



U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

SFM Division Instruction

Division Instruction No.: **SFM-24, Rev. 0**

Division Instruction Title: **Scope of Technical Review of Licensing Actions**

Effective Date: **February 19, 2015**

Primary Contact: **Natreon J. Jordan**

Summary of Changes: (For revisions, indicate changes by placing a vertical line in the margins)

This Division Instruction provides guidance on:

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ML12222A262

OFC:	SFM		SFM		SFM		SFM		SFM	
NAME:	N. Jordan		M. Rahimi		C. Araguas		M. Sampson		A. Csantos	
DATE:	03/25/2014		04/26/2014 2/23/15		05/27/2014		01/15/2015		01/09/2015	

OFC:	SFM		SFM		SFM		SFM			
NAME:	P. Silva		P. Kallan		T. Hsia		M. Lombard			
DATE:	01/28/2015		01/28/2015		02/10/2015		02/19/2015			

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SFM Division Instruction
SFM-24, Rev. 0
Scope of Technical Review of Licensing Actions

1.0 OBJECTIVES

- 1.1 To ensure that the protection of public health and safety is the primary driver for Spent Fuel Management (SFM) technical reviews.
- 1.2 To establish the process by which SFM staff define the scope of a technical review for incoming review actions such as amendment and renewal requests.
- 1.3 To refine the process for developing Requests for Additional Information (RAIs) and to improve SFM's efficiency and consistency when requesting applicants to provide additional information.
- 1.4 To clarify the expectations regarding resolution for issues both within a proposed amendment as well as those outside the scope of review.
- 1.5 To provide staff with alternative methods of resolving regulatory issues with applicants which are outside of the scope of the technical review for the requested licensing action.
- 1.6 To ensure that any identified out-of-scope issues are handled appropriately.

2.0 GUIDANCE SECTION

2.1 General

- 2.1.1 Review Division Instruction SFST-2, *Safety Evaluation Reports*, Section 2.2.3, *Technical Review Guidelines and Philosophy*, on how to perform a technical review. This may assist the reviewer in identifying issues that may be outside of the scope of the requested licensing review or that may possibly establish a need for additional information from the applicant, if applicable.
- 2.1.2 Review Office Instruction SFST-4, *SFST Licensing Process*, Sections 2.7.3 and 2.7.4, which provide guidance on interactions with the applicant and significant new or emergent issues.
- 2.1.3 Review Office Instruction SFST-14, *Acceptance Review Process*, Section 4.2.2, *Technical Staff Criteria*. Out-of-scope issues may be evident during this initial screening process.
- 2.1.4 Review Office Instruction SFST-18, *Part 72 Review Guidance*, Section 2.3.4, which provides guidance on the scope of an amendment request.
- 2.1.5 Review Office Instruction SFST-19, *Non-Casework Technical Issue Resolution Process*, Section 2.3, which may provide guidance applicable to

addressing an out-of-scope issue related to a licensing action, especially in the development of the staff technical position.

- 2.1.6 Unless otherwise directed by the appropriate SFM Branch Chief, the assigned reviewer is the technical lead (TL) for the scope of review determination. Once an issue has been identified, the TL may need to be reassigned based on the technical nature of the issue (i.e., different technical area), staff availability, scheduling concerns, and/or the complexity of the issue. The designation of the TL will be made at the division work scheduling meeting.

2.2 Scope of Review

- 2.2.1 The reviewer should confine the review scope to those topics necessary for the amendment application. More specifically, this should be limited to items or concerns that are directly or indirectly related to the application.
- 2.2.2 If more information is needed to perform a technical review of a current review action, the reviewer determines whether the issue in question is within the scope of review of the current licensing action using the following process:
 - a. If the review action is a new request (i.e., revision 0), the entire Safety Analysis Report (SAR) is considered within the scope of review, and this Division Instruction (DI) is not applicable. The reviewer should proceed with the normal review process and follow the appropriate regulatory guidance. Staff should also be mindful to consider similar and/or preceding designs or packages when conducting the review.
 - b. If the review action is an amendment request, the reviewer should determine if the issue in question is within the scope of the amendment request.
 - i. If the issue in question is included within the changed portions of the amendment request, then the review action is within the scope of review and any questions related to the issue should be handled under OI SFST-3, *Requests for Additional Information*.
 - ii. If the issue is not within the changes requested in the amendment request, but is technically appropriate to address due to: 1) its direct relationship to the proposed changes, 2) being a safety issue that had not been previously identified, or 3) being required to correct an error significant to the operation of the package, then the issue may or may not be outside the scope of review and should be addressed using the guidelines in Section 2.4 of this DI.
 - iii. If the issue is not within the changes requested in the amendment request, and the issue is not a safety issue that had not been previously identified, nor is it required to correct an error significant to the operation of the package, then the issue is outside the scope of review. However, if

the issue raised is an issue of compliance then the reviewer may address this issue using the guidelines of Section 2.4 of this DI.

- iv. If the issue is identified as part of another concurrent review (i.e., more than one amendment is under active review in SFM), then, the reviewer should engage the Project Manager (PM) and the other review team(s) to decide if the issue affects the other ongoing amendment reviews. The issue may be outside the scope of review and should be addressed using the guidelines in Section 2.4 of this DI.
- c. If the review action is a renewal request, the reviewer should determine if the issue in question is within the scope of renewal as part of aging management review.
- i. If the issue in question is included within those items determined to be within scope as part of the aging management review per NUREG-1927, then the issue is within the scope of review.
 - ii. If the issue in question is not included within those items determined to be within scope as part of the aging management review but is technically appropriate to address due to being a safety issue that had not been previously identified or due to being required to correct an error significant to the operation of the package, then the issue may or may not be outside the scope of the review and should be addressed using the guidelines in Section 2.4 of this DI.
 - iii. If the issue in question is not included within those items determined to be within scope as part of the aging management review and is not a safety issue that has not been previously identified nor is required to correct an error significant to the operation of the package, then the issue is outside the scope of the review. However, if the issue raised is an issue of compliance then the reviewer may address this issue using the guidelines of Section 2.4 of this DI.
- 2.3 Prior to engaging and briefing management, the TL should consult with staff peers in an attempt to come to a consensus on the staff's position. This may be accomplished using the Working Group Committee (WGC) established by OI SFST-19, or through a more informal process. If a consensus cannot be reached, then the differing opinions should be summarized and presented to management for a decision during the briefing described in Section 2.4.
- 2.4 The TL and the project manager (PM) engage and brief SFM management on the staff's position and proposed path forward. This briefing could be given at the weekly scheduling meeting or at an alternate mutually agreed upon forum. This briefing should answer the following questions:
- a. What does the issue involve?
 - b. What is the regulatory basis?
 - c. What is the extent of the issue?

- d. Are there any generic implications?
 - e. What is the safety significance of the issue?
 - f. Are there any policy issues?
 - g. What is the staff's technical and regulatory position on the issue?
 - h. What is the proposed path(s) forward to address the issue?
- 2.4.1 The technical and regulatory position (i.e., 2.4.g above) should include the following:
- a. A clear and concise statement as to the TL's position regarding the technical issue being addressed.
 - b. The applicable regulatory citations that are being challenged or that are referenced in the TL's position.
 - c. Whether the TL's position is new or different from a previous staff position.
 - d. A summary of any applicable background information to support the TL's position. This may include:
 - i. A history of the issue that led to the concern.
 - ii. Any communication or licensing actions relevant to the issue.
 - iii. Previous internal staff discussion of the issue.
 - iv. Any associated and relevant staff guidance.
 - v. The applicability of the issue to other licenses or certificates of compliance (CoC).
- 2.4.2 The proposed path forward (i.e., 2.4.h above) regarding resolution of the issue based on the TL's position may take the form of one of the following, however, this list is not all-inclusive and alternate paths may be suggested:
- a. Development of a regulatory tool such as:
 - i. Generic communication
 - ii. Development of guidance, NUREG, ISG, Regulatory Guide, etc.,
 - iii. Consideration for backfitting under 10 CFR 72.62.
 - iv. Consideration for Generic Issues
 - b. Issuance of RAIs using the guidance of OI SFST-3, if the issue is limited to a specific license or CoC holder.
 - c. An alternate path as deemed appropriate by the TL that is sufficient to resolve the identified issue.

- 2.4.3 If the issue was identified in Section 2.2.2.b.ii and is not safety significant, needed to ensure review consistency, nor is it needed to correct an error significant to the operation of the package, then the TL should justify why this issue should be addressed.
- 2.5 When necessary, the TL may request dialogue with the licensee through the appropriate PM to discuss the staff's concerns and seek any new information not included in the review action that may resolve the issue or support the development of the TL's position and potential path forward.
- 2.6 If SFM management agrees with the proposed path forward, based on the developed technical position, the appropriate Branch Chief(s) will assign actions to be taken as appropriate, based on the proposed path forward (See Section 2.4.2 of this DI).
- 2.7 Where actions have been delineated and initiated, the TL updates the SFM Success Plan with an appropriate schedule and milestones, established in consultation with the PM, to resolve the issue.

3.0 RESPONSIBILITIES AND AUTHORITIES

- 3.1 Technical Leader (TL):
 - 3.1.1 Defines the nature of the issue and the regulatory basis.
 - 3.1.2 Determines if the issue is within the scope of the technical review.
 - 3.1.3 Initiates requests for dialogue with the licensee, other NRC office staff, and other stakeholders, as necessary.
 - 3.1.4 Develops a draft technical position and proposed path forward to resolve the issue.
 - 3.1.5 Obtains necessary technical, procedural, and legal support from other cognizant staff.
 - 3.1.6 Solicits and incorporates comments from staff, management, and other offices, as necessary.
 - 3.1.7 Leads the management briefing on the technical position and proposed path forward.
 - 3.1.8 Updates the SFM Success Plan, as necessary and appropriate, to track the status of any actions taken on an issue that is not covered under the RAI process.
 - 3.1.9 Develops generic communications and/or staff guidance on the issue, as necessary.

3.2 SFM Project Manager:

- 3.2.1 Schedules and facilitates any requested dialogue with a licensee or certificate holder to obtain additional clarification on the issue to develop the TL's position, following the guidelines of SFST-15, *Interactions Between Applicants and SFST*.
- 3.2.2 Documents any recordable dialogue or actions in ADAMS.
- 3.2.3 Ensures that any RAIs (OI SFST-3) or generic communications, developed as a result of resolving the issue, are communicated to the affected licensees or stakeholders.
- 3.2.4 Ensures that any changes to the original schedule for the subject action are communicated to the DSFM front office

3.3 Branch Chief(s):

- 3.3.1 Makes the initial determination of staff responsibility.
- 3.3.2 Assigns a technical lead (TL) to process the issue of concern.
- 3.3.3 Coordinates PM support when TL requests interaction with a licensee or certificate holder.
- 3.3.4 Coordinates with the PM when a technical issue may require action(s) by a licensee(s) or stakeholder.
- 3.3.5 Ensures that the issue has been included in any communication with the licensee or stakeholder.
- 3.3.6 Communicates with SFM front office when a potential issue has been identified.
- 3.3.7 Provides comments on draft position and proposed path forward to the TL and affirms the need to engage with other NRC offices, if necessary.
- 3.3.8 Ensures that any generic communications or guidance developed as a result of the issue review has been included in any communications with the appropriate affected licensees and stakeholders.
- 3.3.9 Assigns follow-up actions based on SFM management agreement on the proposed path forward.

3.4 SFM Director or Deputy Director:

- 3.4.1 Provides management oversight and input regarding:
 - a. The initial determination of whether TL responsibility should be assumed for resolution of an identified technical or regulatory issue.

- b. The need to track any issue resolution.
- c. Any follow-up actions based on SFM management agreement on the proposed path forward, and affirms the need to engage with other NRC offices, as appropriate.

4.0 REFERENCES

(NRC 2006) SFST-2, *Safety Evaluation Reports*, Revision 1, September 28, 2006, (ADAMS Package ML062710331)

(NRC 2010) SFST-3, *Requests for Additional Information*, Revision 4, August 19, 2010, (ADAMS Package ML102420469)

(NRC 2009) SFST-4, *SFST Licensing Process*, Revision 4, April 14, 2009, (ADAMS Package ML091100331)

(NRC 2006) SFST-18, *Part 72 Review Guidance*, Revision 1, September 28, 2006, (ADAMS Package ML062710347)

(NRC 2013) SFST-19, *Technical Issue Resolution and Working Group Committee Processes, Roles and Responsibilities*, Revision 1, April 1, 2013, (ADAMS Package ML13093A483)

(NRC 2011) SFST-14, *Acceptance Review Process*, Revision 1, February 3, 2011, (ADAMS Package ML110450435)

(NRC 2010) SFST-15, *Interactions Between Applicants and SFST*, Revision 3, August 19, 2010, (ADAMS Package ML102420471)

Appendix A - Change History

Division Instruction SFM-24

SFM-24 Change History		
Date	Description of Changes Change in Primary Contact Training/Feedback Session	Revision
02/19/2015	Initial Issuance and Training	0