

**Division of Fuel Cycle Safety and Safeguards
Interim Staff Guidance - 07**

Rules of Engagement

Issue:

This Interim Staff Guidance (ISG) encompasses rules of engagement for the integrated safety analysis (ISA) and ISA summary reviews performed by the NRC staff.

Introduction:

The purpose of this ISG is to provide rules of engagement to be followed by both staffs of NRC and licensees/applicants to facilitate communications between those staffs during ISA and ISA summary reviews. By following these rules, it is expected that the NRC technical staff can conduct more efficient reviews of ISA and ISA summaries.

This ISG will provide additional guidance and expectations related to the staff's ISA and ISA summary review guidance contained in Section 3.4.3.2 of NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility."

Discussion:

It is a staff goal to improve staff efficiency and effectiveness, to make more timely licensing decisions, and to better protect the public health and safety and common defense and security, while meeting the business needs of our licensees and applicants, including efficient use of their staffs' time. In achieving this goal, the dependability, predictability, and suitability of NRC reviews within acceptable time frames will also be established.

In an effort to reach this goal for ISA and ISA summary reviews, the NRC staff has created rules of engagement, contained in this ISG, to be followed by NRC reviewers and licensee/applicant personnel.

Regulatory Basis:

10 CFR 70.62(c) requires the licensees and applicants to conduct and maintain site-wide ISAs and submit associated ISA summaries.

10 CFR 70.65(b) requires that an ISA summary be submitted with a license or renewal application (and amendment application as necessary).

Technical Review Guidance:

The rules of engagement for ISA and ISA summary reviews are as follows:

General

- (a) A public pre-submittal meeting should be conducted if an ISA and ISA summary will contain a high degree of complexity which would result in reviewers requiring further clarification if a meeting were not held. No regulatory decisions will be made at this

meeting.

- (b) The applicant/licensee should properly identify and mark proprietary information submitted to NRC and include an affidavit with any such material. Classified information should also be protected and marked appropriately.

Acceptance Reviews

- (c) The staff will perform an acceptance review (within 60 days of receipt of the initial submittal) to ensure that an initial ISA summary submittal contains sufficient information (based on the guidance of NUREG-1520) to form the basis of an initial review. The applicant/licensee should identify and explain the basis for significant or substantial deviations from the Standard Review Plan (NUREG-1520). If the submittal contains sufficient information, an acceptance letter will be sent within 60 days.
- (d) The staff will not accept ISA summaries that do not contain an appropriate scope of information to support a detailed technical and regulatory review. The staff, in a rejection letter (sent within 60 days of the receipt of the initial submittal), will identify the major information deficiencies, that if not addressed in the resubmitted ISA summary, will likely result in a second rejection. The staff will also identify associated guidance for providing the missing information.
- (e) If a site-wide ISA summary submitted to fulfill the requirements of 10 CFR 70.62(c)(3)(ii) is rejected by the staff, interim compensatory measures commensurate with the risk and consistent with normal enforcement and inspection policy may be considered and imposed.

Schedules

- (f) NRC and the licensee/applicant should agree to clearly set a review schedule that balances the applicant's schedule with the NRC staff's schedule.
- (g) If the applicant/licensee does not meet the agreed-to schedule, review will be rescheduled and may result in the review being placed at the bottom of the priority list. To avoid major rescheduling, if the applicant/licensee is unable to meet the agreed-to schedule for a milestone, a letter must be submitted at least two weeks in advance of the milestone providing the new submittal date and reasons for the requested schedule change. NRC staff will assess the impact on the schedule and advise the licensee/applicant of a possible new schedule as appropriate.
- (h) After an ISA summary has been accepted for review, changes to the submitted summary may impact the schedule. The staff will assess the impact on the schedule due to the summary changes and advise the licensee/applicant of a possible new schedule as appropriate.
- (i) Meetings and/or telephone conference calls to discuss and resolve issues should be held after the ISA summary has been submitted. The applicant/licensee should include commitments made during these meetings and calls in formal written responses

submitted to the staff.

(j)

Requests for Additional Information (RAI)

- (k) The NRC's objective is one RAI that adequately communicates the staff's questions/concerns. The staff's expectation is for a licensee's/applicant's RAI response to adequately address the RAI. If the staff's objective or expectation is not met, additional RAIs may be needed with possible impacts on schedule.
- (l) For each RAI item, the staff will reference a specific regulatory requirement and provide justification for the request.
- (m) The applicant/licensee will have normally 30 days but no more than 60 days to respond to an RAI.
- (n) NRC staff review of an RAI response will not start until a complete response is received resulting in a possible impact on the schedule.

References:

U.S. Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Government Printing Office, Washington, DC.

U.S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," NUREG-1520, 2002.

Approved: _____ Date: _____
Director, NMSS/FCSS