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

SFM Division Instruction

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Division Instruction Title:	**Operational Strategies and Management Expectations**
Effective Date:	**August 8, 2016**
Primary Contact:	**DSFM Technical Assistant**

Summary of Changes

1.   New division instruction.

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DATE	7/22/2016		7/27/2016		7/28/2016		7/23/2016	
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Operational Strategies and Management Expectations

1. **OBJECTIVE**

   The purpose of this Division Instruction (DI) is to provide management expectations and guidance to Division of Spent Fuel Management (DSFM, hereafter, the Division) employees to meet division and business line goals to be an independent, transparent, and effective regulator.

2. **GUIDANCE SECTION**

   The Division must continue to identify and implement process efficiencies to complete our mission in light of continuing internal and external factors and resource challenges. The Division engages in frequent assessments of its processes and procedures to assure that they support the Division's commitment to the agency's mission. The Division's role on accomplishing the agency's mission includes:

   - assuring compliance with safety, security, and environmental protection regulatory requirements for Spent Fuel Storage and Transportation (SFST) business line activities, while also

   - identifying and implementing changes to these processes and procedures to improve effectiveness and efficiency of related operations.

   This DI reflects the results of these assessments by providing direction and guidance to DSFM employees (hereafter, the staff) to meet division and business line goals.

   This DI is a living document, and will be revised as new guidance or direction is defined. This DI should serve to promote a reasonable, reliable, predictable, and stable regulatory environment for the safe and secure storage and transport of radioactive materials.

   Division management and staff should take actions to ensure that the processes are effective and efficient for:

   - conducting the review of licensing and certification of compliance (CoC) applications (e.g., CoC, amendment, general/specific Independent Spent Fuel Storage Installation (ISFSI) license),

   - conducting oversight activities, and

   - developing the infrastructure to support licensing and oversight activities.

The key activities and expectations to be adhered to include:

2.1   Pre-application Meetings

    2.1.1   For all but simple applications, DSFM typically holds pre-application meetings to communicate NRC's expectations, gain an understanding of the proposed incoming licensing action, and identify potential regulatory issues.

    2.1.2   DSFM expects that applicants, to the extent that the information is available, pay attention to Requests for Supplemental Information (RSI) or Requests for Additional Information (RAI) on similar applications.

    2.1.3   New analysis methods or strategies should be discussed in pre-application meetings to facilitate effective reviews and to identify safety, security, or environmental issues to the extent practical.

    2.1.4   Regulatory decisions will not be made in pre-application or other public meetings. NRC staff may provide feedback to applicants and solicit and respond to questions from the public during these meetings.

2.2   Acceptance Review Process

    2.2.1   The staff expects the applications to be of high quality (i.e., complete and accurate) without the need for substantial and/or complex requests for additional or supplemental information to address pertinent NRC requirements.

    2.2.2   The staff will use DI SFM-14, "Acceptance Review Process," to document its determination of the application's acceptability for docketing.

    2.2.3   The staff will determine the appropriate timeframe for the applicant to respond to RSIs. Depending on the complexity of the application, the staff will usually allow the applicant between 14 and 28 calendar days to respond to RSIs. The staff considers this time frame sufficient, since the staff assumes that the applicant would have the information requested readily available for submittal.

    2.2.4   If an applicant is not able to respond to the RSIs in the agreed-upon time frame, the application review may be delayed (i.e., to a longer/later review schedule), suspended (i.e., no further staff review until satisfactory resolution), or not accepted for review.

2.3   Work Prioritization

    2.3.1   Casework, licensing support, and oversight activities will be prioritized in accordance with the guidance in DI SFM-10, "Scheduling Casework and Non-Casework Activities." Appendix B provides the priorities for DSFM.

2.3.2 Prioritization will be conducted to:

a) Establish initial review schedules for new applications (i.e., casework).

b) Establish milestone schedules for NRC-initiated work (e.g., licensing support, initiatives, and oversight activities).

c) Adjust schedules based on emergent higher priority work.

d) Identify work to be delayed or suspended when work exceeds available resources.

2.3.3 The Division will implement its prioritization guidance, as described in DI SFM-10, in order to address the action requested by the industry or other stakeholders while properly managing the division's workload. If it is not readily apparent in the application, the staff may ask applicants to provide information in order to facilitate the prioritization of work to be reviewed, including:

a) Intended use of the transportation package or storage system (i.e., domestic or non-U.S. use).

b) Priority of the new request compared to other casework previously submitted by the applicant.

c) Priority level based on the guidance used in the Division.

2.3.4 DSFM will validate the priority of each application, notify the applicant, and process the review of the application in accordance with its priority.

2.3.5 Relative priority of DSFM activities may change as other considerations are identified, including significant changes in the applications during review (e.g., basket designs, materials, fuel types). The staff will issue a communication (e.g., letter, e-mail) to affected stakeholders notifying them of the staff's decision and basis for the change.

2.3.6 As the prioritization guidance may not address every situation, DSFM will apply pertinent considerations (including discussions with applicants) to determine relative prioritization.

2.4 Review schedule and resource estimates

2.4.1 The applicant will be provided with a reasonable/realistic estimate of the review milestone schedule and review resources once an application is accepted for review.

2.4.2 Spent Fuel Licensing Branch (SFLB) project managers will develop and maintain the official project plan with estimated milestone dates.

2.4.3   Estimates of the number of projected reviewer hours will accompany the project plan.

2.5   RAI process guidelines

The review team will follow DI SFM-3, "Requests for Additional Information," when developing RAIs, with the following additional guidance:

2.5.1   DSFM's goal is one round of RAIs for a typical review and a maximum of two rounds of RAIs. RAIs and the applicant's responses need to converge on the information needed for making a regulatory finding.

2.5.2   Technical reviewers will provide a draft safety evaluation report (SER) section to their supervisor with their draft RAIs showing the areas in which the staff needs additional information in order to make the regulatory finding in their respective areas of expertise.

2.5.3   To improve the effectiveness and timeliness of the RAI process, the staff will provide an electronic file in portable document format (.pdf) of the RAIs to the applicant for pre-issuance discussion prior to the concurrence of the licensing branch chief. However, the purpose of the pre-issuance discussions is to clarify the RAIs and not to debate the technical merits of the RAIs. Sharing and discussion of draft RAIs with applicants is expected for all but simple RAIs.

2.5.4   Due dates for RAI responses will be clearly communicated to the applicant in the RAI transmittal letter. Generally, the staff will provide 30 days to the applicant for responding to the RAIs, while (in rare instances) a longer time frame may be appropriate. Failure to respond within agreed-upon timelines may result in a DSFM management decision regarding delay/suspension/continuation of the associated review. RAI process discipline is essential in order to prevent long response times that can result in unavailability of the original team of reviewers, creating inefficient reviews.

2.5.5   Applicant submittals that are not responsive to RAIs may be considered grounds for delaying or suspending a review.

2.5.6   DSFM management will be notified of, and concur on, additional rounds of RAIs for a given review prior to sending the RAIs to the applicant.

2.5.7   DSFM management's decision regarding delay/suspension/continuation of review may be warranted if:

a)   RAIs indicate significant deficiencies in the application.

b)   Applicants provide RAI responses that change the technical basis, design, or otherwise expand the scope of the original application (e.g., change in design, material, or fuel from the original submittal).

2.6   Perform effective and efficient technical reviews by using existing guidance in SFM-2, "Safety Evaluation Reports," to conduct reviews.

2.7   Use the Prompt Issue Resolution (PIR) process to escalate and resolve issues in a timely manner

    2.7.1   Issues that arise, which require management's attention, will be identified and discussed during DSFM's weekly coordination meeting.

    2.7.2   DSFM's management team will align on a path towards resolution for each issue by the end of each meeting to the maximum extent possible. The PM and/or Branch Chiefs will execute such decisions following the PIR discussion.

    2.7.3   Any recommendations regarding possible delay, suspension, or other major schedule changes compared to the project plan shared with the applicant will be brought to DSFM management for attention and decision using the PIR process.

2.8   Take definitive action regarding status of application reviews

    2.8.1   The Division is committed to perform effective and efficient reviews of applications in accordance with established agency performance metrics. However, applications must be of high quality to support a predictable review process.

    2.8.2   Reviews may be delayed or suspended for the following reasons, which may be indicative of an application that is not of high quality:

        a)   The applicant fails to respond to RSIs/RAIs within the agreed upon time frame.

        b)   The application requires three or more rounds of RAIs.

        c)   The applicant's response to RAIs results in changes to the application that expands beyond the original scope of review (e.g., change in design, material, or fuel from the original submittal).

        d)   The applicant needs to perform additional work (e.g., tests or calculations) that would take a considerable amount of time to complete.

    2.8.3   Application reviews may be terminated for a variety of reasons:

        a)   The staff determines that the application does not meet the NRC requirements.

b) The staff determines that the application does not have sufficient information to continue the review.

c) The applicant fails to respond to RSIs/RAIs or communicate to the staff its intentions regarding a submittal in a reasonable time frame (e.g., more than 60 days).

3. RESPONSIBILITIES AND AUTHORITIES

No additional responsibilities besides responsibilities already discussed in the Division Instruction.

4. REFERENCES

None

5. APPENDICES

Appendix A. Change History

Date	Brief Description of Changes	Revision
8/08/16	Initial Issuance	0

Appendix B. Workload Prioritization

Prioritization of DSFM workload has generally been based on the level of safety significance and need associated with an action or request. In addition, other important tasks that directly or indirectly support licensing reviews (e.g., oversight, guidance development, rulemaking, Commission-directed tasks) were not considered in the previously issued work prioritization definitions (e.g., NRC RIS-2005-27). These activities must be included in the prioritization of workload in order to ensure that the importance of this work is not misplaced and future efficiencies continue to be realized.

To assist in managing DSFM's workload with its limited resources, as well as aid in the budgeting and planning future workloads, DSFM developed the following prioritization system based on, and consistent with, the agency's re-baselining common prioritization methodology:

Priority	Description
1	Activities needed to ensure the immediate safe and secure operation and handling of radioactive materials following storage or transport events.
2	Activities to ensure the safe and secure near-term (i.e., up to 6 months) use of radioactive materials in the United States (U.S.).
3	Activities to ensure the safe and secure long-term (i.e., greater than 6 months) use of radioactive materials in the U.S.
4	Activities to support the national spent fuel and high-level waste management strategy.
5	Activities to ensure the safe and secure use of radioactive materials only outside the U.S.
6	Activities to improve agency processes or improve stakeholder confidence, including responses to stakeholder requests for information.
7	Activities in deferred/suspended review status and unbudgeted activities.