations and licensees' understanding, NRC offices are emphasizing greater communication between review staff and licensees.

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Abbreviations

NRC	Nuclear Regulatory Commission
RAI	request for additional information

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April 25, 2017

The Honorable John Barrasso
Chairman
Committee on Environment and Public Works
United States Senate

The Honorable Shelley Moore Capito
Chairman
Subcommittee on Clean Air and Nuclear Safety
Committee on Environment and Public Works
United States Senate

The Honorable James M. Inhofe
United States Senate

The Nuclear Regulatory Commission (NRC), the independent nuclear regulatory agency of the United States, reviews about 2,500 licensing actions per year in its regulation of commercial nuclear power plants and other uses of nuclear materials, such as in nuclear medicine, through licensing, inspection, and enforcement of NRC's requirements. Through the licensing process, NRC may authorize an applicant to conduct the following activities: (1) construct, operate, and decommission commercial reactors and fuel cycle facilities; (2) possess, use, process, export and import nuclear materials and waste, and handle certain aspects of their transportation; and (3) site, design, construct, operate, and close waste disposal facilities. To become licensed for the aforementioned activities (or to amend, renew, or transfer an existing license), an entity must submit an application to NRC and, if applicable, respond to any requests for additional information (RAI) from NRC staff. According to NRC documents, RAIs are intended to help agency staff obtain information needed to make a regulatory decision that is fully informed, technically correct, and legally defensible.¹ NRC documents also state that RAIs are necessary when information is not included in an applicant's initial submission, is not contained in any other docketed correspondence, or cannot reasonably be inferred from the information available to agency

¹Nuclear Regulatory Commission, "Office of New Reactors NRO Office Instruction: Processing Requests for Additional Information," NRO-REG-101 (July 10, 2014) and U.S. Nuclear Regulatory Commission, "Office of Nuclear Reactor Regulation Office Instruction: License Amendment Review Procedures," LIC-101, Revision 4 (May 25, 2012).

staff. For example, agency staff may use RAIs during an environmental review to look for new or updated information on the issues they are reviewing as part of a license renewal. In other cases, agency staff may use RAIs to obtain information missing from an initial application, such as qualifications of applicants using nuclear materials for medical purposes.

Three NRC offices are responsible for reviewing and approving licensing actions and associated RAIs:

- the Office of New Reactors, which is responsible for licensing and processing license amendment requests for new reactors;
- the Office of Nuclear Reactor Regulation, which is responsible for licensing for operating nuclear power reactors;
- and the Office of Nuclear Material Safety and Safeguards, which is responsible for the safe and secure production of nuclear fuel; the safe storage, transportation, and disposal of high level radioactive waste and spent nuclear fuel; and the transportation of certain radioactive material.²

These offices operate under the Executive Director for Operations, the arm of NRC that carries out the policies and decisions of the five-member Nuclear Regulatory Commission.

NRC's use of RAIs has come under scrutiny in the past. During the late 1990s, the Senate Environment and Public Works Committee identified concerns regarding excessive use of RAIs that resulted in unnecessary increased costs and schedule delays. More recently, in 2015, NRC's Inspector General cited concerns about RAIs in a report on oversight of spent fuel pools, including the amount of time it took to complete the RAI process and the resources required to conduct and review complex research and analyses requested through RAIs.³

You asked us to review NRC's use of RAIs in the licensing process. This report examines: (1) NRC's guidance for developing and issuing RAIs

²The Office of Nuclear Material Safety and Safeguards has four RAI-issuing divisions: Material Safety, State, Tribal, and Rulemaking Programs; Spent Fuel Management; Fuel Cycle Safety, Safeguards and Environmental Review; and Decommissioning, Uranium Recovery, and Waste Programs.

³Office of the Inspector General, U.S. Nuclear Regulatory Commission Defense Nuclear Facilities Safety Board, "Audit of NRC's Oversight of Spent Fuel Pools," OIG-15-A-06 (Feb. 10, 2015).

and how it differs across offices; (2) how many RAIs NRC has issued over the past 5 years and the kinds of activities that elicit RAIs; and (3) strengths and weaknesses of NRC's processes to develop RAIs identified by NRC and licensees, and the actions NRC is taking to address concerns.

For all three objectives, we interviewed a nongeneralizable sample of 12 industry licensees.⁴ We selected interviewees from a set of licensing actions submitted within the randomly selected month of March 2015.⁵ From the set of licensing actions submitted to NRC in March 2015, we randomly selected two licensees that submitted a licensing action to the Office of New Reactors, four licensees that submitted to the Office of Nuclear Reactor Regulation, and six licensees that submitted to the Office of Nuclear Material Safety and Safeguards, in keeping with the general proportion of licensing actions processed annually by each office. Our approach ensured that selected licensees had recent experience working with NRC and that we obtained at least two licensees' perspectives for each of the three RAI-issuing offices. We interviewed licensees by using a standard set of questions that included questions about: (1) the licensees' experience with RAIs, (2) the effect of RAIs on site operations, (3) NRC guidance pertaining to RAIs, (4) past and current challenges with RAIs, and (5) strengths and weaknesses of the RAI process. We analyzed the licensees' responses and grouped them into categories developed through team consensus. When referring to the findings from this analysis, we use "some" to refer to responses from 2 or 3 licensees, "several" to refer to responses from 4 or 5 licensees, "half" to refer to responses from 6 licensees, "many" to refer to responses from 7 to 9 licensees, and "most" to refer to responses from 10 licensees.⁶

To examine NRC's guidance for the development and issuance of RAIs, we reviewed applicable sections of title 10 of the Code of Federal

⁴Because this was a nongeneralizable sample, our results are not generalizable to all licensees and applications but provide examples of licensee perspectives on RAIs.

⁵We use the term "licensing action" to describe licensing activities that feature the submission of an application to NRC, a review by NRC staff, and a determination by NRC whether or not the applicant's assumptions are technically correct and the proposed activity will not threaten the environment.

⁶We did not find agreement among more than 10 licensees on any of the categories we identified.

Regulations.⁷ We also reviewed guidance documents specific to each of NRC's RAI-issuing offices. These documents included, among others, office instruction for the Office of New Reactors,⁸ the Office of Nuclear Reactor Regulation's License Amendment Review Procedures,⁹ and guidance documents for the four RAI-issuing divisions of the Office of Nuclear Material Safety and Safeguards.¹⁰ To ensure the completeness and relevancy of the information, we interviewed knowledgeable NRC officials from the offices that issue RAIs and use these documents. We asked NRC officials about efforts underway to maintain the focus on improving the RAI process and staff compliance with guidance. We also asked the nongeneralizable sample of 12 industry licensees about their experiences using NRC guidance documents when addressing RAIs.

In an effort to determine the number of RAIs issued by NRC in the past 5 years, we asked NRC officials to estimate how many RAIs they issued, to describe internal and external tracking systems they use, and to describe the ability of these systems to provide information on the number of additional, follow-up questions issued to licensees. We also reviewed NRC's guidance for tracking RAIs, issuing follow-up questions, and managing the licensee response to RAIs. To identify the type of information contained in RAIs, we asked NRC officials to describe common reasons for RAI issuance and reviewed a nongeneralizable sample of three licensing actions with RAIs.¹¹ The sample contained one

⁷See 10 C.F.R. § 2.102(a). NRC's regulations state that during the review of an application by NRC staff, an applicant may be required to supply additional information. The regulations also call for NRC staff to establish a schedule for the agency's review of the application and to specify the intermediate steps between the time of docketing until the completion of the review.

⁸Nuclear Regulatory Commission, "Office of New Reactors NRO Office Instruction: Processing Requests for Additional Information," NRO-REG-101 (July 10, 2014).

⁹Nuclear Regulatory Commission, "Office of Nuclear Reactor Regulation Office Instruction: License Amendment Review Procedures," LIC-101, Revision 4 (May 25, 2012).

¹⁰Guidance documents we reviewed include: Nuclear Regulatory Commission, "Fuel Cycle Licensing Review Handbook," Revision 5, (July 2015); Nuclear Regulatory Commission, "Consolidated Guidance About Materials Licenses," *NUREG-1556*, Vol. 20 (December 2000); Nuclear Regulatory Commission, "Decommissioning and Uranium Recovery Licensing Instructions/Procedures," Revision 2, (Mar. 27, 2009); and Nuclear Regulatory Commission, "SFM Division Instruction: Operational Strategies and Management Expectations," SFM-26, Rev. 0 (Aug. 8, 2016).

¹¹Because this was a nongeneralizable sample, our results are not generalizable to all licensing actions but provide illustrative examples of the types of information included in RAIs and processes followed by different NRC offices.

randomly selected licensing action from each of the three RAI-issuing offices submitted within the randomly selected month of March 2015. The examples also reflected different types of licensing actions, as one was for a license renewal, another was for a license amendment request, and the third was for a relief request.¹² We also asked the nongeneralizable sample of 12 industry licensees about the type of information requested in RAIs they received.

To assess the strengths and weaknesses of NRC's processes for developing and issuing RAIs, we asked for the perspective of NRC officials and conducted interviews with the 12 industry licensees or applicants, as noted above. To obtain additional perspective, we also interviewed an industry interest group representative who interacts with both industry and NRC on regulatory issues. To identify NRC efforts to address concerns raised, we reviewed updates made to guidance documents and asked NRC officials and licensees about actions taken to mitigate challenges.

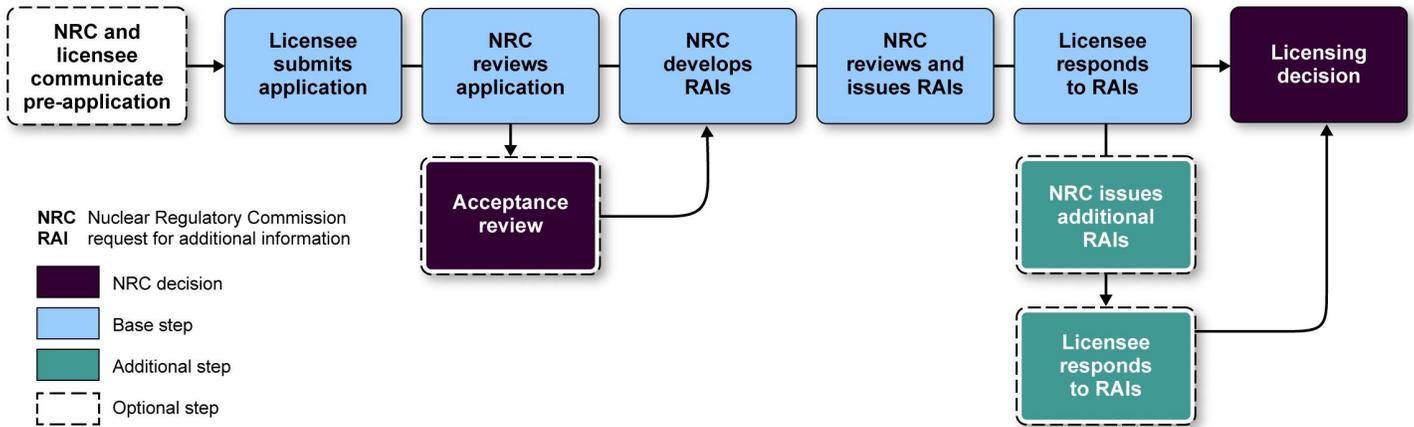
We conducted this performance audit from June 2016 to April 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The process for developing and issuing RAIs begins with either pre-application activities or the submission of an application (see fig. 1), and is generally consistent across the NRC offices that use RAIs.

¹²A relief request allows a licensee to deviate from a regulatory requirement.

Figure 1: Summary of Process Used By Nuclear Regulatory Commission Offices to Develop and Issue Requests for Additional Information



Source: GAO analysis of Nuclear Regulatory Commission information. | GAO-17-344

Pre-application activities occur before NRC receives an application; these activities may include a meeting between the licensee and NRC staff, or communication between parties via phone or e-mail. NRC offices assign each licensee a project manager or license reviewer who is responsible for overseeing the licensing process and coordinating with review staff. Pre-application activities provide an opportunity for licensees to ask clarifying questions of NRC staff and for NRC staff to prepare for the review of an incoming application. Not all license applications or NRC offices include this step, as pre-application activities vary based on the complexity of the application. All licensing actions across NRC offices, however, include the submission of an application. After NRC receives an application, officials may conduct an acceptance review to ensure there is enough information contained in the application to perform a technical review. NRC considers submitted applications “tendered” until the acceptance review is complete. If it is found during acceptance review that the application does not contain sufficient information, the application may remain tendered while the applicant submits supplemental information, or may be denied.

The process of developing and issuing RAIs begins after either the submission of the application or acceptance review and culminates in a licensing decision. NRC reviewers have to make a conclusion that what the licensee is proposing provides a reasonable assurance of safety; this allows reviewers to complete a safety evaluation report and conduct both a technical review and a regulatory review. If NRC’s reviewers are able to arrive at a conclusion with the information that the licensee provided in

the application, then there is no need for NRC to issue an RAI. However, if there are areas where the information the licensee has submitted appears incomplete, then NRC staff will address these areas by developing and preparing RAIs for management review.¹³ After management review, NRC issues RAIs to licensees. Prior to issuance, NRC staff may also send draft RAIs to the licensee and reach out to the licensee via telephone to ensure that the information that NRC needs is understood and that the RAI language is clear. In such cases, NRC would issue the formal RAIs after this outreach. The licensee is then expected to submit responses to the RAIs within a specified period of time, typically within 30 or up to 60 days. The NRC review team may develop and issue additional, follow-up questions to the original RAIs—also known as “additional rounds”—if the review staff requires more information than the licensee’s initial response contained. When the NRC review team has the information needed to ensure a fully informed, technically correct, and legally defensible decision, it will either approve or deny the license application.

Individual NRC Offices Have Their Own Guidance to Issue RAIs and Are Updating It in an Effort to Improve the RAI Process

Each NRC office that issues RAIs has its own guidance, and the Office of Nuclear Reactor Regulation, the Office of New Reactors, and some divisions in the Office of Nuclear Material Safety and Safeguards have efforts underway to update guidance intended to improve oversight of RAIs. Guidance for developing and issuing RAIs is generally the same across individual offices that issue them but also reflects each office’s own specific responsibilities and procedures.

NRC Offices Have Their Own Guidance to Issue RAIs, and Offices Have Efforts Under Way to Update Guidance Intended to Improve RAI Oversight

NRC offices that issue RAIs each have their own guidance, and some offices have been updating their guidance over the past year in an effort

¹³NRC uses contractors when the agency does not have staff with the specific expertise required to support the review of a particular license application.

to improve the RAI process. This updated guidance includes an increased focus on ensuring staff compliance with the process through managerial review. The Office of Nuclear Reactor Regulation's guidance on RAIs is contained in an office instruction document for license amendment-review procedures called LIC-101. In April 2016, the Office of Nuclear Reactor Regulation issued an expectations memorandum to staff intended to provide additional guidance and clarity to expectations addressed in existing office guidance and practice. For example, the expectations memorandum elevates the issuance of additional questions on the same topic to divisional management to discuss the need for an additional round of RAIs before submitting them to a licensee. The memorandum also calls for the branch chief to review the draft safety evaluation report and confirm that the holes in the draft report align with RAIs. This is a change from the version of LIC-101 that officials had been using.¹⁴ NRC incorporated changes contained in the April 2016 expectations memorandum into a new edition—version five—of LIC-101 in January 2017.¹⁵ The Office of Nuclear Reactor Regulation's management also issued a memorandum in August 2016 to all operating reactor licensees that stated, among other things, that staff will actively seek opportunities to conduct an on-site audit or a public meeting in order to reduce the number of rounds of RAIs.

In the Office of New Reactors, office instruction document NRO-REG-101 provides information to guide staff in the processing of RAIs. In 2008, the office also produced a detailed pamphlet on the RAI process—called a job aid—intended to help standardize office practices, ensure proper focus in the reviews, and enhance efficiency. In October 2016, management in the Office of New Reactors issued a memorandum to staff on the effective use of RAIs in new reactor licensing reviews. According to the memorandum, all RAIs in the Office of New Reactors will be reviewed up through division management, and the office director will review samples of RAIs in an effort to keep informed of issues deemed high priority identified in reviews. This memorandum accompanied an updated RAI job aid to replace the earlier version, as well as two other job aids focused on carrying out audits and confirmatory analysis, in which NRC staff conduct an independent assessment of a licensee's

¹⁴Nuclear Regulatory Commission, "Office of Nuclear Reactor Regulation Office Instruction: License Amendment Review Procedures," LIC-101 Revision 4, (May 25, 2012).

¹⁵Nuclear Regulatory Commission, "Office of Nuclear Reactor Regulation Office Instruction: License Amendment Review Procedures," LIC-101 Revision 5, (Jan. 9, 2017).

calculation. The updated RAI job aid contains some modifications to the text from the 2008 version that include, for example, instruction to division management to audit draft RAIs to assure conformance with office expectations for quality.

RAI guidance for the Office of Nuclear Material Safety and Safeguards' Division of Spent Fuel Management is contained in an instruction document referred to as SFM-3.¹⁶ The division issued a new instruction document in August 2016—referred to as Office Instruction 26—that is intended to provide management expectations and guidance to employees.¹⁷ The document calls for staff to follow the existing division guidance for RAIs and outlines new guidance that staff are required to follow as well. This new guidance includes preparing, for supervisory review, a draft safety evaluation report showing the regulatory holes that call for RAIs. The new guidance also calls for notifying management of additional rounds of RAIs and receiving management concurrence before issuance. The office's Division of Material Safety, State, Tribal and Rulemaking Programs relies on guidance contained in Volume 20 of a multi-volume series of guidance documents on materials licenses called NUREG-1556.¹⁸ Volume 20 provides guidance on administrative licensing procedures and, according to officials, is currently being updated along with the other volumes in the series. Officials told us that Volume 20 is expected to be published as a draft report for comment in spring 2017 and published as a final report sometime that year.

According to officials, procedures to process RAIs in the Division of Decommissioning, Uranium Recovery, and Waste Programs were first issued in 2000. These procedures include the requirement that a draft safety evaluation report be used to support RAIs, calls for RAIs to refer to specific portions of regulation, guidance, or both when issued to licensees, and encourages staff to conduct telephone conferences to discuss technical issues and possible resolution. The instruction document covers licensing as it applies to all project managers, technical reviewers, and staff within the Division of Decommissioning, Uranium

¹⁶Nuclear Regulatory Commission, "DSFM Division Instruction Change Notice: Requests for Additional Information," SFM-3, Rev. 5.

¹⁷Nuclear Regulatory Commission, "SFM Division Instruction: Operational Strategies and Management Expectations," SFM-26, Rev. 0 (Aug. 8, 2016).

¹⁸Nuclear Regulatory Commission, "Consolidated Guidance About Materials Licenses," NUREG-1556, Vol. 20 (December 2000).

Recovery, and Waste Programs. According to officials, the most recent revision to the procedures in 2009 did not include changes to specific procedures guiding the development of RAIs.

In addition to guidance, NRC's offices have practices in place intended to ensure management and staff continue to focus on improving RAIs. Officials from each of the NRC offices that issue RAIs said that their management is continually focused on improving RAIs. For example, officials from the Office of New Reactors told us there are plans to assess the revised process for developing and issuing RAIs throughout upcoming license reviews to look for additional opportunities for improvement. In the Office of Nuclear Material Safety and Safeguards, officials told us that RAIs receive attention from the management of all divisions and that office leadership is working with licensee representatives to identify ways to improve the RAI process. Officials also told us that because most of the staff are involved in the process to develop and issue RAIs, it is an essential component of their work. As a result, their work on RAIs will factor into their performance review. According to officials, NRC's standards for employee assessments are written at a general level for almost all staff at NRC. Technical staff are evaluated against four standards: planning and implementation, problem solving and analysis, communication, and professional development and organizational effectiveness.

NRC Offices' Guidance Reflects Their Specific Responsibilities and Procedures, but Processes Are Similar across Offices

According to NRC officials, the individual guidance developed by each office reflects the office's own responsibilities and procedures. Guidance may differ across offices when a license application requires review by multiple technical branches; one office may issue RAIs to the licensee as they are completed by a technical branch, while another may wait to issue RAIs until all relevant technical branches have completed the initial review. For example, the *Fuel Cycle Licensing Review Handbook* used by the Division of Fuel Cycle Safety, Safeguards and Environmental Review in the Office of Nuclear Material Safety and Safeguards notes that if the same regulatory issue occurs in more than one technical section, the issue should be addressed in a general section rather than multiple times in each section. The handbook also encourages reviewers to issue one set of RAIs, as opposed to multiple sets.

Guidance on the response times given to licensees also differs among NRC offices. Consequently, the Office of Nuclear Reactor Regulation's guidance document, LIC-101, calls for licensees to respond to RAIs in 30 days or within a timeframe specified by the review team. Updates intended to align LIC-101 with the office's expectations memorandum include guidance for a default response period of 30 days, an extended response period of 60 days, and approval for a longer response period if the review schedule allows. However, the Office of Nuclear Material Safety and Safeguards' *Fuel Cycle Licensing Review Handbook* calls for the project manager to set a response date of 30 to 60 days. The Office of New Reactors' guidance for RAIs references NRC regulations calling for responses within 30 days of the date of the request, and states that applicants will be encouraged to respond to questions once they have prepared their responses, rather than respond to packages of multiple questions on a set date. The Office of New Reactors' guidance also requires that officials use email to transmit RAIs.

In addition, guidance on the level of management's review given to RAIs varies by NRC office. RAIs issued for combined license applications and early site permits in the Office of New Reactors are automatically sent to branch managers and are reviewed by both division management and the Office of General Counsel.¹⁹ Guidance for the Office of Nuclear Reactor Regulation states that RAIs should be reviewed by branch managers. It also calls for branch managers and staff to discuss the need for a second round of RAIs and whether alternative methods to obtain information—such as a public meeting or an audit—may be more effective and efficient. In the Office of Nuclear Material Safety and Safeguards, the level of management review is determined by the guidance of each division. For example, in the Division of Spent Fuel Management, RAIs must be submitted to branch management for review, and divisional management must be notified of additional rounds of RAIs.

Nevertheless, based on our review of the guidance, the guidance is generally the same across the offices. Specifically, guidance for the different offices describes similar processes for issuing RAIs, including

¹⁹A combined license application requires the applicant's qualifications, design safety, environmental impact, operational programs, site safety, and verification of construction, and authorizes the licensee to construct and operate a nuclear power plant at a specific site. An early site permit authorizes a specific site for a nuclear power facility, requiring that the applicant address site safety issues, environmental protection issues, and emergency preparedness in the application.

the reason for issuing an RAI, the procedures undertaken to develop RAIs, and time frames during the process. Guidance for all offices states that RAIs should be used to gain the information needed for making a licensing decision, and due to recent updates, most office guidance also states that RAIs be used to fill gaps in a safety evaluation report. The process for developing and issuing an RAI is also similar across all offices, and includes: (1) the development of RAIs by technical reviewers based on information contained in an application, (2) the review of proposed RAIs by management, (3) the issuance of RAIs to licensees for response, and (4) the incorporation of information received through RAIs into the safety evaluation report and final licensing decision. Additionally, guidance across all offices includes direction on setting time frames for issuing RAIs and receiving responses from licensees.

NRC Offices Do Not Track the Number of RAIs They Issue, and Certain Activities Often Elicit RAIs

NRC offices do not track the number of RAIs and do not know how many they have issued over the past 5 years, and there is no legal requirement for NRC to track the number of RAIs it issues. According to NRC officials and some licensees we interviewed, certain activities and circumstances often elicit RAIs, such as complex licensing actions and activities for which regulations are unclear.

Offices Do Not Track the Number of RAIs That NRC Issues, and There Is No Legal Requirement to Do So

NRC offices that issue RAIs do not specifically track the number of RAIs that they issue, and there is no legal requirement for the agency to track the number of RAIs. An official from the Office of New Reactors estimated that a combined license application could have 1,000 RAIs, while a license amendment request could have few, if any, RAIs. Officials added that the number of RAIs issued in a given review varies depending on the complexity and size of the requested licensing action. Officials also said the number of RAIs per year depends on how many license applications the office receives; it can take 5 years or more to review and make a decision on a combined license application. In contrast, for plants that are licensed, officials said that NRC typically reviews 20 to 25 license

amendments per year. According to officials, the Office of Nuclear Reactor Regulation reviews about 700 licensing actions per year, and officials also estimated that on average, each licensing action has 5 to 10 RAIs. Officials added that the Office of Nuclear Material Safety and Safeguards reviews about 1,800 license applications or amendments per year, with varying numbers of RAIs per action.

NRC officials cannot say with certainty how many RAIs they have issued over the past 5 years, in part because the current internal tracking systems used by the Office of Nuclear Reactor Regulation and the Office of Nuclear Material Safety and Safeguards do not track the number of RAIs. Officials in the Office of Nuclear Reactor Regulation told us that they do not track the number of RAIs because RAIs are only one component in the broader licensing process. Instead, officials said, they focus more on whether the office is carrying out licensing activities in an efficient, effective manner. The Office of New Reactors has an internal tracking system, called eRAI, which is specifically configured to manage RAIs and is capable of tracking the number of RAIs per year. However, according to an official, the office does not use eRAI to track the number of RAIs. Instead, the Office of New Reactors uses eRAI to monitor RAIs associated with applications that can be up to 12,000 pages long, identify related questions, and track RAIs by regulatory issue area.

Some NRC offices have been working to update their internal tracking systems for licensing actions. These updates are intended to, among other things, allow officials to better track milestone dates in the licensing action process, such as the date that an RAI response is due. For example, the Office of Nuclear Reactor Regulation is changing to a new system called the Replacement Reactor Program System, which tracks major milestones within each of the licensing reviews. Unlike the previous system, the new system can track multiple rounds of RAIs. In addition, according to NRC officials, the Division of Spent Fuel Management in the Office of Nuclear Material Safety and Safeguards is moving to a web-based tracking system from a system that only tracked milestone dates. The new system is intended to track RAIs and to help identify issues early in the process that may influence the timeliness of the review. Elsewhere in the Office of Nuclear Material Safety and Safeguards, officials in the Division of Fuel Cycle Safety, Safeguards and Environmental Review told us that they are upgrading their tracking system and will use the same one as the Division of Spent Fuel Management. Further, the office's Division of Material Safety, State, Tribal, and Rulemaking Programs is also in the process of enhancing its tracking system by streamlining the

process to allow the staff to issue licensing actions directly from the system.

NRC officials told us that tracking the number of RAIs is challenging and may not reflect the role that RAIs play in the licensing process. According to officials, counting the number of RAIs may be challenging because different reviewers can refer to an RAI as a single question, or as a letter to a licensee containing several questions. Officials also told us that the number of RAIs does not capture the variance in size and complexity of RAIs; for example, NRC may request simple editorial changes that require little effort and time on the part of the licensee, or RAIs may request additional technical analyses that require more effort and time to address.

RAIs Are Not Unusual, and Certain Activities Often Elicit RAIs

NRC officials told us that receiving RAIs as part of a licensing action is not unusual, and officials and licensees we interviewed said that RAIs are often issued for the following activities and circumstances: complex licensing actions, activities for which regulations are unclear, new activities, and when the initial application does not contain adequate information or detail.

Complex licensing actions: NRC officials told us that licensing actions and the associated RAIs vary greatly in complexity, and the number of RAIs issued may vary depending on the complexity of the review. Some actions are simple and may take 40 to 80 hours to review, while others are more complex and may take more than 5,000 hours for review. Many licensees we interviewed stated that they would expect to receive more RAIs for more complex licensing actions. For example, a licensee we interviewed told us that most of the RAIs the company receives are related to technical specifications, which are NRC's standardized requirements for its approved reactor types. Officials from this licensee said they may receive additional questions for technical specifications and issues that are plant-specific, such as differences in equipment when compared to other plants with the same reactor type, and more detailed drawings and information about the plant's equipment. Conversely, another licensee told us that a simple license amendment request for a name change on a license did not elicit any RAIs.

Unclear regulatory guidance: Some licensees we interviewed also said that they would expect to receive more RAIs for activities for which regulations are unclear and may require increased coordination between NRC and the licensee. One licensee described an instance where guidelines pertaining to the licensing action were not clear, and it took several years and additional RAIs to try to reach agreement with NRC. NRC officials told us that licensees are most likely to receive RAIs in cases where they request an exception to regulatory guidance. NRC officials and licensees said that a request for an exception can occur, for example, when a licensee asks NRC for a license to use a construction material that is not referenced in regulatory guidance. Further, NRC officials said that applications for new reactors typically elicit RAIs, particularly when technology proposed by licensees does not align with regulations, such as the shift from analog instrumentation and controls used in most operating reactors to digital instrumentation and controls proposed for new reactors.

First-of-its-kind activities: NRC officials told us that a new type of licensing action may require more RAIs. Half of the licensees we interviewed told us that they received RAIs when requesting a license for an activity that is the first of its kind or is setting a precedent. For example, a licensee stated that the company received RAIs for a license amendment that was one of the first submitted to NRC for a particular activity.

Quality of the application: Officials told us that the number of RAIs associated with each license application often depends on the quality of the application. For example, a license application or response to an RAI that does not contain adequate information can result in more than one round of RAIs. Conversely, an application that is comprehensive and addresses all of the requirements outlined in NRC guidance is less likely to receive RAIs, and if RAIs are issued, they are less likely to receive more than one round of RAIs. Some licensees told us that they may receive RAIs for issues that may have been addressed in another application or, as one licensee stated, were otherwise obvious; licensees noted that this was likely because NRC wanted that information included as part of the docket.

The nongeneralizable sample of licensing actions that we reviewed reflected several different types of licensing actions and contained RAIs that varied in format. We reviewed three licensing actions that contained RAIs—each one representing one of the three offices that issue RAIs. One action was for a license renewal, another was for a license

amendment request, and the third was for a relief request. One of the licensing actions received four RAIs sent in two separate e-mails several weeks apart. NRC officials described these as “official” RAIs, which they followed with an email identifying apparent editorial errors in the application. In another example, NRC sent a licensee two draft RAIs in advance of the formal RAI submission. With regard to the types of information that NRC asked in its RAIs, one RAI asked for clarification on technical specifications the licensee used to support its request. Another asked for specific information about the equipment used, including name and model number, as well as details concerning maintenance. In the third example, NRC asked for clarification about testing completed for a particular piece of equipment in order to approve a license renewal. Because this was a nongeneralizable sample, our results are not generalizable to all licensing actions but provide illustrative examples of the types of information included in RAIs.

Licensees Were Generally Satisfied with the RAI Process but Also Identified Weaknesses, Which NRC Has Made Recent Efforts to Address

Many of the licensees we interviewed were generally satisfied with the current process to develop and issue RAIs and identified certain strengths. NRC officials and licensees also identified two common weaknesses in the process to develop and issue RAIs, weaknesses that NRC has made recent efforts to address.

Licensees We Interviewed Were Generally Satisfied with the RAI Process and Identified Certain Strengths

Many of the licensees we interviewed expressed satisfaction with NRC’s current process to develop and issue RAIs and acknowledged the role of RAIs in the licensing process. Some said that they viewed them as a natural part of interacting with a regulator. For example, one licensee said that RAIs are needed to allow for formal communication between NRC and licensees on issues that may arise again in future licensing actions. Some licensees said that the experience with NRC had been positive, and another stated that the RAI process worked well for completing licensing actions.

Licenses identified NRC guidance as a strength of the RAI process. Most licenses we interviewed told us that they found NRC guidance to be helpful; such guidance includes regulatory documents, procedural documents, and memorandums. For example, the majority of the licenses we interviewed that worked with the Office of Nuclear Reactor Regulation said that the office's April 2016 expectations memorandum was a positive step by the agency and an improvement in the RAI process. Specifically, one licensee told us that the policy of ensuring that RAIs ask for information needed to fill a gap in the safety evaluation report—as outlined in the memorandum—was an appropriate procedure. Some licenses also said that they found it particularly useful when NRC reviewers identified for them specific passages of a guidance document relevant to the licensing action or RAI.

Licenses we interviewed also identified NRC's openness to communication and engagement as a strength of the RAI process. Most licenses we interviewed said that communication with NRC staff during the process to develop and issue RAIs was helpful, including pre-application meetings, informal interactions via phone or e-mail, and coordination with project managers. As mentioned above, pre-application meetings provide an opportunity for the licensee and NRC to clarify potential issues or questions before the initial license application is submitted and RAIs are issued. Of those licenses we interviewed who participated in a pre-application meeting, the majority said that the meeting helped to either resolve or clarify issues before the acceptance review. Some licenses said that pre-application meetings were particularly helpful when NRC staff assigned to the review participated, with one licensee stating that it was critical for the staff member who develops RAIs to be present. A licensee also stated that participating in a pre-application meeting significantly reduced the number of RAIs issued later in the process. Additionally, some licenses told us that informal interactions via phone or e-mail with NRC staff also helped to resolve issues quickly, as opposed to clarifying or resolving issues through formal correspondence. Similarly, several licenses noted that the active engagement of project managers in the review process improved the efficiency of the review and the quality of RAI questions. For example, officials from one licensee said that in recent years NRC's project manager e-mailed draft RAIs to them, which allows the licensee to review them in advance, ask clarifying questions, and propose response times. In another case, a licensee told us that a project manager included divisional management in a conference call to discuss RAIs, which resulted in NRC withdrawing some RAIs.

In addition, several licensees we interviewed noted NRC's responsiveness to industry operational issues and time constraints in the review process as a strength. Several licensees described instances in which operational issues or time constraints required flexibility from NRC, and they told us that NRC worked with them to ensure uninterrupted operation or service. Some licensees told us that NRC extended the response time required for RAIs when licensees asked for additional time. In another instance, a licensee described a case where NRC expedited the review process to prevent a disruption in patient medical care that relies on radiological material. An industry interest group representative we interviewed told us that both industry and NRC should take steps to ensure that the recent improvements to the process to develop and issue RAIs are maintained going forward.

Licensees Identified Two Common Weaknesses in the RAI Process, Which NRC Has Made Recent Efforts to Address

Licensees and NRC officials that we interviewed identified weaknesses in the RAI process, including two commonly mentioned ones: (1) a gap between NRC's expectations and licensees' understanding of what should be included in a license application and (2) staff departure from guidance that leads to RAI questions that appear to be redundant or beyond the scope of the review.

Gap in expectations and understanding: NRC officials and licensees whom we interviewed told us that a gap between NRC's expectations and licensees' understanding of license application content can be a weakness of the RAI process. Both NRC officials and licensees stated that inconsistencies may exist between NRC's expectations and licensees' understanding of what should be included in a licensing application, especially in cases of complex or new activities. According to NRC officials, such inconsistencies can lead to reviewers' using RAIs to gather the information needed to make a licensing decision. NRC officials said that varying levels of understanding regarding expectations may result in confusion for licensees and may incentivize them to exert fewer resources when developing an initial application. According to one NRC official, licensees may submit an application containing enough technical information to pass the acceptance review with the understanding that NRC will develop RAIs to address unresolved issues in the application. Officials added that the standard and level of detail required for issuing a licensing action is more stringent than that for an acceptance review. For

half of the licensees, expectations have become clearer in the last several years as a result of increased communication with NRC. However, several licensees we interviewed identified unclear or inconsistent expectations as a current concern. For example, one licensee described a case where a license amendment received RAIs on a new activity for which NRC did not have permanent guidance in place. The licensee rescinded the license amendment request rather than expend the resources needed to answer RAIs according to NRC's interim guidance.

The Office of New Reactors, the Office of Nuclear Reactor Regulation, and the Division of Spent Fuel Management in the Office of Nuclear Material Safety and Safeguards have made recent efforts to address inconsistencies between NRC's expectations and licensees' understanding by emphasizing greater communication between review staff and licensees. The Office of New Reactors placed more emphasis on the pre-application period in which the NRC review team works with licensees to resolve questions and potential issues that otherwise may necessitate formal RAIs. In addition, through its April 2016 expectations memorandum, the Office of Nuclear Reactor Regulation's management is encouraging project managers and review staff to engage in increased communication with licensees to resolve questions, in addition to placing increasing emphasis on acceptance review. Division of Spent Fuel Management leadership has also made recent efforts to encourage more frequent conversations through updated guidance. Some licensees we interviewed recognized NRC's efforts, and one licensee told us that NRC officials have recently been more receptive to discussing RAIs over e-mail, a practice which has helped to make the process more efficient. It is too soon to tell whether these initiatives will address the gap in expectations between NRC and licensees in the long term.

Staff departure from guidance: NRC officials and licensees both told us that some staff may depart from guidance by issuing redundant or unrelated RAIs, which may require additional time and resources for the licensee to address. According to officials and licensees, an RAI is redundant if the information requested is contained in or could be inferred from information contained in the original license application, other correspondence, or a response to a previous RAI. Likewise, an RAI is unrelated to the application if the information requested is not necessary for making a regulatory decision or filling a gap in the safety evaluation report. NRC officials said that ensuring staff adherence to internal guidance regarding appropriate RAIs can be challenging, and many of the licensees we interviewed identified the influence of individual staff reviewers as a weakness of the process to develop and issue RAIs. Half

of the licensees we interviewed said that they noticed questions that were either redundant or seemed to appear unrelated to a regulatory requirement, but which may have been intended to satisfy the individual reviewer's curiosity. Some licensees also said that inexperienced reviewers may ask redundant questions or revisit issues that have already been resolved and codified in the licensing document through prior communication with NRC. According to licensees, redundant or out-of-scope RAIs create additional work for them, and most of the licensees interviewed identified the impact of RAIs on resources as a related weakness of the RAI process. For example, one licensee reported receiving questions outside of the scope of the license application that required additional analyses and work—nearly doubling the length of the review and costing the licensee almost double the amount in fees budgeted for the review.

In an effort to mitigate concern over the influence of individual staff reviewers, the Office of New Reactors, Office of Nuclear Reactor Regulation, and the Division of Spent Fuel Management in the Office of Nuclear Material Safety and Safeguards recently updated guidance and introduced more management review of RAIs. As mentioned above, updated NRC guidance includes an increased focus on ensuring staff compliance with the RAI process. For example, the offices and division cited above have recently updated internal guidance to clarify the expectation that staff reviewers use RAIs to fill holes in a draft safety evaluation report. Guidance updated by all three offices also includes calls for elevating questions at least to divisional management: in the Office of Nuclear Reactor Regulation and the Division of Spent Fuel Management, all second-round RAIs require division management approval; and in the Office of New Reactors, all RAIs require divisional management approval and the office director reviews samples of RAIs on high priority issues. Half of the licensees we interviewed expressed that these efforts represent an improvement in the RAI process. Several licensees specifically described the expectations memorandum issued by the Office of Nuclear Reactor Regulation as an improvement, and officials from one licensee noted that they have seen progress with NRC's management intervening when potential unnecessary questions are identified. Because these efforts were made recently, it is too early to assess the effectiveness of such approaches to mitigating the influence of individual staff reviewers.

Agency Comments and Our Evaluation

We provided a draft of this product to NRC for comment. NRC generally agreed with our findings and provided technical comments, which we incorporated as appropriate. NRC's comments are reprinted in Appendix I.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to appropriate congressional committees and the Chairman of the Nuclear Regulatory Commission. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or ruscof@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

A handwritten signature in black ink that reads "Frank Rusco". The signature is written in a cursive style with a long, sweeping horizontal line extending to the right from the end of the name.

Frank Rusco
Director, Natural Resources and Environment

Appendix I: Comments from the Nuclear Regulatory Commission



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

March 17, 2017

Mr. Frank Rusco, Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20226

Dear Mr. Rusco:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your e-mail dated February 14, 2017, which provided the NRC an opportunity to review and comment on the U.S. Government Accountability Office (GAO) draft report GAO-17-344, "Nuclear Regulatory Commission: Efforts Intended to Improve Procedures for Requesting Additional Information for Licensing Actions are Underway."

The NRC staff appreciates the opportunity to review the draft report, and we appreciate the GAO staff's professionalism and many constructive interactions during this GAO engagement. Overall, the NRC agrees with the draft report and its findings. The draft report accurately describes the request for additional information process and the efforts the NRC has taken to make this process more efficient and effective. In the enclosure to this letter, we have provided some minor comments and clarifications for your consideration.

Thank you again for the opportunity to provide comments on the GAO report. Please feel free to contact Mr. John Jolicoeur at (301) 415-1642 or John.Jolicoeur@nrc.gov if you have questions or need additional information.

Sincerely,

A handwritten signature in blue ink that reads "Victor M. McCree".

Victor M. McCree
Executive Director
for Operations

Enclosure:
NRC Comments on Draft Report
GAO-17-344

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Frank Rusco, (202) 512-3841 or ruscof@gao.gov

Staff Acknowledgments

In addition to the individual named above, Hilary Benedict (Assistant Director), Bridget Grimes, and Rachel Rhodes made key contributions to this report. Tim Bober, Kevin Bray, Antoinette Capaccio, Cindy Gilbert, Timothy M. Persons, and Dan Royer also made important contributions.

Appendix III: Accessible Data

Agency Comment Letter

Text of Appendix I: Comments from the Nuclear Regulatory Commission

March 17, 2017

Mr. Frank Rusco, Director

Natural Resources and Environment

U.S. Government Accountability Office 441 G Street, NW

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Victor M. Mccree

Executive Director for Operations

Enclosure:

NRC Comments on Draft Report GA0-17-344

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