



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

Division of Fuel Management

Division Instruction

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**Upon removal of Appendix B,
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ACCEPTANCE REVIEW PROCESS¹

1. OBJECTIVES

- 1.1 Define the purpose, process, and format for acceptance reviews of licensing actions (i.e., new applications, license renewals, and license amendments).
- 1.2 Provide a framework for performing an acceptance review upon receipt of a licensing or certification action.
- 1.3 Reduce unnecessary delays in reviewing licensing or certification actions.
- 1.4 Enhance the Division of Fuel Management's (DFM) consistency and efficiency when performing acceptance reviews.

2. GUIDANCE

An overview of, and expectations for, the overall licensing and certification process is found in Division Instruction (DI) LIC-FM-1, "Overview and Expectations of the Licensing and Certification Process" (Ref. [4.1](#)). This DI supplements LIC-FM-1 and incorporates recommendations for improvement (see [appendix A](#) and [appendix C](#)).

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 requests for additional information (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) FF-FM-1, "Processing Fuel Cycle Facilities Licensing Actions" (Ref. [4.3](#)),
- 2) FF-FM-2, "Implementation of U.S. - IAEA Safeguards Agreement" (Ref. [4.4](#)),
- 3) ST-FM-1, "Processing 10 CFR Part 72 Actions" (Ref. [4.5](#)), and
- 4) TR-FM-1, "Processing Transportation-Related Actions" (Ref. [4.6](#)) this DI when processing actions specifically related to FF or SFST actions.

¹ For changes or revisions to this DI, follow the guidance in DI ADM-FM-1, "Development, Revision, and Maintenance of Division of Fuel Management Instructions," (Ref. [4.2](#)), section 2.3, "Revision of a DI."

2.2 Purpose of the Acceptance Review Process

The quality of an application has a significant impact on the resources expended in the review process. A high-quality application benefits the staff as well as the applicant (i.e., applicant, licensee, vendor, certificate holder). Applications that include sufficient information, in terms of scope and depth, allow the staff to use time and resources more efficiently. An application lacking critical information results in additional staff and applicant time, and resources for the review and could prevent the staff from completing its technical review.

Following receipt of an application, the staff conducts an acceptance review to assess its completeness in terms of the scope of the information provided and the technical depth of the information. This review supports safety and timeliness objectives by identifying, early in the review, any information needed to complete the application and to allow the staff to conduct its safety review in a timely manner.

The acceptance review process is not for determining the technical adequacy or acceptability of the applied methodologies. Rather, the acceptance review determines whether the applicant provided sufficient information in the application to proceed with a detailed technical review. Missing information (e.g., description of design features) or analyses are examples of insufficient information.

The acceptance review, in addition to assessing the adequacy of the application, also allows the staff to estimate the resources needed and the schedule for conducting the review.

2.3 High-level description of the acceptance review process

- 2.3.1 The acceptance review begins on the day the application is received. Typically, this is the date when the application is docketed in the Agencywide Documents Access and Management System (ADAMS). Section 2.9, “Withholding determinations,” of DI LIC-FM-1, “Overview and Expectations of the Licensing and Certification Process” (Ref. [4.1](#)), includes guidance for processing incoming applications containing Safeguards Information (SGI) or classified information. Sections 2.5 to 2.9 of DI LIC-FM-1 include guidance related to “Housekeeping” steps (e.g., docketing, creating an Official Record copy of the request).
- 2.3.2 The acceptance for simple reviews may be completed quickly and issued via email. More complex applications can take longer, and the acceptance should be issued via a formal response letter.
- 2.3.3 The Project Manager (PM) should follow section 2.11, “Planning,” of DI LIC-FM-1, “Overview and Expectations of the Licensing and Certification Process” (Ref. [4.1](#)), when assembling the review team.²

² As part of this process, staff should conduct “assignment and alignment” meetings, as needed, to discuss reviewer assignments, establish review priority, and identify any potentially challenging technical issues.

- 2.3.4 The PM solicits input from the applicant regarding potential review milestones, noting that a formal review schedule will be developed as the review team conducts the acceptance review, and enters a preliminary milestone schedule in the Web-Based Licensing (WBL) database.
- 2.3.5 The review team examines the application at a high level to determine whether it contains sufficient technical information in scope and depth to conduct the detailed technical review or not. Based on the review team's assessment, an application may be accepted, not accepted, or the review team may request supplemental information to make its final determination (see [section 2.8](#), "Requests for Supplemental Information," of this DI).
- 2.3.6 The PM and the team should consider conducting a meeting with the applicant, a site visit (especially for new licenses or designs; large, unique, or potentially complex applications; or new processes for existing licensees), or a regulatory audit during the acceptance review to better understand any unique aspects of the request that may support a more efficient use of time and resources during the review.
- 2.3.7 The PM should coordinate with the review team to revise the preliminary milestone schedule developed per section 2.3.4 above and include resource estimates for the review. The development of the review schedule should include the major milestones of the review (e.g., RAIs). For guidance related to schedule changes, see DI LIC-FM-1, "Overview and Expectations of the Licensing and Certification Process" (Ref. [4.1](#)), sections 2.17.3, 2.18.2, and 3.0, and DI LIC-FM-6, "Scheduling Casework and Non-Casework Activities" (Ref. [4.7](#)).
- 2.3.8 The technical review team decides whether the application has sufficient information to be accepted or not and informs the PM (see [section 2.11](#) "Detailed Discussion of Acceptance Review Results," of this DI).
 - a) If the application is acceptable, the PM emails the applicant and prepares and issues the acceptance letter in accordance with the agreed-upon schedule, or earlier, if possible.
 - b) If the application is unacceptable, the staff, in consultation with management, may offer the applicant the opportunity to withdraw the application before not accepting it.
 - (1) If the opportunity to withdraw is accepted, the applicant should request to withdraw the application in writing (either by letter or email), and the PM should prepare and issue a withdrawal acceptance letter.
 - (2) If the applicant declines to withdraw, then the PM should proceed to prepare and issue the non-acceptance letter.
- 2.3.9 If the application is determined to be acceptable for review, the PM should conduct an alignment meeting with the review team, including support offices (e.g., technical reviewers, Office of the General Counsel (OGC), Office of Nuclear Security and Incident Response), when applicable, to

align on the expected focus, scope, level of detail, and review approach of each review area, the associated milestone schedule, and the estimated number of hours³ needed to conduct their portion of the review. The level of effort should be scaled to the complexity of the application. After the meeting, the PM should document the results and update the dates recorded in WBL (i.e., STIMS or FFIMS). If the final review schedule is significantly different than previously discussed with the applicant, the PM should contact the applicant and explain the change in schedule.

- 2.3.10 The acceptance letter must provide the applicant the proposed completion date, estimated review effort, and the major milestone schedule consistent with the dates recorded in WBL. If the action involves multiple phases (e.g., rulemaking subsequent to the technical review), the acceptance letter should provide an estimate of when the subsequent phases will be completed (e.g., typically the rulemaking activities will be completed within 6 months of the end of the technical review).

2.4 Types of Actions for which Acceptance Reviews are conducted

Acceptance reviews are performed for the following incoming types of actions (not all inclusive):

- 1) a license for a new facility or design,
- 2) amendments and renewal requests,
- 3) exemption requests
- 4) licensing reviews which do not result in a change to the license (e.g., an updated decommissioning cost estimate submitted before changes to funding instruments are executed),
- 5) first-time revalidation recommendation requests, and/or
- 6) one-of-a-kind or first-of-a-kind designs.

2.5 Timeliness of Acceptance Reviews

- 2.5.1 The staff should complete the acceptance review as soon as practicable (e.g., within 60 days of docketing). The staff should complete the acceptance review of simple and routine action requests in a shorter timeframe.
- 2.5.2 Once the technical staff is identified and assigned to perform the technical review, the PMs should discuss and agree with the review team on the schedule for completing the acceptance review. Division Instruction LIC-FM-6, "Scheduling Casework and Non-Casework Activities" (Ref. [4.7](#)), includes guidance for developing schedules for processing actions by the

³ In 2020, the Office of the Chief Financial Officer published information providing low and high estimated levels of effort and costs for both NRC and contractors for the [Fuel Facilities](#) and [Spent Fuel and Transportation](#) business lines in an effort to assist NRC staff in estimating the level of effort and costs per regulatory action and inform stakeholders.

division.

- 2.5.3 The staff may start the acceptance review in parallel with the docketing process, when the PM receives an advanced copy of the application and the reviewers are assigned promptly [see LIC- FM-1, “Overview and Expectations of the Licensing and Certification Process” (Ref. [4.1](#))].
- 2.5.4 During the acceptance review the staff should define the scope of the technical review, discuss the level of technical details necessary to conduct the review, consider the technical review’s potential outcomes, and determine whether contractor support is necessary.

2.6 Regulatory guidance

The staff should follow the guidance in applicable Regulatory Guides (RGs), Standard Review Plans (SRPs), and other regulatory documents when performing an acceptance review, but only to verify that the scope of the information provided is acceptable. The guidance should not be used to perform a detailed review during acceptance.

2.7 Determining acceptability of the application

2.7.1 Tasks included in an acceptance review

- a) Following the arrival of an application, the assigned PM determines the scope of the acceptance review by evaluating if a review team is needed or if the application is of an administrative nature (e.g., a position title change, review of the qualifications of an applicant’s technical staff, an address change). For simple actions, such as an administrative change, the approval letter may be used to satisfy the acceptance review of the application.
- b) During the acceptance review, the PM ensures that the individuals involved in the acceptance review use the applicable templates included in [appendix B](#) of this DI.
- c) Once the acceptance review is completed, the staff should issue the acceptance to the applicant using the templates provided in [appendix B](#) of this DI. This correspondence should be docketed in ADAMS, and the date of the correspondence should be recorded in WBL in ADAMS, and the date of the correspondence should be recorded in WBL.

2.7.2 Sufficiency of the information in the application

- a) The staff should verify that the application includes the following information:
 - (1) Required contents of an application per the applicable regulatory requirements.
 - (2) A demonstration of compliance with the regulatory requirements using methods from applicable guidance

- (e.g., SRPs, RGs, Interim Staff Guidance), or using alternative methods and a justification for using the alternative methods or omission.
- (3) References to applicable industry codes and standards, American Society of Mechanical Engineers code cases, SRPs, RGs, NRC Technical Reports (e.g., NUREGs), or Interim Staff Guidance used in accordance with the appropriate limitations and conditions; and
 - (4) Appropriate descriptions of the analysis supporting the demonstration of safety.
- b) Sufficiency issues may impact the staff's ability to complete the detailed technical review in a timely manner and may result in an unacceptable application or a longer review schedule. Examples of sufficiency issues in an application may include, but are not limited to, the following:
- (1) Missing information, analyses, and/or evaluations required by the applicable regulations (i.e., Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 40, 70, 71, 72 (Ref. [4.8](#)), or any other applicable regulation).
 - (2) Illegible figures, drawings, equations, and/or text.
- c) If, during the acceptance review, the review team determines that an application does not contain sufficient information to proceed with detailed technical review, and the insufficiencies cannot be adequately addressed through the RAI process (i.e., may require more than a single round of RAIs), but are not significant enough to result in the staff's rejection of the submittal, the lead PM should discuss the issue with their supervisor to determine if a request for supplemental information (RSI) should be considered. If approved, the PM should initiate the RSI process (see [section 2.8](#), "Requests for Supplemental Information," of this DI).

2.7.3 Considerations during the acceptance review

During the acceptance review, the PM should look for opportunities to coordinate noticed meetings between the review team and the applicant that provide a holistic understanding of the application and facilitate the acceptance review. The purpose of these meetings, which may involve the entire review team or specific technical areas, is to facilitate the acceptance review by allowing NRC staff to identify key information, align on the scope of the application, or resolve basic questions.

- a) The staff should use its technical and regulatory judgment, applicable RGs, SRPs, and other regulatory guidance to conduct the acceptance review. The review team should also consider holding a call or meeting with the applicant, or a visit (for complex reviews) to the applicant's facility to become familiar with the

applicant's proposed facilities and activities to facilitate the review.

- b) The technical reviewers should communicate their findings to the PM (i.e., whether the application is acceptable or not and why). The PMs will communicate the review team's findings to their management with a final recommendation whether to accept the application for conducting a detailed technical review, issue RSIs, or decline to accept.

NOTE 1: There is no need to docket (i.e., add in ADAMS under the application's docket No.) the individual technical reviewers' findings of their acceptance review.

- c) Reviewing the application for technical sufficiency enables the staff to:
- (1) identify significant deficiencies in the application
 - (2) develop a predictable schedule and estimate necessary resources
 - (3) identify possible issues in the review
 - (4) assess significant deficiencies in the application that may be difficult to resolve in a single round of RAIs and therefore may need to be resolved prior to acceptance (through RSIs, etc.).
- d) If problems or deficiencies are identified in the application, the staff should consider issuing RSIs, offer an opportunity to withdraw the submittal, or issue a non-acceptance letter, as a result of the acceptance review.
- e) Deviation from NRC guidance
- (1) Regardless of whether or not the applicant uses the NRC's guidance or an alternative approach, the acceptance review should assess whether the application is sufficiently complete to allow the staff to conduct its safety review.
 - (2) For an approach that deviates from NRC's guidance, the staff should verify there is sufficient information provided to conduct a technical evaluation of the applicant's approach.
 - (3) The staff should assess whether the applicant provided or referenced sufficient information or documentation to support the deviation (i.e., enclosures or supplements to the application, incorporated by reference, other).

2.7.4 Using precedents during acceptance reviews

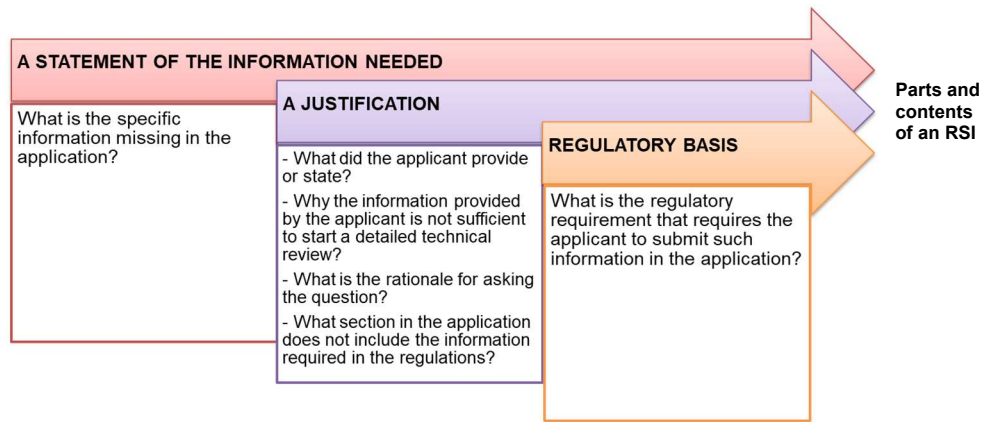
- a) A precedent of approval, by itself, is not sufficient justification for acceptance.
- b) The staff should consider the following information when evaluating the acceptability of using precedent(s) when reviewing an application:
 - (1) past staff's approvals are based on specific provisions contained in the previous evaluations and specific circumstances, whose use in another evaluation may not be appropriate unless the applicant demonstrates the applicability of the prior approval.
 - (2) new safety-significant knowledge and information may make the previous precedent no longer applicable.
- c) The staff should determine if the applicant used and justified cited precedents appropriately and provided justification for any deviations from the cited precedent(s).

2.8 *Requests for Supplemental Information (RSI)*

During the acceptance review, the review team may determine that an application contains insufficient information to conduct a detailed technical review, but the deficiencies are not significant enough to result in rejecting the application. In this case, the staff should consider issuing an RSI. If an RSI is to be issued, the PMs should coordinate with the technical review team to develop the RSI(s), should revise the draft review schedule to account for the time to develop, issue, and receive RSI responses, and communicate the changes to the review team and their Branch Chiefs (BCs).

2.8.1 What is an RSI?

- a) An RSI is a request for information that had not been included in the application and is needed for the NRC staff to make its determination on whether or not to accept the application.
- b) Once the missing information is identified, the NRC staff should consider issuing an RSI to obtain it. An RSI template can be found in [appendix B](#) of this DI.
- c) An RSI and an RAI consist of essentially the same parts and attributes (see LIC-FM-3, "Requests for Additional Information" (Ref [4.9](#)), for information about the parts and attributes of an RAI). These parts are the following: a statement of the information that is needed, a justification, and a regulatory requirement. The figure below provides guidance about the type of information included in each part of an RSI.



2.8.1 Process for issuing an RSI

The PM issues RSI(s), if needed, in accordance with the agreed-upon review schedule and following discussion with the applicant.

- a) The applicant responds to the RSI(s) in accordance with the agreed-upon review schedule, or earlier, if possible.
- b) The technical review team reviews the applicant’s RSI response for adequacy and responds to the PM in accordance with the agreed-upon schedule, or earlier, if possible.

2.8.3 Differences and similarities between RSIs and RAIs

While similar in structure, RSIs differ in scope from RAIs. Since RSIs are based on the staff’s determinations during the acceptance review, they seek bulk or general information (e.g., sections, topics, basis, models, etc.) that is missing from the application. The RAIs, on the other hand, are more specific information requests based on the detailed review that is needed to determine whether a regulatory requirement is met. The RAIs are requested after the detailed technical review has begun. The following table summarizes the main differences between these types of requests:

	RSI	RAI
Information Needed	Focuses on the sufficiency of the information in the application.	Focuses on ensuring that the information contained in the application, demonstrates how regulatory requirements for safe design and operations are met.
Justification	Describes deficiencies and how these relate to the question and regulatory requirement(s).	
Regulatory Requirement(s)	Focuses on regulatory requirements related to the general contents of an application to ensure that the staff can conduct a technical review.	Focuses on specific regulatory requirements that the applicant must demonstrate for the NRC to approve the action requested.

2.8.4 Letter offering an opportunity to supplement the application (RSI letter)

- a) The RSI letter should include the following information (see also the Templates in [appendix B](#) of this DI):
 - (1) the staff's information requests as described in the table above
 - (2) the requested time frame for submitting the response to the requests, and
 - (3) a statement that failure to submit the information within the time frame requested may result in non-acceptance of the application and cessation of staff review activities.
- b) The PM consolidates the supplemental information requests and any observations from the technical reviewers, coordinates with the applicable members of the review team to ensure internal alignment on the content of the RSI, and keeps the BC informed. After discussing the supplemental information requests with the applicant, as described in [section 2.14](#), "Actions after issuing the RSI," of this DI, the PM should finalize a letter to the applicant providing the supplemental information requests.
- c) The RSI letter should be sent to the applicant as soon as practicable.

2.9 Observations

- 2.9.1 Observations could be developed during the acceptance review process. They are questions that may become RAIs later during the detailed technical review and for which the staff does not need an immediate response to start the technical review. These are provided mostly for the applicant's awareness. Template LIC-FM-2-6 in [appendix B](#) provides a sample observation.
- 2.9.2 During the acceptance review, the staff may submit observations in addition to RSIs related to the area under review.
- 2.9.3 In contrast with RSIs, applicants have the option of not responding to observations; however, they may choose to do so. If an applicant decides to respond to observations and the staff finds the responses acceptable, the number of RAIs may be reduced.
- 2.9.4 The PM should meet with appropriate members of the review team to ensure internal alignment on the content of the observations and keep the BC informed. Once the observations have been sent to the applicant in the RSI letter, the PM should also coordinate a call/meeting between the applicant and the technical staff to ensure mutual understanding of the expectations for the observations and RSIs (i.e., a formal response to observations is not required, but may reduce RAIs).

2.9.5 See DI LIC-FM-3, “Requests for Additional Information” (Ref [4.9](#)), for detailed guidance on the RAI process.

2.10 Peer Reviews

2.10.1 The BCs should consider the use of peer reviews when developing RSIs or observations (see [section 2.9](#), “Observations,” of this DI) of issues to identify in the acceptance letter, especially if there are significant issues identified which are likely to impact the review.

2.10.2 DI LIC-FM-8, “Peer Reviews” (Ref. [4.10](#)), provides detailed guidance on peer reviews.

2.11 Detailed Discussion of Acceptance Review Results

The acceptance review process is intended to ensure that the review team only accepts complete applications for detailed technical review. Incomplete or poor-quality applications should not normally be accepted.

The result of the acceptance review should be provided to the applicant in a formal letter. However, when expediting simple actions, an email may be used to inform applicants of the results of the review. The email must be docketed in ADAMS.

Following the review team’s determination, the PM should inform their BC about the outcomes of the acceptance review and provide the team’s determination and recommendation (i.e., accept, request supplemental information, or not accept). If the staff determines that the application is missing information, the staff may teleconference with the applicant to discuss the following options:

- 1) supplementing the application to provide the additional information addressing the insufficiencies (see discussion below),
- 2) non accepting\rejecting the application, and
- 3) the applicant’s withdrawal of the application.

The licensing BC makes the final decision for accepting an application or for issuing an RSI. The PM signs the letter to the applicant. The division level management makes the final determination for not accepting an application and signs the non-acceptance letter (see DI ADM-FM-2, “Signature Authority and Concurrence Guidance,” Ref. [4.11](#)).

2.11.1 Acceptable application

- a) The staff will consider an application to be acceptable for a detailed technical review upon the staff’s conclusion that:
 - (1) the application appears to contain sufficient technical information, both in scope and depth, to complete the detailed technical review; and

- (2) informational needs identified during the acceptance review are not significant and are likely to be resolved during the RAI process.
- b) Upon final determination that an application is acceptable for review, the PM should:
 - (1) notify the applicant, (acknowledgement can be done informally via email) (see template LIC-FM-2-3 in [appendix B](#) of this DI); and
 - (2) document the acceptance of the application in a letter to the applicant.

NOTE 2: for administrative tasks, an email may be used in place of the acceptance letter, provided it contains the key elements of the acceptance letter and the email is docketed in ADAMS under the applicable docket number as an Official Agency Record (OAR).

- c) If an application is determined to be acceptable for review and there is no need for supplemental information, the acceptance should be issued as soon as practicable.
- d) The acceptance letter may identify issues that do not necessarily require the applicant’s response via RSIs, but that will need to be resolved through the detailed technical review (i.e., the RAI process). Additional guidance is provided in [section 2.9](#), “Observations,” of this DI (an example acceptance letter is provided in [appendix B](#) of this DI).
- e) For an application that is found acceptable, the acceptance letter should contain the following information:
 - (1) Acknowledge that the request for the licensing action has been received
 - (2) In the acceptance letter, provide the applicant with the following information:
 - (i) Enterprise Project Identification Number (EPID)
 - (ii) Estimated date for completing the technical review
 - (iii) The estimated resources (e.g., work hours) and the estimated cost to conduct the review. Division Instruction LIC-FM-1, “Overview and Expectations of the Licensing and Certification Process” (Ref. [4.1](#)), and the job aid titled “Estimating Review Times and Costs” (see [appendix B](#)) provide additional guidance to assist the staff in estimating the number of hours

that a review may take as well as the estimated cost (see [section 2.3.9](#) and [Footnote 3](#) above). Template LIC-FM-2-1, “Acceptance of Submittal,” in [appendix B](#) of this DI provides an example of an acceptance letter.

- (3) For a license renewal, include a paragraph notifying the applicant of the status of timely renewal. The paragraph should state that the license will not expire until the Commission makes a final determination on the renewal application, in accordance with the timely renewal provision of 10 CFR 40.42(a), 10 CFR 70.38(a), 10 CFR 71.38(a), or 10 CFR 72.54(a); and
- (4) If applicable, acceptance of major licensing actions (e.g., new licenses, license renewals, complex amendments) should be noticed in the *Federal Register*⁴ to give the public the opportunity to request a hearing or submit comments within 30 to 60 days of the publication of the notice. Note that, unless specifically required by regulation, posting major applications and their associated acceptance letters on the [NRC’s public website](#) provides sufficient notice to the public of an opportunity to request a hearing. For non-major applications, adding the public portions of the application and the acceptance letter (if one is issued) in ADAMS provides sufficient notice to the public of an opportunity to request a hearing.

2.11.2 Supplementing the application (see also [section 2.8](#) above)

- a) If an application lacks the information necessary for the staff to conduct the detailed review, the staff may take the following actions:
 - (1) discuss with the review team the information insufficiencies to ensure that all parties understand these and that there is agreement that the insufficiencies are within the scope of the review.
 - (2) conduct a conference call between the applicant and the technical reviewer(s) for those areas of the application where insufficiencies have been identified to communicate and discuss the deficiencies.
- b) The staff may ask the applicant to supplement its application by developing and issuing an RSI. [Section 2.8](#) of this DI includes guidance for developing RSIs.

⁴ See the [NRC’s internal web page](#) for guidance on *Federal Register* notices and information on the NRC’s *Federal Register* Notice Program.

2.11.3 Non-acceptance or withdrawal of the application

- a) The staff may determine that an application is unacceptable if:
 - (1) the staff has identified major deficiencies that would prevent the staff from conducting an effective technical review; or
 - (2) the applicant is unresponsive to an RSI, or if the responses provided have been determined to be inadequate to address the staff's concerns; or
 - (3) the applicant does not provide the requested information within the agreed-upon time frame.
- b) The PM should communicate to their BC the staff's recommendation to discontinue the review. The review team and their BCs should discuss the information insufficiencies to ensure that all parties understand what is missing and agree that the insufficiencies are within the scope of the review (see LIC-FM-1, "Overview and Expectations of the Licensing and Certification Process" (Ref. [4.1](#)) for information to determine the scope of a review).
- c) Division level management must align with the staff's decision to not accept the application.
 - (1) Once the decision to not accept is final, the staff should contact the applicant to discuss the basis for its decision and that it intends to issue the letter of non-acceptance. The applicant should also be made aware that it may withdraw the application pursuant to 10 CFR 2.107.
 - (2) If the applicant chooses to withdraw its application, it should do so in writing (e.g., by email to the PM) prior to that date. The staff should provide a written response approving the withdrawal. Examples of both non-acceptance of an application and withdrawal acknowledgement letters are provided in [appendix B](#) of this DI. The PM should ensure that the email is docketed in ADAMS under the applicable docket number as an OAR.
- d) Should the applicant decline the opportunity to withdraw, then the staff should issue the non-acceptance letter. The non-acceptance letter should discuss the basis for the staff's determination and the technical deficiencies of the application. An offer to submit a revised application addressing the deficiencies should also be provided. The letter should state that the NRC staff is terminating work on the application and serve as a basis to close the Cost Activity Code (CAC)/EPID and WBL record.

2.12 *Readily Available Information*

- 2.12.1 Readily available information is information that the applicant can provide within a short time period (e.g., 15 to 21 calendar days), allowing the NRC staff to proceed with the acceptance review.
- 2.12.2 Applicants must provide their responses to the RSI within the agreed-upon time frame for the DFM staff to determine whether the application is acceptable for detailed technical review.

2.13 *Communication of requests for supplemental information to the applicant*

- 2.13.1 The PM should inform the applicant that the staff determined that supplemental information is needed before the application can be accepted for a detailed technical review. The PM should arrange a conference call with the applicant to discuss the RSIs. The PM should provide the applicant a draft of the RSIs, via email, after technical BC's concurrence, and offer a phone call to the applicant to discuss the draft RSI. If the RSIs contain sensitive information, the PM should transmit the information to the applicant using acceptable methods (e.g., encrypt documents with a password, provide to the applicant through separate correspondence).
- 2.13.2 If the applicant accepts a discussion of RSIs over the phone and the discussion requires the participation of the applicable reviewers, the PM should set up a phone call with the applicant and the appropriate reviewers. During the call to discuss the draft RSIs, the staff should:
 - a) clearly identify the omitted or insufficient information to the applicant.
 - b) establish a time frame, in agreement with the applicant (when possible), for when the information should be submitted (the response date should be documented in the RSI letter).
 - c) ensure the applicant understands the purpose of the RSIs without getting into the details of the proposed responses during the call.
 - d) gain an understanding of whether the applicant plans to submit the information within the time frame established in the letter; and,
 - e) Provide the applicant the opportunity to justify the apparent omission of sufficient information by identifying where the responsive information is contained in the application. The staff should evaluate this justification to determine whether the information is still needed to perform the detailed technical review. If the staff determines that the insufficiency is still valid, the staff will include the insufficiency in the RSI letter to the applicant.
- 2.13.3 If the information to be discussed includes detailed information, or the PMs or their supervisor, determines that the discussion should take place in a public meeting, the PM and the applicant may arrange a noticed

meeting to discuss the insufficient information. Since a noticed meeting requires notification 10 days in advance, the meeting may further impact the time needed to resolve the RSIs and finalize the acceptance review.

2.14 Actions after issuing the RSI

2.14.1 Applicant response to requests for supplemental information

If the requested supplemental information is provided within an acceptable time frame, the PM should ensure that the supplement is provided to the appropriate members of the review team.⁵ Generally, the technical staff should review the supplementary information within 5 to 14 calendar days after receiving it from the PM to determine if it is responsive to the staff's concerns. The same criteria used in the initial acceptance review should be applied, although the review should be focused on the areas where a lack, or insufficient information, was previously identified.

2.14.1.1 Acceptable supplemental information

- i) Acceptance of the supplemental information will be evaluated on a case-by-case basis.
- ii) If the information provided in response to the RSIs is both timely and responsive, notify the applicant by issuance of the acceptance letter, and transition into a detailed technical review.
- iii) The applicant may provide supplemental information to correct an error in the application.

2.14.1.2 Unacceptable supplemental information

- i) If the technical reviewers determine that the RSI responses are not acceptable, they should promptly contact the PM to discuss the information deficiencies.
- ii) If the technical review team determines that the applicant did not adequately respond in the established time frame or the supplemental information is unresponsive to the staff concerns, the review team should document the basis for their conclusion and inform their BCs and the PM.
- iii) The PM should coordinate an alignment meeting between the review team and appropriate BCs to discuss the review team determinations and recommendations. See [section 2.11.3](#) of this DI for

⁵ The PM is responsible for tracking the submission of the information by the applicant and distribution of the submitted information to the technical staff. The technical staff is responsible for identifying any issues (e.g., staff reassignments or other high priority work) that may impact the acceptance review schedule to the PMs and their BCs.

additional information about non-acceptance of an application.

2.15 Review Time and Cost Estimates in the Acceptance Letter

2.15.1 In general, the acceptance letter should include the following as these relate to completing the technical review and issuing the requested action:

- a) estimate of the resources (e.g., staff hours and contract costs)
- b) The estimated cost for conducting the technical review based on the latest cost rates.
- c) The number of hours needed for the technical review based on the feedback from the members of the review team as approved by their branch managers.
- d) If applicable, cost of contract to support the review.⁷
- e) A statement noting that changes in schedule and resource estimates may occur depending on various factors (e.g., the findings of the technical review, urgent assignments).

2.15.2 OGC time is not direct-fee recoverable, and those hour estimates should not be included in the total.

3. RESPONSIBILITIES AND AUTHORITIES⁸

3.1. Administrative Assistant

Processes and dispatches documents related to acceptance reviews.

3.2 Licensing Assistant

Proof-reads, tracks, and formats documents related to the acceptance review process.

3.3 Project Manager

- 3.3.1 Manages the schedule.
- 3.3.2 Interacts with the applicant and the technical review team.
- 3.3.3 Ensures that the review stays on track.
- 3.3.4 Keep management informed of the status of the acceptance review.

⁷ For existing contracts, the lead PM should contact the appropriate Contracting Officer Representative when estimating contract money for a review

⁸ See also DI LIC-FM-1, "Overview and Expectations of the Licensing and Certification Process," section 3.0, "Responsibilities and Authorities" (Ref. [4.1](#))

3.4 *Technical Reviewer*

- 3.4.1 Conducts the acceptance review of the application within the established timeframe.
- 3.4.2 Ensures that its review is within NRC regulatory requirements as these relate to the completeness of the application.

3.5 *Branch Chief*

- 3.5.1 Assigns staff for the acceptance review.
- 3.5.2 Reviews and concurs on the review team products.

3.6 *Division, Deputy Director*

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

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.

- 4.0 U.S. NRC, [NMSS/DFM Division Instruction LIC-FM-1](#), “Overview and Expectations of the Licensing and Certification Process.”
- 4.1 U.S. NRC, [NMSS/DFM Division Instruction, ADM-FM-1](#), “Development, Revision, and Maintenance of Division of Fuel Management Instructions.” (not publicly available)
- 4.2 U.S. NRC, [NMSS/DFM Division Instruction, FF-FM-1](#), “Processing Fuel Cycle Facilities Licensing Actions.”
- 4.3 U.S. NRC, [NMSS/DFM Division Instruction, FF-FM-2](#), “Implementation of U.S. - IAEA Safeguards Agreement.”
- 4.4 U.S. NRC, [NMSS/DFM Division Instruction ST-FM-1](#), “Processing 10 CFR Part 72 Actions.”
- 4.5 U.S. NRC, [NMSS/DFM Division Instruction, TR-FM-1](#), “Processing Transportation-Related Actions.”
- 4.6 U.S. NRC, [NMSS/DFM Division Instruction LIC-FM-6](#), “Scheduling Casework and Non-Casework Activities.” (not publicly available)
- 4.7 [Title 10](#) of the *Code of Federal Regulations* Parts 40, 70, 71, and 72.
- 4.8 U.S. NRC, [NMSS/DFM Division Instruction LIC-FM-3](#), “Requests for Additional Information.”

- 4.9 U.S. NRC, [NMSS/DFM Division Instruction LIC-FM-8](#), “Peer Reviews.” (not publicly available)
- 4.10 U.S. NRC, DFM [NMSS/DFM Division Instruction ADM-FM-2](#), “Signature Authority and Concurrence Guidance.” (not publicly available)

Appendix A. Change History

Date	Brief Description of Changes	Revision No.
12/21/21	<p>Initial issuance. This instruction compiles guidance from the Fuel Facilities Business Line and Spent Fuel Storage and Transportation Business Line.</p> <ul style="list-style-type: none"> - This DI incorporates guidance from, and supersedes, the following sections of the Division of Fuel Cycle Safety, Safeguards, and Environmental Review Licensing Review Handbook: <ul style="list-style-type: none"> • section 2.2.5, “Technical Review” • section 8.3.2, “Creating an Official Record Copy of the Request” • section 8.3.3, “Creating a Public Record of Each Licensing Action” • section 8.5, “Acceptance Reviews” - This DI incorporates guidance from, and supersedes, DI SFM-14, “Acceptance Review Process.” - This DI also incorporates recommendations from the following documents: <ol style="list-style-type: none"> 1) Smarter Licensing Working Group Recommendations⁹ (see appendix C) 2) Recommendations related to the licensing process in GAO-20-362, “Nuclear Regulatory Commission: Fee-Setting, Billing, and Budgeting Process Have Improved, but Additional Actions Could Enhance Efforts.”¹⁰ 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)¹¹ 	0

⁹ 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. [ML20099F354](#).

¹⁰ The GAO-20-362 report can be found at <https://www.gao.gov/products/gao-20-362>.

¹¹ 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](#).

Date	Brief Description of Changes	Revision No.
6/30/22	<p>- Addresses the following:</p> <ol style="list-style-type: none"> 1) Editorial and formatting changes throughout the DI. 2) A revision to section 2.1, “Specific Division Instructions for fuel facilities, spent fuel storage, or transportation actions” to remove reference to the Risk Tool for spent fuel storage-related acceptance reviews. 3) A revision to the first sentence in paragraph 3 of section 2.2, “Purpose of the Acceptance Review Process,” as follows: <ul style="list-style-type: none"> ▪ “The acceptance review process does not <u>primarily</u> determine the technical adequacy or acceptability of the applied methodologies nor the accuracy of the results, <u>although clearly inadequate input or errors can be an example of insufficient submitted information.</u>” 4) A revision to the information in section 2.13.2, item b, to clarify that the staff should establish, during the call to discuss draft requests for supplemental information (RSIs), a time frame, <u>in agreement with the applicant</u>, for when the information should be submitted, and that the RSI response date should be documented in the RSI letter. 5) A revision to section 2.15, “Estimating Review Time and Cost” to change the title to “Review Time and Cost Estimates in the Acceptance Letter.” The section has also been revised to, mainly, point out that the letter should include a note informing the applicant that changes in schedule and resource estimates may change. Minor revisions to this section were also made. 	1

Appendix B. Acceptance Review 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. 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. [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 Business Line. Therefore, the staff incorporated the applicable recommendations into this Division Instruction (DI).

Table C.1 below lists the NT and MT 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.

**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.	2.3.4 2.3.7 2.3.9 2.3.10 2.11.1(e)(2)
NT1-2	Share with the licensee metrics and estimated hours needed for completing the technical review.	2.3.9 2.3.10 2.11.1(e)(2)
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).	2.3.9 2.3.10 2.11.1(e)(2)
NT1-29	Improve and incorporate into review guidance early alignment between the NRC staff and the applicant on the scope and content of the submittals/review.	2.3.5 2.3.9
NT2-4	Consider holding meetings with the applicant prior to submitting the application or during the acceptance review to better understand unique aspects of the application and technical review.	2.3.6 2.7.3 (introduction) 2.7.3(a)

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

SLR No.	Summary of Recommendation	Section(s)
NT2-7b	Consider holding a site visit, especially for major license amendments, renewals, and new applications during the pre-application or acceptance review process that includes all expected reviewers.	2.3.6 2.7.3(a)
NT2-27	Hold early review team meetings to align on the scope of the review and identify any unique considerations.	2.3.9
NT3-5	Encourage combining multiple steps (e.g., acceptance and approval letters) of the review process for simple actions.	2.3.2 2.5.1 2.5.3 2.7.1(a) 2.11 (introduction)
NT3-28	Revise guidance to allow combining review steps for short-duration and straight-forward license application reviews.	2.3.2 2.5.1 2.7.1(a) 2.11 (introduction)
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.	2.9.4 2.13.1 2.13.2
MT1-15	Incorporate into review guidance the use of integrated, multi-disciplined, review teams.	2.3.5 2.3.9
MT1-18	Ensuring the appropriate NRC staff to conduct the technical review is identified and that resource estimates are consistent with the projected scope, focus, and level of detail of each review area.	2.3.9
MT1-27	Apply a holistic approach to gain early alignment on the expected scope and focus of the review, identify unique considerations, and need for management approval to modify the scope, if needed.	2.8 (introduction)
MT1-29	Improve and incorporate, into review guidance, the early processing, alignment, and documentation of the expected focus, scope, and level of detail of reviews and share this information with the applicant.	2.8 (introduction)
MT1-31	Develop job aid to support review considering risk factors and impacts (i.e., risk considerations associated within specific phases of a review including schedule risk and review/decision-making risks).	2.3.9