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Office of Nuclear Material Safety and Safeguards

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Division Instruction

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**Upon Removal of Appendix B,
this document is uncontrolled.**

Division Instruction
LIC-FM-4, Revision No. 1

Safety Evaluation Reports¹

1. OBJECTIVES

The purpose of this Division Instruction (DI) is to provide general guidance for developing safety evaluation reports (SERs) for licensing actions issued by the division. The guidance provided in this procedure applies to the Fuel Facilities (FF) and Spent Fuel Storage and Transportation (SFST) Business Lines. The guidance applies to all safety evaluations, including those for spent fuel storage and transportation packages for Certificates of Compliance (CoCs), environmental reviews, license renewals, license transfers, revalidation reviews, letter authorizations, and quality assurance plan approvals.

- 1.1 Describe the purpose, scope, process of developing, content, and general format of SERs.
- 1.2 Enhance the clarity and understanding of SERs.
- 1.3 Enhance the Division of Fuel Management's (DFM's) consistency and efficiency when developing and issuing SERs.

2. GUIDANCE SECTION

An overview of, and expectations for, the overall licensing process is found in DI LIC-FM-1, "Overview and Expectations of the Certification and Licensing Process of Spent Fuel and Radioactive Material" ([Ref. 4.2](#)). This DI supplements LIC-FM-1 and incorporates recommendations for improvement (see [Appendix E](#)).

The project manager (PM) oversees the development of an SER. The staff documents its review, evaluation, and regulatory findings related to an NRC-regulated action in an SER. The SER:

- 1) presents the results of the staff's review and evaluation,
- 2) includes the safety findings necessary to grant or deny the licensing action,
- 3) forms the basis for staff testimony, if necessary, and
- 4) communicates with stakeholders and serves as a knowledge management tool for future reviews under the same docket number or other licensing actions with similar issues.

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. [4.1](#)).

To facilitate the development of SERs, the staff created the following information resources:

- 1) [Appendix B](#), “Safety Evaluation Report Templates,”
- 2) [Appendix C](#), “Safety Evaluation Report Development Process Flow Chart,”
- 3) [Appendix D](#), “Format of Safety Evaluation Report Sections.”

2.1 SER development process and communications

2.1.1 Outline

The PMs should provide an outline, or an example, of an SER, applicable to the action requested, to the technical staff involved at the beginning of the application review. [Appendix B](#) includes examples and templates of SERs and the staff are encouraged to use these standard formats.

2.1.2 Peer Reviews

- a) Branch Chiefs (BCs) should consider the use of peer reviews when developing the draft SER (DSER), final SER (FSER), and preliminary SER (Part 72), especially if there are significant issues identified by the lead reviewer.
- b) A peer review is optional and is at the discretion of the appropriate BC.
- c) The peer review is not intended to be another full review, but rather an independent assessment of the issues identified by the lead reviewer.
- d) LIC-FM-8, “Peer Review Procedure” ([Ref. 4.3](#)), provides guidance on peer reviews.

2.1.3 Interdisciplinary Issues

2.1.3.1 The technical staff should incorporate, when necessary, input from other disciplines (as applicable) to the contents of the DSER, FSER, and preliminary SER (Part 72) to ensure completeness of the input provided to the PM as well as to avoid repetition in the SER.

2.1.3.2 The technical staff should proactively communicate and coordinate issues with other disciplines to ensure that issues are appropriately addressed in the various sections of the SER.

2.1.3.3 If there are two or more reviewers are involved in the development of one section of the DSER/FSER, the applicable

reviewers and BCs should concur on the DSER/FSER section.

- 2.1.3.4 The staff and PM should ensure that the appropriate sections of the SER are cross-referenced through the SER, when necessary.
- 2.1.3.5 When appropriate, the PM and technical staff should seek input from inspectors. This coordination is important to ensure that the proposed licensing actions are aligned with oversight activities.

2.1.4 Draft SER

- 2.1.4.1 The DSER is the document that the staff develops concurrently with the requests for additional information (RAIs).
- 2.1.4.2 The staff should provide peer reviewed RAIs and a peer reviewed DSER (at the discretion of the BC as specified in 2.1.2.b of this DI) to their BC prior to the issuance of RAIs. The applicable BC approves the DSER input. Then, the BC, or designee, provides the approved DSER input to the PM.
 - (1) *If the staff has requests for additional information (RAIs), the staff provides the draft SER input to the PM appropriately marked to clearly indicate where the RAI response(s) will fill the gap(s) in information. RAIs should be provided separately from the draft SER input (in a separate section or file).*
 - (2) *If the staff does not have RAIs, the staff provides a complete draft SER to the PM with no information gaps.*

2.1.5 Preliminary SER

For certificates of compliance (CoCs) under Part 72, only, the staff develops a preliminary SER (PSER) as the SER does not become final until the effective date of the CoC. Follow steps 2.1.3.1 and 2.1.3.2 to develop a DSER and steps 2.1.7 to develop the PSER (For additional information related to processing CoCs for storage systems, see ST-FM-1, "Processing Actions Related to 10 CFR Part 72 Certificates, Licenses, and Consolidated Storage Facilities" ([Ref. 4.4](#))).

2.1.6 SERs containing sensitive or classified information

- 2.1.6.1 When possible, the staff should prepare an SER that can be made available to the public.
- 2.1.6.2 If the SER contains classified information, the staff should follow the applicable NRC policies and procedures including

using approved media to write and transmit classified information.

2.1.6.3 The PM and staff technical reviewers should follow NRC's guidance to mark SERs containing sensitive or classified information. To the extent possible, for SERs containing sensitive or classified information, the staff should issue a separate redacted public version of the SER or as an appendix that can be separated from the public version if the redacted parts of the SER are significant.

2.1.6.4 If the application contains sensitive or classified information, the PM should send the SER (with technical staff and technical BCs concurrence) to the applicant using an approved method for communicating sensitive or confidential information for a review in order to ensure that sensitive or classified information is not inadvertently released (see NMSS-Policy & Procedure 7-04, "Handling Requests to Withhold Proprietary Information from Public Disclosure" ([Ref. 4.5](#))).

2.1.7 Applicant's Review

2.1.7.1 The PM may provide a preliminary version of the SER to the applicant if there are any items that need to be fact checked or to identify any proprietary information. Any comments from the applicant should be limited to corrections of statements of fact or identification of proprietary information. Comments or edits from the applicant should be resolved prior to the issuance of the final SER or preliminary SER (Part 72 only).

2.1.7.2 The PM should include documentation or an email stating the staff resolution of comments or edits received as a result of the applicant's review of the final SER or preliminary SER (Part 72 only) on the docket.

2.1.8 Final SER and Preliminary SERs

2.1.8.1 The staff develops the FSER after receiving sufficient responses to RAIs and finalizing the technical review. Note: the equivalent PSEr for Part 72 CoCs is defined in Section 2.1.4 of this DI.

2.1.8.2 The staff should ensure that crosscutting issues are addressed in its PSEr or FSEr input.

2.1.8.3 The staff has its FSEr peer reviewed by a colleague in its branch before obtaining concurrence from the BC (see [Section 2.1.2, "Peer Reviews"](#)).

The BC concurs on the FSEr input. The BC, or designee,

provides the FSER input to the PM.

- 2.1.8.4 For CoCs for storage systems under 10 CFR Part 72, the PM changes the title of the PSER to FSER and issues a letter to the applicant in coordination with the rulemaking process. At that time, the SER, CoC, and certificate appendices become final.

2.2 SER Sections

2.2.1 In general, the format of the SER should follow the topics listed in the SRP. It is not necessary to cover all the topics of the SRP, only those that are applicable to the action requested by the applicant.

2.2.2 The SER may include simple figures of the cask, facility, or package design if it is determined that the figure is necessary for the evaluation.

2.2.3 If there is no effect related to the proposed changes, then, the staff shall state the basis for that conclusion in the SER. For example,

“The applicant evaluated the decay heat of the proposed contents, which it is significantly less than the decay heat previously evaluated for the Model No. ST-00 package. Therefore, the previous thermal evaluation for the package bounds the decay heat of the proposed allowable contents.”

2.2.4 When possible, each section in the SER should be numbered, consistent with the chapter in the SRP.

2.2.5 Appendixes [B](#) and [D](#) of this DI include some templates and general guidance about the contents of the sections in a SER.

2.3 ***New or complex applications (transportation packages, storage systems, or facilities; fuel facilities renewals)***

As a guideline, a complex application is one that includes at least half of all SRP review sections in the SER. For additional guidance, see LIC-FM-1 ([Ref. 4.2](#)).

2.3.1 The SER should include the evaluation of all the technical areas of the applicable SRP related to the action requested.

2.3.2 For complex revisions and amendments, the staff describes how the proposed change affects the safety of the system or facility.

2.4 ***Amendments and revisions***

- 2.4.1 The SER for amendments and revisions should only address the changes requested by the applicant unless a new safety issue is identified. For additional information regarding whether a requested amendment is within the scope of a review, see division instruction LIC-FM-1 ([Ref. 4.2](#)).
- 2.4.2 The SER for simple revisions and amendments (e.g., minor changes to drawings) should only include the affected sections. The summary section of the SER should note the remaining sections (e.g., thermal, criticality, shielding) that are not affected due to the changes requested by the applicant.

2.5 *Simple applications (e.g., package renewals, some amendments, reviews, administrative changes, or requests)*

As a guideline, a simple application may be an administrative change or a change that does not require a multidisciplinary team and includes only a few pertinent SRP review sections in the SER.

- 2.5.1 The following are examples of simple applications:
 - a) An administrative review that does not propose any design, operational, fabrication, or maintenance changes. In this case, the review may consist of ensuring that the information referenced in the CoC or license is in ADAMS and changing the expiration date.
 - b) Change the company's name and/or address in the CoC or license due to an organizational change in a company.

- 2.5.2 For simple applications, the SER may consist of the following sections:
 - a) Summary
 - b) Evaluation
 - c) References (if more than one reference)
 - d) Conditions
 - e) Conclusion

The SER may include an environmental section (as needed), depending on the type of requested action (see LIC-FM-1, Section 2.21 for when an EA or EIS is required).

2.6 *Exemptions*

- 2.6.1 The SER for an exemption should only address the action requested by

the applicant and include the disciplines impacted by the exemption requested.

- 2.6.2 For exemptions related to financial assurance or decommissioning funding, the SER is published in the *Federal Register*. The SER is prepared by a staffer from the financial assurance group.

2.7 Partial approvals, rejections, and withdrawals

2.7.1 The staff does not prepare a SER if the applicant withdraws the application.

2.7.2 In situations in which the requested action is not granted in whole, the SER is usually presented in the following ways:

- a) The staff may write an SER that rejects the application in whole or that approves, in part, and rejects, in part, the application. In any case, the basis for the staff's conclusions and findings must be clear and concise.
- b) If there are any limits and/or restrictions imposed as a condition of the approval, they need to be addressed as requirements in the license, technical specifications, or certificate of compliance. The SER should clearly describe the basis for the conditions of the approval.
- c) If there are any unresolved issues that would preclude the issuance of a license, certificate of compliance, or other approval, these issues should be clearly characterized in the SER. If any such information is identified, the technical reviewer should notify the PM as soon as practical.

2.8 SER Supplements

2.8.1 For SER supplements (to an initial SER with open items), the reviewer should only evaluate and make the appropriate findings that remain open from the initial SER.

2.8.2 If the staff has identified an emergent issue on which the staff has taken an action (i.e., issued a bulletin, generic letter, or an order), the reviewer should take this into account during the review of an open or previously closed area during the preparation of the SER.

2.9 General Writing Guidance

The reviewer should document the scope and focus of what was reviewed as part of the technical review in order to assist in knowledge management and regulatory consistency for future reviews. The description of the scope should include the technical areas that are addressed. Documenting the focus should

cover the specific areas or aspects that were reviewed, the depth of the review (e.g., screening versus detailed review) and the approach (e.g. confirmatory analysis, sampling, etc.).

The staff considers that the SER should be comprehensible to a wide audience with no greater than a basic level of understanding of engineering principles. It is recognized that such a person may have to do some independent study and/or research to fully understand the SER.

Additional writing guidance can be found in [Appendix D](#).

2.10 SER Format

2.10.1 The staff should follow the NRC style guidance, when applicable, when writing the SER.

2.10.2 The PM communicates to the team the format to be used in the SER, including the references section in the SER.

2.10.3 If a SER exceeds ten (10) pages in length, it should contain a table of contents.

2.10.4 If the SER includes a references section, the staff should include the reference section before the “Conditions” section of the SER. The staff should include the applicable reference citation through the SER.

2.10.5 Additional guidance on the SER format is provided in [Appendix D](#).

2.11 Additional actions requiring SERs

Some additional actions for which the staff develops an SER are the following:

- 1) License transfer (Fuel Facilities)
- 2) Revalidation recommendation (Packages)
- 3) Letter authorization for a shipment
- 4) Quality assurance plan approvals or change

2.12 Cover Letter

2.12.1 The PM prepares a cover letter or memo with a concurrence page for the SER. (See LIC-FM-1 ([Ref 4.2](#)) for guidance of how to process cover letters in hardcopy and electronic form.)

2.12.2 Examples and templates of cover letters for SERs are found in [Appendix B](#).

2.13 Concurrence

- 2.13.1 The SER itself does not have a concurrence page or include a signature. The PM prepares a cover letter as noted in Section 2.12 of this DI.
- 2.13.2 If a reviewer does not agree on the contents of the FSER and cannot resolve the issues through the available venues, the reviewer can use the non-concurrence process (see Management Directive (MD) 10.158, “NRC Non Concurrence Process” ([Ref. 4.6](#))). In this situation, this MD will be reflected on the concurrence block of the transmittal letter to indicate the non-concurrence.
- 2.13.3 During concurrence, the PM and the BCs concur, with the licensing supervisor signing the final action dates the SER.
- 2.13.4 *For actions related to fuel facilities*, once the SER is ready to enter formal concurrence, the PM should provide a courtesy copy to the project inspector (PI) in parallel with the concurrence process. This allows the PI to be aware that the licensing action is nearing completion. The PI and their supervisor should be placed on distribution for the final package.
- 2.13.5 For actions related to storage and transportation of radioactive materials under NRC’s jurisdiction, the inspection group can review the concurrence packages, but is not required to concur unless an inspector is part of the review team.

2.14 Final Processing

- 2.14.1 After the PM gathers concurrences, the PM enters the NRC 665 form, the cover letter, the FSER (or PSER), and other documentation related to the action requested in the administrative assistants’ log (see ADM-FM-3, “Administrative Functions” ([Ref. 4.7](#))).
- 2.14.2 The administrative assistant dates the cover letter, the SER, and other documents in the concurrence package for the action requested (see LIC-FM-1 ([Ref. 4.2](#)) for additional information about the processing of licensing actions).
- 2.14.3 For licensing actions related to storage and transportation, the SER is issued on NRC letterhead.
- 2.14.4 For new licenses of fuel facilities, the SER can also be published as a NUREG. Guidance for publishing SERs as NUREGs can be found in [Appendix B](#).
- 2.14.5 The SER is docketed in ADAMS as an official agency record.

3. RESPONSIBILITIES AND AUTHORITIES²

3.1 *Administrative Assistant*

Dates the cover letter, SER, and other documents in the concurrence package for the action requested (see LIC-FM-1 ([Ref. 4.2](#)) for additional information about the processing of licensing actions).

3.2 *Licensing Assistant*

3.2.1 Ensures that the format throughout the SER is consistent and verifies that the appropriate docket number, certificate number, EPID, etc. is accurately referenced in the SER.

3.2.2 Works with the PM to ensure consistency of the SER style and format.

3.2.3 Proofreads the concurrence package for the SER.

3.3 *Project Manager*

3.3.1 Coordinates and develops the SER, including consolidating the input from the licensing assistant, technical staff, branch chiefs, and Office of the General Counsel (OGC) (when applicable).

3.3.2 Uses the appropriate SRPs and RGs in the development of the SER and license or certificate of compliance.

3.3.3 Works with the review team in following appropriate SER style and format.

3.3.4 Keeps the technical staff (and OGC attorney, when necessary) informed (by periodic meetings, etc.) of significant licensing and project issues related to the cask, package, or facility review, such as possible schedule delays.

3.3.5 Sends the applicable SERs to the OGC for no legal objection (NLO) review.

3.3.6 Updates the SER title after rulemaking for actions related to 10 CFR Part 72 certificates of compliance.

² See also Responsibilities and Authorities in LIC-FM-1, "Overview and Expectations of the Certification and Licensing Process" ([Ref. 4.2](#)).

3.4 Technical Staff

- 3.4.1 Uses the appropriate SRPs and RGs in the development of the SER.
- 3.4.2 Follows the appropriate SER style and format.
- 3.4.3 Proofreads the draft and FSER or PSER prior to providing it to the PM.
- 3.4.4 Incorporates input into their SER section from applicable technical areas, including crosscutting issues related to his/her/their area of review as needed.
- 3.4.5 Provides a draft and FSER in their technical area.
- 3.4.6 Provides the FSER input to his/her/their supervisor (or the assigned peer reviewer) for approval prior to submitting it to the PM.
- 3.4.7 Keeps the PM informed regarding the status of the review prior to formal input.
- 3.4.8 Follows the appropriate technical and writing guidance in the development of the SER.
- 3.4.9 Reviews comments on SER input for technical accuracy.

3.5 Licensing Branch Chief or designee

- 3.5.1 Assigns a PM for processing the licensing action request and coordinating the development of the SER.
- 3.5.2 Reviews the SER and CoC prior to issuance.
- 3.5.3 Signs the cover letter of the SER (see ADM-FM-2, “Signature Authority and Concurrence Guidance” ([Ref. 4.8](#)) for additional information about DFM signature authority).
- 3.5.4 Dates the SER.
- 3.5.5 Ensures that the corresponding signature date is included on the CoC.

3.6 Technical Branch Chiefs or designee

- 3.6.1 Ensures that the technical staff follows the appropriate NRC guidance when developing the SER, including style and format guidance.
- 3.6.2 Approves draft SER input.
- 3.6.3 Ensures that the technical staff provides SER input in a timely manner.

- 3.6.4 Concur on the final SER input provided by their technical staff
- 3.6.5 Ensures that there are no technical overlaps or inconsistencies across the SER sections.
- 3.6.6 The technical branch chief informs the decision maker of significant issues that may impact the review. See the Delegation of Authority provisions of ADM-FM-2 ([Ref. 4.8](#)).

3.7 Division, Deputy Director

- 3.7.1 Provides final concurrence in accordance with signature authority guidance (unless otherwise delegated). See the Delegation of Authority provisions of ADM-FM-2 ([Ref. 4.8](#)).

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, NMSS/DFM Division Instruction ADM-FM-1, “Development, Revision, and Maintenance of Division of Fuel Management Instructions,” ADAMS Accession No. [ML20167A103](#).
- 4.2 U.S. NRC, NMSS/DFM Division Instruction LIC-FM-1, “Overview and Expectations of the Certification and Licensing Process of Spent Fuel and Radioactive Material,” ADAMS Accession No. [ML20295A524](#).
- 4.3 U.S. NRC, NMSS/DFM Division Instruction LIC-FM-8, “Peer Review Procedure,” ADAMS Accession No. [ML21174A144](#).
- 4.4 U.S. NRC, NMSS/DFM Division Instruction ST-FM-1, “Processing Actions Related to 10 CFR Part 72 Certificates, Licenses, and Consolidated Storage Facilities,” ADAMS Accession No. [ML21084A472](#).
- 4.5 U.S. NRC, [NMSS-P&P 7-04](#), “Handling Request to Withhold Proprietary Information from Public Disclosure.” (not publicly available)
- 4.6 U.S. NRC, [Management Directive 10.158](#), “NRC Non-Concurrence Process.”
- 4.7 U.S. NRC, NMSS/DFM Division Instruction ADM-FM-3, “Administrative Functions,” ADAMS Accession No. [ML20224A273](#).

- 4.8 U.S. NRC, NMSS/DFM Division Instruction ADM-FM-2, “Signature Authority and Concurrence Guidance,” ADAMS Accession No. [ML21061A270](#). (not publicly available)
- 4.9 U.S. NRC NUREG-1379, “NRC Editorial Style Guide,” ADAMS Accession No. [ML093280744](#).

Appendix A. Change History

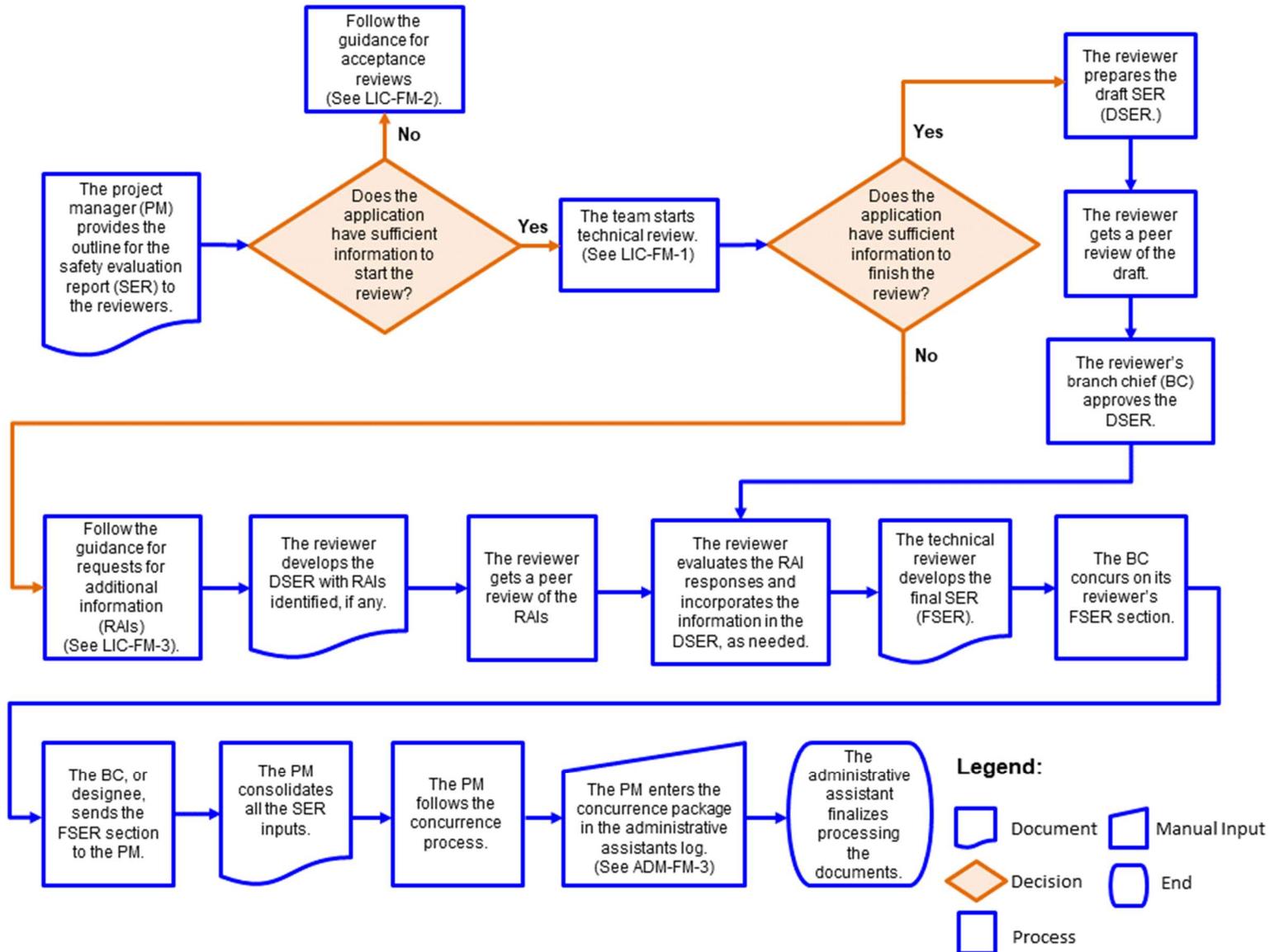
Date	Description of Changes	Revision
03/23/22	<p>Initial issuance. This instruction compiles guidance from the Fuel Facilities Business Line and Spent Fuel Storage and Transportation Business Line.</p> <p>This division instruction is based on division instruction SFM-2, “Safety Evaluation Report” (ADAMS Accession No. ML15160A459) of the former Division of Spent Fuel Management and applicable sections of the FCSE Licensing Review Handbook (ADAMS Accession No. ML18304A078) of the former Division of Fuel Cycle Safety, Safeguards, and Environmental Review, including “SER Administrative” (ADAMS Accession No. ML082470485), and “SER Major Licensing Action” (ADAMS Accession No. ML082470487).</p> <p>This DI also incorporates recommendations from the Smarter Licensing Working Group Recommendations³ (see Appendix E)</p>	0
09/30/22	<p>Addressed the requirement for a draft SER to be peer reviewed in Section 2.1.4.2 and clarified that a peer review of a DSER is at the discretion of the Branch Chief per the guidance of Section 2.1.2.b.</p>	1

³ 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](#).

Appendix B. Safety Evaluation Report 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. Safety Evaluation Report Development Process Flow Chart



Appendix D. Format of Safety Evaluation Report Sections

General Writing Guidance

The staff **should avoid** the following.

- a) Conclusory-only statements that do not provide enough detail when documenting the following areas:
 - (1) The applicant's analysis, methodology, and conclusions used to meet a requirement.
 - (2) The staff's review and evaluation of that input (e.g., considering the applicant's assumptions, staff's confirmatory analysis, etc.)
 - (3) The acceptance criteria for determining that NRC regulatory requirements were met.
- b) Hyperbole and intensifier modifier type adjectives (e.g., very, extremely), especially when quantification is required.
- c) Citing a verbal "discussion" with the applicant.
- d) Repetition of information in the application without appropriate attribution.

The staff **should** do the following.

- a) Use simple, clear, understandable, and concise language. (Ref. 4.1)
- b) Use active voice rather than passive voice. For example:
 - (1) Active: The NRC performed independent material testing for fracture toughness.
 - (2) Passive: Independent material testing for fracture toughness has been performed by the NRC
- c) Minimize use of acronyms and abbreviations. If used, ensure that the first instance is properly identified by spelling out the term followed with the corresponding abbreviation shown in parentheses.
- d) Use no more than two subordinate levels of outline, when possible.
- e) Summarize, not reiterate, the information in the application. The SER should reference specific sections in the application, as needed, and supporting information. If a specific citation of

information is needed in the SER, ensure that it is attributed accordingly.

- f) Be precise when discussing requirements and guidance: “must” and “shall” are associated with requirements, whereas “should” refers to NRC guidance in documents such as standard review plans and regulatory guides, and “may” refers to other references.
- g) Maintain objective tone when choosing the tense used, especially when discussing an applicant’s proposed request (e.g., “The applicant proposed to revise Table 2 of the license” rather than “Table 2 of license is revised”).
- h) Use past tense when detailing the applicant’s information (the applicant stated the results were ...) and when describing staff actions (staff determined that the results were bounding because ...). Use present tense when describing staff’s conclusions and findings (staff finds that...).
- i) Use words such as “find,” “conclude,” “determine,” that denote NRC’s role as regulator, rather than non-regulatory verbs such as “concur” or “agree.”
- j) Ensure that the applicant and application are consistently identified throughout the SER. For example, all SER sections shall refer to the same document (e.g., application, SAR, FSAR). In addition, all sections of the SER shall refer to the applicant in the same manner (e.g., licensee, applicant, certificate holder).
- k) Clearly identify the actions performed by the staff versus actions performed by the applicant.
- l) Cite a document as evidence (e.g., codes, standards, etc.) where appropriate.

I. SUMMARY (or EXECUTIVE SUMMARY)

The summary section is an executive summary. The project manager (PM) develops the “Summary” and/or “General Information”/ “Background” section considering staff’s input. The reviewer should not repeat this information nor provide detailed information regarding the historical information exchange (through the use of RAIs) with the applicant during the review process. This section includes the following information:

- 1) Applicant’s name and preferred abbreviation.
- 2) Date of application [include Agencywide Documents Access and Management System (ADAMS) Accession number] and supplements.
- 3) Summary of the requested action.

- 4) Summary of the requested action.
- 5) Reference the CoC, license, or letter that the SER addresses.
- 6) Conclusion of the staff (e.g., meets requirements of 10 CFR Part 71 or 10 CFR Part 72).
- 7) For a license, the date of notice and publication of the environmental review.
- 8) Standard Review Plan and/or applicable regulations used for the review.

II. GENERAL INFORMATION (or BACKGROUND)

This section is typically prepared by the PM with staff's input. The general information/background section includes the following:

- 1) A narrative summary of the issues, regulatory documents involved, and specific actions.
- 2) A brief description of the package storage system, licensee, or facility.
- 3) Historical/chronological perspective (i.e., the application dates, requests for additional information (RAI), list of supplements and responses with their ADAMS Accession numbers, and other related material to provide a record of and an underlying basis for the action).

II. EVALUATION SECTION

For a renewal of a transportation package with no changes to the licensing documents (e.g., application referenced in the certificate of compliance), this section does not include sections for technical disciplines (unless the applicant requests a renewal in combination of an amendment).

For new applications or complex renewals, the "Evaluation Section" includes all the technical disciplines related to the applicable standard review plan (SRP).

1) Writing the Evaluation Section

The reviewer should not explain verbatim the SRP criteria. Any unusual staff positions on safety evaluation methodology should be discussed with the applicant prior to starting the review. The reviewer should not provide any information unrelated to the evaluation, such as Code definitions, reference materials, etc.

- a. The SER format should be proposed by the Project Manager and agreed to by the technical review team at the beginning of the review; this can occur during the kickoff meeting and then re-verified prior to draft SER input. The need for adequate documentation in the SER is required for long and short SER formats. In addition, editorial formatting should be consistent throughout the SER (e.g., each section will start with a general introduction under the heading and not titled as x.1).
- b. The evaluation section is a summary of pertinent design features, inputs, assumptions, analysis methods, and related material to support each SRP

finding. The evaluation section addresses the major technical sections (e.g., criticality, structural, confinement, thermal, shielding, accident analyses, maintenance and tests, etc.) based upon the guidance provided in the associated SRP.

- c. Where the technical approach of the applicant is adequate but differs from the SRP, the reviewer should so state in the SER and clearly explain the rationale for the staff's conclusions regarding the applicant's position.
- d. If the SER discusses an action proposed to be performed in the future by the applicant but is not captured in a license condition, certificate condition or technical specification, consider whether the resulting information is necessary for the SER evaluation, and if so, the reason it is unnecessary as a condition to make a regulatory finding for the present evaluation should be documented in the SER.
- e. If a staff position has been previously developed and it is being used in the context of the technical review but it is not in the approved version of the SRP or an approved Interim Staff Guidance (ISG), the reviewer should state the use of the position in the SER.
- f. Content of each Technical Section and Subsections
 - i. State the specific technical area and its relevance to the licensing action.
 - ii. Summarize the applicant's relevant technical information. Each technical section should not repeat the entire technical details of the application that are found in the General Information section.
 - iii. Describe the staff's review (e.g., evaluation, analysis) that is relevant to the safety and regulatory aspects. This may include:
 - (A) A description of the major aspects of the applicant's analysis
 - (B) Types and extent of staff review (e.g., confirmatory). Note: Where independent/confirmatory calculations are performed, clearly explain how that supports the findings (e.g., if the staff performed independent modeling or confirmatory calculations, were the results comparable to the applicant's? Were the results within criteria specified in the applicable SRP or relevant regulatory guide?)
 - (C) Approaches and assumptions that impact the margin of safety.
 - (D) Limits/conditions that need to be imposed to control and maintain the inputs and assumptions of the analysis.
 - (E) Conclusions relating to the adequacy of the applicant's analysis, assumptions, etc.
 - (F) A determination and an explanation as to why the requested

action meets the regulatory requirements and SRP and/or RG criteria or does not. The applicant may show that it meets the regulatory requirements by comparing with SRP acceptance criteria, other relevant technical criteria, established staff positions, or industry standards, etc.

- (G) If an SRP and/or RG applies, then the reviewer should document the specific acceptance criteria met by the applicant, e.g., “The staff confirmed that the applicant’s structural analysis under normal and accident conditions the component meets ASME Boiler and Pressure Vessel Code (cite sections) stress allowable. Therefore, the staff finds this acceptable.”
- (H) Unless clarity dictates that regulations should be cited elsewhere, the reviewer should cite the applicable regulations at the beginning of the major technical section, rather than in each subsection, to avoid repetitiveness.
- (I) Proper attribution is necessary when documenting the applicant’s input, staff review, and acceptance criteria with its associated conclusion and finding. This can be achieved through the use of appropriate lead-in phrases, as exemplified below:

Section X.Y of the application described ...
 According to the applicant ...
 The staff performed a confirmatory analysis of ...
 Based on this comparison, staff concludes ...
 The staff determined ...
 The staff confirmed the applicant’s analysis is ...
 The staff reviewed the analysis in SAR section X.Y ...
 The staff verified that the applicant’s stress value ...

g. Conclusions and regulatory finding per section

State the conclusions and regulatory findings on the issues and the technical basis for how the staff arrived at them. Each finding would be within the relevant section/subsection of the SER; this provides clarity. The evaluation shall support the staff’s bases for a conclusion and for determining the applicant’s ability to meet the finding in the SRP.

Note 1: Conclusions within a technical section are often associated with staff’s judgements of an applicant’s analysis, assumption, etc. Regulatory findings, or findings, are associated with the final concluding statements that often have a regulatory component, such as those found in the SRP.

Note 2: Use affirmative conclusions and words such as “find,” “conclude,” “determine” that denote NRC’s role as regulator, rather than non-regulatory verbs such as “concur” or “agree.”

Example:

"Based on the statements and representations in the application, the staff concludes that the structural design meets the staff's guidance in NUREG-2215 and is acceptable."

Conclude each major technical section with a statement as to whether the application meeting the appropriate part of the CFR.

Example:

"Based on the statements and representations in the application, the staff concludes that the thermal design has been adequately described and evaluated, and that the thermal performance of the package meets the requirements of 10 CFR Part 71."

III. REFERENCES

If references (e.g., documents, technical references) are needed to support conclusions and final staff positions, they shall be included at the end of each SER section, consistent with the SRP. In general, all references discussed in the SER should be listed here. The version number and/or date of each reference should be listed so that it is clear which was used in the staff's review. The references should contain an ADAMS ML number or hyperlink to where they can be found (if available). If a reference is not publicly available, indicate this by adding "(not publicly available)" at the end of the reference. The format for references shall be consistent with agency standards (see [NUREG-1379, "NRC Editorial Style Guide" \(Ref. 4.9\)](#)).

IV. CONDITIONS SECTION (As applicable)

- 1) If there are limiting conditions that need to be imposed, they should be highlighted for incorporation into the license, technical specifications, or certificate of compliance.
- 2) Those limiting conditions that are enumerated in the license, technical specifications, or certificate of compliance shall be identified in the condition section and the bases established for each in the appropriate SER technical section.

V. SER CONCLUSION SECTION

Examples of a conclusion statement for a new approval or amendment\revision:

"The staff performed a detailed safety evaluation of the application for [license\certificate Amendment No. X, Revision No. X to License\Certificate of Compliance No. XXXX [storage and transportation only...for the (Model No.) (package or storage system)]. The staff performed the review in accordance with the guidance in NUREG-XXXX, "Title," Rev. X, issued in [Month Year]. Based on the statement and representations contained in the application, as supplemented, and the conditions established in the license\certificate of compliance [for 10 CFR Part 72 applications add the following: "and its appendices (technical specifications)], the staff concludes that the license\ certificate of compliance, as revised, meets the requirements of [applicable regulation (e.g., 10 CFR Part 72)].

Therefore, there is reasonable assurance that the [SSCs] will be constructed and operated safely.”

“Based on the statements and representations in the application, as supplemented, the staff concludes that the [e.g., Model No. 8-120B package design] has been adequately described and evaluated and that these changes, subject to the conditions listed above, do not affect the ability of the package to meet the requirements of 10 CFR Part 71. Therefore, there is reasonable assurance that the [SSCs] will be constructed and operated safely.”

“Based on the reviews documented in this Safety and Safeguards Evaluation of [licensee’s company name]’s License Renewal Application, the staff concluded that there is reasonable assurance that the activities to be authorized by the issuance of a renewed license for [licensee’s company name] will not constitute an undue risk to the health and safety of the public. Furthermore, the staff determined that the renewal application meets the requirements of 10 CFR 70.33.”

“The staff recommends that the license for [licensee’s company name] be renewed for a [number of years]-year term in accordance with the statements, representations, and conditions in the license renewal application dated [month day, year], subject to the identified license conditions detailed in this Safety and Safeguards Evaluation Report.”

Appendix E. 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 (FF) Business Line (BL), 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. The LT actions are being completed as resources permit.

Table C.1
Smarter Licensing Recommendations Incorporated into Division Instruction
LIC-FM-4, Safety Evaluation Reports

SLR ⁵ No.	Summary of Recommendation	Section(s)
NT4-12	Use the tools (e.g., job aids and templates) available to the NRC staff to draft SER with RAIs filling gaps and seek to minimize the potential for multiple rounds of RAIs.	2.1.4.2 2.1.4.2(1)
NT4-13a	Ensure the continuity of the quality, effectiveness, and efficiency of the licensing review process during NRC staff turnover.	2.1.4.2 2.1.4.2(1)
MT1-21	Provide guidance to ensure the SER documents the scope and focus of NRC staff reviews of licensing actions.	2.10
MT-1-25a	Facilitate inspector involvement early in the licensing review process.	2.1.3.5 2.13.4 2.13.5

⁵ SLR means "Smarter Licensing Recommendation"; NT means "Near Term"; MT means "Mid Term"