

DISPOSITION OF JULY 8, 1999 STAFF REQUIREMENTS MEMORANDUM ISSUES ON PROPOSED PART 70 RULEMAKING

In response to SECY-99-147, the Commission issued a Staff Requirements Memorandum (SRM), dated July 8, 1999. The Commission approved for public comment the proposed rulemaking for Part 70 related to the domestic licensing of special nuclear material.

One area covered by the Commission comments is backfit. The Commission approved the staff's position to defer a backfit provision until the safety basis has been established and incorporated in the license, and after licensees and staff have gained experience with implementation of the Integrated Safety Analysis (ISA) requirements of the rule. At the same time, the Commission directed that the rulemaking package for the final rule should include the staff's assessment, justification, and conclusions concerning the backfit provision. Further, the Commission directed the staff to solicit public comments on what would constitute a reasonable period of time, including supporting rationale, before a backfit provision should be implemented.

The Commission also directed the staff to:

1. Consider the use of public meetings and workshops to discuss and refine the proposed rule requirements and associated guidance, in particular the ISA summary and the Standard Review Plan (SRP);
2. Ensure that decommissioning guidance for fuel cycle licensees includes consideration of the risks addressed in the operational ISA;
3. Reconsider the reporting frequency for ISA summary updates since it appeared that the 90-day frequency in the proposed rule is inconsistent with comparable requirements placed upon power reactor licenses; adopt an annual update absent a compelling justification to the contrary; and solicit public comments on the 90-day frequency for reporting ISA summary updates;
4. Ensure that terms such as "unlikely" and "promptly," and the context of their use are defined clearly in the final SRP; and
5. Ensure that the SRP continues to clearly acknowledge that licensees and applicants may provide alternative approaches to those presented in the SRP.

The following discussion describes how the staff implemented the Commission direction.

Issue 1: Backfit

A. Commission Direction in SRM to SECY-99-147

The Commission, in the SRM on SECY-99-147, directed the staff as follows:

"...The Commission has approved the current staff position to defer a backfit provision until the safety basis has been established and incorporated in the license, and after licensees and staff have gained experience with the implementation of the integrated safety analysis (ISA) requirements of the rule. The Federal Register notice should solicit comments on what would constitute a reasonable period of time, including supporting rationale, before a backfit provision should be implemented. The rulemaking

package for the final rule should include the staff's assessment, justification, and conclusions concerning a backfit provision..."

B. Staff Response to SRM

All comments received on backfit recommended that a backfit provision similar to that in 10 CFR 50.109 or 10 CFR 76.76 should be included in the rule. In general, the comments also favored an immediately effective provision.

A backfit provision is included in the final rule as §70.76 to help ensure consistent application of regulations as well as the consideration of costs and benefits for changes imposed on licensees resulting from changes in staff positions.

The proposed wording in § 70.76 is similar to the current language in §76.76 for gaseous diffusion plants with two exceptions, sections 70.76 (a)(3) and 70.76 (a)(4)(i). The change in section 70.76(a)(3) relates to a change of the standard from "substantial increase" to "increase" and is responsive to Commission direction in an SRM dated December 1, 1998, on the draft proposed rule. § 70.76(a)(4)(i) relates to the backfit requirements being inapplicable to changes associated with bringing the facility in compliance with the requirements of the new subpart H. In addition, provisions have been added to the final rule package identifying when the backfit provision goes into effect. For each licensee, the backfit provision becomes effective for subpart H requirements as soon as NRC approves that licensee's ISA summary pursuant to § 70.66; for requirements other than Subpart H, it becomes effective immediately after NRC publication of backfit guidance.

Attachment 6 to this Commission paper includes a discussion of the staff's reasoning for the proposed resolution regarding backfit.

Issue 2: Decommissioning Guidance for Fuel Cycle Licensees

A. Commission Direction in SRM to SECY-99-147

The Commission, in an SRM to SECY-99-147, directed the staff as follows:

"...The staff should ensure that decommissioning guidance for fuel cycle licensees includes consideration of the risks addressed in the operational ISA..."

B. Staff Response to SRM

The SRP being developed for the revised Part 70 contains a decommissioning chapter which references a draft decommissioning SRP being developed in the Division of Waste Management. The decommissioning SRP addresses the risks analyzed in the ISA. It states that, for Part 70 licensees, the decommissioning plan should include a summary of how the licensee will ensure that the risks addressed in the facility's ISA, including nuclear criticality safety risks, will be addressed during decommissioning.

Issue 3: Reporting Frequency for ISA Summary Updates

A. Commission Direction in SRM to SECY-99-147

The Commission, in an SRM to SECY-99-147, directed the staff as follows:

“...The reporting frequency...needs to be reconsidered. It appears that the 90-day frequency proposed by the staff is inconsistent with comparable requirements placed upon reactor licensees. The staff should solicit specific comments from stakeholders on this issue during the public comment period. Absent a compelling justification to the contrary, the staff should adopt an annual update requirement.”

B. Staff Response to SRM

Comments received on this subject in response to the Commission request recommended that the 90-day reporting requirement be changed to 12-24 months.

In developing the final rule, the staff was responsive to the Commission direction considering the differences in the change process associated with §70.72 and §50.59 for reactors, the comments received, and the staff’s need to know, in a reasonably timely manner, significant facility changes that have been made without staff pre-approval.

The revised §70.72 language is as follows:

“for any changes that affect *the list of items relied on for safety contained in the integrated safety analysis summary*, as submitted in accordance with §70.65, but do not require NRC pre-approval, the licensee shall submit revised pages to the integrated safety analysis summary, to NRC, *quarterly, within 30 days after the end of the calendar year quarter.*”

“A brief summary of all changes to the records required by Sec. 70.62(a)(2) of this part, that are made without prior Commission approval *and revised pages to the integrated safety analysis summary*, must be submitted to NRC *annually, within 30 days after the end of the calendar year.*”

The revised language (shown above in italics) retains the 90-day (quarterly) reporting only for changes related to the items relied on for safety; all other changes required under the proposed rule language to be reported in 90 days would be relaxed to annually. Furthermore, “90 days” in the proposed rule has been changed to “quarterly” to emphasize that the rule does not require continual reporting, as some commenters interpreted the proposed rule. Rather, all changes that affect the items relied on for safety that were made in a quarter can be reported at one time and still meet the 90-day time period that was in the proposed rule.

The revised rule language is based on the analogy that “items relied on for safety” in Part 70 are generally equivalent to “technical specifications” in Part 50, in that they both establish the safety envelope for facility operations. Attachment 6 includes a description of the staff’s reasoning for the proposed resolution regarding reporting frequency for ISA summary updates.

Issue 4: Definition of terms such as “unlikely” and “promptly”

A. Commission Direction in SRM to SECY-99-147

The Commission, in an SRM to SECY-99-147, directed the staff as follows:

“...The staff should ensure that such terms [“unlikely” and “promptly”] and the context of their use are defined clearly in the final SRP.”

B. Staff Response to SRM

The rule language does not specify the definitions of “unlikely” and “highly unlikely” and requires that applicants and licensees provide to NRC the definitions of these terms as the applicant/licensee has applied them. In Chapter 3 of the draft SRP, the staff provides guidance for the definition of the terms “unlikely” and “highly unlikely.”

With respect to “promptly,” the staff provided guidance for the definition of the term “promptly” in SRP chapter 11 as “within five working days.” The term “promptly” is used in the rule as follows:

1. § 70.62(a)(3): “A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure.”
2. § 70.72(e): “If a change covered by § 70.72 is made, the affected on-site documentation must be updated promptly.”

Issue 5: Alternative approaches to those presented in the SRP

A. Commission Direction in SRM to SECY-99-147

The Commission, in an SRM to SECY-99-147, directed the staff as follows:

“...the staff should ensure that the SRP continues to clearly acknowledge that licensees and applicants may provide alternative approaches to those presented in the SRP...”

B. Staff Response to SRM

The SRP makes clear that alternate approaches to meeting NRC regulations are acceptable by stating in the Introduction that the SRP

“...is a guidance document...” and “...does not prevent licensees or applicants from suggesting alternate means of demonstrating compliance...”

Also, in the body of the SRP, additional language has been included to reinforce this perspective, e.g.,

“...an applicant that has met the following acceptance criteria, or has provided an acceptable alternative, should be considered to have an acceptable...program.”

Issue 6: Use of Public Meetings and Workshops / Use of web

A. Commission Direction in SRM to SECY-99-147

“...The staff should consider the use of public meetings and workshops to discuss and refine the proposed rule requirements and associated guidance, in particular, the ISA summary and the Standard Review Plan. The ISA Guidance Document and updated versions of the draft SRP should be posted on the web to enhance distribution and solicitation of input. During the public comment period and development of the final rule, the staff should make continued use of NRC’s website...”

B. Staff Response to SRM

With respect to the Commission direction on public meetings and workshops, the staff held public meetings and workshops on September 14-15, 1999, February 9, 2000 and April 18-19, 2000. At the September meeting, the staff presented the provisions of the proposed rule in order to facilitate comments. Following that presentation, stakeholder comments on the Part 70 Standard Review Plan were discussed.

At the February meeting, the staff’s proposed resolutions of stakeholder comments on the SRP were discussed. Following the February meeting, revised chapters of the Standard Review Plan were posted on the NRC website. At the April meeting, these revised chapters, stakeholder comments, and the staff’s proposed resolutions to those comments were discussed. The chapters were further revised based on the written comments received and the discussions at the April meeting. The views expressed at the conclusion of the April meeting was that there is general agreement on all chapters of the SRP except chapter 11. On chapter 11 (management measures), the differences were characterized as philosophical in nature as follows:

- The NEI/Industry view expressed at the April meeting: for existing licensees, the management measures should be limited to programs currently in place, and documentation of management measures should be limited to that in existing approved license applications.
- The NRC staff view: sufficient information on management measures needs to be submitted to enable the staff to conclude, with reasonable assurance, that the management measures applied to items relied on for safety, as documented in the ISA Summary, ensure that the items will be available to perform their functions, when needed, consistent with the performance requirements of 10 CFR 70.61. Staff recognizes that documentation in existing license applications address related requirements under current Part 70 requirements. The SRP is not solely driven by subpart H requirements, but also by the existing Part 70 requirements. For example, documentation has already been submitted in relation to certain requirements for approval listed in 70.23, i.e., the applicant is qualified by reason of training and

experience; proposed equipment and facilities are adequate, and applicant's proposed procedures to protect health are adequate. No further documentation would be needed if the existing documentation of management measures in the license application is sufficient to satisfy the new subpart H requirements.

Subsequent to the April meeting, the concern with respect to chapter 11 was clarified. The NEI/industry concern appears to be related to the level of detail that will be needed in the description of management measures, rather than general disagreement with the need to document this information. Staff is making arrangements for a meeting with stakeholders to consider some examples developed by the industry, and to discuss the level of detail, with respect to management measures, necessary to satisfy the rule.

With respect to the ISA summary, NEI is coordinating the development of industry guidance relating to the content of these submissions. NRC staff provided comments on a proposed outline, and will provide comments on drafts of the guidance as they are developed and made available to NRC staff for review.

With respect to the Commission direction regarding use of the NRC website, the staff continued using that website to enhance distribution of Part 70 related material and solicit input. The staff posted letters received from stakeholders containing comments on the rule and the Standard Review Plan, the staff's proposed resolution of comments provided on the Standard Review Plan, and revised chapters of the Standard Review Plan.