



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 24, 2020

MEMORANDUM TO: Division of Fuel Management Staff
Office of Nuclear Materials Safety and Safeguards

FROM: Andrea L. Kock, Director /RA/
Division of Fuel Management
Office of Nuclear Materials Safety and Safeguards

SUBJECT: LICENSING PROCESS EXPECTATIONS

The purpose of this memorandum is to provide high-level expectations to staff in the Division of Fuel Management (DFM) in the Office of Nuclear Materials Safety and Safeguards (NMSS) for processing licensing actions. Licensing is one of the core U.S. Nuclear Regulatory Commission (NRC) functions, and there is a rich history of guidance on how to accomplish this aspect of our government business in a more risk-informed manner (e.g. SRM-SECY-98-0144, Yellow Announcement 99-019, "Risk-Informed Decision-making for Nuclear Material and Waste Applications" Agencywide Document Access Management System [ADAMS] Accession No. ML080720238). Going forward, risk informed thinking must be applied as we execute our licensing processes. The Commission recently reaffirmed this in Staff Requirements Memorandum SECY-19-0036, "Application of the Single Failure Criterion to NuScale Power LLC's Inadvertent Actuation Block Valves", dated July 2, 2019 (ADAMS Accession No. ML19183A434).

We've made substantial progress over the last few years in both business lines to further risk-inform decision making in the licensing process. For example, on January 15, 2019, the Director of NMSS issued "Key Principles for Nuclear Materials Safety and Safeguards Reviews" (ADAMS Accession No. ML19015A290). The purpose of that memorandum was to reiterate some of the key principles that guide the way we conduct our work and make decisions, particularly with respect to the concept of "reasonable assurance of adequate protection." Specifically, these key principles are:

- focus staff resources and expertise on the most safety-significant portions of a licensing decision;
- focus staff effort on reaching a "reasonable assurance" conclusion based on the entire system performance rather than an individual component; and
- enable the staff to acknowledge that a new technology may be safer than an existing technology although it may lack operating experience and years of performance data or may not meet the regulatory review standards developed for the existing technology.

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This memo builds on this progress and the Commission's substantial history related to risk-informed decisions to reaffirm and expand previous expectations related to risk-informed decision making for fuel cycle and spent fuel management activities.

Enclosed are expectations for various steps in the licensing process for the fuel cycle and spent fuel business lines. Many of the expectations included in this memorandum are not new and were previously included in the fuel facility and spent fuel business line licensing instructions. This memorandum communicates best practices from both business lines and includes some new expectations based on agency-wide insights from our transformation initiatives. All-inclusive DFM licensing guidance will be issued in the spring of 2020. When barriers are encountered in meeting these expectations, work to remove these barriers; and engage the DFM management team to help you overcome challenges.

I encourage you to engage the DFM leadership team if further clarity is needed. As we work to implement this guidance, your DFM management team is committed to an open environment for raising issues and discussing differing opinions; it is our expectation that differing views be raised and thoughtfully discussed as part of a healthy decision-making process. Once a final decision is made and the reason for the decision is communicated, it is also expected that the decision will be supported and implemented. Thank you for your continued commitment to our mission.

Enclosure:
Licensing Process Expectations

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Licensing Process Expectations

Prioritization of Licensing Activities

Staff are expected to work on projects assigned by their supervisors and to raise questions or conflicts to management for resolution, as needed. Adjustments to workload priorities will be made on an as needed basis. Further context and details on establishment of workload priorities will be provided in a future division instruction.

Preapplication Meetings

Frequent and early communications between the NRC staff and the licensee/applicant through pre-application review meetings help avoid unnecessary delays in the processing of submittals and support the transparency principle of good regulation. These early interactions also provide opportunities to understand any unique or complex aspects of a future application that enable better planning; identifying of specific skills; and establishing the initial expectations for the scope, focus, and level of detail of the staff reviews. As a result, preapplication meetings are highly encouraged, especially for large, unique, or potentially complex applications.

Acceptance Reviews

Although it is not a detailed technical review, a thorough acceptance review is integral to the efficient review of a licensing submittal. A requested licensing action will be considered received by the NRC on the date it is placed into ADAMS. Acceptance reviews are performed to allow the NRC staff to determine whether a requested licensing action is complete and acceptable for docketing. The acceptance review should focus on whether the applicant has submitted sufficient information for the NRC staff to initiate its review. As part of the acceptance review process, individual reviewers should estimate the number of hours anticipated to complete their review of the requested licensing action. Project Managers will establish acceptance review schedules that support timely agency decisions. Consideration should be given to whether to hold a meeting with the licensee/applicant during the acceptance review to better understand any unique aspects of the request. For reviews that are expected to be of short duration (e.g., <60 days) and straightforward, consideration can be given to forego the acceptance review phase and perform the technical review using an established timeliness metric for such reviews instead.

Assignment and Alignment

Planning the processing of a licensing actions is a critical step in ensuring that the work is completed in a timely and effective manner. Early alignment on the focus, scope, and level of detail of review for a licensing action is an integral part of any NRC review. Project Managers should coordinate early discussions with the review team and the applicable branch chief (e.g., during preapplication meeting preparations or during the acceptance review), and division management when necessary, to align on the scope and areas of focus for the review, and the scope and focus areas should be determined based on the integrated risk/significance of various aspects of the review. During these meetings, review teams should discuss the application, including all proposed changes that need evaluation, facility-specific issues, application complexities, or background information (e.g., licensing and design basis, stakeholder interests, time-charging expectations). The team should also identify if there are other ongoing reviews for applications that may overlap with the current application. Teams should understand all members' expertise as it pertains to the review, and they should discuss how risk will be integrated across the review. The above considerations should form the basis for the scope, focus, level of detail, schedules, and resource estimates for each aspect of the review. Any challenges or concerns should be elevated to management early in the planning process and whenever they arise during the actual review.

Schedules and Resources

The NRC is expected to practice good stewardship in fulfilling its regulatory obligations. Project Managers should solicit input from a licensee/applicant regarding their need date for licensing reviews and should develop a schedule for each review. Milestones may vary based on the complexity of the licensing action and estimated timeline. However, in all cases, the schedules will support the metrics established by the Nuclear Energy Innovation and Modernization Act. Schedules should be realistic, consider available resources for both NMSS and partner offices, be proposed and agreed upon promptly by both NMSS and partner staff, should include the assumptions used in developing the schedule, and should be developed to support agency metrics. Letters acknowledging acceptance of a licensing action for NRC review shall include a review schedule with a targeted completion date as well as any assumptions that were used in developing the schedule. Furthermore, the acceptance letter shall provide the expected number of total hours for the anticipated NRC review (including project management and technical review). When events occur that impact these initial estimates, an update should be provided to the licensee/applicant through appropriate docketed correspondence, and to branch and division management if these changes impact major milestones (acceptance review, RAIs, draft or final SER or EA). In addition, the justification for and length of delay should be documented in the schedule to support a comprehensive history of the project. Other updates to the licensee/applicant should be provided, as appropriate (e.g., e-mail correspondence or phone conversations). Site visits offer a unique opportunity to fully understand the safety aspects of a review and the implications of any regulatory decisions and are highly encouraged prior to receiving an application, during acceptance review, and/or during the request for additional information (RAI) phase of the review.

Review Scope and Depth

In general, licensing guidance in Standard Review Plans (SRPs), Regulatory Guides (RGs), and similar documents should be applied with a mindset of being risk informed. Reviews should not follow the SRP guidance verbatim; rather, professional judgement should be applied to focus on aspects of the application that are most safety significant. It is important to remember that SRPs and RGs are guidance documents, not requirements. Reasonable assurance of adequate protection can be demonstrated multiple ways. Frequently, engineering judgement is necessary to adjust the scope and depth of the NRC's review of an application. In making this determination, consideration should be given to the stage of the licensing process (e.g., renewals do not need to consider unchanged aspects of the facility), the level of defense-in-depth necessary, the available safety margin(s), the presence of required programs or management controls (e.g., NRC approved change control processes or programs that are required to ensure regulatory requirements are met), and the credit that can be applied in licensing given the entire regulatory framework (i.e., the licensing process is just one aspect of the NRC's ability to regulate and oversee safety and security). Confirmatory analysis should be focused on the most safety significant aspects of an application and the number and depth of confirmatory analyses should be adjusted based on safety margins, the existence of management controls, existing regulations, and areas included in inspection oversight.

Requests for Additional Information

The process of developing requests for additional information (RAIs) should focus on obtaining enough information to determine fulfillment of a regulatory requirement in which the NRC has regulatory authority. A RAI should not be issued unless a draft safety evaluation (SE) has been developed identifying where in the safety evaluation the information is needed to make a regulatory finding. A RAI consists of: (1) a question (description of the action needed), (2) a justification (summary of the rationale for asking the question), and (3) a regulatory basis (regulatory requirement(s) that the applicant must meet). Prior to formal issuance, RAIs should

be discussed with the licensee/applicant in draft form to ensure understanding, including the significance and level of effort envisioned by the NRC in responding to the RAI. Project Managers should also offer a call with the licensee before they submit responses to RAIs to ensure the licensee's response addresses the information needed. If more than one round of RAIs is needed, DFM management approval should be obtained. A job aid exists to help form RAIs at "Reference Guide for Developing Requests for Additional Information."

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Safety Evaluations

The SE should provide sufficient information to explain, in plain language, the staff's rationale and conclusions to someone unfamiliar with the licensee's request. The SE includes a brief description of the proposed change, the regulatory requirements related to the issue, and an evaluation that explains why the staff's disposition of the request satisfies the regulatory requirements. The SE needs to describe how the staff performed the review that conveys the focus, scope, and level of detail of the review and outlines any specific unique features of the review (e.g., if a sampling approach is used, the SE needs to clearly identify how samples were selected and what specific aspects, processes, or SSCs were sampled). This documentation not only supports openness and clarity, but also ensures future reviewers of follow-on applications understand what the review considered and how the review was performed. Risk insights should be considered to inform the level of detail necessary in the SE to reach a reasonable assurance determination. Only the minimal detail necessary to document the above information should be included in the SE.

Interaction with Stakeholders

The NRC's Principles of Good Regulation serve as a guide to both agency decision-making and individual behaviors. Consistent with these principles, it is imperative that DFM licensing actions be conducted in a transparent manner. Diligence should occur regarding the dispositioning of 10 CFR 2.390 requests for withholding of information from the public. Documents claimed and/or marked as proprietary must be reviewed to determine if all the information contained in the document is indeed truly proprietary in nature. If any portion is not proprietary, either the request for withholding should be denied or a public, nonproprietary (redacted) version may be submitted. All regulatory processes must be transacted openly and candidly. Regulatory positions must be easily understood and readily applied, and they should be administered promptly, fairly, and decisively.