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

Division of Fuel Management

Division Instruction

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Division Instruction Title: Overview and Expectations of the

Certification and Licensing Process

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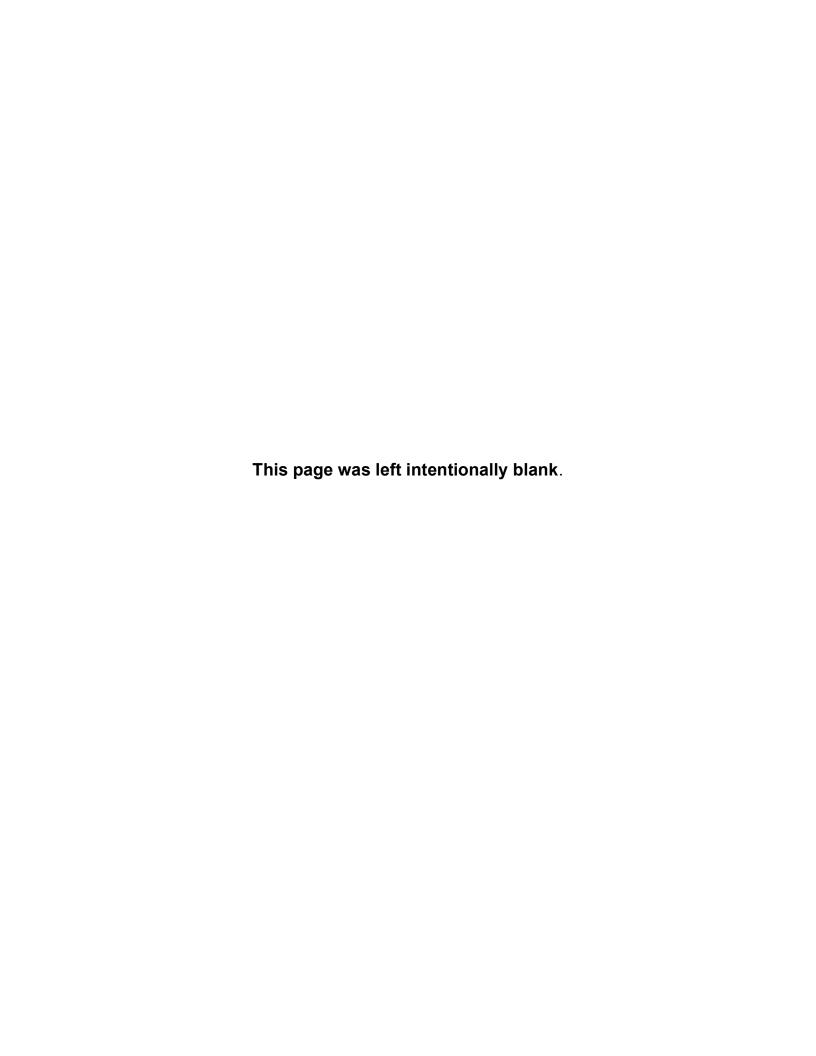
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Upon removal of Appendix B, this document is uncontrolled.



Overview and Expectations of the Certification and Licensing Process

1. OBJECTIVES

- 1.1 Establish a consistent process for reviewing licensing and certification actions applicable to the Fuel Facilities (FF) and Spent Fuel Storage and Transportation (SFST) Business Lines (BLs).
- 1.2 Delineate Division of Fuel Management (DFM) management's expectations for reviewing applications and interacting with applicants¹.
- 1.3 Define roles and responsibilities of the staff for the licensing and certification actions applicable to the FF and SFST BLs.

2. GUIDANCE SECTION

This DI includes high-level expectations for the licensing and certification process in DFM. The staff developed supplemental guidance to this DI applicable to both the FF and the SFST BLs related to acceptance reviews, requests for additional information (RAIs), safety evaluation reports (SERs), and other licensing and certification products or processes (e.g., peer reviews, audits). Section 2.1 of this DI includes additional information about this supplemental guidance.

1) Division of Fuel Management Business Lines

The DFM is responsible for the following BLs:

- a) Fuel Facilities (FF) [i.e., Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40 and Part 70 actions], and
- b) Spent Fuel Storage and Transportation (SFST) (10 CFR Part 71 and Part 72)

2) Expectations for licensing and certification processes within the FF and SFST BLs

- a) This DI provides guidance to manage the FF and SFST BLs effectively and efficiently.
- b) All staff [i.e., project managers (PMs), technical reviewers, supervisors, etc.] are expected to continually pursue enhancements to the review process while performing specific certification and licensing reviews.

¹ To improve readability, the word "applicant" will be used throughout this DI to represent applicants, licensees, certificate holders, and vendors.

c) The review process, and any subsequent enhancements to it, should reflect the U.S. Nuclear Regulatory Commission's (NRC's) vision, mission, goals (i.e., safety, security, and organizational excellence), and values (i.e., integrity, excellence, service, respect, cooperation, commitment, and openness).

d) In general, the NRC PM is expected to interact with the applicant, the technical reviewers, and the appropriate branch chiefs (BCs) to determine the best approach to review the requested actions contained in a specific application. The following subsections include additional information, guidance, and considerations for improving the efficiency and effectiveness of the review.

3) Templates and Job Aids

The staff can find templates, examples, and job aids to facilitate processing the licensing and certification actions on the <u>DFM Job Aids and Templates</u> <u>SharePoint site</u> and in <u>Appendix B</u> of this DI.

NOTE 1: In order to supplement and facilitate the use of this DI, this document includes hyperlinks to documents with guidance related to specific processes, job aids, and templates.

2.1 Common and specific division instructions for fuel facilities, spent fuel storage, or transportation actions

- 2.1.1 There are selected DIs that implement the licensing and certification process in DFM that are common to both the FF and SFST BLs, particularly for acceptance reviews, RAIs, and SERs, as well as for other licensing and certification products or processes (e.g., topical report reviews, licensing audits, peer reviews, and other topics). A peer review is optional and at the discretion of the appropriate BC.
- 2.1.2 Guidance that is specific to actions for fuel facilities and spent fuel storage and transportation applications is in the following DIs (this is not an all-inclusive list):
 - a) <u>FF-FM-1</u>, "Processing Fuel Cycle Facilities Licensing Actions" (Ref. 4.1)
 - b) <u>FF-FM-2</u>, "Implementation of U.S. IAEA Safeguards Agreement" (Ref. 4.2)
 - c) ST-FM-1, "Processing 10 CFR Part 72 Actions" (Ref. 4.3), and
 - d) TR-FM-1, "Processing Transportation-Related Actions" (Ref. 4.4).

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

2.2 General considerations

2.2.1 The scheduling of licensing or certification reviews should consider numerous factors, including:

- a) the need for the action(s)
- b) the scope of the requested action(s)
- c) staff availability, etc.
- 2.2.2 The DFM staff may consider various approaches to facilitate the review, such as:
 - sub-dividing the review to allow flexible due dates for the various technical disciplines involved in the review based on reviewer availability
 - b) shortening the review schedule, combining review process steps (when possible), and increasing its priority to support a quicker review of simple, straightforward applications, etc.

2.3 Primary licensing or certification activities

The licensing or certification process usually consists of the following activities:

- 1) interactions with applicants (e.g., pre-licensing interactions, pre-application meetings)
- 2) receipt and docketing of the application
- 3) acknowledging the receipt of an application
- 4) creating a record of the action(s) requested
- 5) review of requests for withholding information
- 6) prioritization of activities and actions
- 7) review work planning (i.e., staff assignments, scheduling, etc.)
- 8) estimating resources
- 9) tracking of the action(s) requested
- 10) team meetings
- 11) acceptance reviews
- 12) technical reviews

- 13) environmental reviews (storage and fuel facilities actions only)
- 14) rulemaking (certificate of compliance for storage systems only)
- 15) issuance of the final licensing or certification documents

2.4 Interactions with applicants

The licensing BC, or designee, identifies a PM as the primary NRC's contact for a specific licensing action. The PM should establish and maintain regular communications with the applicant.² These regular interactions (e.g., public meetings, teleconferences, email, or other types of communication) enable the PM and the applicant to ensure and support the following:

- 1) effective planning for upcoming applications or reviews
- 2) awareness of the status of on-going reviews
- 3) mutual understanding of potential review issues
- 4) opportunities to discuss and resolve issues in a timely manner
- 5) transparency and two-way communication on schedules and milestones for the reviews
- 6) discussions about the potential need for site visits, etc.

For large applications, the PM may seek to schedule regular status interactions with the applicant.

As appropriate, the PM is responsible for docketing a written summary of interactions with the applicant, which should include the following:

- 1) a list of participants and their affiliations
- 2) a summary of the discussions that occurred
- 3) any follow-up actions resulting from the call or meeting

For new license reviews or design certifications (e.g., large, unique, or potentially complex applications, new processes for existing licensees), applicants may submit a letter of intent to the NRC staff in advance of the formal application. The NRC staff can use this letter as a basis to select the review team and hold a pre-submittal public meeting (also known as a

Sensitive (i.e., SUNSI and Safeguards Information (SGI)) and classified information cannot be discussed over non-secure telecommunications and/or in public meetings. If necessary, closed meetings may be held with the applicant to discuss SUNSI, SGI, and/or classified issues.

pre-application meeting) and consider the need for a site visit, if appropriate.

The staff should not consult with the applicant on specific methods for complying with regulations. In general, PMs should ensure that all interactions with applicants are in accordance with the NRC's Principles of Good Regulation and would not be perceived by members of the public as improper or collusive.

2.4.1 Routine communications

- a) The PM should hold periodic communications with the applicant to discuss the 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) In general, communications between the staff and the applicant (i.e., without external stakeholders) are acceptable, provided the interactions involve general discussions on schedule or logistics and/or are for clarifying docketed information.
- c) Conference calls must not be used in lieu of public meetings,³ if these involve detailed technical, regulatory, and/or policy discussions. Further guidance on whether a public meeting is warranted is contained in Section <u>2.4.2</u>, "Public Meetings," of this DI.
- d) Oral communications should not be used as a licensing basis unless a summary is formally documented in the Agencywide Documents Access and Management System (ADAMS).
- e) Information received via telecommunications that impact a licensing action must be summarized and documented in ADAMS.
- f) Quick reference guide QRG-LIC-FM-1-1, "Telephone Call Interactions with Applicants During Reviews of Actions Requested" (see <u>Appendix B</u> of this DI), includes guidance about performing and documenting conference calls with the applicants, licensees, vendors, and certificate holders.

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This subitem refers to discussions of substantive issues (for example, a discussion of a proposed RAI response that includes details of the type of analysis made, how analyses were performed, etc. or discussion that may significantly impact or deviate from approved NRC's guidance). Discussions of substantive issues must be conducted during a public meeting. The PM must announce these interactions to the public.

2.4.2 Public meetings

The NRC staff can coordinate public meetings, as needed, to discuss significant issues about ongoing reviews. 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. The PM can review a copy of the job aid titled "Guidelines for Interactions Between Applicants and the Division of Fuel Management" (see Appendix B of this DI), prior to a public meeting.

- a) The staff must follow the guidance in Management Directive (MD) 3.5, "Attendance at NRC Staff-Sponsored Meetings" (Ref. 4.5).
 On March 19, 2021, the NRC issued a Federal Register Notice, "Enhancing Participation in NRC Public Meetings" (Ref. 4.6), with defined public meeting categories as well as guidance on their characteristics. The categories include the following:
 - (1) Observation meeting;
 - (2) Information meeting with a question and answer session; and
 - (3) Comment gathering meeting.
- b) General guidance related to public meetings (e.g., a public meeting checklist) can be also found at the NRC's public website page, "About Meetings Open to the Public." Best practices for conducting public meetings can be found on the NRC Intranet page, "Public Meeting Best Practices." In addition, the Job Aids, Quick Reference Guides, and Templates in Appendix B of this DI (not publicly available) are found in ADAMS folder "NMSS DFM DivProcedures," specifically in subfolders. Separately, a DFM SharePoint site was created that links to the Job Aids, Quick Reference Guides, and Templates.
- c) The PM is responsible for preparing and concurring on the meeting notice.
 - (1) Applicants or stakeholders should provide publicly available handouts for public meetings (including pre-application meetings) at least 7 calendar days in advance of the meetings to allow enough time for the NRC staff to become familiar with the information.
 - (2) If the handouts contain sensitive information (typically proprietary), the PM should encourage applicants to provide these a few days in advance of the meeting for the staff to perform a review to determine if the information needs to be withheld from public disclosure.

d) Meeting notices are posted using the NRC's Public Meeting Notice System⁴ (PMNS) [see ADM-FM-2, "Signature Authority and Concurrence Guidance" (Ref. 4.7), for signature authority]. The PMNS system is used to automatically post the meeting notice in ADAMS and on the NRC's public meeting website.

- e) The notice for public meetings should be published at least 10 calendar days (not counting holidays) before a public meeting, in order to comply with the agency's performance indicator. Public meeting notices that will be published fewer than 10 calendar days before the meeting require approval and concurrence by DFM management [see ADM-FM-2, "Signature Authority and Concurrence Guidance" (Ref. 4.7), for additional information about signature authority for public meeting notices]. Closed public meeting notices are not required to be posted in the PMNS system. Closed notices do not need to be posted 10 days in advance (Ref. 4.5).
- f) The PM should complete a meeting summary within 30 working days and document it in ADAMS. For closed meetings, a public version of the summary should be placed in ADAMS.
- g) Quick reference guide QRG-LIC-FM-1-2 (see <u>Appendix B</u> of this DI), includes additional information for conducting public meetings.
- h) The PM must provide opportunity for the public to provide feedback consistent with the guidance in MD 3.5, Section D (Ref. 4.5).

2.4.3 Pre-application meetings

Pre-application meetings can occur prior to the submittal of new, large, unique, or complex applications. The meetings can be public, non-public, or a combination of both, depending on the type of information to be discussed. For additional guidance, go to Appendix B of this DI.

During pre-application meetings, the staff is primarily in a "listening mode," in order to gain an understanding of the application. The staff may ask questions to help better understand the applicant's approach or specific aspects of the proposed application but should avoid making any specific requests or providing specific direction to the applicant.

a) In preparation for each meeting, the PM should identify the appropriate technical areas needed for the review of the application and, if necessary, inform their BC. The PM's BC or the

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In order to access PMNS, a potential user needs to be granted rights to the system. If an error is encountered when accessing the system, send a request for access to PublicMeetingHelp@nrc.gov. The request will be processed and an email confirming access will be sent in a reply. After being granted access to the system, the URL, https://adamsicm.nrc.gov/pmns, links to the key PMNS site.

PM will then request the technical BC(s) to assign the needed technical reviewers. Once the technical reviewers are assigned, the PM should request their attendance at the meeting.

- b) The technical BC will assign the appropriate individual(s) to attend the pre-application meetings.
- c) Frequent and early communications between the NRC staff and the applicant (e.g., pre-application meetings) provide a number of benefits to facilitate the review including:
 - (1) early identification of potential safety or regulatory issues,
 - (2) avoiding unnecessary delays in the processing of submittals consistent with the NRC's Principles of Good Regulation,
 - (3) providing opportunities for staff to gain a better understanding of the applicant's processes or activities associated with the proposals or requested actions,
 - (4) providing opportunities to have a better understanding of any unique or complex aspects of a proposed application,
 - (5) enabling better planning by identifying specific skills needed for the review, and
 - (6) providing information to support the staff's initial understanding of the required scope, focus, and potential level of detail for a review.
- d) When preparing for a pre-application meeting, DFM staff should consider the following:
 - (1) the review guidance, in order to expand on the intent and focus of the meetings, and
 - (2) information in job aids that supports early interactions to improve review planning.
- e) The technical review team, in consultation with management, should consider holding the pre-application meetings at the applicant's facility, when feasible, if it would better facilitate the NRC staff's understanding of the application.
- f) When evaluating the location for each pre-application meeting, the staff should consider if the following items would facilitate and benefit the review:
 - (1) a site tour to better understand the proposed application and proposed regulated activities,

- (2) additional interactions with the applicant's staff, and
- (3) increased access to documentation or presentations at the facility or other agreed upon location.

NOTE 2: Regulatory decisions will not be made in public and pre-application meetings. The NRC staff may provide feedback to applicants and solicit and respond to general questions from the public during these meetings.

- g) NRC staff discussions with applicants should include the following topics:
 - (1) any guidance, including standard review plans and regulatory guides, that the applicant should consider when developing their application,
 - (2) lessons learned or relevant information (e.g., similar, or related licensing actions, NUREGs, industry documents, etc.) that could benefit the review, and
 - (3) new analysis methods or strategies that would facilitate an effective review.

The pre-application meetings provide for an early understanding of the scope of the review and facilitate, as well as inform, the development of an overall review schedule and resource estimates.

2.4.4 Site visits or audits

A site visit is especially recommended for new, large, unique, or complex applications. For detailed guidance on site visits and audits see DI LIC-FM-7, "Licensing Audits" (Ref. 4.8).

- a) Site visits or audits offer unique opportunities to better understand the safety aspects of a review; risk associated with a facility, system, or activity; and the implications of any regulatory decisions. The staff is encouraged to consider conducting a site visit or audit during the pre-application phase, the acceptance review, the technical review, or the RAI development phase of the review.
 - (1) Staff considering a site visit or audit should discuss the need with their supervisor. In addition, the PM's supervisor should be notified early in the process if the PM and/or team determines that a site visit or audit would be beneficial to the review.

(2) All site visits that require travel will need to be approved by the traveler's immediate supervisor, and be conducted in accordance with the guidance in DI ADM-FM-2, "Signature Authority and Concurrence Guidance" (Ref. 4.7). The PM's supervisor will consider budget constraints, resource implications, and other administrative factors, along with the technical benefits described by the PM (e.g., familiarization with the facility and activities involved in or affected by the application, clarification of information in the application) when determining whether to authorize a site visit or audit.

- (3) PMs should coordinate with the licensee and NRC regional points of contact to schedule site visits and determine if any security documentation (e.g., NRC Form 277, "Request for Visit" available on the NRC Forms Library SharePoint site, or training documentation for escorted/unescorted access requests) is needed.
- b) The staff should use applicable licensing and inspection guidance when performing site visits and site audit reviews.

2.4.5 Correspondence and emails

- a) Correspondence
 - (1) Letters provide the primary formal means of communication with licensees or applicants.
 - (2) Written communications should be made publicly available when possible, in accordance with 10 CFR Parts 2 and 9, except for specified reasons [e.g., classified information, sensitive unclassified non-safeguards information (SUNSI), proprietary information, safeguards information, etc.].
 - (3) Letters should be written in plain language so that a third party (e.g., stakeholder) is able to understand the content. An LA should assist the PM preparing letters and must be on concurrence.
- b) Email communications
 - (1) Although an email is an informal means of communication, it may be used to perform the following:
 - i) acknowledge the receipt of documents,
 - ii) coordinate meetings and conference calls,
 - iii) communicate status of a particular licensing action,

- iv) provide electronic copies of letters or guidance,
- v) exchange other information with licensees, or
- vi) transmit the acceptance of minor licensing actions that must be docketed [e.g., updates to financial assurance, changes to a Security Program, changes to a Fundamental Nuclear Material Control Plan (FNMCP)].
- (2) Email is not intended to replace formal means of written communication such as acceptance letters, requests for additional information, letters to transmit license amendments, SERs, or any other licensing determinations for licensing actions.
- (3) Emails that contain information relevant for a licensing finding or determination, including those between the technical reviewers and the PM, must be docketed. Routine communications between PMs and technical reviewers do not need to be docketed.

2.5 Docketing

- 2.5.1 Applicants can submit documentation either electronically or in hard copies, see the <u>Electronic Submittals Application</u> page on the NRC public website. There is also additional information in <u>Section 2.8</u>, "Create an official record of the request," of this DI.
- 2.5.2 For a new license or certification application, the LA will usually assign a docket number and provide it to the assigned PM or point-of-contact. The LA generates the docket number in the Web-Based Licensing (WBL) system.
- 2.5.3 If the applicant submits the documentation electronically, the ADAMS staff generates an email requesting a SUNSI review of the documents to determine if they should be released to the public.

2.6 Acknowledging the receipt of the submittal

- 2.6.1 The PM sends an email (or letter, if a more formal response is warranted) to the applicant acknowledging the receipt of the submittal. This communication can be docketed.
- 2.6.2 The PM may start the review process as soon as the submittal is received, which may be in advance of the ADAMS receipt date (this can be due to mail delivery of hard copies, document processing queues, withholding review, submittal of advanced copies by email, etc.).

2.6.3 For expedited actions, the PM may combine multiple phases of a review into a single correspondence including:

- a) acknowledgement letter
- b) acceptance letter
- c) documentation of the NRC staff's review
- d) issuance of the findings, if appropriate

When this approach is feasible, the PM manually enters the dates in WBL. For example, the acceptance and issuance dates may be the same.

2.7 Receipt of an application

After an incoming licensing action has been received, the PM should send an email to the applicant acknowledging it.

2.8 Create an official record of the request

- 2.8.1 Many licensing actions will go directly to the Document Control Desk in accordance with the communications requirements in the regulations (e.g., 10 CFR 70.5). The documents are placed in ADAMS under the appropriate docket number for the facility.
- 2.8.2 If a docket number does not yet exist, see <u>Section 2.5</u> "Docketing," of this DI for additional guidance.
- 2.8.3 The following information <u>must not be placed</u> in ADAMS:⁵
 - a) Documents containing <u>Export Controlled Information</u>.
 - b) Safeguards Information (see MD 12.7, "NRC Safeguards Information Security Program" Ref. 4.9)
 - c) Classified Information (see MD 12.2, "NRC Classified Information Security Program" Ref. 4.10)
- 2.8.4 In most cases, PMs receive a notification through email distribution (i.e., E-Rids). Individuals on the electronic distribution list for the docket will receive an email notification message (E-Rids message) to inform them that an Official Record Copy exists.

NOTE 3: Individuals may request updates to the E-Rids list by sending and contact <u>RidsManager Resource</u> for E-rids issues and <u>ADAMS IM</u> for ADAMS related issues.

2.8.5 If a licensing action contains sensitive information, the PM must establish a public record of it. Redacting (if necessary) and releasing the transmittal letter is adequate.

NOTE 4: Section 189 of the Atomic Energy Act of 1954, as amended, establishes the right of any person to request a hearing if their interests may be affected by a Commission proceeding (which includes all licensing actions). A person cannot exercise their right for a hearing if they have no knowledge of the licensing action. Therefore, there must be a public record of every licensing action.

2.8.6 The date that the application is considered received by the NRC ("Received Date") is the date when the application or submittal is declared in ADAMS.

2.9 Withholding determination

- 2.9.1 After receiving the application (usually by receiving an E-Rids message), the PM reviews the documentation package to determine whether the materials can be released to the public [i.e., Sensitive Unclassified Non-Safeguards Information (SUNSI) review] [e.g., proprietary, security related, 10 CFR Part 2 (e.g., 10 CFR 2.390)].
- 2.9.2 The PM should use the guidance in NMSS Policy and Procedure 7-04, "Handling Request to Withhold Proprietary Information from Public Disclosure" (Ref. 4.11), to make this determination for proprietary information.
- 2.9.3 The staff can find additional guidance about performing SUNSI reviews for sensitive information in DI ADM-FM-6, "Handling Sensitive Information" (Ref. 4.12).
- 2.9.4 The PM should complete the <u>SUNSI</u> review within 5 business days. The results must be documented via email to <u>ADAMS IM</u>. The PM must copy the LA in the email.
- 2.9.5 The PM should prepare proprietary withholding determination correspondence in accordance with 10 CFR 2.390.

2.10 Prioritization

- 2.10.1 DFM staff should prioritize work using the division's internal guidance (see QRG-LIC-FM-1-3, "Work Prioritization Guidance," in <u>Appendix B</u> of this DI). The staff is expected to work on projects assigned by their supervisors and to raise questions or identify conflicts to management for resolution, as needed.
- 2.10.2 Supervisors (e.g., BCs) should adjust workload priorities, as necessary (e.g., if necessary, use the add/shed/defer process to address workload fluctuations).

2.10.3 On occasion, the DFM management may create "focused review teams." The concept of a "focused review" (see QRG-LIC-FM-1-3, "Work Prioritization Guidance," in <u>Appendix B</u> of this DI), is defined as assigning a dedicated team that focuses all available time on reviewing one application. DFM management will decide whether to approve and implement this type of review.

2.11 Planning

Planning the review of a licensing action is a critical step to ensure that the work is completed in a timely and effective manner. Early alignment with the review team on the focus, scope, milestone schedule, and level of detail for the review is an integral part of a timely and efficient review.

2.11.1 **Assign a PM**

- a) The licensing BC (or designee) must always consider the PM's workload prior to assigning a review.
- b) When the NRC receives an application and it is placed into docketing, the licensing BC (or designee) assigns a PM as the lead for the review of the application. If a PM had previously been assigned as the main NRC point-of-contact for a facility or vendor, the review is usually assigned to him or her.
- c) Once assigned, the PM sends an email to the applicant acknowledging that the request has been received by the NRC.
- d) If the application is from a facility that does not have a previously assigned PM, the review can be assigned to any PM that has the capacity to process the application.

2.11.2 Requesting an EPID, identifying a CAC, and running a CAC report

- a) The PM should also request the LA to assign a new Enterprise Project Identifier (EPID) associated with the appropriate cost activity code (CAC) (See ADM-FM-3, Administrative Functions," Ref. 4.13). The EPID will be used to track the hours and charge the licensee for the time spent on the review.
- b) The PM should provide the review team the applicable CAC/Docket No./EPID combination for the review. For guidance for identifying the appropriate CAC, the staff should refer to ADM-FM-4, "Tracking Work and Charging Time" (Ref. 4.14).
- c) Quick Reference Guide QRG-LIC-FM-1-4, listed in <u>Appendix B</u> of this DI, includes additional information about opening Enterprise Project Identifier (EPID) and adding CAC/Docket No./EPID combinations in the staff's HRMS. The job aid also includes information about how to run a report to see the hours charged to CACs and EPIDs.

2.11.3 Identify the review and support disciplines

a) The assigned PM identifies the technical disciplines needed to conduct the review of the application (e.g., radiological/chemical safety, physical security, criticality, thermal, structural, environmental, etc.) and informs their BC.

- b) The PM's BC should request the appropriate managers in the technical branches, Centers of Expertise, and supporting offices (e.g., OGC, Regional staff, others) for their staff's participation in any pre-application meetings (see Section 2.4.3 of this DI) and subsequent technical review. Once the technical reviewers are assigned, the PM should coordinate their participation at the meeting and during the formal technical review.
- c) The licensing organization requests assistance from other organizations (e.g., branches, offices) using the appropriate process [e.g., WBL, a reviewer work request (RWR)]. The request must include the initial estimated number of hours to perform their portion of the review as well as proposed due dates of major deliverables (e.g., RAIs, SER) see Section 2.12, "Estimating resources," of this DI.
- d) The DFM staff should consider whether an environmental review is needed.
 - (1) If an environmental review for the proposed action is necessary, the PM's BC should request support from the NMSS Division of Rulemaking, Environmental, and Financial Support, Environmental Center of Expertise, Environmental Review Materials Branch to perform the review.
 - (2) The staff should follow the guidance in NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs" (Ref. 4.15), for conducting environmental reviews. Also, consider the summary guidance entitled, "Environmental Reviews," (ADAMS Accession No. ML21162A173).
- e) The PM should request inspector involvement in the licensing or certification process, as appropriate, to provide practical insights based on experience with existing facilities. This participation should be early in the review to gain inspector observations that might be important to oversight, as well as to ensure that the development of license or certificate conditions, etc. are clear and inspectable.

2.11.4 Scheduling

a) The PM is responsible for developing a schedule that takes into account the numerous aspects of a licensing action request including the date by which the applicant needs the action to be completed and the staff's availability to support the review.

- b) The PM communicates the proposed completion date to the applicant and, to the extent possible, key milestones that involve engaging the applicant (e.g., site visits, RAIs). At a minimum, the PM must provide the proposed completion date to the applicant in the acceptance letter.
- c) DFM establishes business line metrics to track the completion date against the proposed completion date (for example, within 15 percent over or 25 percent under, on average).
- d) The DI LIC-FM-6, "Scheduling Casework and Non-Casework Activities" (Ref. 4.16), includes guidance for scheduling casework and non-casework activities.

2.11.5 Considering efficiencies: Scheduling and Review process

- a) The PM is encouraged to look for efficiencies in the review process that do not compromise the quality of the NRC staff's review or diminish stakeholder interactions (e.g., access to supporting documentation, clarification calls, and public meetings). This may include:
 - (1) expediting review schedules for simple straightforward actions to complete them ahead of schedule
 - (2) combining and/or eliminating unnecessary review steps and milestones (e.g., combining the acceptance review and completion of the SER for simple, straightforward actions that do not need RAIs)
 - (3) docketing emails instead of processing formal letters to the applicant
 - (4) utilizing interactions with the applicant to accomplish multiple tasks (e.g., conducting a site visit to familiarize technical reviewers with the facility, while also engaging the licensee in clarifying draft RAIs)
 - (5) seeking concurrences in parallel, etc.

b) When seeking to implement the types of efficiencies discussed in this section, the PM needs to gain alignment on the following:

- (1) schedules and activities with the technical reviewers and their associated BC and, as appropriate, any other organizations that might be involved in the specific activities [e.g., including the Office of the General Counsel (OGC) staff for a site visit] and adjustments to the scheduling and tracking metrics to reflect the proposed efficiencies.
- (2) the impact for the review team on the overall schedule if an interim metric is modified. For example, the PM should align with the review team to determine if a shorter acceptance review reduces the overall review schedule.
- (3) the activities that the applicant can support to improve the efficiency and effectiveness of the review.
- c) The acceptance email or letter should identify the enhanced actions being taken and the expected completion date should reflect the implementation of any efficiencies in the review.

2.11.6 Staff assignments, schedule approvals, and resource approvals

- a) The licensing organization requests support from technical organizations [e.g., using WBL or issuing a RWR (see <u>Appendix B</u> of this DI)].
- b) When requesting resources for their assigned case, PMs should:
 - (1) identify the disciplines needed for the review, and
 - (2) provide the proposed schedule to the applicable BCs.
- c) Where possible, PMs may identify DFM staff for the reviews and discuss them with the appropriate BCs.
- d) The DFM BCs assign staff, approve schedules, and approve resources to support the review. In doing so, BCs should consider the reviewers' workloads and resources availability.
- e) The BCs should consider using WBL to assign staff and approve schedule and resources. The following NRC internal link includes training resources for using WBL:

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

f) In cases in which a member of the review team is reassigned or leaves the DFM, staff and supervisors should follow the guidance in the document titled, "Guidelines for Continuity of Review." Also, the BCs should make the appropriate staff reassignments and approvals in WBL, if possible.

2.12 Estimating resources (staff and hours)

NOTE 5: LIC-FM-2 includes information about how to develop estimates and communicate these to the applicants. The staff can also find guidance related to estimating the number of hours to perform a review in job aid J-LIC-FM-1-2, "Estimating Review Times and Costs."

2.12.1 General Considerations

In general, the estimate of resources needed for a review should be based on the following considerations:

- a) work hours required for previous, similar actions;
- b) PM's knowledge of the application;
- c) technical reviewers' estimates, as approved by their BC, for each area of review considering the scope, focus, level of detail, and approach to their review;
- d) The time needed to conduct a peer review, if applicable;
- e) possible additional time to resolve major factors that could impact the level of effort (e.g., extensive RAIs, supplements); and
- f) the need for contractor support.

NOTE 6: OGC hours are not direct fee-recoverable and should not be included in the resource estimates.

2.12.2 After acceptance

The acceptance letter must include the total estimated number of hours, cost estimates, and overall schedule (i.e., the estimated date for completing the review of the applicant's submittal).

- a) After supervisors assign the technical reviewers, the PM should confirm the estimated number of hours with the review team.
- b) After confirming the estimated number of hours with the team, the PM should compile the total number of hours for the technical review and include it in the acceptance letter.

2.12.3 Estimate adjustments

a) When events occur that impact the estimates provided to the applicant in the acceptance letter, the PM should provide an update to the applicant either by letter or email. This communication is added to the application's docket.

b) For changes to estimates related to high visibility actions (e.g., licensing a new facility) that may have an impact on major milestones [e.g., RAIs, draft or final SER (DSER or FSER), or environmental review], the PM should provide an update to their BC and division management to discuss schedule impacts.

2.13 Tracking the action requested

2.13.1 FFIMS and STIMS

The DFM uses the WBL [i.e., the Fuel Facilities Information Management System (FFIMS) and spent fuel storage and transportation's activities in the Storage and Transportation Information Management System (STIMS)] to track licensing and certification actions (i.e., casework or cases). The division tracks the following in WBL:

- a) Assigned PM
- b) Scheduled milestones
- c) Staff assignments and approvals
- d) Resources
- e) Metrics

The PMs are responsible for entering items b) and d) in WBL. The system calculates the metrics for the cases and has reports to track most of the actions assigned to the PMs.

2.13.2 STIMS and FFIMS training materials

The division tracks fuel facilities' activities in the FFIMS module and spent fuel storage and transportation's activities in the STIMS module of WBL. The following SharePoint site includes guidance and training materials related to STIMS and FFIMS:

https://usnrc.sharepoint.com/teams/NMSS-STIMS/SitePages/Home.aspx.

2.13.3 STIMS and FFIMS records

After receiving the email from ADAMS, in most cases, the LA in consultation with the PM will create a record in WBL (i.e., FFIMS or STIMS) for the incoming licensing or certification action requested.

The LA emails the assigned PM, or designee, the application's identification number (ID) assigned by WBL.

2.14 Performance indicators and reporting requirements (metrics)

The DFM establishes internal and Congressional indicators to measure its performance (Ref. 4.17) and reports requirements under the Nuclear Energy Innovation and Modernization Act (NEIMA) (Ref. 4.18).

- 1) The primary licensing/certification metrics start on the date the acceptance email or letter is issued by the NRC staff (i.e., acceptance date).
- 2) The staff can find the Congressional budget justification (CBJ) (<u>Ref. 4.17</u>) performance metrics for DFM by clicking on the phrase "<u>Fuel Facilities</u>" and the phrase "<u>Storage and Transport</u>."
- 3) The NRC's NEIMA licensing and certification timeliness performance indicators (called generic milestone schedules) are available on the NRC webpage, "Generic Milestone Schedules of Requested Activities of the Commission" (Ref. 4.19).
- 4) Deviation from the estimated completion timeline and resource stated in the acceptance letter should be communicated to the applicant (by email or letter), documented, and docketed in ADAMS, and reflected in WBL.

2.15 Team meetings

2.15.1 Early alignment meetings

- a) Once the application has been docketed and the reviewers assigned, the PM should hold an internal alignment meeting (e.g., kick-off meeting) with the entire review team to discuss the following information:
 - the action requested;
 - (2) scope of the review;
 - (3) the tasks, major milestones, and the schedule; and
 - (4) any other information relevant for the review of the action requested.
- b) The PM should also coordinate meetings of the review team (including OGC, NSIR, etc.) and applicable BCs. These meetings should include:
 - (1) early discussions (e.g., during pre-application meeting preparations or during the acceptance review) to understand the proposed application, establish

- risk-informed considerations in setting the overall scope and focus of review in a holistic manner, and identify any unique review considerations.
- (2) early engagement of existing technical groups or external independent technical experts in the review process.
- c) Following the early assignment and alignment team meeting, the PM in coordination with the applicant should discuss the need and timeframe for conducting a site visit, if applicable. A site visit is especially recommended for new, large, unique, or complex actions.
- d) The document titled "Early Alignment Meetings" (see <u>Appendix B</u> of this DI) located in the <u>DFM SharePoint site</u> includes additional guidance about these types of meetings.

2.15.2 General guidance for team meetings

- a) The review team should consider the following guidance to inform discussions at team meetings [(see <u>Appendix B</u> for additional information about items (1) and (2)]:
 - (1) <u>Job aid titled "Questions to guide assignment and alignment meetings;"</u>
 - (2) <u>Job aid titled "Collaborative Initial Review Implementation in the Licensing and Certification Process."</u>
- b) During the meetings, the PM should verify that the review is proceeding consistent with the applicable review guidance (e.g., SRPs, RGs, or ISGs) and schedule. All review team members should discuss at least the following information:
 - (1) interdisciplinary and overlapping areas in the application;
 - (2) possible safety, regulatory, and crosscutting issues as well as any schedule conflicts [see LIC-FM-6, "Scheduling Casework and Non-Casework Activities" (Ref. 4.16), for guidance on scheduling casework and non-casework activities];
 - (3) specific issues related to the action requested;
 - (4) application complexities;
 - (5) background information (e.g., licensing and design basis, stakeholder interests, time-charging expectations);
 - ongoing reviews for applications that may overlap with the current application; and

(7) how risk will be integrated across the review.

2.16 Acceptance review

- 2.16.1 The acceptance review is conducted after the review team is established. The level of effort for the acceptance review should be scaled to the complexity of the application. The acceptance for simple reviews may be completed quickly and its completion notified to the applicant via email (some applications may not require an acceptance review). More complex applications can take longer and be issued via a formal response letter.
- 2.16.2. An acceptance review is not a detailed technical review, but it is integral to the efficient review of licensing submittals. The staff expects the applications to be of high quality (i.e., complete, and accurate) without the need for substantial or complex requests for supplemental information or RAIs to address applicable NRC requirements.
- 2.16.3 The staff will use DI LIC-FM-2, "Acceptance Review Process" (Ref. 4.20), to document its determination of the application's acceptability. The staff should also consider guidance in the following documents:
 - a) "Collaborative Initial Review Implementation in the Licensing and Certification Process" job aid in Appendix B of this DI.
 - b) "Determining the Scope of the Review" job aid in Appendix B of this DI.
 - c) DI LIC-FM-8, "Peer Reviews" (Ref. 4.21), during acceptance and technical reviews, to the extent practical.
- 2.16.4 The regulations in 10 CFR Part 2 require publishing notices in the *Federal Register* when certain licensing actions are accepted for review.

2.17 Prompt Issue Resolution (PIR)

The Prompt Issue Resolution (PIR) process is used to escalate and resolve issues in a timely manner. Any challenges or potential areas of concern should be elevated to DFM management early in the planning process, if possible, and whenever these arise during the review.

- 2.17.1 During a review, any issues identified that require management's attention should be identified and discussed at a meeting with the DFM management team and in preparation for meetings with the applicant. Examples of issues that may require management's attention are as follows (not an all-inclusive list):
 - a) Schedule delays on major licensing actions (e.g., new fuel facility, new consolidated storage facility)

- b) Possible termination of a review due to lack of applicant's action
- c) Need of more than one round of RAIs
- d) Technical, regulatory, and safety concerns that may result on terminating a review or rejecting an application
- e) Resource's constraints that cannot be resolved at the branch chief-level
- f) Potentially missing metrics
- 2.17.2 The DFM management team will seek alignment on a path towards resolution of each issue by the end of each meeting, to the maximum extent possible. The PM and/or BCs will implement any management decisions following the PIR discussion.
- 2.17.3 Any PIR recommendation regarding potential delays, suspension, or other major changes to the review schedule should be communicated to the applicant and documented in WBL (see Section 2.6 of this DI for guidance about documenting interactions with applicants).

2.18 Technical review

The technical review starts after the acceptance review is completed. The staff should use guidance in DI LIC-FM-8, "Peer Reviews" (Ref. 4.21), and J-LIC-FM-1, "Job Aid-Determining the Scope of the Review" (see Appendix B of this DI), during acceptance and technical reviews, to the extent practical.

2.18.1 Meetings

The PM should schedule meetings, as necessary, to facilitate the review.

- a) The PM and the review team should use the guidance in Section 2.15, "Team Meetings," of this DI when conducting team meetings.
- b) The PM should coordinate and participate in all interactions with the applicant during the technical review. The PM serves as the single point-of-contact for NRC staff for all licensing casework, and the technical reviewers should coordinate with the PM to interact with the applicant. The PM is expected to be cognizant of the content of any discussions during interactions (calls, meetings, site visits, etc.) between NRC staff and the applicant.

2.18.2 Schedule revisions after accepting the application

a) When a change in a review may impact the schedule (e.g., scope or focus of a technical review, slippage in scheduled interim milestones or deliverables, increased review hours, change in reviewers, etc.), the assigned technical reviewer should discuss the potential impacts and proposed resolutions with their BC and the PM. If the proposed resolutions include changes to the schedule or estimated hours, after discussion with their supervisor, the technical reviewer should send an email to the PM and the PM's BC (with copy to their BC) stating the need for the change. If there is disagreement regarding the proposed changes, then the cognizant BCs should discuss potential resolutions and, as necessary, elevate the issue to DFM management.

- b) During the technical review, the PM, in consultation with the review team, may need to revise the schedule due to unexpected circumstances (e.g., complex RAIs, delays in RAI responses, other safety issues, delays from support staff due to other higher priority activities, etc.). When this happens, the PM should notify the applicant via letter or email, after obtaining approval from the cognizant BCs. This communication should be placed in the docket.
- c) When a PM identifies a significant delay that is beyond their control, the PM must notify their BC and provide the reason for the delay. If an extension is approved, it should be reflected in the WBL (STIMS or FFIMS) system.
- d) If there is a potential impact on a metric (e.g., CBJ or NEIMA metrics), a discussion with division management must occur well in advance [ideally, early enough that strategies may be employed to place the review on a success path towards meeting the metric(s)]. The discussion should include changes to dates and a description of the issues that potentially and adversely impact meeting a metric. The PIR process can be used to initiate this discussion (see Section 2.17 of this DI).
- e) If a metric is missed, the PM must record the reasons in the "Notes" field of the "Information" tab of the record in WBL. An accurate record is important to ensure corrective actions are identified and implemented.

NOTE 7: Changes to a proposed completion date that is tracked for a CBJ or NEIMA metric needs BC of DFM/STLB or DFM/FFLB approval, as appropriate.

2.18.3 Issues and reassignments during the review

a) The review team members should discuss significant new technical issues (or policy setting issues) identified during a review with the applicable subject matter experts at regularly scheduled team meetings. The PM should ensure that division management is informed of any significant emerging issues.

- b) In the event of the need to revise the initial reviewer assignments, schedule, resources, or other aspects related to on-going reviews, the PM:
 - (1) should continue work on the submittal while coordinating with the BC on ways to resolve the issue(s)
 - (2) may request to add reviewers to the review
 - (3) should revise the review schedule, consistent with the guidance in Section 2.18.2, "Schedule revisions after accepting the application"; and
 - (4) should notify the applicant of any changes.
- c) If a technical reviewer is replaced by another individual during a licensing review, the technical BC should alert the PM and licensing BC of the change. In the event the PM becomes unavailable, the back-up PM or a temporary PM assigned by the licensing BC will provide coverage until the BC assigns a permanent replacement, as needed. To facilitate turnover, the staff may refer to the job aid titled "Guidelines for Continuity of Review."

2.18.4 RAI process guidelines

- a) The review team will follow the guidance in DI LIC-FM-3, "Requests for Additional Information" (Ref. 4.22), when developing RAIs.
- b) The division's goal is one round of RAIs for a typical review. To achieve this goal, it is important that the RAIs and the applicant's responses converge on the information needed for making a regulatory finding. The quality of the application and RAI responses have a significant impact in determining whether additional rounds of RAIs are necessary.

2.18.5 Safety Evaluation Report

The review team will follow the guidance in DI LIC-FM-4, "Safety Evaluation Reports" (Ref. 4.23), when performing the review and documenting its findings, and consider the following additional guidance:

a) The technical reviewers should provide their DSER input along with draft RAIs to the PM through their BCs.

- b) In its DSER input, the reviewer should identify the areas in which RAI responses are needed to make the safety and regulatory findings related to the application. This practice should help focus the development of draft RAIs, support any mid-review technical staff turnover, and save time in developing the final SER. The DSER is a pre-decisional document and is for internal use only.
- c) The SER technical inputs should focus on the specific review scope, level of depth, and approach (e.g., if a sampling approach is taken it should identify what was sampled).

2.19 Federal Register notices

<u>Job aid</u> J-LIC-FM-1-4, "Issuing *Federal Register* Notices," includes a discussion of the process to issue an FRN. The staff can find or monitor issuance of FRNs at the following website: https://www.federalregister.gov/.

2.20 Hearings

- 2.20.1 In the event that DFM receives a hearing request, the PM will coordinate the staff's actions with the assigned OGC attorney [see LIC-FM-10, "Hearing Process" (Ref. 4.24)].
- 2.20.2 Hearings opportunities are not provided for 10 CFR Part 71 actions.

2.21 Publishing a notice of issuance: Actions requiring an EA or EIS

- 2.21.1 For an action requiring the publication of an environmental assessment (EA) or an environmental impact statement (EIS), the PM prepares an FRN with the results of the review.
- 2.21.2 If the final action meets the requirements in 10 CFR 2.106, the PM prepares and requests to publish a notice in the *Federal Register* **before** closing the WBL record or the billing codes. The regulation requires publishing a notice when issuing certain documents such as:
 - a) a license or an amendment of a license for which a notice of proposed action has been previously published;
 - b) actions with respect to an application for construction authorization for a high-level radioactive waste repository at a geologic repository operations area;
 - a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to 10 CFR Parts 60 or 63; or

d) actions with respect to a license to receive radioactive waste from other persons for disposal under 10 CFR Part 61.

2.22 Final licensing or certification action

2.22.1 Business-line specific DIs

For specific actions related to the FF or SFST BLs, the PM should use the DIs referenced in <u>Section 2.1</u> of this DI for additional guidance that supplements this DI when processing fuel facilities, storage, or transportation actions.

2.22.2 Final concurrence package

The assigned PM prepares the concurrence package and coordinates concurrences. The final package will be signed by the designated manager [see ADM-FM-2, "Signature Authority and Concurrence Guidance" (Ref. 4.7)].

2.22.3 The ADAMS profile and addition of relevant documents in ADAMS

The PM should verify that the relevant documents related to the cases for which they are responsible have been finalized and placed in ADAMS. This review should include verifying that documents are legible and have been profiled properly (i.e., correct submittal date, document title, public versus proprietary/sensitive, docket number, etc.).

2.22.4 Closing the EPID

After all the WBL milestones are completed, the PM should request the LA to close the EPID number.

2.22.5 Un-assigning the CAC

After all the WBL milestones are completed, the PM and individuals that are part of the review team should request that their supervisor un-assign the CAC from the NRC's Human Resource Management System profile. The PM should remind all technical reviewers to make the same request to their supervisor. Removing closed billing codes will help to prevent billing errors.

2.22.6 Closing the WBL record

After completing all WBL (i.e., FFIMS or STIMS) milestones, the PM should request the licensing assistant to close the action in WBL by providing the ADAMS accession number for the close out action (e.g., via email). This ensures the action is properly tracked in WBL through final issuance.

2.23 Communications with NRC management and the Commission

2.23.1 Among the ways for PMs to communicate the status of a review to NRC management are emails, briefings, weekly plans, and highlights (e.g., <u>DATLAS</u>), and briefings to division management using the <u>DFM One Pagers</u>. The information should be provided in a timely and succinct manner in order to keep management informed about the status, challenges, and progress of licensing or certification activities.

2.23.2 When a new, large, unique, or complex review nears or reaches completion, management may approve issuance of a "One-Week Look Ahead" or "Daily Note" as a way to provide agency managers and the Commission a summary of significant daily and near-term activities that may be of interest across the agency. The OEDO Procedure 0350, "NRC Daily Notes and One-Week Look Ahead" (Ref. 4.25), and the job aid titled "Daily Notes and One Week Look Ahead Reminders," provide guidance for writing Daily Notes and One-Week Look Ahead.

2.24 Lessons learned

- 2.24.1 The staff should consider documenting lessons learned after completing new, large, unique, or complex licensing actions.
- 2.24.2 The PM should meet with the review team to collect lessons learned.
- 2.24.3 Lessons learned can be documented in a memorandum to the DFM Director, which is docketed in ADAMS or as recommended by the licensing BC.

3. RESPONSIBILITIES AND AUTHORITIES

The following additional roles, responsibilities, and authorities are solely defined for purposes of casework performed pursuant to this procedure.

3.1 Administrative Assistant

- 3.1.1 Adds documents in ADAMS, as requested.
- 3.1.1 Dispatches and distributes final correspondence.
- 3.1.3 Verifies that documents generated by DFM, including all correspondence, meet NRC format and content guidance.

3.2 Licensing Assistant

- 3.2.1 For new applicants, assigns a docket number and provides it to the assigned PM.
- 3.2.2 Proofreads, edits, and concurs on all correspondence to ensure that these meet applicable NRC guidance.

- 3.2.3 Revises and concurs on *Federal Register* notices for publication.
- 3.2.4 Creates and closes WBL entries and assists with opening new EPIDs.
- 3.2.5 Maintains point-of-contact and address lists for applicants/licensees, vendors, and/or certificate holders in STIMS and/or FFIMS.
- 3.2.6 Adds incoming certification or licensing action requests in STIMS and/or FFIMS.
- 3.2.7 Assists in tracking performance indicators for DFM.
- 3.2.8 Assists in preparing information related to assigned cases, as requested.

3.3 Project Manager

- 3.3.1 Serves as the primary point-of-contact with the applicant and DFM staff and management on items related to the assigned licensing and certification actions.
- 3.3.2 Oversees and manages the review, preparation, and issuance of licensing or certification actions, or other documents submitted by applicants.
- 3.3.3 Coordinates, prepares, and participates in meetings, hearings, and briefings related to assigned actions.
- 3.3.4 Performs and coordinates activities related to the licensing and certification processes.
- 3.3.5 Ensures reviews are conducted incorporating any available risk insights and consistent with Commission and management direction.
- 3.3.6 Maintains licensing and certification documents and information during a review.
- 3.3.7 Develops, proposes, maintains, updates, and tracks the schedule of assigned certificate or licensing reviews.
- 3.3.8 Communicates schedule changes and delays to the technical review team, and their supervisors, as well as the applicant(s).
- 3.3.9 Integrates information obtained from all sources and ensures the proper dissemination to the applicable internal and external stakeholders
- 3.3.10 Consolidates technical reviewers' input and applicable RAIs and responses into the DSER.
- 3.3.11 Prepares and concurs on meeting notices, meetings summaries, and *Federal Register* Notices, as appropriate.

3.3.12 Prepares correspondence and coordinates concurrence and processing related to assigned actions.

- 3.3.13 Keeps DFM management informed of challenges for complex or first-of-a-kind issues.
- 3.3.14 Supports other NRC HQ organizations in answering questions about the action assigned as it relates to coordination activities.
- 3.3.15 Prepares and coordinates information requests for other offices (e.g., Office of Nuclear Security and Incident Response, OGC, etc.), if necessary.

3.4 Licensing Branch Chief

- 3.4.1 Serves as the first line supervisor for the PM and provides oversight for the licensing and certification processes.
- 3.4.2 Serves as the liaison with the DFM staff, management, and other NRC organizations on items related to licensing and certification actions under DFM's responsibility.
- 3.4.3 Assigns PMs to incoming licensing or certification actions. (The BC can delegate this responsibility.)
- 3.4.4 Ensures that casework is completed on time and well within CBJ and NEIMA metrics. Maintains clear communication with division management timeliness of casework.
- 3.4.5 Discusses late casework with PM and technical BC, as necessary.
- 3.4.6 Informs DFM management about challenges in completing high visibility actions.
- 3.4.7 Responsible for casework relative prioritization, scheduling process, and tracking organizational performance against timeliness metrics.
- 3.4.8 Provides reviews for concurrence on documents related to licensing and certification actions (e.g., acceptance letters, RAIs, licenses, Certificates of Compliance, SERs, etc.) for clarity and consistency.
- 3.4.9 Signs and concurs on documents as specified in DI ADM-FM-2, "Signature Authority and Concurrence Guidance" (Ref. 4.7).
- 3.4.10 Ensures a smooth transition among PMs, as much as possible, when a PM departs or joins an in-progress licensing review.
- 3.4.11 Ensures reviews are conducted incorporating any available risk insights and consistent with Commission and management direction.

3.5 Technical BC⁵

3.5.1 Serves as the main point-of-contact for actions assigned to their branch.

- 3.5.2 Provides status of actions pertaining to its branch during scheduling meetings.
- 3.5.3 Discusses and makes decisions, considering staff's feedback, on technical issues brought by the staff during a review. Early communication with division management on significant technical issues impacting the staff's findings regarding reasonable assurance of adequate protection. Use the PIR process as deemed necessary.
- 3.5.4 Keeps DFM management appropriately informed of technical issues that arise during a review.
- 3.5.5 Assigns staff and peer reviewers (as needed) to support acceptance reviews, technical reviews, and actions assigned to DFM needing the technical knowledge of the branch.
- 3.5.6 Reviews and proofreads technical reviewer(s) input for clarity, content, grammar, and technical adequacy.
- 3.5.7 Ensures that the input provided by the reviewers includes the necessary technical and regulatory basis to reach a reasonable assurance determination.
- 3.5.8 Ensures that technical staff casework is completed on time.
- 3.5.9 Reviews technical basis for exemptions to the regulations or denials of an application.
- 3.5.10 Provides reviewed technical bases to the licensing BC with copy to the assigned PM.
- 3.5.11 Promptly informs the licensing BC and assigned PM about schedule conflicts, workload issues, and when delays are necessary.
- 3.5.12 Ensures a smooth transition among reviewers, as much as possible, when a reviewer departs or joins an in-progress licensing review.
- 3.5.13 Ensures reviews are incorporating any available risk insights and applying them consistent with Commission and management direction.

⁵ Technical BCs include supervisors that assign staff to support the review of an action, including quality assurance (QA) reviewers and inspectors to support technical reviews.

3.6 Technical Reviewer⁶

3.6.1 Follows NRC guidance when reviewing assigned actions and developing regulatory products (e.g., RAIs, DSER, FSER, etc.).

- 3.6.2 Develops regulatory documentation (e.g., RAIs, DSER, FSER, etc.) and provides these to a peer reviewer, if assigned, and their supervisor for final review.
- 3.6.3 Reviews and proofreads input for clarity, content, grammar, and technical adequacy.
- 3.6.4 Engages the pertinent technical reviewers on discussions that may impact multiple areas of the review.
- 3.6.5 Communicates to the PM the need for meetings or telephone calls with the applicant to discuss technical issues or clarify information submitted by the applicant.
- 3.6.6 Ensures that input includes the necessary technical and regulatory basis to reach a reasonable assurance determination.
- 3.6.7 Promptly informs their supervisor and assigned PM about schedule conflicts and when delays are identified.
- 3.6.8 Brings new policy or key technical issues to their supervisor and informs the applicable PM.
- 3.6.9 Concurs on final regulatory documents, as appropriate.
- 3.6.10 Ensures there is continuity of work when departing from assigned responsibilities by facilitating the transition between the departing and the incoming technical reviewers.
- 3.6.11 Ensures reviews are conducted incorporating any available risk insights and consistent with Commission and management direction.

3.7 Division Management

- 3.7.1 Ensures effective cooperation within the NRC and with external organizations on actions related to licensing and certification reviews under DFM's responsibility.
- 3.7.2 Informs the staff about DFM's and NRC's priorities.
- 3.7.3 Decides, with the BCs, work assignments to be shed or deferred based on the information available.

Technical reviewers include individuals serving in a reviewer role on a specific action (e.g., QA reviewers and inspectors).

3.7.4 Briefs the Commission, Office of the Executive Director of Operations, or Congress, when necessary, on the status of the business lines under DFM's responsibility.

- 3.7.5 Decides whether to terminate the review of high-visibility actions due to significant issues identified during the review or significant delays on providing information to the staff.
- 3.7.6 Ensures that performance indicators and reporting requirements are met and reported in a timely manner.
- 3.7.7 Signs and concurs on documents as specified in DI ADM-FM-2 "Signature Authority and Concurrence Guidance" (Ref. 4.7).

3.8 Technical Assistant

- 3.8.1 Track's performance indicators and reporting requirements for DFM.
- 3.8.2 Consolidates and reports performance indicators and reporting requirements for DFM.

4. REFERENCES

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. NRC, <u>NMSS/DFM Division Instruction FF-FM-1</u>, "Processing Fuel Cycle Facilities Licensing Actions." (Not publicly available)
- 4.2 U.S. NRC, <u>NMSS/DFM Division Instruction FF-FM-2</u>, "Implementation of U.S. IAEA Safeguards Agreement." (Not publicly available)
- 4.3 U.S. NRC, <u>NMSS/DFM Division Instruction ST-FM-1</u>, "Processing 10 CFR Part 72 Actions." (Not publicly available)
- 4.4 U.S. NRC, <u>NMSS/DFM Division Instruction TR-FM-1</u>, "Processing Transportation-Related Actions." (Not publicly available)
- 4.5 U.S. NRC, <u>Management Directive 3.5</u>, "Attendance at NRC Staff-Sponsored Meetings."
- 4.6 U.S. NRC, Policy Statement, "Enhancing Public Participation in NRC Meetings," *Federal Register*, Vol. 86, No. 52, pp. 14964-14968, March 19, 2021.
- 4.7 U.S. NRC, <u>NMSS/DFM Division Instruction ADM-FM-2</u>, "Signature Authority and Concurrence Guidance." (Not publicly available)
- 4.8 U.S. NRC, NMSS/DFM Division Instruction LIC-FM-7, "Licensing Audits."

4.9 U.S. NRC, <u>Management Directive 12.7</u>, "NRC Safeguards Information Security Program."

- 4.10 U.S. NRC, <u>Management Directive 12.2</u>, "NRC Classified Information Security Program."
- 4.11 U.S. NRC, Office of Nuclear Material Safety and Safeguards Policy and Procedures, Policy and Procedure 7-04, "Handling Requests to Withhold Proprietary Information from Public Disclosure. (Not publicly available)
- 4.12 U.S. NRC, <u>NMSS/DFM Division Instruction ADM-FM-6</u>, "Handling Sensitive and Classified Information." (Not publicly available)
- 4.13 U.S. NRC, <u>NMSS/DFM Division Instruction ADM-FM-3</u>, "Administrative Functions."
- 4.14 U.S. NRC, <u>NMSS/DFM Division Instruction ADM-FM-4</u>, "Tracking Work and Charging Time." (Not publicly available)
- 4.15 U.S. NRC, <u>NUREG-1748</u>, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs."
- 4.16 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-6</u>, "Scheduling Casework and Non-Casework Activities." (Not publicly available)
- 4.17 U.S. NRC, "Op Plans, Budget, and Performance," https://www.nrc.gov/about-nrc/plans-performance.html.
- 4.18 *Nuclear Energy Innovation and Modernization Act* (NEIMA), Public Law No. 115-439, 132 Stat. 5565 (2019).
- 4. 19 U.S. NRC, "Generic Milestone Schedules of Requested Activities of the Commission" [Nuclear Energy Innovation and Modernization Act (NEIMA)].
- 4.20 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-2</u>, "Acceptance Review Process."
- 4.21 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-8</u>, "Peer Reviews." (Not publicly available)
- 4.22 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-3</u>, "Requests for Additional Information."
- 4.23 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-4</u>, "Safety Evaluation Reports."
- 4.24 U.S. NRC, <u>NMSS/DFM Division Instruction LIC-FM-10</u>, "Hearing Process." (Not publicly available)
- 4.25 U.S. NRC, <u>OEDO Procedure 0350</u>, "NRC Daily Notes and One-Week Look Ahead." (Not publicly available)

Appendix A. Change history

Date	Brief Description of Changes	
	Initial issuance. This instruction compiles guidance from the Fuel Facilities Business Line and the Spent Fuel Storage and Transportation Business Line. This version incorporates guidance from, and supersedes, the following documents or information resources: 1) "Division of Fuel Cycle Safety, Safeguards, and Environmental	No.
12/3/21	 Review Licensing Review Handbook" [Parts of Sections 1, 3, 4, 8 (Sub-sections 8.3.3, 8.3.4, 8.11), and 14]. (Non-Public) 2) SFM-4, "SFST Licensing Process," ADAMS Accession No. ML091100331. (Non-Public) 3) SFM-15, "Interactions between Applicants and SFST," ADAMS Accession No. ML102420471. (Non-Public) 4) SFM-19, "Technical Issue Resolution and Working Group Committee Processes, Roles and Responsibilities," ADAMS Package Accession No.: ML13093A483. (Non-Public) 5) SFM-24, "Scope of Technical Review of Licensing Actions," ADAMS Accession No. ML12222A262. (Public) 6) LIC-SFM-26, "Operational Strategies and Management Expectations," ADAMS Accession No. ML16222A251. (Public) 	0
	This version incorporated recommendations from the following documents: 1) Smarter Licensing Working Group Recommendations ⁷ (see Appendix C of this DI) (Public) 2) Recommendations related to the licensing process in GAO-20-352, "Nuclear Regulatory Commission: Fee-Setting, Billing, and Budgeting Process Have Improved, but Additional Actions Could Enhance Efforts." (Public) 3) Recommendations related to the Office of the Inspector General's (OIG) OIG-21-A-08, "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. ML21103A001) (Public)	

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>.

The GAO-20-352 report can be found at https://www.gao.gov/products/gao-20-362.

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

Appendix A. Change history (continue)

Date	Brief Description of Changes	
5/12/22	Revision. Editorial changes. Clarify in Section 2.18.4, that "the quality of the application and RAI responses have a significant impact when developing additional rounds of RAIs." Move the example for documenting lessons learned to Appendix B.	

Appendix B. Licensing- and certification-related templates

Templates, Quick Reference Guides, 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. Smarter Licensing Recommendations in this Division Instruction

The 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. ML19115A016). 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, "Working Group Recommendations for Building a Smarter Fuel Cycle Licensing Program" (ADAMS Accession No. ML20099F354). The staff created an action plan (AP), published July 10, 2020 (ADAMS Accession No. ML20184A267), 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 (FFBL), most of these recommendations are also applicable to the licensing and certification processes managed by Spent Fuel Storage and Transportation BL. Therefore, the staff incorporated the applicable recommendations into this Division Instruction (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. Additional LT actions are being completed as resources permit.

Table C.1
Smarter Licensing Recommendations Incorporated into this Division Instruction

SLR No.	Summary of Recommendation	Section(s)
NT1-1	Establish schedule and estimate date of completion of technical review with input from licensee.	2.4, 5) 2.11.4, a) 2.11.4, b) 2.11.5, b(3) 2.12.2 (first paragraph)
NT1-2	Share metrics and estimated hours needed for the completing the technical review with the licensee.	2.12.2 (first paragraph)
NT1-3	Update status of the review as it progresses, including using of routine status calls between the NRC and the applicant.	2.4 (introduction, second sentence) 2.4 (second paragraph - after first set of numbered bullets) 2.4.1, a)
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).	2.11.4, a) 2.11.4, b) 2.11.5, b)(1) 2.12.2 (first paragraph)
NT1-29	Improve, and incorporate into review guidance, the early processing, alignment, and documentation of the expected focus, scope, and level of detail of reviews and sharing this information with the applicant.	2.11 (introduction) 2.12.1, c) 2.15.1

Table C.1
Smarter Licensing Recommendations Incorporated into this Division Instruction (cont.)

SLR No.	Summary of Recommendation	Section(s)
	Meeting with the applicant during the acceptance review	223(0)
NITO 4	phase to better understand the unique aspects of the	2.4.3, c)(3)
NT2-4	applicant's request and identify complexities or unique	2.4.3, c)(4)
	aspects of the review.	, , ,
	Meeting with the applicant during the acceptance review	
NT2-4	phase to better understand the unique aspects of the	2.4.3, c)(3)
1412-4	applicant's request and identify complexities or unique	2.4.3, c)(4)
	aspects of the review.	
		2.4 (5 th paragraph)
	Holding site visit during the pre-application or acceptance	2.4.3, e) (second paragraph)
NT2-7b	review phases that includes all expected reviewers.	2.4.4 (introduction)
		2.4.4, a)
	Apply a holistic approach in gaining early alignment on the	2.15.1, c) 2.4.4 (introduction)
NT2-27	expected scope of the review and need for management	2.4.4 (Introduction)
1412-21	approval to modify the scope, if needed.	2.15.1
	approved to mounty the ecope, in needed.	2.2, item 2) in second
		paragraph
NTO 5	Encourage combining multiple steps (e.g., acceptance and	2.6.3, second paragraph
NT3-5	approval letters) for simple applications.	2.11.5, a)(1)
		2.11.5, a)(2)
		2.11.5, c)
NT3-17	Develop an automated tool to track licensing actions in	2.11.4, c)
	accordance with NEIMA.	2.14
		2.2, item 2) in second
	Revise guidance and associated metrics to allow	paragraph 2.6.3 (second paragraph)
NT3-28	combining review steps for expected short-duration and	2.0.5 (second paragraph)
	straight-forward license application reviews.	2.11.5, a)(1) 2.11.5, a)(2)
		2.11.5, c)
	Hold a site visit, especially for major license amendments,	2.4.4 (introduction)
NT4-7a	license renewals, and new applications, at the draft RAI	2.4.4, a)
	phase involving the pertinent reviewers.	2.11.5, a)(4)
	Use the tools (e.g., job aids and templates) available to the	2.18.5, a)
NT4-12	NRC staff to minimize the potential for multiple rounds of	2.18.5, b)
	RAIs.	
NT4 40-	Ensure the continuity of the quality, effectiveness, and	2.18.3, c)
NT4-13a	efficiency of the licensing review process during NRC staff	2.18.5, b)
	turnover. Incorporate into review guidance the use of integrated,	
MT1-15	multi-disciplined, review teams.	2.18.3, a)
	Ensure internal work requests identify appropriate NRC	
MT1-18	staff and that resource estimates are consistent with scope,	2.15.1
	focus, and level of detail of each review area.	'
MT4 04	Provide guidance to ensure the SER documents the scope	2.4.3, f), second paragraph
MT1-21	and focus of NRC staff reviews of licensing actions.	2.18.5, b) (second paragraph)
MT1-25a	Facilitate inspector involvement early in the licensing	2.11.3, e)
IVI I 1-23a	review process.	,
MT1-27	Implement NT2-27 and incorporate into appropriate training	2.18.2, a)
1-21	and job aids.	2.18.2, b)

Table C.1
Smarter Licensing Recommendations Incorporated into this Division Instruction (cont.)

SLR No.	Summary of Recommendation	Section(s)
MT1-29	Implement NT1-29 and incorporate into appropriate training	2.18.2, a)
WHT-29	and job aids.	2.18.2, b)
	Institutionalize post-review lessons learned activities of new	
LT5-26	or complex applications to improve guidance and inform	2.24.1
	future new and novel application reviews.	