

NUCLEAR MATERIAL USERS INSTRUCTIONS FOR PRE-APPLICATION ENGAGEMENTS

January 27, 2026

1.0 PURPOSE

Streamline Nuclear Material Users (NMU) pre-application engagement process to achieve more efficient and reliable licensing thus enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials for the benefit of society.

2.0 OBJECTIVES

- 2.1 Establish a consistent process for pre-application engagements and related documentation in the context of licensing activities for NMU.
- 2.2 Delineate expectations and tools for pre-application engagements and interactions, to enable clear two-way communication and understanding between NRC staff and prospective applicants, with a goal to improve the quality of the applications.
- 2.3 Define roles and responsibilities of the staff in pre-application engagements.

3.0 BACKGROUND

On May 28, 2025, the Office of Nuclear Materials Safety and Safeguards (NMSS) issued a licensing efficiency expectations memo, ([ML25143A040](#)), establishing expectations, effective immediately, to improve the efficiency, predictability, and timeliness of the materials licensing programs. These expectations were informed by the U.S. Nuclear Regulatory Commission's (NRC's) updated mission statement and associated guidance (ML25106A353)¹, the NRC's Principles of Good Regulation, and ongoing efforts of the Materials Licensing Efficiencies and Processes (M-LEAP) initiative undertaken in response to the licensing efficiency mandate in section 505 of the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act). One of the taskings under the "Immediately Implement Near Term Efficiencies" of the May 28, 2025, NMSS memo, was for staff to establish Business Line instructions for the expectations for pre-application engagements.

On July 10, 2025, NRC published procedure-0235 titled, "[Driving Regulatory Decisions Through More Effective Communications](#)." This document provides guidance on how NRC staff should 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.

On July 16, 2025, an NMU agency team, consisting of staff from the Division of Materials Safety, Security, State, and Tribal Programs (MSST) in NMSS, Regions I, III, and IV, led by MSST, kicked off the initiative on streamlining pre-application engagements. The team brainstormed pre-application engagement practices, ways to better help licensees in the pre-application phase, usefulness and ease of NRC website tools for licensees/ applicants in the

¹ "SECY-25-0031: Enclosure 1 - Mission Statement Implementation Guidance" (Agencywide Documents Access and Management System [ADAMS] Accession Number ML25106A353).

current landscape, and ideas to improve efficiencies in the process. The staff reviewed the best practices across other NRC Business Lines and Agreement State practices, including the Agreement State web pages for licensing and the interface with applicants/ licensees.

On July 31, 2025, the team concluded an internal survey of NMU licensing staff and received feedback on the topic.

On August 20, 2025, the team facilitated a government-to-government meeting with the Agreement States to present the pre-application engagement streamlining initiative. The staff received comments and suggestions, which included the best practices from the Agreement State experience and NRC staff inputs.

On August 21, 2025, the team facilitated a virtual public meeting and engaged members of the public, NMU licensees, Agreement States, Tribal Nations, Federal agencies, and other stakeholders with a discussion and feedback on the topic. The meeting was well attended, and the staff received several insightful comments. The meeting summary, dated September 8, 2025, is available publicly in ADAMS (ML25247A201).

The team considered the feedback and suggestions of internal and external stakeholders to inform the development of this guidance for NRC staff, as well as new tools and guidance for NMU licensees and prospective applicants in the NRC public webpage:

<https://www.nrc.gov/materials/miau/engagement-resources>.

4.0 REQUIREMENTS

There are no requirements identified for pre-application engagements.

5.0 EXPECTATIONS

Pre-application engagement encourages two-way dialog with a goal to maximize openness and transparency. While voluntary, pre-application engagement often benefits applicants by increasing the quality of an application, minimizing the need for supplemental information during the acceptance review, and ensuring NRC has the resources available to conduct the review.

Key to success in these discussions is having open, candid conversations about potential review issues and what the potential resolutions to those challenges may look like. In the past, staff may have held back from sharing their thoughts because they were concerned about appearing to consult the applicant. There is, however, a difference between consulting, which we do not do, and clearly stating our regulatory needs, which we must do.

The following best practices are relevant for staff behavior during pre-application engagements, as documented in the NMSS May 28, 2025 licensing expectations memo:

- Take the initiative to use alternate paths when the normal approach does not provide a benefit commensurate with the resource investment. Examples include discussions with applicants about submitted or staff-initiated exemptions on a case-by-case basis.
- Use preapplication engagement to understand unique technical issues, align on regulatory paths, and identify efficiencies for the licensing review.

- During meetings with applicants and licensees, openly express questions and concerns, clearly communicate the safety or security basis, and discuss options under the regulatory framework.

6.0 GUIDANCE

6.1 Pre-application meetings

- a) Pre-application meetings are voluntary. These meetings can occur prior to the submittal of new, large, unique, novel, or complex licensing applications. The meetings can be public, non-public, or a combination of both, depending on the type of information to be discussed.

For Sealed Source and Device (SSD) applications (covered by NUREG 1556, Volume 3, Section 11.2), either the NRC or prospective applicants may request meetings to discuss licensing applications before they are submitted. Meetings between the NRC and prospective applicants may occur at an NRC office or at the prospective applicant's facility, if it is determined that a meeting would enhance the NRC's understanding of the product.

- b) Frequent and early communication between the NRC licensing staff and the prospective applicant can provide several benefits that facilitate efficiency in the subsequent review including:
 - 1) early identification of potential safety, technical, or regulatory issues, and early engagement on those issues with NRC management as needed.
 - 2) early identification of any unique or complex aspects of a proposed application.
 - 3) enabling better planning by identifying specific skills needed for the review.
 - 4) providing information to support the staff's initial understanding of the required scope, focus, and potential level of detail for a review, and any coordination needed with Agreement States or with other NRC organizations. For example, an applicant may apply for a possession license from an NRC region and may also be applying for an exempt distribution license with the NRC.
 - 5) enabling coordination on the scope/ jurisdiction of the license or SSD certificates, and allowing the prospective applicant to discuss and understand the regulatory requirements, associated guidance, regulatory options, applicable fees, and the timeline of NRC reviews.

For example, a new applicant sourcing radioactive material from an international entity and conducting business within the United States may be required to obtain multiple authorizations, including an NRC or Agreement State license for possession and/or use of the material, a separate license for distribution, and a Sealed Source and Device (SS&D) registration certificate. Early engagement with the prospective applicant is strongly recommended to ensure an efficient and coordinated review process. Such engagement should address key topics, including the NRC licensing process, the applicant's schedule and operational

needs, NUREG-1556 application guidance and associated checklists, available options within the licensing framework, pre-licensing visits, and applicable fees. Early communication and planning can facilitate timely review and effective cross-coordination among NRC headquarters, regional offices, and Agreement States, as appropriate.

- c) Pre-application engagements should foster a culture of proactive, helpful, and mission driven interaction with prospective applicants, with effective and open communication between the parties to gain mutual understanding. The approaches could include the following:
 - 1) It is crucial for the NRC to understand and clearly communicate positions and concerns during the licensing process. In addition, to meet the agency's mission, it is necessary for the staff to provide proactive and timely information to prospective applicants as they work through the licensing process.
 - 2) 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 the regulatory framework.
 - 3) The staff may ask questions to help better understand the prospective applicant's approach or specific aspects of the proposed application but should avoid making any specific requests or providing specific directions to the prospective applicant.
 - 4) The staff may clearly explain the requirements that would apply to the prospective applicant's operations or application. The staff may explain regulatory requirements and acceptance criteria, including the origin and purpose of those requirements.
 - 5) The staff may guide the prospective applicant to the NRC publicly available tools and resources <https://www.nrc.gov/materials/miau/engagement-resources>), and facilitate follow up conversations before the application is submitted for staff review, if it can be potentially beneficial.
 - 6) The staff should engage in discussions on a range of ideas and options that could be used to address a regulatory issue, including by sharing publicly-available information on successful approaches from past experience and precedents.

6.2 Public Pre-application Meetings

- a) The staff can coordinate public meetings, as needed, to discuss significant issues in pre-application meetings. These types of meetings are announced on the NRC's Web site to provide the public and other stakeholders the opportunity to participate. Public meetings can occur in person, by phone, or using software that allows for virtual meetings.
- b) The staff must follow the guidance in [Management Directive \(MD\) 3.5](#), "Attendance at NRC Staff-Sponsored Meetings" (ML21180A271). On March 19, 2021, the NRC issued a *Federal Register* Notice, "Enhancing

Participation in NRC Public Meetings” ([86 FR 14964 \(March 19, 2021\)](#) [[Document No. 2021-05787](#)]), with defined public meeting categories as well as guidance on their characteristics. The three categories are as follows:

- 1) Observation meeting;
- 2) Information meeting with a question-and-answer session; and
- 3) Comment gathering meeting.

NOTE 1: Regulatory decisions will not be made in public pre-application meetings. The NRC staff may provide feedback to prospective applicants and solicit and respond to general questions from the public during these meetings.

6.3 Preparation for Pre-application meetings and documentation

- a) The licensing staff should charge time spent to an Enterprise Project Identifier (EPID) associated with pre-application engagement activity, as identified by the cognizant organization, with appropriate cost activity code (CAC).
- b) The licensing staff should coordinate and set up the meeting or calls and prepare to use appropriate techniques to provide walk-through and information regarding the licensing process. Pre-application interactions could also include (1) providing information on filling out the NRC application checklist or forms, (2) viewing and discussing portions of a draft application, or (3) discussing acceptance criteria to facilitate application completeness and sufficiency.
- c) Information received via phone or e-mail interactions that impact a licensing action must be summarized and documented in ADAMS, and docketed, as appropriate.
- d) For complex or controversial issues (e.g., alternative approaches or licensing options, potential requests for exemptions), the staff should consider engaging NRC management early and including the management in the pre-application meetings.

7.0 RESPONSIBILITIES AND AUTHORITIES

- 7.1 NMU Licensing staff consisting of technical reviewers from MSST, or Regions I, III, IV, should facilitate pre-application meetings when requested by the prospective applicant, for actions under their authority, and document appropriate information in ADAMS.
- 7.2 NMU Licensing staff should engage with MSST early if an emerging medical technology may require evaluation by the Standing Committee for Reviewing

Emerging Medical Technologies to determine appropriate medical use licensing pathway.

- 7.3 MSST reviewers should engage with Regions or Agreement States early, and lead the coordination on pre-application discussions, where the prospective applicant request includes a combination of licenses or registration requests and includes exploration of alternative approaches.
- 7.4 MSST will have programmatic oversight of the pre-application engagement process and will institute continuous improvements in consultation with regional stakeholders.