Division of Fuel Cycle Safety and Safeguards Interim Staff Guidance - 05

Additional Reporting Requirements of 10 CFR 70.74

Issue

Effective dates for the additional reporting requirements of 10 CFR 70.74, Appendix A to 10 CFR Part 70, and NRC Bulletin 91-01, "Reporting Loss of Criticality Safety Controls."

Introduction

The purpose of this Interim Staff Guidance (ISG) is to clarify what parts of Appendix A to 10 CFR Part 70 are effective as of October 18, 2000; what parts are effective after the submittal of the Integrated Safety Analysis (ISA) Summary, in accordance with 10 CFR 70.62(c)(3)(ii); and when the reporting requirements in NRC Bulletin 91-01, currently referenced in fuel cycle licenses, are superceded by the requirements of 10 CFR 70.74.

This ISG supplements information in Sections 5.4.1, 5.4.3.4.7, and 11.4.3.6 of NUREG-1520.

The information in NUREG-1718 is not affected by this ISG, because a MOX fuel fabrication facility would be a new facility, and therefore (as with any other new Part 70 facilities) the complete submittal of an ISA Summary (i.e., an ISA Summary covering the entire facility) would be necessary before an operating license could be granted. Thus, all requirements of Appendix A to 10 CFR Part 70 would apply to a facility of this type and the provisions of NRC Bulletin 91-01 would not apply.

Discussion

After October 18, 2000, existing licensees must comply with the reporting requirements of (a)(1), (a)(2), and (b)(4) of Appendix A to Part 70. The new reporting requirements require reporting, (1) to the NRC Operations Center within 1 hour: an inadvertent nuclear criticality, and an acute intake by an individual of 30 mg or greater of uranium in a soluble form; and (2) to the NRC Operations Center within 24 hours any natural phenomenon or other external event (including fires internal or external to the facility) to the facility that has affected or may have affected the intended safety function, availability, or reliability of one or more items relied on for safety. All the other reporting requirements listed in Appendix A are held in abeyance until after the complete submittal of the ISA Summary provided in accordance with 10 CFR 70.62(c)(3)(ii). "Complete submittal" means that an ISA summary that includes the entire facility and all licensed processes must have been submitted to NRC. Partial ISA Summary submittals under 10 CFR 70.62(c)(3)(ii) or as part of a license amendment do not meet this criterion.

Many existing fuel facility licenses include reporting requirements in accordance with NRC Bulletin 91-01. These remain conditions of these licenses until the complete submittal of the ISA Summary to NRC, and NRC has issued a licensing action to delete these requirements. Therefore, between October 18, 2000, and complete submittal of the ISA Summary, both the requirements of Bulletin 91-01 (as committed to in the license) and paragraphs (a)(1), (a)(2), and (b)(4) of Appendix A of Part 70 apply. Following complete submittal, the NRC

Bulletin 91-01 requirements in the license will be superceded by the requirements of 10 CFR 70.74 upon issuance of an NRC licensing action to effect this change. It should also be noted that additional immediate reporting requirements in 10 CFR 20.2202(a) and 10 CFR 70.50(a) still apply.

It is expected that many of the reporting requirements of Appendix A of Part 70 will cover existing license provisions pertaining to NRC Bulletin 91-01. If this is true, then meeting the Appendix A requirements will be sufficient. If this is not true, then both sets of reporting requirements must be met until the NRC takes licensing action to delete the existing Bulletin 91-01 requirements.

A new facility would require submittal of an ISA Summary prior to being licensed, and thus, for a new Part 70 facility (e.g., gas centrifuge or MOX facility), all the provisions of Appendix A to Part 70 apply.

Regulatory Basis

Each licensee shall report to the NRC Operations Center the events described in Appendix A to Part 70. [10 CFR 70.74(a)(1)]

Licensees must comply with the reporting requirements in this appendix, except for (a)(1), (a)(2), and (b)(4), after they have submitted an ISA Summary in accordance with §70.62(c)(3)(ii). Licensees must comply with (a)(1), (a)(2), and (b)(4) after October 18, 2000. [Appendix A to Part 70]

Specific reporting requirements are contained in paragraphs (a), (b), and (c) of Appendix A to Part 70.

Technical Review Guidance

The staff has concluded that an applicant complies with the reporting requirements of its license and 10 CFR Part 70 provided that the following is met:

- An existing licensee has a program in place that requires reporting the events listed under paragraphs (a)(1), (a)(2), and (b)(4), of Appendix A of Part 70. By a "reporting program" is meant a formal mechanism codified in plant procedures to ensure that events are appropriately reported to the NRC.
- An existing licensee has a program in place that requires reporting all events listed under Appendix A of Part 70 upon complete submittal of its ISA Summary, as required under 10 CFR 70.62(c)(3)(ii).
- An existing licensee has a program in place that requires reporting the loss of double contingency protection, as required by its license commitments to follow NRC Bulletin 91-01, prior to complete submittal of its ISA Summary as required under 10 CFR 70.62(c)(3)(ii) and subsequent NRC licensing action to eliminate the NRC Bulletin 91-01 requirements.

 A new applicant has a program in place that requires reporting all events listed under Appendix A of Part 70 upon complete submittal of its ISA Summary as required under 10 CFR 70.62(c)(3)(ii).

Recommendation

Whereas the complete submittal of a licensee's ISA Summary is required no later than October 18, 2004 (per 10 CFR 70.62(c)(3)(ii)), no change to NUREG-1520 is warranted to reference NRC Bulletin 91-01. All the provisions of Appendix A of Part 70 will apply upon complete submittal of the ISA Summary.

References

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NRC Bulletin 91-01, "Reporting Loss of Criticality Safety Controls," October 18, 1991.

NRC Bulletin 91-01, Supplement 1, "Reporting Loss of Criticality Safety Controls," July 27, 1993.

Approved: ___

___ Date: _____

Director, NMSS/FCSS

Division of Fuel Cycle Safety and Safeguards Interim Staff Guidance - 06

Correcting Performance Deficiencies and Implementing Corrective Measures

Issue:

Timing for existing licensees to submit and obtain NRC approval of alternative schedules for correcting unacceptable performance deficiencies identified during the conduct of an Integrated Safety Analysis (ISA).

Introduction:

The purpose of this Interim Staff Guidance (ISG) is to clarify the requirements associated with the correction of unacceptable performance deficiencies identified during the conduct of the ISA, and to ensure that existing licensees who identify unacceptable performance deficiencies that cannot be corrected by October 18, 2004, have a process for requesting additional time with which to effect corrective actions.

Discussion:

10 CFR 70.62(c)(3)(ii) requires existing licensees to complete an ISA, correct all unacceptable performance deficiencies identified during the conduct of the ISA, and submit for NRC approval, an ISA summary no later than October 18, 2004. 10 CFR 70.62(c)(3)(iii) requires the licensee to implement appropriate compensatory measures to ensure adequate protection while the unacceptable performance deficiencies are being corrected.

70.62(c)(3)(ii) offers existing licensees a process for requesting additional time with which to effect corrective actions for the performance deficiencies identified during the conduct of the ISA. 70.62(c)(3)(ii) states that an alternative schedule may be approved if the alternative is warranted by the following considerations: (a) adequate compensatory measures have been established; (b) technical feasibility of completing the corrective actions by October 18, 2004; and (c) other site-specific factors considered on a case-by-case basis that are beyond the control of the licensee.

Regulatory Basis:

10 CFR 70.62(c)(3)(ii) and (iii)

Technical Review Guidance:

10 CFR 70.62(c)(3)(ii) does not state that a request for an alternative schedule must be submitted and approved prior to the required October 18, 2004, deadline for submitting an ISA summary. However, as a practical matter, in order for an existing licensee to meet the October 18, 2004, date to correct all unacceptable performance deficiencies (which is an explicit regulatory requirement), it would be reasonable for a licensee seeking an alternative schedule to submit this request so as to allow sufficient time for the staff to review and, if appropriate, approve the request prior to October 18, 2004.

NRC approval of the alternative schedule will consider whether the identified compensatory measures result in the deficient accident sequence meeting the performance requirements, the complexity and feasibility of implementing the intended items relied on for safety (IROFS), site-specific factors, factors beyond the control of the licensee, and the adequacy of the compensatory measures. In determining compensatory measures, licensees may need to deviate from their ISA methodology. Doing so would be a reason that NRC review of the alternate schedule and compensatory measures is required.

If the licensee can demonstrate that performance requirements continue to be met through the use of compensatory measures, NRC approval would normally be given. If the licensee cannot demonstrate meeting the performance requirements, the staff will consider the acceptability of the compensatory measures on a case-by-case basis. If the schedule for correcting the unacceptable performance requirements or the licensee's proposed actions are not acceptable, the staff must make a determination as to whether there is adequate assurance of safety for continuing the process in question.

Recommendations:

This guidance should be used in conjunction with Chapter 3.0 of NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," in the review of an existing licensee's ISA summary to ensure that an alternative schedule has been approved by NRC and that acceptable compensatory measures have been identified for deficiencies discovered by the existing licensee during the conduct of its ISA.

References:

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

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

Approved: ____

Date: _____

Director, NMSS/FCSS

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 submittel 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.

Requests for Additional Information (RAI)

- (j) 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.
- (k) For each RAI item, the staff will reference a specific regulatory requirement and provide justification for the request.
- (I) The applicant/licensee will have normally 30 days but no more than 60 days to respond to an RAI.
- (m) 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

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