

# U.S. Nuclear Regulatory Commission Office of Executive Director for Operations

# **OEDO Procedure**

Office Procedure No.: **OEDO Procedure-0235** 

**Driving Regulatory Decisions Through More Effective Communications** Procedure Title:

Effective Date: July 2, 2025

Revision No: 0

Approved By: **Jody Martin** 

Date Approved: July 2, 2025

**Primary Contacts:** Scott Flanders, Andrea Kock, Mohammed Shuaibi

Comments:

Training/Special Instructions: None

ADAMS Accession No.: ML25167A039

TABLE OF CONTENTS			
1.	WHY IS THIS IMPORTANT?	3	
2.	OBJECTIVES	3	
3.	INTRODUCTION	3	
4.	EFFECTIVE COMMUNICATIONS	4	
5.	CONSULTING	8	
APPENDIX A. CHANGE HISTORY			
APPENDIX B. DOS AND DON'TS11			
APPENDIX C. SPECIFIC EXAMPLES			
	Preapplication and Acceptance Review Activities	13	
	Detailed Technical Reviews	13	
	Oversight and Inspection Activities	14	

# Driving Regulatory Decisions Through More Effective Communications

# 1. WHY IS THIS IMPORTANT?

The U.S. Nuclear Regulatory Commission (NRC) is committed to meeting its <u>mission</u> in a manner that establishes and maintains appropriate working relationships with licensees, applicants, and vendors consistent with the NRC's <u>Principles of Good Regulation</u> (POGR) and the Be riskSMART (spot, manage, act, realize, teach) approach. Central to the mission is effective and open communication between the parties to gain mutual understanding. This document provides guidance that is necessary to facilitate a mindset shift in how we communicate to achieve more efficient and reliable regulatory activities thus enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials for the benefit of society. While this document is focused on engagements with licensees, applicants and vendors, the concepts are generally applicable to all NRC activities (i.e., work on codes and standards committees, corporate and mission support activities, etc.).

As the agency undertakes modernization to better support innovation and national energy goals, staff engagement must reflect not only independence but also clarity and responsiveness. This guidance supports a culture of proactive, helpful, and mission-driven interaction with regulated entities.

#### 2. OBJECTIVES

- 2.1 Serve as a resource for staff that provides appropriate strategies and practices for regulatory engagements with licensees, applicants, and vendors.
- 2.2 Provide best practices to facilitate timely and efficient resolution of regulatory activities while maintaining independence and transparency.
- 2.3 Provide clearly documented expectations and guidance to staff that can be used to support timely updating of agency procedures as we gain experience using this guidance.

## 3. INTRODUCTION

The NRC is committed to meeting its mission in a manner that maintains relationships of mutual understanding and respect with licensees, applicants, and vendors and ensures effective communication and regulatory efficiency. It is crucial for the staff to understand and clearly communicate positions and concerns during licensing reviews and oversight activities. In addition, to meet the agency's mission in its entirety, it is necessary for the staff to provide proactive and timely assistance to licensees, applicants, and vendors as they work through the licensing process or oversight activities. For example, "enabling the safe and secure use and deployment of civilian nuclear energy technology and radioactive material," inherently includes elements such as:

- explaining licensing and oversight processes to licensees, applicants, vendors, or other external stakeholders such as government officials, non-government stakeholders, and members of the public
- explaining regulatory requirements and acceptance criteria, including the origin and purpose of those requirements
- ensuring that a licensee understands the requirements that apply to its facility or its operations
- clearly identifying and describing information gaps that prevent the staff from making a regulatory finding and the basis supporting the need for the information
- engaging in discussions on a range of ideas and options that could be used to address
  a regulatory issue, including successful approaches from past experience and
  precedents. The staff should clearly communicate to the licensee, applicant, or vendor
  that they are ultimately responsible for demonstrating that past experience or examples
  being cited are applicable to the current issue being discussed.

#### 4. EFFECTIVE COMMUNICATIONS

Effective communication between staff and a licensee, applicant, or vendor requires clear, timely articulation of positions and concerns, with questions asked to ensure mutual understanding. For its part, the staff should fully and completely describe and explain staff positions and concerns to a licensee, applicant, or vendor regarding technical or regulatory issues. Similarly, if an application or other information provided by a licensee, applicant, or vendor is unclear, the staff may need to ask questions to ensure complete understanding. Seeking or providing such clarification, whether orally or in writing, is not consulting. When offering a position, concern, or question, the staff should include an explanation of the technical, safety and regulatory basis. In some cases, when the staff identifies information gaps, the licensee, applicant, or vendor may not know or understand what information is missing or why the staff needs certain information. In those cases, the staff should clearly identify the missing information and explain why it is needed.

Providing clarification allows the licensee, applicant, or vendor to make their own informed decision about how to proceed. However, when providing clarification, the staff should not impose new or changed staff positions or interpretations of requirements as this may result in backfitting, forward fitting, or concerns with "issue finality."

All staff members have a responsibility to use the most effective engagements with licensees, applicants, and vendors. This includes using the most effective means for communications (e.g., public meetings, closed meetings when justified, technical audits, clarification calls, etc.). It is also important to employ active listening skills and stay alert to situations where the staff and licensees, applicants, or vendors may be talking past each other or where there appear to be issues that need to be communicated and addressed but have not been raised. The staff should actively engage in these situations to ensure that necessary clarification and resolution are provided in a timely manner. In addition, it is expected that the staff will provide clear, candid, and constructive feedback regardless of whether the interaction is public or nonpublic in order to facilitate timely decision-making.

Effective communication generally includes the following elements:

- Prepare in advance for meetings and other interactions, including establishing agreement on the goals and scope of an interaction. Check back at the end of an interaction to ensure the goals were met and communications were clear.
- Be accurate, clear, and concise in verbal and written communications. Check for mutual
  understanding among all parties using techniques such as three-way communication
  (repeat the question or statement that was made and check for verification of
  understanding).
- Discuss the regulations and regulatory guidance that apply to the given technical subject and related technical areas. If gaps are identified, explain the particular regulatory requirement that does not appear to have been met.
- Describe the purpose of the regulations, how they address specific public health and safety or security hazards, and how proper implementation reduces or eliminates these hazards.
- Identify the critical and necessary information that is missing to make a regulatory decision. Articulate the safety or security concern related to any deficiencies.
- Seek only the information necessary to support the regulatory decision. Ensure the level
  of detail and documentation necessary is consistent with the importance of the issue.
   Staff can provide an overall framework to licensees, applicants, and vendors of the
  scope and magnitude of the response expected.
- Discuss regulatory and safety/security issues associated with options presented by a licensee, applicant, or vendor.
- Be open to engaging in discussions on the merits of different options and solutions (i.e., whether and to what extent options might address regulatory issues), while being careful not to direct or recommend implementation of any specific solution.
- Point to existing operating experience and/or generic communications (published or from personal experience). If the information is not publicly available, do not refer to specific licensees, applicants, or vendors or provide information that is protected from public disclosure (e.g., proprietary information).
- Discuss relevant past precedents where possible solutions are documented (e.g., previous applications, requests for additional information (RAIs) and inspections that address similar issues), being sure to share only publicly available information.

Use the most effective and efficient communication approach (e.g., public meetings, closed meetings when justified, clarification calls, technical audits, written correspondence, etc.) for achieving common understanding of regulatory issues, information gaps, and possible options for addressing them. Consistent with the Commission's public meeting policy (86 FR 14964, March 19, 2021) and associated guidance in NRC Management Directive (MD) 3.5, "Attendance at NRC Staff-Sponsored Meetings," (Agencywide Documents Access and Management System

Accession No. ML21180A271) the staff may use nonpublic interactions when appropriate. Following nonpublic interactions, the staff should create publicly available records of the interactions as specified in MD 3.5, office instructions, or other applicable guidance. The substance of conversations that go beyond clarification, logistics, or information that is already publicly available must be made public (either in a public meeting, publicly available meeting summary, or by being placed on the docket) unless the discussions involve classified, safeguards, proprietary, or other sensitive information. All information that is material to a final NRC decision or action must be docketed and must be made public unless otherwise protected from public disclosure. These actions provide for public awareness and involvement and also allow similarly situated licensees, applicants, or vendors to benefit from the information.

MD 3.5 includes examples and scenarios of staff-sponsored meetings that are typically open or typically closed to public attendance. These examples establish a thought process that can be used to make decisions on any meeting scenario. In general, meetings involving technical discussions that could directly affect an NRC regulatory decision or action should be public meetings, unless the meeting involves discussion of classified, safeguards, proprietary, or other sensitive information. The examples of nonpublic meetings in MD 3.5 include meetings to obtain clarification on RAIs, regulatory audits, and inspections. The management directive states that opening discussions to the public in these situations would "create an unnecessary administrative burden and impede the efficient execution of the NRC's safety and regulatory responsibilities" and could also (in the cases of audits or inspections) result in the release of preliminary, pre-decisional, or unverified information.

Consistent with the public meeting policy statement and the guidance in MD 3.5, the staff should strive to balance openness and transparency with the need for efficient and effective regulation when deciding on the best path for engagement with licensees, applicants, and vendors. In doing so, the staff should take into account the NRC's updated mission statement, which reflects direction in the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act) (Public Law 118-67; 138 Stat. 1457) to conduct licensing and regulation "in a manner that is efficient and does not unnecessarily limit ... the civilian use of radioactive materials and deployment of nuclear energy; or ... the benefits of civilian use of radioactive materials and nuclear energy technology to society." The staff should employ nonpublic interactions in situations where the staff determines that a particular issue can be resolved more efficiently in a nonpublic meeting, such as in the following examples:

• Staff reviewers issue RAIs or requests for confirmatory information (RCIs) to obtain additional information they need to make regulatory decisions. After draft RAIs or RCIs are issued, the licensee, applicant, or vendor is offered an opportunity to meet with the staff to clarify the questions and minimize any potential misinterpretation of the request. As stated above, clarification calls may be nonpublic to avoid unnecessary administrative burden. The public is ultimately informed of the NRC's activities because the RAIs or RCIs, and the responses, will be made public (unless the information discussed is protected from public disclosure). The staff has also held nonpublic calls about RAIs or RCIs to allow licensees, applicants, or vendors to provide an overview of their proposed responses. The purpose of such calls is to provide staff feedback on whether the responses appear to be sufficient to allow the staff to continue its review. This type of call reduces the need for follow-up RAIs and thus leads to more efficient reviews. In these calls, the staff can discuss the substance of the responses to ensure understanding and to provide feedback on whether the responses appear to address the staff's questions and/or concerns. The staff should not

state or imply that no additional follow-up questions will be needed, or that the substance of the responses is acceptable to resolve an issue or to meet regulatory requirements.

- The staff conducts regulatory audits for one or more reasons, including to efficiently gain an understanding of the bases underlying an application; to verify calculations or analyses; to better understand areas of potential concern; to identify information that will require docketing to support a staff decision; or to confirm a licensee's implementation of a program or process. The staff has also used audits to discuss information necessary to meet NRC requirements and to discuss an applicant's proposed approaches to addressing NRC questions or concerns, as described in the examples below. As stated above, audit discussions between a licensee, applicant, or vendor and the staff are not open to the public because they could result in the release of preliminary, pre-decisional, or unverified information, and because public participation in audits would create an unnecessary administrative burden and impede the efficient execution of the NRC's safety and regulatory responsibilities. Additionally, technical information discussed in audits is often proprietary or otherwise protected from public disclosure (an independent reason for audits to be closed to the public). To maintain public awareness, the staff issues a publicly available audit plan before conducting an audit and a publicly available audit summary after the audit is completed and before any regulatory action is taken. The audit summary should provide a clear description of the audit activities, including identifying potential RAIs that were discussed, describing open items and proposed closure paths, and identifying any deviations from the audit plan.
  - The staff has used audits during various types of licensing reviews (e.g., design certifications, license amendment requests, environmental reviews) to discuss highly challenging technical issues with applicants. In these situations, the applicant and the staff were not aligned on whether the applicant's approaches met NRC requirements or whether the applicant had provided the necessary level of detail in submitted information for the NRC to make its required findings. These audits included discussions of the applicant's options for addressing staff concerns that were critical to establishing understanding of the issues and allowing the applicant to identify a path forward that would satisfy NRC requirements. Public audit summaries were prepared to document the discussions.
  - The staff has used audits during reviews of topical reports to discuss highly technical issues with licensees, applicants, or vendors. During such discussions, the staff can describe potential limitations and conditions that are being considered in the safety evaluation for the topical report. Sharing this information allows the licensee, applicant, or vendor an opportunity to revise the topical report to eliminate the need for the limitations or conditions. Public audit summaries should document these discussions.
- During closed drop-in meetings, discussions of stakeholders' opinions regarding topics such
  as the NRC's understanding of codes and standards or the NRC's implementation of the
  regulations are appropriate if they are limited to building a shared understanding of
  stakeholder concerns that are not directly related to a particular regulatory action or
  decision.

Appendix B provides additional recommendations when communicating with licensees, applicants, and vendors.

#### 5. CONSULTING

As discussed above, "consulting" is defined here as directing or recommending implementation of a specific solution to resolve a particular regulatory issue. While consulting is prohibited, constructive engagement is encouraged. Staff are not only permitted, but expected, to explain requirements clearly, describe acceptable approaches, share regulatory perspectives on things to consider when evaluating acceptable alternatives, and help applicants understand how to succeed within the regulatory framework. Consulting may undermine the public trust in the NRC as a fair and impartial regulator. The staff's job is to perform objective, independent reviews or evaluations (e.g., licensing reviews, regulatory audits, inspections) to determine whether an application is acceptable or whether a licensee is conducting activities in accordance with applicable requirements. The staff cannot favor, promote, or otherwise provide a competitive advantage to particular technologies or particular licensees, applicants, or vendors.

Licensees, applicants, and vendors are ultimately responsible for maintaining the safety and security of their designs and facilities. In addition, licensees, applicants, and vendors are responsible for demonstrating that their facilities and operations comply with regulatory requirements by providing sufficient information to the NRC for the staff to be able to independently make its required reasonable assurance finding.

To meet the agency's mission, it is necessary for the staff to provide assistance, when appropriate, to licensees, applicants, and vendors as they work through the licensing process or oversight activities in a proactive and timely manner. Furthermore, clearly articulating and clarifying issues is necessary to ensure efficiency, consistent, and safety-focused decision making. Generally, the following activities are *not* considered consulting:

- explaining licensing and oversight processes to licensees, applicants, or vendors
- explaining acceptance criteria and regulatory requirements, including the origin and purpose of a regulatory requirement
- ensuring that a licensee understands the requirements that apply to its facility or operations
- identifying and describing information gaps, the safety implication of these gaps, and the regulatory basis for information needs
- noting that NRC-issued regulatory guides are one acceptable method for meeting NRC requirements
- discussing a range of options as long as the staff does not direct or recommend implementation of a particular choice
- referring a licensee, applicant, or vendor to publicly available guidance and methods
- imposing limitations and conditions on the approval of a topical report

Staff should refer to Appendix C for specific examples of activities that are not considered consulting.

The following are examples of consulting and should be avoided:

- directing or recommending a licensee, applicant, or vendor to make a *specific* change to a submission (e.g., an application or topical report)
- directing or recommending a licensee, applicant, or vendor to use a specific methodology or solution that would provide a basis to conclude that the requested licensing action provides reasonable assurance of adequate protection
- directing or recommending a licensee, applicant, or vendor to use a *specific* solution to address a regulatory deficiency in a licensing application
- providing comments or advice in any forum that would give an advantage to one licensee, applicant, or vendor over another

Keep in mind that the staff cannot commit the NRC to a course of action or direct a specific action to comply with NRC requirements (e.g., "If you do X, we will find your application acceptable" or "You have to do X to restore compliance"). Staff should be careful not to imply such a promise or commitment even if not explicitly stated. If the staff is aware of only one potential approach for addressing a regulatory issue, the staff should inform the licensee, applicant, or vendor of this approach but remind them it is ultimately their responsibility to select and implement an appropriate solution. In these discussions the staff should also note that there may be other viable solutions, and the staff would be open to considering them.

Finally, on occasion, licensees ask agency employees for recommendations to help them solve programmatic problems. Agency employees are prohibited from recommending the services of one or more people or organizations for a project under NRC regulatory jurisdiction. Providing such a recommendation violates Title 5 of the Code of Federal Regulations Section 2635.702, "Use of public office for private gain," which prohibits Federal employees from using public office for endorsement of any product, service, or enterprise. However, the agency also has an obligation to provide assistance where possible in helping individual licensees solve problems where the health and safety of the public is involved. Staff should refer to the Oversight and Inspection Activities discussion in Appendix C for further information.

# **APPENDIX A. CHANGE HISTORY**

Date	Description of Changes	Revision
07/02/25	Initial issuance.	0

# **APPENDIX B. DOS AND DON'TS**

When communicating with licensees, applicants, and vendors						
Do	⇒ Don't					
<ul> <li>Describe the specific regulatory issue and its safety significance.</li> </ul>	<ul> <li>Simply cite the regulatory requirement without describing the issue and its significance.</li> </ul>					
<ul> <li>Direct the licensee, applicant, or vendor to the appropriate regulatory guidance.</li> </ul>	<ul> <li>Imply guidance is a requirement or establish new requirements.</li> </ul>					
<ul> <li>Provide an accurate, clear and concise technical or regulatory basis by referring to the applicable regulatory standard, acceptance criteria, and relevant guidance documents.</li> </ul>	<ul> <li>Simply identify an issue without providing the regulatory basis.</li> </ul>					
<ul> <li>Identify and discuss possible options and alternatives for licensees, applicants, or vendors to consider, including pointing to past precedents or NRC regulatory guides (without making commitments).</li> </ul>	<ul> <li>Recommend or direct implementation of a specific solution to resolve a regulatory issue when multiple options exist, as the licensee, applicant, or vendor is ultimately responsible for deciding which solution to implement.</li> </ul>					
<ul> <li>Be accurate, clear and concise when asking or responding to questions, or when providing comments.</li> </ul>	<ul> <li>Include unnecessary detail or make overly broad or vague statements.</li> </ul>					
<ul> <li>Ensure staff positions align with the regulatory requirements and established agency positions.</li> </ul>	<ul> <li>Provide a staff position that goes beyond the regulatory requirements or that is different from the established NRC position.</li> </ul>					
<ul> <li>Identify information gaps and request that additional information needed to make a regulatory decision be submitted on the docket.</li> </ul>	<ul> <li>Ask for information that is already on the docket or information that is not necessary for a regulatory decision.</li> </ul>					
<ul> <li>Use discussions with a licensee, applicant, or vendor to establish or enhance the staff's understanding of proposed modifications or resolutions in support of a regulatory action or decision.</li> </ul>	<ul> <li>Make licensing and regulatory decisions during verbal communications with a licensee, applicant, or vendor.</li> </ul>					
<ul> <li>Consider the most efficient use of all available forums including regulatory audits, pre-application interactions, etc., to ensure a continuous flow of information.</li> </ul>	<ul> <li>Engage only through written communications and a limited number of public meetings.</li> </ul>					

<ul> <li>Ensure final regulatory decisions are communicated through established processes and formal documents.</li> </ul>	<ul> <li>Communicate licensing and/or regulatory decisions or other binding commitments during informal interactions with a licensee, applicant, or vendor.</li> </ul>
<ul> <li>Place on the docket information received from external stakeholders that was necessary for regulatory decision-making to ensure public disclosure and transparency.</li> </ul>	<ul> <li>Fail to place on the docket information received from external stakeholders that was necessary for regulatory decision-making.</li> </ul>
Escalate unresolved issues in a timely manner to management once the staff and licensees, applicants, or vendors have reached a common understanding of each other's positions on a regulatory issue.	Cycle back and forth or let regulatory issues linger with applicants, licensees, or vendors without meaningful progress in the resolution of a regulatory issue.
Share when it appears that there is only one viable regulatory pathway to resolve an issue yet keep an open mind to other options that the licensee, applicant, or vendor may come up with.	<ul> <li>Let the licensee, applicant, or vendor unnecessarily struggle to identify an acceptable path if you know of a viable path to resolving a regulatory issue.</li> </ul>

#### APPENDIX C. SPECIFIC EXAMPLES

## Preapplication and Acceptance Review Activities

Applicants with novel design features or approaches may only have conceptual design information and may seek staff feedback regarding these conceptual designs. In addition, new applicants may not be familiar with the NRC's licensing processes. Staff can refer prospective applicants here for general information. It is also expected that staff will provide feedback to prospective applicants that would be useful in preparing a formal licensing application. So long as the staff does not provide specific advice or direction on how to address technical issues or staff concerns, or provide advice that would advantage one entity or one technology over another, this feedback would not be considered consulting.

Pre-application interactions can occur in the context of other regulatory evaluations, including those related to license amendments for existing facilities. Since pre-application review has been demonstrated to be a key component of a successful application, it is critical to encourage pre-application interactions and to provide clear and direct feedback on any regulatory or safety/security gaps during such meetings.

An example of guidance for pre-application engagements is the Division of Advanced Reactors and Non-power Production and Utilization Facilities (DANU) interim staff guidance DANU-ISG-2022-01, "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications – Roadmap," (ML23277A139). This document was issued in March 2024 to provide guidance on preparing non-light-water reactor applications and to provide guidance to the staff on how to review such an application.

At a public meeting, an applicant had misconceptions about the applicability of certain regulations and therefore ruled out some technical approaches. To successfully address the misconception, the staff explained key terms in the regulations and how the regulations are applied, and discussed the pros and cons of the approaches. The staff also explained that one approach would require two exemption requests while another approach would require only one exemption request. This feedback is not consulting.

#### **Detailed Technical Reviews**

After an application has been submitted and accepted for review by the staff, the formal, detailed technical review of the docketed material begins. However, there are cases where information gaps exist in the submittal. In some cases, these gaps may result in the staff being unable to proceed with their detailed review until additional information is provided. There are several mechanisms by which the staff may gain additional detailed information needed to make a complete and comprehensive safety determination. The necessary supplemental information may be obtained by conducting a regulatory audit or by formally requesting submission of additional information on the docket through an RCI or RAI. Section 4 of this document describes the effective use of clarification calls to discuss RCIs and RAIs.

In reviews of topical reports, staff safety evaluations sometimes contain limitations and conditions which impose additional restrictions on the applicability of that topical report or identify additional actions that are required to support a plant-specific licensing action

referencing that topical report. Imposing these limitations and conditions in the approval of a topical report is not consulting.

In resolving a regulatory issue during a detailed technical review, if the staff is aware of only one potential approach for addressing a regulatory issue, the staff should inform the licensee, applicant, or vendor of this approach but remind them it is ultimately their responsibility to select and implement an appropriate solution. In this situation the staff must not provide assurance that if this approach is used that the staff would find it acceptable. In these discussions the staff should also note that there may be other viable solutions, and the staff would be open to considering them. These activities are not consulting.

## Oversight and Inspection Activities

On occasion, licensees ask inspectors for help resolving issues. Inspectors may direct licensees to publicly available documents on the NRC website, such as NUREGs, information notices, regulatory guides, or inspection manual chapters. The inspector can also discuss approaches that have been successful from past experience or potentially could be successful in addressing the issue in accordance with the regulations.

If the inspector receives a request for third party assistance, the inspector may refer the requestor to a professional group, such as the American Nuclear Society, the Conference of Radiation Control Program Directors, Inc. or the Health Physics Society that may maintain lists of qualified consultants; equipment manufacturers; or service providers. Alternatively, the inspector may refer the licensee to other licensees that have solved a similar problem. When providing the name of a group or a licensee, the inspector should take special care not to create a perception of endorsing a particular third party, particularly when recommending a third party with whom the inspector has a personal or long-standing working relationship.

As described in NUREG-BR-0075, "NRC Field Policy Manual," Revision 4 (ML041170225), if the inspector receives a request for third party assistance related to an immediate health and safety issue, the inspector should collect sufficient information to determine if immediate assistance is needed and consult with their supervisor if time permits. In this case, the inspector may choose to offer immediate technical assistance or may refer the licensee to a specific third party. Following recommendations of a specific third party, the inspector should inform their supervisor (if not already done) and document the situation.

During inspections, licensee staff may also ask the inspector if the program will still be in compliance with applicable requirements if the licensee makes a proposed/hypothetical change to its program. While the inspector cannot guarantee that the changes will result in compliance, the inspector can and should explain the applicable requirements, the purpose of the requirements, and what inspectors look for in assessing compliance with those requirements. The inspector can and should share any known operating experience or point to existing publicly available guidance documents that the licensee can consider in making their own risk-informed decision on how they choose to proceed.