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U.S. Nuclear Regulatory Commission Office of Nuclear Material Safety and Safeguards

Division of Fuel Management

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Requests for Additional Information¹

1. OBJECTIVES

- 1.1 Define the purpose, process, and format for requests for additional information (RAIs).
- 1.2 Assist the U.S Nuclear Regulatory Commission (NRC) staff in focusing RAIs on the pertinent issues necessary to complete the safety review for making a regulatory decision.
- 1.3 Enhance the clarity and understanding of RAIs both during the development of draft RAIs and after their issuance.
- 1.4 Promote NRC staff engagement with applicants (i.e., applicants, licensees, vendors, certificate holders).
- 1.5 Enhance the Division of Fuel Management's (DFM) consistency and efficiency when requesting additional information from applicants.

2. GUIDANCE SECTION

An overview of, and expectations for, the overall licensing process is found in Division Instruction (DI) LIC-FM-1, "Overview and Expectations of the Certification and Licensing Process" (Ref. <u>4.1</u>). This DI supplements DI LIC-FM-1 and incorporates recommendations for improvement (see <u>Appendix A</u> and <u>Appendix D</u>).

2.1 Specific Division Instructions for Fuel Facilities, Spent Fuel Storage, or Transportation Actions

This DI includes high-level expectations of the licensing and certification process in DFM. The staff developed guidance common to both the Fuel Facilities and Spent Fuel Storage and Transportation Business Lines (FF and SFST BLs, respectively) to implement these expectations related to the development of RAIs, safety evaluation reports, and other licensing and certification products or processes actions (e.g., peer reviews, audits).

The staff can find additional guidance that is specific to processing FF BL and/or SFST BL actions in the following DIs (not an all-inclusive list):

- 1) <u>FF-FM-1</u>, "Processing Fuel Cycle Facilities Licensing Actions" (Ref. <u>4.3</u>)
- 2) <u>FF-FM-2</u>, "Implementation of U.S. IAEA Safeguards Agreement" (Ref. <u>4.4</u>)

¹ For changes or revisions to this DI follow the guidance in Section 2.3, "Revision of a DI," of DI ADM-FM-1, "Development, Revision, and Maintenance of Division of Fuel Management Instructions," (Ref. <u>4.2</u>)

- 3) <u>ST-FM-1</u>, "Processing 10 CFR Part 72 Actions" (Ref. <u>4.5</u>), and
- 4) <u>TR-FM-1</u>, "Processing Transportation-Related Actions" (Ref. <u>4.6</u>)

To the extent practicable, the DIs listed in items 1 to 4 above supplement this DI when processing actions specifically related to FF or SFST actions.

2.2 What is an RAI?

- 2.2.1 An RAI is the mechanism that the NRC staff uses for obtaining the additional information needed to make a regulatory decision as to whether a license or a certificate should be granted, renewed, modified, or denied.
- 2.2.2 The RAIs request information that enables the staff to determine compliance of an aspect of the application with one or multiple regulatory requirements in which the NRC has regulatory authority.

2.3 Types of RAIs

The staff uses first round RAIs, subsequent round RAIs (i.e., second, third, etc.), and staggered RAIs (i.e., issued in phases such as by technical area, in parts such as by chapter, or at different times such as every 2 weeks, monthly, or when completed), as discussed below. All RAIs, as well as the corresponding responses submitted by the applicant, should be added to the Agencywide Documents Access and Management System (ADAMS) under the docket number of the assigned ongoing licensing action request. See <u>Appendix B</u> of this procedure for templates of RAI-related documentation.

2.3.1 First Round of RAIs

The staff should develop the RAIs, if necessary, following acceptance of the application for detailed review. The review team should seek to develop a single round of RAIs to obtain all of the information needed to complete their review and make a regulatory and safety finding for the licensing action requested by the applicant.

If the staff determines that an applicant's responses to the first round of RAIs are not clear or complete enough to make a regulatory finding, the staff may request the applicant to clarify the responses through a phone call or via e-mail. The staff should consider the responses to the first round of the RAI complete when it receives the clarifying information from the applicant.

2.3.2 Subsequent Rounds (i.e., second, third, etc.) of RAIs

 Subsequent rounds of RAIs may be needed as the result of new or incomplete information submitted by the applicant in the initial RAI responses or if the RAI responses increase the scope of the review. However, prior to drafting a subsequent round of RAIs,

the staff should consider:

- (1) convening a secondary (expert) peer review panel, to determine if there is a reasonable expectation of timely resolution of the issues related to the application, and
- (2) aligning with DFM management on outstanding technical issues.
- b) The staff may also issue a subsequent round(s) of RAIs due to significant safety and regulatory concerns within the scope of the review.
- c) Subsequent rounds of RAIs require division management (i.e., Director/Deputy Director) concurrence. As such, prior to issuing subsequent rounds of RAIs, the staff should discuss with division management the need for the subsequent rounds of RAIs, the additional information that has been requested, and the regulatory basis for the subsequent RAIs.

2.3.3 Staggered RAIs

- a) The staff should consider issuing staggered RAIs when staff involved in the review provide complete and approved RAIs at different timeframes (e.g., more than 2 weeks apart).
- b) The staff issues staggered RAIs in separate transmittal letters, or docketed e-mails, until issuing a final staggered RAI letter, or docketed e-mail, with the last group of RAIs. The last letter includes an estimated timeframe for issuing the requested action if responses are acceptable and provided in a timely manner.
- c) The goal of staggered RAIs is to provide the applicant time to start working on responses to RAIs that are ready for issuance, instead of waiting for the complete set of RAIs to be developed. Use of the staggered RAI process can help improve the efficiency of NRC's actions by informing applicants of issues earlier in the process and for the applicant to allocate the resources focused on responding to the RAIs as early as possible. As an example, some technical RAIs do not take long to answer if only additional clarification is being sought when compared to RAIs that require consultation or additional modeling/analysis.
- d) Staggered RAIs are not often used and may have unique aspects. When using the staggered RAIs approach the project manager (PM) should:
 - (1) Inform the applicant that a staggered RAI approach will be used.

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(2)	Ensure that the applicant understands the process and
	inform the applicant of the planned transmittal of the
	specific RAI (e.g., radiation safety, chemical safety,
	decommissioning financial assurance, etc.) before
	transmittal.

- Offer the applicant the opportunity for a phone call to discuss the draft RAI, prior to their issuance, to ensure there is mutual understanding of the questions by both the applicant and the NRC staff (see section 2.7.2, "Teleconferences and e-mails," and <u>Appendix C</u> of this DI).
- (4) Transmit the staggered RAIs to the applicant via letter or by e-mail. The letter or e-mail should be docketed and placed in ADAMS as publicly available, as appropriate. The applicant may provide staggered responses to RAIs as discussed and agreed upon with the PM.

NOTE 1: It is recommended that all documents related to a staggered RAI be included in an ADAMS package.

- (5) Copy the PM's branch chief (BC), the assigned technical reviewers, and their BCs on the e-mail transmitting the RAIs to the applicant. <u>Appendix B</u> of this DI provides a template for developing the e-mail with the staggered RAIs (see template No. LIC-FM-3-6 in <u>Appendix B</u> of this DI).
- (6) Manually identify, in the scheduling system (e.g., in a note field), the various staff/discipline committed dates for providing RAIs.²

2.4 Developing RAIs

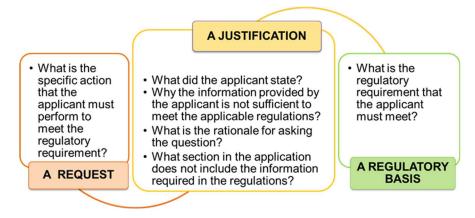
2.4.1 Format and Content of an RAI

a) Each RAI should have three parts: (a) a request or statement of the action needed (i.e., brief discussion on requested information), (b) a justification, and safety nexus for requesting the information (description of what is missing or unclear), and (c) the specific regulatory basis. The figure below includes the main structure of an RAI with corresponding questions that the staff should consider when developing each part of an RAI. (<u>Appendix B</u> to this DI includes the ADAMS Accession Numbers for the RAI Quick Reference Guide and RAI-related document templates).

² The electronic scheduling system does not have multiple RAI dates to capture staggered RAIs, but only has a single date field for when RAIs are expected to be issued. For a staggered RAI approach, the PM should identify in a note field in the scheduling system with the agreed upon submission dates for the various reviewers. The date of the latest agreed upon submission of RAIs should be used for the formal RAI issuance date in the scheduling system and used for reporting purposes.

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b) The RAIs should be a request in the form of a statement (i.e., not a question). Use action verbs, such as those listed below and avoid passive verbs such as 'describe' or 'discuss.'

SAMPLE LIST OF ACTION VERBS			
analyze	assess	attach	clarify
conclude	define	demonstrate	determine
differentiate	distinguish	establish	evaluate
explain	identify	illustrate	indicate
justify	label	list	measure
name	provide	reproduce	resolve
show	specify	state	

- c) The following sections provide a brief description of each part of an RAI. As the staff develops an RAI, each part of an RAI should be clear, complete, specific, and descriptive in order to obtain the information that the staff needs for making a regulatory finding. Additional information regarding each part of an RAI and its relationship to clarity, completeness, specificity, and an acceptable description has been included in <u>Appendix B</u> of this DI ("RAI Quick Reference Guide").
 - (1) Statement of the action needed: a concise statement of the additional information that the staff needs to make its regulatory decision and the action that the applicant should take to meet the regulatory requirement. This statement should clearly identify the information needed to meet the regulatory requirement in question. Use action verbs but avoid general, non-specific actions such as 'describe' or 'discuss' [see sample list of action verbs above.]
 - (2) Justification or reason for requesting the information includes a brief discussion of the information provided by the applicant (i.e., section number and title, table number and title, etc.) and why it does not meet the regulatory requirements (i.e., why the reviewer was unable to make a determination).

(3) The specific regulatory basis that the applicant should meet as these relate to the information requested: the staff should reflect the specific regulatory citation(s) directly related to the information requested.

NOTE 2: In most cases, general requirements in the regulations (e.g., Title 10 of the *Code of Federal Regulations* (10 CFR) (Ref. <u>4.7</u>) Section 70.22, "Contents of applications") should not be used as the basis for RAIs. The RAI should refer instead to performance requirements or other more specific sections of the regulations.

2.4.2 Preparing and Reviewing RAIs

The staff develops RAIs after completing the acceptance review.³ The staff should only develop RAIs if the application does not include the necessary information to reach a safety and regulatory finding for the action requested. The PM should seek inspector insights during the staff review and in the development of RAIs, especially for large or complex applications. This participation should be early in the review to gain inspector observations (e.g., applicant performance and inspection findings and observations that are related to the application and/or specific areas of review) that might aid in understanding specific details of the application and focusing staff RAIs on specific aspects of the review as well as to ensuring the resulting safety evaluation and any conditions, etc. are clear and inspectable.

The staff should pay particular attention to ensuring that complete information is provided on new and unique features of the application. In addition, the staff should review similar previous applications to ensure that RAIs are not generated on issues that have been previously addressed.

- a) The staff should ensure that the RAIs are fully informed, technically correct, and legally defensible regarding the requested action. RAIs should include the following:
 - (1) A concise description of the information required to make a safety and/or security determination.
 - (2) A description of the information deficiencies in which a response is necessary to show compliance with the applicable regulatory requirements and, as appropriate for the application, consistency with NRC review guidance to demonstrate compliance with the applicable regulatory requirements.

³ See guidance on acceptance reviews in DI LIC-FM-2, "Acceptance Reviews" (Ref. <u>4.8</u>).

- (3) A reference to the applicable regulatory requirement.
- b) Technical reviewers should use the proper format for their RAIs (see <u>Appendix B</u>, "Templates," of this DI) and draft safety evaluation report (DSER) input.
- c) The draft RAIs should be provided separately from the DSER input (either in a separate file or in a single file before or after the DSER).
- d) The technical reviewer should identify in the DSER⁴ where the evaluation of the RAI response (missing information) will be discussed and why it is needed. For guidance on developing SERs see DI LIC-FM-4, "Safety Evaluation Reports" (Ref. <u>4.9</u>).
 - (1) Each RAI statement should correspond to a section in the DSER that is incomplete because of the need of information.
 - (2) The staff should highlight the section in the body of the DSER where the discussion regarding the additional information provided by the applicant and its corresponding technical evaluation will be incorporated (see <u>Section 2.11</u>, "Evaluating the RAI Response(s)," of this DI).
- e) Technical reviewers should provide the RAIs along with the DSER input to their branch chief for approval and copy the PM in that communication. The purpose of the DSER input is for the BC and the PM to be able to understand the context for the RAIs and to communicate this context to the applicant, as appropriate.
- f) Following BC review and approval, the technical reviewers' BC or designated staff should forward the draft RAI and DSER input to the PM.⁵

Approval of the technical reviewer's draft RAI input does not constitute BC's concurrence, since the PM may need to revise the RAI input when integrating it into the RAI letter. These revisions may include editorial and/or formatting changes and are made to ensure clarity and/or readability of the questions, formatting, and completeness (i.e., contains the question, justification, and regulatory basis) for incorporation into the final letter. The PMs should provide the final RAI package/letter to the BCs for concurrence. The RAI letter is not final until concurred on by the technical and licensing BCs.

⁴ DI LIC-FM-4, "Safety Evaluation Reports" (Ref. <u>4.9</u>), includes guidance for developing DSERs and FSERs.

⁵ Organizations supporting the division should use their approved methods to provide their input.

2.4.3 Addressing Crosscutting RAI Issues

- a) The technical reviewer should coordinate with the review team on any potential crosscutting issues. The PM should arrange meetings(s) for the review team to discuss and identify potential crosscutting issues.
- b) The technical reviewer, the technical reviewer's BC, and/or the PM should determine whether any additional technical disciplines should review the RAI input and coordinate as appropriate.
- c) The review team and BCs should work together to ensure the issuance of a quality product and timely identification of crosscutting issues.

2.5 Peer Reviews

- 2.5.1 The BCs should consider the use of peer reviews when developing RAIs, especially if there are significant issues identified by the lead reviewer.
- 2.5.3 DI LIC-FM-8, "Peer Reviews" (Ref. <u>4.10</u>), provides guidance on peer reviews.

2.6 Use of Templates and Job Aids

- 2.6.1 Templates and job aids are listed in <u>Appendix B</u>.
- 2.6.2 Templates of RAI-related documents, including the recommended format, can also be found in the following SharePoint library: \

https://usnrc.sharepoint.com/teams/nmss-fm-templatesandaids

2.6.3 The PM and the staff should use templates to the extent possible, when developing correspondence and documentation related to RAIs, to ensure consistency of documents generated by the division.

2.7 Communications During the RAI Process

2.7.1 Engagements with the Applicant

a) The staff should communicate with the applicant via teleconferences, public meetings, and other avenues, as appropriate, to enhance clarity and understanding during the development of draft RAIs and after issuing RAIs to licensees [see Section 2.4 of LIC-FM-1, "Overview and Expectations of the Certification and Licensing Process" (Ref. <u>4.1</u>), for further guidance about interactions with the applicant]. The PM should hold periodic communications with the applicant to discuss the technical review progress (i.e., status of the review), requests for information, addition of contractors to support the review, changes

in schedule, cost, and/or number of hours provided in the acceptance letter, which could cause an increase on the applicant's bill, etc.

- b) Engagement with licensees may facilitate the staff's understanding of licensee submittals, reduce the number of RAIs, and enhance licensees' understanding of RAIs and their ability to respond to them effectively. These interactions are to be conducted in accordance with the NRC's openness policies and documented, as appropriate, in ADAMS.
- c) The PM and management should discuss with the applicant regarding the best approach for conducting the various aspects of the review; especially for large, complex, and/or novel applications.⁶

2.7.2 Teleconferences and E-mails

- a) Early communication between the PM, reviewers, and the applicant improve the responses to the RAIs. Therefore, the PM should offer the applicant an opportunity to hold a teleconference with the cognizant technical reviewer(s) to discuss draft RAIs prior to their issuance (see <u>Appendix C</u> of this DI). Once the RAI package is finalized, the formal RAIs should be provided to the applicant.
- b) The PM may offer the applicant conference calls with the reviewers to further clarify the RAIs once these have been issued and/or to discuss the licensee's proposed RAI responses.
- c) Appendix C includes guidance on telephone calls conducted during the development and resolution of RAIs.

2.7.3 Site Visits

Site visits can improve the efficiency and effectiveness of the staff's review by improving their understanding of the information provided in the application and providing familiarization with the specific activities, processes, and conditions associated with the action, especially for major licensing actions (e.g., complex amendment, renewal, new application, etc.). The PM, technical reviewers, and staff from any other NRC organization (e.g., Office of the General Counsel (OGC), Regional staff, environmental, others) involved with the review of the action should consider the benefits of conducting a site visit during the RAI development stage. For guidance on site visits, see DI LIC-FM-7, "Licensing Audits" (Ref. 4.11).

⁶ The staff is evaluating the potential benefit of processing and tracking RAIs electronically (e.g., using an electronic dashboard and/or applicant interface) for DFM-related applications involving large, complex, and/or novel applications. Future updates of this guidance may include any approved actions for such approaches.

- a) When appropriate during RAI development, site visits should be scheduled prior to the formal issuance of RAIs, but after draft RAIs are developed. At this stage, a site visit would help in the discussion of the staff review questions and clarify information in the application needed by the staff to make its safety and regulatory determination.
- b) The table below summarizes the actions that the staff should take before, during, and after a site visit with regard to RAIs:

BeforeDevelop draft RAIsDevelop the draft safety evaluation	 During Ask for missing information Discuss draft RAIs 	After • Revise, add, or eliminate draft RAIs, as needed
safety evaluation identifying the areas where the additional information is needed	 Discuss draft RAIs for understanding and clarity (see Appendix C of this DI) 	 RAIs, as needed Coordinate with other technical reviewers on RAIs that may include cross cutting issues

2.8 Correspondence

As part of the acceptance review, the PM should communicate to the applicant, in writing, when within the planned review schedule the potential RAIs will be issued, when the applicant's responses are expected, and when the final action may be issued should the RAI responses be determined to be acceptable and the responses are provided within the proposed timeframe (see DI LIC-FM-2, "Acceptance Review Process" (Ref. 4.8), Template LIC-FM-2-1, "Acceptance of Submittal," Template LIC-FM-2-2, "Acceptance of Incoming Request - Parts 71 and 72," and Template LIC-FM 2-5, "Acceptance of Renewal Application Parts 30, 40, and 70"). For guidance on developing a schedule see DI LIC-FM-6, "Scheduling Casework and Non-Casework Activities" (Ref. 4.12). The PM should also communicate to the applicant if the efforts to develop the RAIs and/or review their responses may result in significant changes to the schedule and in the work hours and/or cost estimates provided in the acceptance letter.

2.8.1 RAI Transmittal Letter

a) The PM is responsible for preparing the RAI transmittal letter (<u>Appendix B</u> provides a list of RAI templates for corresponding with applicants). Typically, the questions in the RAI transmittal letter should be organized following the standard review plan chapter or section (see template Nos. <u>LIC-FM-3-1 to LIC-FM-3-5</u> of this DI). The RAIs may be included as an enclosure to the transmittal letter.

- b) The PM should:
 - (1) consolidate the RAIs into a unified document with consistent format throughout.
 - (2) verify that the RAIs follow the appropriate format and guidance for developing RAIs.
 - (3) aid in identifying crosscutting issues.
- c) If the PM makes major changes to the technical reviewer's RAI input, the PM should obtain approval from the technical reviewer and, if necessary, the technical reviewer's BC before putting the RAI letter into concurrence to ensure that the intent of the RAI did not change and that the RAI is technically accurate.
- d) The staff should ask the applicant to reference the previous round of RAIs, if applicable, related to the RAI response in the cover letter providing the requested information.

2.8.2 Review and Handling of Sensitive Information

- a) The RAI letter and\or its enclosure(s), RAI responses, and information submitted by the applicant that the applicant considers proprietary should be reviewed to determine if they include proprietary information. The staff should review NMSS Policy and Procedure 7-04, "Handling Requests to Withhold Proprietary Information from Public Disclosure" (Ref. <u>4.13</u>), when determining if the documents include proprietary information.
- b) The PM compiles the RAI concurrence package and reviews it for consistency and protection of sensitive (e.g., proprietary information), or classified information. Technical reviewers should identify any RAIs derived from proprietary sources or believed to be proprietary.
 - (1) In general, an RAI deemed to be proprietary would be derived from a predetermined proprietary source and/or contains proprietary information.
 - (2) If information in an RAI is determined to be proprietary, the PM should prepare two versions of the RAI (i.e., enclosures to the transmittal letter): one version including the proprietary items (non-public) for transmittal to the licensee and a redacted version for public disclosure. The transmittal letter and the two versions of the RAI should be properly profiled in ADAMS.
 - (3) <u>Appendix B</u> of this DI includes templates for drafting letters discussing proprietary and non-proprietary RAIs. All RAI

letters should be publicly available. If an RAI letter discusses proprietary information, then the proprietary information should be included as a separate enclosure (i.e., separate document in ADAMS with its own ADAMS Accession Number).

(4) To the extent practicable, PMs should request applicants to submit public versions of documentation and responses to the RAI. For responses to RAIs that contain/discuss proprietary information, applicants should include these in a separate enclosure. The PM and technical staff should ensure that NRC requirements for handling proprietary information are maintained.

2.8.3 Transmission of Sensitive Information

- a) The PM should send draft RAIs that may contain, or are derived from, proprietary information, to the applicant as a protected document using NRC approved transmission methods [see Management Directive 12.5, "NRC Cybersecurity Program" (Ref. <u>4.14</u>), Section VI, Subsection M, "Exchange of Electronic Information"].
- b) The PM should avoid transmitting sensitive information via email (e.g., password-protected documents). All sensitive information (i.e., proprietary information or other forms of sensitive information) must be encrypted for transmittal outside of NRC facilities prior to sending it. The PM must encrypt the information using Federal Information Processing Standards (FIPS⁷) 140-2 validated encryption modules. The NRC has installed "<u>SecureZip</u>" on all laptops to enable the staff to appropriately encrypt sensitive information (see <u>Appendix B</u> of this DI). The NRC has also implemented the use of <u>BOX- Enterprise File Synchronization and Sharing</u> to better meet the agency's needs to securely collaborate and share files with external stakeholders.
- c) The PM should not provide passwords to the recipient(s) via email. The PM should use a different method (e.g., text or phone) for this purpose (see <u>Standard NRC Announcement</u>, "Cybersecurity Awareness: Handling Sensitive Information via E-mail," dated February 6, 2017).

⁷ FIPS are standards and guidelines for federal computer systems that are developed by the National Institute of Standards and Technology (NIST) in accordance with the Federal Information Security Management Act (FISMA) and approved by the Secretary of Commerce. To provide FIPS 140-2 encryption, <u>SecureZIP</u> is available within the MS Office applications or from their NRC provided workstation. Instructions can be found in the <u>NRC Service</u> <u>Catalog</u> for enabling the FIPS mode in SecureZIP and encrypting e-mails and attachments in Microsoft Outlook.

2.8.4 RAI Concurrence⁸

- a) All assigned technical reviewers and their BCs should have the opportunity to concur on the RAI package and identify any remaining crosscutting issues.
- b) The DFM PM and management ensure that RAIs are issued consistent with the signature authority specified in DI ADM-DFM-2, "Signature Authority and Concurrence Guidance" (Ref. <u>4.16</u>).
- c) The NRC staff is encouraged to complete the concurrence process of the RAI letter electronically (e.g., <u>e-concurrence</u> as listed in <u>Appendix B</u> of this DI).
- d) Concurrence by technical reviewers means that the RAIs:
 - (1) are technically accurate, clear, and complete.
 - (2) are concise, specific, and descriptive; and
- e) For crosscutting RAI issues, the technical reviewer should discuss with their BC whether any additional BCs or technical disciplines should concur on the RAI letter. When concurring on the RAIs, technical reviewers and their BCs are expected to identify any remaining crosscutting issues.
- f) If the PM revises the RAIs during the concurrence process, the PM should require the appropriate technical reviewer to review any revisions made and obtain approval from both the technical reviewer and the technical reviewer's BC, prior to issuing the RAI. Minor editorial changes made by the PM do not require re-concurrence.
- g) BCs should review the RAIs submitted by their staff and confirm the following (the BC may delegate⁹ the review of some of these items to peer reviewers):
 - (1) The need for the RAI (i.e., safety and/or compliance)
 - (2) Quality of the write up (e.g., clarity and conciseness)
 - (3) Technical adequacy and clarity of the RAI
 - (4) That the RAI is formatted appropriately:

⁸ Per OEDO Procedure-0357, "Correspondence Management" (Ref. <u>4.15</u>), "concurrence" is defined as "initialing a piece of correspondence to indicate agreement with information in the correspondence on the basis of the individual's knowledge, experience, and responsibility."

⁹ If the BC is absent, the BC should delegate the concurrence of the RAI letter to the acting BC.

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- (ii) corresponds to a specific section in the draft SER developed by the staff,
- (iii) conforms to DFM's procedures/instructions, proper grammar, and guidance in the appropriate standard review plan (i.e., no review gaps), and
- (iv) includes accurate and specific supporting regulatory citations.
- h) The BCs keep the PM informed about the resolution of their concurrence comments with their staff.
- If, during the concurrence process, the staff or management disagrees or has concerns with the contents of an RAI, the staff and/or manager should reach out to the appropriate individuals (i.e., staff and/or management) and have an open dialog about the concerns. If the staff and/or manager cannot resolve the disagreements on the contents of the RAI letter, the staff/manager should use the appropriate NRC processes to address their concern(s) (e.g., open door policy, non-concurrence process, etc., as necessary).

2.9 Issuing the RAI

2.9.1 Interactions with the Applicant Prior to Issuing the RAI

- a) Prior to issuing the RAI, the PM should schedule a conference call with the applicant to discuss the draft RAI and ensure there is clear understanding of what is needed for an appropriate response by the applicant.
- b) Any minor editorial changes to the RAIs proposed by the applicant as a result of the call, as well as the basis for the change, should be coordinated by the PM with, and approved by, the technical staff as appropriate.
- c) If the applicant's comments to the draft RAIs are significant enough, and warrant further discussion at a subsequent teleconference, the PM should:
 - (1) notify their BC of the issue.
 - (2) coordinate the resolution of the applicant's comments with

the appropriate technical reviewers prior to the teleconference, and

(3) prepare a written summary of the discussion of the teleconference with the applicant. The summary should be profiled accordingly in ADAMS with the appropriate docket number and sensitivity level of the information discussed at the meeting.

2.9.2 Issuance of RAIs

- a) The staff should issue a comprehensive RAI package, if necessary. The BCs of all assigned technical reviewers should have concurred on the package.
- After obtaining all concurrences, the PM should provide a copy of the concurred RAI package (i.e., letter and enclosures) to the administrative assistant for final processing (i.e., profiling in ADAMS, prepare for PM or cognizant manager signature, etc.) and dispatching.
- c) The PM or the administrative assistant should ensure that the final version of the document is docketed in ADAMS and properly profiled prior to its issuance and distribution.
- d) The administrative assistant should prepare the original signed RAI letter, enclosures, and copies for distribution. The RAI letter may be digitally signed and electronically transmitted with its enclosures to the applicant. Copies of the RAI letter and its enclosures can also be provided electronically to the intended receivers on the document's distribution list.

2.9.3 Subsequent Rounds of RAIs

If additional rounds of RAIs are necessary, the staff should issue these through a formal RAI letter. Division management concurrence is required for additional (i.e., second, third, etc.) rounds of RAIs.

2.9.4 Complete or Partial Reissuance of RAIs

Complete or partial reissuance of RAIs should be done by letter to the applicant. The responses should be provided in writing and within a time frame agreed upon with the licensee.

2.9.5 Teleconferences

Prior to issuing subsequent RAIs, the PM should provide the applicant an opportunity to schedule a teleconference to discuss the draft questions and offer the applicant the opportunity for a subsequent teleconference to discuss the applicant's draft responses to the RAI prior to submittal [see

Section 2.7.2 of this DI].

2.10 RAIs Timeline and Scheduling

- 2.10.1 The time allotted to develop and respond to RAIs depends mainly on the complexity of the case. (See DI LIC-FM-6, "Scheduling Casework and Non-Casework Activities" (Ref. <u>4.12</u>), for additional information in this regard.) All inputs and concurrences should be completed in accordance with the approved schedule.
 - a) <u>Draft RAI</u>. The staff may offer the applicant the opportunity to schedule a call to discuss the draft RAI to ensure there is mutual understanding of the information being requested. If the applicant agrees, the staff should share the draft RAI with the applicant within a reasonable amount of time before the meeting.
 - b) <u>RAI Responses</u>. Responses to RAIs are generally requested within 30 days from the date these are issued. However, depending on special circumstances [i.e., resources issues, availability of licensee staff, time of the year (e.g., holidays)], a response date may also be agreed upon with the licensee. The staff may also offer the applicant an opportunity to schedule a call to discuss the draft RAI responses, before the applicant officially submits these, to ensure these accurately respond to the questions in the RAI letter.

NOTE 3: Under the current congressional budget justification performance metrics, the NRC's "technical review clock" starts on the date an application is accepted (i.e., the date of the acceptance letter), stops when the final, comprehensive RAI package/letter is issued, and restarts when the staff receives <u>acceptable</u> RAI responses.

2.10.2 With regard to staggered RAIs, the applicant may submit the responses to the RAIs separately or altogether. The schedule for the applicant responses for each set of staggered RAIs should be mutually agreed upon between the PM and the applicant.¹⁰

2.11 Evaluating the RAI Response(s)

- 2.11.1 The PM should provide the responses to the cognizant technical reviewers who should evaluate the responses and use them to complete the DSER.
- 2.11.2 The staff should use the applicable licensing review guidance when evaluating the acceptability of the RAI response(s).

¹⁰ The agreed upon date of the final set of staggered RAI responses should be used for reporting purposes.

- 2.11.3 Clarification of RAI responses may be needed after receipt of RAI responses.
 - a) The staff may contact the licensee to seek clarification of RAI responses to have a better understanding of the responses for inadequate responses, or for responses that do not completely address the questions asked. This clarification should only relate to the ongoing\current round of RAIs and should not increase the scope of the review beyond the topics addressed in the RAIs. Topics beyond the RAIs would be considered as a subsequent round of RAIs (i.e., second, third, etc. round).
 - b) The staff can clarify RAI responses with the applicant through a phone call or by e-mail.
 - c) For clarification of RAI responses occurring by a phone call and needed to make a regulatory finding:
 - (1) The PM can provide the clarification questions to the applicant in an e-mail.
 - (2) The applicant can provide a clear, written response to the clarification questions by e-mail or supplement the RAI response by letter.
 - (3) The PM ensures that the information provided by the applicant is added in ADAMS under the docket number corresponding to the action requested.
 - d) The following are *examples* of clarifications of RAI responses:
 - (1) The result of a phone call or e-mail communication with the applicant related to the current round of RAIs (i.e., a formal RAI letter), but not to new information submitted by the applicant in the formal RAI response.
 - (2) A request to provide an analysis or calculation package that was referenced or summarized in the RAI response.
 - e) The staff should not consider an RAI response complete until the applicant satisfactorily responds to any clarification questions related to an RAI letter. The receipt date of the RAI response is the date when the applicant provides all the information needed to clarify the RAI responses [i.e., the date of the letter or communication (e.g., e-mail) submitting the acceptable responses to clarification questions].
- 2.11.4 In case a technical reviewer determines that the RAI response(s) do(es) not provide sufficient information, the PM should discuss the issue with his/her supervisor to determine the appropriate course of action. In some cases, division management may need to be informed of complex

technical issues or scheduling concerns. OGC should also be consulted for complex technical issues that may have legal ramifications.

- 2.11.5 The PM may need to seek further input or clarification from the applicant via conference call or by written correspondence or issue subsequent rounds of RAIs. If, after all reasonable efforts to address the issues have been exhausted, the issues are still unresolved, then the staff should recommend to DFM management not accept the application pursuant to 10 CFR 2.108. If non-acceptance of the application is approved by DFM management, the staff should then prepare and issue the denial letter discussing the basis for not accepting the application.
- 2.11.6 If a hearing has been granted regarding an applicant's submittal, the PM should be aware that additional rules and guidance govern the NRC staff's actions. In this case, division staff should interface closely with OGC to determine the proper course of action. If the licensee chooses to withdraw an application, the staff may need to publish a Notice of Withdrawal of Application pursuant to 10 CFR 2.107(c) or 2.1302, as applicable.

2.12 RAI Response Warning and Termination Letters: Non-responsiveness

- 2.12.1 The PM should discuss with the applicant when the applicant displays a pattern of submitting incomplete or non-responsive submittals or is chronically late in responding to RAIs.
- 2.12.2 The initial contact with the applicant should be a telephone call, followed by a letter, to the applicant summarizing the inadequacies and proposing an alternate path forward. A timeframe (i.e., number of days) for the applicant to provide a response should be provided in the letter. If the problem persists, NRC management should pursue resolution with the applicant.
- 2.12.3 If the problem remains unresolved, management may choose to deny the application or direct the PM to suggest that the applicant withdraw the application. The following table summarizes the actions that the staff should take if a non-responsiveness pattern arises:

	If the applicant	DFM Action	
1	misses the due date for an RAI response and is nonresponsive to requests from the PM.	The PM informs the applicant that the non-responsiveness can result in the termination of the review.	
2	continues to be nonresponsive or extends the RAI response date by three months.	The PM informs his/her BC. The BC should discuss the issue with division management (i.e., Director and/or Deputy Director) to determine the course of action, including termination of the review.	

	If the applicant	DFM Action
3	fails to respond to an RAI within the time allotted, by more than 3 months from the proposed RAI response submittal date.	The BC may issue a warning e-mail of intent to terminate the application to the applicant (see template LIC-FM-3-9 in <u>Appendix B</u> of this DI).
4	fails to respond to the RAI within the time allotted in the warning e-mail.	The BC may terminate the review (see template LIC-FM-3-9 in <u>Appendix B</u> of this DI).

2.13 Tracking RAIs

The PM should be aware of reporting requirements for tracking RAIs to fulfill Congressional reporting requirements.

2.14 Continuity of Work

Effective turnover practices should be applied when team members change during the licensing review process. In some cases, a review team member may depart after RAIs have already been dispatched to the applicant. In such cases, the departing technical reviewer and his/her supervisor should discuss and coordinate with the PM and his/her supervisor (i.e., the licensing BC) to ensure continuity and success of the review to minimize the loss of knowledge or information.

If a technical reviewer or PM is reassigned to other activities within the division or the agency, or leaves the agency during a licensing review, the staff should refer to the document titled "<u>Guidelines for Continuity of Review</u>" (see <u>Appendix B</u> of this DI), located in the <u>Division of Fuel Management Job Aids and Templates</u> <u>SharePoint Site</u> to ensure a good turnover of information.

3. **RESPONSIBILITIES AND AUTHORITIES**¹¹

3.1 Administrative Assistants

- 3.1.1 Process RAI letter(s) in ADAMS.
- 3.1.2 Dispatch RAI correspondence.

3.2 Licensing Assistants

- 3.2.1 Ensures that RAIs follow proper grammar and technical writing guidance [see NUREG-1379, NRC Editorial Style Guide (Ref. <u>4.17</u>)].
- 3.2.2 Discuss editorial changes to the RAI letter and its enclosures with the PM.

¹¹ See also Responsibilities and Authorities in LIC-FM-1, "Overview and Expectations of the Certification and Licensing Process" (Ref. <u>4.1</u>).

3.3 Project Manager

Manages the overall RAI process and schedule, interacts with the applicant and the technical reviewers to ensure the RAI process stays on track, for ensuring that RAIs meet the correct format and content [see <u>Section 2.4.1</u>, "Format and Content of an RAI," of this DI], and for keeping management informed of any developments in, and overall status of, the RAI process.

3.4 Technical Reviewers

Review the information submitted by the applicant, develop RAIs when necessary, and provide RAI input to the PM as scheduled.

3.5 Technical Branch Chief

Reviews and approves RAI input and concurs on the RAI letter/package. *Director or Deputy Director*

Provides final concurrence in accordance with signature authority guidance (unless otherwise delegated).

4. REFERENCES

3.6

The staff makes many documents available to the public (e.g., NRC Management Directives). However, not all of the references in this section are publicly available. Links are provided for all documents that the NRC staff uses. The staff should use the latest version of the documents.

- 4.1 U. S. Nuclear Regulatory Commission (NRC), <u>NMSS/DFM Division Instruction</u> <u>LIC-FM-1</u>, "Overview and Expectations of the Certification and Licensing Process."
- 4.2 U.S. NRC, <u>Division Instruction ADM-FM-1</u>, "Development, Revision, and Maintenance of Division of Fuel Management Instructions." (not publicly available)
- 4.3 U.S. NRC, <u>NMSS/DFM Division Instruction, FF-FM-1</u>, "Processing Fuel Cycle Facilities Licensing Actions."
- 4.4 U.S. NRC, <u>NMSS/DFM Division Instruction, FF-FM-2</u>, "Implementation of U.S. IAEA Safeguards Agreement."
- 4.5 U.S. NRC, <u>NMSS/DFM Division Instruction ST-FM-1</u>, "Processing 10 CFR Part 72 Actions."
- 4.6 U.S. NRC, <u>NMSS/DFM Division Instruction, TR-FM-1</u>, "Processing Transportation-Related Actions."
- 4.7 <u>Title 10</u> of the Code of Federal Regulations

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- 4.8 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-2</u>, "Acceptance Review Process."
- 4.9 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-4</u>, "Safety Evaluation Reports."
- 4.10 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-8</u>, "Peer Reviews." (not publicly available)
- 4.11 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-7</u>, "Licensing Audits."
- 4.12 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-6</u>, "Scheduling Casework and Non-Casework Activities." (not publicly available)
- 4.13 U.S. NRC, <u>Office of Nuclear Material Safety and Safeguards Policy and</u> <u>Procedures</u>, <u>Policy and Procedure 7-04</u>, "Handling Requests to Withhold Proprietary Information from Public Disclosure. (not publicly available)
- 4.14 U.S. NRC, Management Directive 12.5, "NRC Cybersecurity Program."
- 4.15 U.S. NRC, Office of the Executive Director for Operations (<u>OEDO</u>) Procedure 0357, "Correspondence Management." (not publicly available)
- 4.16 U.S. NRC, <u>NMSS/DFM Division Instruction ADM-FM-2</u>, "Signature Authority and Concurrence Guidance." (not publicly available)
- 4.17 U.S. NRC, <u>NUREG-1379</u>, "NRC Editorial Style Guide," Revision 2, May 2009.

Appendix A. Change History

Date	Brief Description of Changes	Revision No.
01/31/22	 Initial issuance. This instruction consolidates and updates guidance previously contained in separate instructions for the Fuel Cycle Facilities Business Line and Spent Fuel Storage and Transportation Business Line. This DI incorporates guidance from, and supersedes, the following sections of the Division of Fuel Cycle Safety, Safeguards, and Environmental Review Licensing Review Handbook: Section 4.1.2, "Conference Calls and Meetings" Section 8.7, "Requests for Additional Information" This DI incorporates guidance from, and supersedes, SFM-3, "Requests for Additional Information." This DI incorporates guidance from, and supersedes, SFM-3, "Requests for Additional Information." This DI also incorporates recommendations from the following documents: Smarter Licensing Working Group Recommendations¹² (see <u>Appendix C</u>) Recommendations related to the licensing process in <u>GAO-20-362</u>, "Nuclear Regulatory Commission: Fee-Setting, Billing, and Budgeting Process Have Improved, but Additional Actions Could Enhance Efforts."¹³ Recommendations related to the Office of the Inspector General's (OIG) <u>OIG-21-A-08</u>, "Audit of The U.S. Nuclear Regulatory Commission's, Use of Requests for Additional Information in Licensing Processes for Spent Nuclear Fuel." (ADAMS Accession No. <u>ML21103A001</u>)¹⁴ 	0

¹² Memorandum from Jacob I. Zimmerman (NRC) to Kock Andrea (NRC), "Working Group Recommendations for Building a Smarter Fuel Cycle Licensing Program," April 30, 2020, Agencywide Documents Access and Management System (ADAMS) Accession No. <u>ML20099F354</u>.

¹³ The GAO-20-362 report can be found at <u>https://www.gao.gov/products/gao-20-362</u>.

¹⁴ The OIG-21-A-08 report can be found at <u>https://www.nrc.gov/docs/ML2110/ML21103A001.pdf</u>. The NRC staff memorandum for the status of recommendations of OIG-21-A-08 can be found at ADAMS Accession No. <u>ML21140A224</u>.

Appendix B. RAI-Related Quick Reference Guides and Templates

Templates, job aids, and additional guidance documents are generally not publicly available since they are staff tools to implement the guidance in the Instructions and do not contain policy or guidance themselves.

Appendix C. Guidance on Telephone Calls During Development and Resolution of RAIs

The project manager (PM) may coordinate phone calls¹⁶ between the applicant and the reviewers to request clarification of information provided in the initial submittal and/or in response to requests for additional information (RAIs). The information discussed during the call may include the following:

- 1) <u>Location or clarification of certain information submitted in the application</u>. If the staff has questions about the location of information in the application or needs a brief clarification of units, language, nomenclature, etc., the PM may contact the applicant to clarify these types of questions.
- 2) Discuss draft RAIs prior to their issuance. Prior to issuing the RAI, the PM should schedule a conference call with the applicant to discuss the draft RAI. In preparation for the call, the PM should transmit the draft RAI letter via e-mail, marked as "DRAFT," to the applicant. The technical reviewer(s) that generated the RAIs should be available to participate in the call to discuss their specific information request with the applicant. The purpose of the call is to ensure there is clear understanding of the questions by the applicant and to ensure that the requested information is not already addressed elsewhere in the current submittal. The applicant is not expected to nor be required to provide responses to the draft RAIs. To support clarity and understanding of the draft RAI, the staff should be prepared to share, during the call, their perspective of the scope and significance of the "gap" in information needed to finalize the safety evaluation, and at a high level, the effort (see below) and detail the licensee is expected to incur for providing the responses. These high-level discussions should ensure that what the staff views as necessary to address an RAI is consistent with the licensee understanding and view of the request. These discussions will also support the PM and licensee in determining a reasonable timeframe (i.e., 30/60/90 days) for the applicant to respond [see Section 2.7.2 of this Division Instruction (DI)].

In determining the level of effort and detail for the applicant to provide its response, the U.S. Nuclear Regulatory Commission (NRC) staff should consider if responding to the RAI would require:

- a) minimal effort, mostly clarifying the information in the submittal, that can be provided within a few weeks.
- b) moderate effort by the applicant, which may involve some limited new work/analyses with a response within 30 to 60 days and is unlikely to result in subsequent rounds of questions on the new information.
- c) significant effort by the applicant, which may involve significant new

¹⁶ Typically, public meetings should not be necessary during communications with applicants during the RAI development stage of review, especially in discussing draft RAIs or draft applicant responses to RAIs. In conducting teleconferences, the PM should ensure conversations between the staff and applicant are maintained within the context of understanding and clarifying the application, draft RAIs, and draft applicant responses to RAIs. If detailed technical discussions are needed to understand specific aspects of the application, these discussions should be held separately from discussions on draft RAI or RAI responses and should follow the guidance for conducting a public meeting per NRC <u>Management Directive 3.5</u>, "Attendance at NRC Staff-Sponsored Meetings."

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work/analyses or will likely require more time (e.g., more than 60 or 90 days) to respond, and/or is likely to result in subsequent rounds of questions on the new information.

3) Discuss the applicant's draft response to RAIs prior to their issuance. During the discussion of the draft RAI, the staff should offer the applicant the opportunity for a subsequent phone call to discuss the draft responses to the RAI prior to the applicant's formal submission. The purpose of the call is to ensure the applicant's draft responses adequately address the RAIs (i.e., demonstrates the applicant properly understood the staff RAI), that any supporting information to address the RAI is being provided, and to ensure subsequent rounds of RAIs are avoided.

If during the discussions the NRC staff and the applicant identify the need for additional time to fully respond to the RAIs, the applicant and the NRC staff should agree on a submittal date. The PM should document the due date in an RAI letter, or docketed e-mail to the applicant following the call.¹⁷ The PM should offer the applicant the opportunity for additional calls to discuss and finalize the responses.

- 4) <u>Applicant requests for meetings or calls after issuance of RAIs</u>. The applicant may request a meeting or a call to gain a better understanding of the RAI question after the staff issues the official RAI letter (or docketed e-mail).
 - a) Additional information requested by telephone or e-mail
 - (1) The staff may request additional information that is necessary for a licensing action during a telephone conference call or electronic mail exchange with an applicant. Following the call, the staff should prepare a summary of the call and docket it in the ADAMS database. E-mails requesting information should also be docketed in ADAMS.
 - (2) The RAIs and the applicant's responses needed for making a regulatory finding, based on a telephone call or e-mail interaction, should be:
 - (i) documented,
 - (ii) reviewed for sensitive information,
 - (iii) docketed in ADAMS with the appropriate profile and docket No., and
 - (iv) treated as an Official Agency Record in accordance with the Federal Records Act (44 U.S.C. Chapter 33).
 - (3) The PM can enter the information related to the teleconference in ADAMS or solicit help from the administrative staff to enter the information.

¹⁷ If, after issuing the RAI letter or docketed e-mail, the applicant determines and informs the PM that additional time to respond (beyond the due date established in the letter) is needed, the PM should inform the applicant that the additional time should be requested in writing (or via e-mail) to avoid termination of the technical review and rejection of the licensing request due to lack of responsiveness to the RAIs. The applicant's request should be docketed in ADAMS. The PM should document the new due date in a letter, or docketed e-mail, to the applicant.

- (4) Depending on the outcome of the conference call, the PM should perform one or more of the following actions to document the results of the call and next steps:
- b) Document the phone call
 - (1) The PM should document the phone call by summarizing the discussion in a "Note to File" (see template No. LIC-FM-3-10 in <u>Appendix B</u> of this DI) or by using <u>NRC Form</u> 699, "Conversation Record," or any other acceptable method (i.e., memorandum to her/his supervisor, e-mail). The PM lead should ensure that meeting participants, including the applicant, review the summary before it becomes final. Then, enter the summary and corresponding supporting documentation in ADAMS.
 - (2) Forward the summary of the teleconference by electronic mail to all participants and enter the electronic mail into ADAMS or solicit help from the administrative staff to enter the e-mail into ADAMS.
 - (3) Any information requested to enable the staff to determine whether an aspect of the application complies with one or multiple regulatory requirements in which the NRC has regulatory authority should be requested by a formal written RAI.
- 5) <u>Discuss the status of the technical review and other issues</u>. The PM should hold telephone calls with the applicant to discuss the status of the review, addition of contractors to support the review, changes in schedule and/or costs, and/or number of hours provided in the acceptance letter, which could cause an increase on the applicant's bill.

Appendix D. Smarter Licensing Recommendations in this Division Instruction

The U.S. Nuclear Regulatory Commission (NRC) staff established the Smarter Licensing working group to identify and implement recommendations to improve the effectiveness and efficiency of the nuclear fuel cycle facilities licensing program. This effort is described in the charter of the working group dated April 26, 2019 (ADAMS Accession No. <u>ML19115A016</u>). The NRC working group collected recommendations from the NRC staff, industry, and the Nuclear Energy Institute, as described in a memorandum dated April 30, 2020, "<u>Working Group</u> <u>Recommendations for Building a Smarter Fuel Cycle Licensing Program</u>" (ADAMS Accession No. <u>ML20099F354</u>). The staff created an action plan (AP), published July 10, 2020 (ADAMS Accession No. <u>ML20184A267</u>), which grouped the recommendations into three general categories: Near-term (NT) actions, Mid-term (MT) actions, and Long-term (LT) actions.

Even though the Smarter Licensing Recommendations were developed by the Fuel Facilities Business Line, most of these recommendations are also applicable to the licensing and certification processes managed by Spent Fuel Storage and Transportation Business Line. Therefore, the staff incorporated the applicable recommendations into this DI.

Table C.1 below lists the recommendations of the NRC's Smarter Licensing working group that were incorporated into this DI. The table consists of the Smarter Licensing Recommendation (SLR) number, a brief summary of the recommendation, and the DI section number where the recommendation is addressed. The MT actions to develop guidance and job aids are also documented in Appendix B of this DI. The LT actions are being completed as resources permit.

SLR No.	Summary of Recommendation	Section(s)
NT1-1	Establish schedule and estimate date of completion of technical review with input from licensee.	2.8
NT1-2	Share metrics and estimated hours needed for the completing the technical review with the licensee.	2.8
NT1-6a	Coordinate and share with the applicant the review milestones/schedule including milestones for actions/areas to be completed by supporting organizations (e.g., OGC, external contributors, centers of excellence).	2.8
NT4-7a	Hold a site visit, especially for major license amendments, license renewals, and new applications, at the draft RAI phase involving the pertinent reviewers.	2.7.3
NT4-8	Ensure RAIs have a clear regulatory basis and leveraging existing job aids and templates to meet this expectation.	2.4.1
NT4-9a	Provide and discuss draft RAIs to the applicant to confirm understanding of request and anticipated level of effort needed to develop the response.	2.3.3, d)(3) 2.7.1, b) 2.7.2, a) 2.9.1, a) 2.10.1, a) Appendix C, Item (2)

Table D.1 Smarter Licensing Recommendations (SLR) Incorporated into this Division Instruction

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SLR No.	Summary of Recommendation	Section(s)		
NT4-9b	Hold discussions with applicant when a draft response to an RAI is developed to ensure the response appropriately addresses the NRC staff request.	2.7.1, b) 2.7.2, b) Appendix C, Item (3)		
NT4-10	Establish RAI timeliness metric considerations for application reviews in which RAIs are developed in a phased manner.	2.3.3, d)(1) 2.3.3, d)(2) 2.3.3, d)(3) 2.3.3, d)(6) 2.13		
NT4-11	Ensuring clarification calls with the applicant to support clarity and understanding of RAIs is not disincentivized by the meeting notice metrics.	2.3.3, d)(3) 2.7.1, b) 2.7.2, a) 2.9.1, a) 2.10.1, a) Appendix C, Item (2)		
NT4-12	Use the tools (e.g., job aids and templates) available to the NRC staff to minimize the potential for multiple rounds of RAIs.	2.3.2, a)(2) 2.3.2, c) 2.4.2, d) 2.4.2, d)(1) 2.4.2, e) Appendix B		
NT4-13a	Ensure the continuity of the quality, effectiveness, and efficiency of the licensing review process during NRC staff turnover.	2.4.2, d) 2.4.2, d)(1) 2.4.2, e) 2.14		
NT4-22	Use an electronic interface with applicants, including in support of review planning and implementation, such as for the RAI phase.	2.7.1, c)		
MT1-15	Incorporate into review guidance the use of integrated, multi-disciplined, review teams.	2.4.3, a)		
MT1-25a	Facilitate inspector involvement early in the licensing review process.	2.4.2 (introduction)		