

DISCUSSION OF MAJOR ISSUES PART 70 PROPOSED RULE

The major subject areas for which comments on the proposed rule were received and changes made to the proposed rule text were: (1) the time period for reporting changes made to the ISA summary; (2) backfit; (3) degree of detail in the ISA summary; (4) failure log for items relied on for safety; and (5) extension of period for completion of the ISA. These subject areas are discussed below.

1. Time period for reporting changes made to the ISA summary.

The proposed rule required that, for any changes that affect the ISA summary, licensees submit revised pages of the ISA summary to NRC within 90 days of the change. The justification for the 90-day update was the need for the staff to be informed about the changes within a reasonable amount of time, and, if necessary, to discuss the basis for the change with the licensee.

In its SRM dated July 8, 1999, the Commission stated that "...the reporting frequency for the ISA summary updates needs to be reconsidered. It appears that the 90-day frequency proposed by the staff is inconsistent with comparable requirements placed on reactor licensees... Absent a compelling justification to the contrary, the staff should adopt an annual update requirement." Several comments received on the proposed rule supported the view that the 90-day reporting is burdensome and recommended that the frequency be changed to annual.

The revised rule language only retains the 90-day (i.e., quarterly) reporting for changes related to the items relied on for safety; all other changes which were required in the proposed rule to be reported in 90 days would now be reported to NRC annually.¹ Furthermore, "90 days" in the proposed rule has been changed to "quarterly" to emphasize that the rule does not require continual reporting. Rather, all changes that affect the items relied on for safety that were made in a 3-month period can be reported at one time.

The revised rule language provides change reporting under Part 70 that is generally consistent with the comparable requirements placed on reactor licensees, considering a general equivalence between "items relied on for safety" in Part 70 and "technical specifications" in Part 50. The nature of technical specifications and the items relied on for safety is as follows:

- ! With respect to technical specifications, §50.36 states that technical specifications include safety limits; limiting safety system settings; limiting control settings; limiting conditions for operation; surveillance requirements; design features, which if altered or modified, would have a significant effect on safety;

¹This would include information other than that relating to items relied on for safety contained in the ISA summary, such as information demonstrating compliance with performance requirements, including a description of the management measures, and descriptions of: the site; the facility; each process analyzed in the ISA; criticality monitoring and alarms; ISA team qualifications and methods; and the proposed standards for chemical exposure.

and other items. Essentially, the technical specifications establish the safety envelope of the facility.

- ! 70.4 defines “items relied on for safety as “...structures, systems, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in §70.61 or to mitigate their potential consequences...” Since the items relied on for safety are what maintains operation of the facility within the performance requirements, they too establish the safety envelope of the facility.

Considering the parallel between technical specifications and items relied on for safety, the revised rule language is viewed as less onerous than the reporting requirements for reactors, when considering the differences in the respective change control processes. In particular, for reactors, all changes to technical specifications must be pre-approved by NRC, effectively requiring the reporting of all changes to technical specifications before the change is made. The revised Part 70 language is not as restrictive -- it allows some changes to items relied on for safety to be made without NRC pre-approval and subsequently reported to NRC quarterly.

In conclusion, the revised 10 CFR 70.72 reporting would allow licensees flexibility yet still enable the staff to be knowledgeable of the changes within a reasonable amount of time, and if necessary, discuss the basis for the change with the licensee. The change from the proposed rule language is responsive to the Commission direction, responsive to the comments received, and permits the staff to know, in a reasonably timely manner, facility changes that have been made to the safety envelope without staff pre-approval. A more detailed discussion of this issue, including examples, is provided in the Annex to this attachment.

2. Backfit.

The proposed rule did not contain a backfit provision. Without a baseline determination of risk, as provided by the initial ISA process, it was not clear how a determination of incremental risk, as needed for a backfit analysis, would be accomplished. In its SRM dated July 8, 1999, the Commission directed the staff to “...solicit comments on what would constitute a reasonable period of time...before a backfit provision should be implemented.” Comments received on backfit supported the establishment of an immediately effective backfit provision. In responding to the comments received, the staff has included a backfit provision, §70.76, in the final rule. §70.76 states that “For each licensee, this provision shall become 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, this provision becomes effective immediately after NRC publication of backfit guidance.”

The 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).

With regard to §70.76(a)(3), the corresponding language in Part 76 is:

“... the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of public health...”
(underline added).

In §70.76(a)(3), the word “substantial” has been removed and now reads “... that there is an increase in the overall protection of public health...”

The change to §70.76(a)(3) was made as a result of the Commission direction contained in the December 1, 1998 SRM for the draft rule package as follows:

"The Commission supports a requirement that any new backfit pass a cost-benefit test, without the "substantial" increase in safety test. The Commission believes that modest increases in safety at minimal or inconsequential cost could be justified on a cost benefit basis".

With regard to §70.76(a)(4), as in Part 76, this section states that backfit analyses do not need to be performed in specific circumstances including situations where the change is required for the licensee to come into compliance with a regulation. The §70.76 language retains all of the current §76.76 language and adds another subsection which clearly states that backfit analyses are not required for those changes required for the licensees to come into compliance with Subpart H. This added provision can be viewed as being encompassed by the existing §76.76(a)(4)(i) which is included as §70.76(a)(4)(ii). However, §70.76(a)(4)(i) has been added to remove any confusion concerning the applicability of backfit analysis to facility changes required to satisfy the new performance requirements of Subpart H.

Staff plans to develop guidance based on the guidance that has already been developed for implementation of the Part 76, 72.48, and 50.109 backfit provisions. The guidance would resolve the technical issues associated with implementation of the backfit provision. One of these issues is the changing of “substantial increase” to “an increase” in §70.76(a)(3) as stated above. This change will have to be addressed in the new guidance and a description of what costs justify “an increase” will have to be developed. The Part 76 guidance contains examples of factors which can be used to assess the “substantial increase” clause. Another issue to be considered in the new guidance is how to analyze risks and perform cost benefit analyses for chemical exposures associated with the processing of special nuclear material. The guidance developed by NMSS to implement §76.76 (Policy and Procedures Letter 1-53) clearly states that there is no current guidance on chemical exposure in NUREG/BR-0058. Instead the guidance states that it will use the “net benefits” approach in NUREG/BR-0058. This approach involves the use of a qualitative non-monetary methodology to derive the value of the safety/safeguards improvement, taking into consideration the specific facility hazards. This approach may be in opposition to industry submitted comments in their February 12, 1999 letter which indicated that a quantitative approach should be used to the maximum extent possible. Consequently, the staff anticipates that developing guidance on this issue may be challenging and controversial.

Staff plans to engage stakeholders actively in the development of the guidance document. In fact, the staff would prefer if stakeholders draft an initial version of the guidance for the NRC's consideration. After the rule is published and the technical aspects discussed above are further examined (by NMSS, OGC, Regions and CRGR), the staff plans to solicit public comments on the staff's resolution of the issues before a draft document is written, and solicit a draft of the guidance document prepared by stakeholders. With consideration of these comments and suggested text, a draft document will be developed by staff and published for public comment. The staff plans to conduct a series of public meetings to discuss issues at the various stages in the process. After consideration of comments and meeting discussions, the guidance will be developed and published following NMSS, OGC, Regional and CRGR review and approval. Training sessions for the staff on how to implement this process will be held after the guidance is approved.

3. Degree of detail in the ISA summary.

The proposed rule required the submission of an ISA Summary with each application for a license, license renewal, or license amendment (as necessary). The rule also identified the information that must be contained in the ISA Summary [70.65(b)(1)-(9)]. In the SRM dated July 8, 1999, the Commission directed the staff to consider, after discussions at public meetings and workshops, revisions to the requirements on the contents of the ISA summary. The comments on the level of detail in the ISA summary were not extensive and were limited to suggesting that: (1) the prescriptive footnote describing "types of accident sequences" be removed from the rule, (2) items relied on for safety be described at a "systems level" rather than "in sufficient detail to understand their functions in relation to the performance requirements," and (3) the description of processes be limited to those that have "safety implications." In response to the first suggestion, the footnote has been removed, and additional guidance regarding "types of accident sequences" has been provided in the SRP. With respect to the second suggestion, no change in the rule language has been made, because the staff believes the current language allows for the description of items relied on for safety at a "systems level," and because the staff believes it is necessary to understand the functions of the items relied on for safety. In response to the third suggestion, no change in the rule language has been made because the staff believes it is necessary for NRC to review the completeness of the ISA. Although the staff agrees with the general intent of the comment, its adoption could adversely affect the effectiveness and efficiency of the staff's review by removing information from the reviews that is important to evaluating the thoroughness of the ISA and the staff's understanding of the processes.

Section 70.66(c)(2) has been added to the rule to clarify that the level of detail in the ISA Summary, together with other information available, must be sufficient for NRC to conclude that the performance requirements are satisfied.

In addition, the staff is working with Stakeholders currently developing an ISA Summary guidance document. 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.

4. Failure log for items relied on for safety.

The proposed rule required that licensees establish and maintain a log documenting when any item relied on for safety fails to perform its function. Such information may be useful to licensees and the NRC in assessing the basis for evaluating the likelihood of item failure or the adequacy of management measures for these items relied on for safety. The comments received reflected concern with the prescriptive nature of the rule language and suggested that a performance-based approach would be preferable. For example, a view expressed in a comment was, as long as the failure information is properly tracked, and as long as that information can be readily retrieved for NRC inspection, the means of accomplishing those objectives should not be a consideration. In response to the comments, the rule language has been changed, as recommended, to incorporate a performance-based approach. The final rule, therefore, does not require that licensees maintain a log of such failures, as long as the information is readily available and retrievable.

5. Extension of period for completion of the ISA.

The proposed rule required that existing licensees complete an ISA, correct all unacceptable deficiencies, and submit an ISA summary within four years of the effective date of the rule. One comment expressed concern with the recommended time period, and suggested that it be extended to five years. The staff believes that the four-year time period in the proposed rule is reasonable. Most of the licensees to which the rule applies are already well advanced in performing ISAs. However, the staff recognizes that there may be some instances where modifications resulting from the ISA cannot be completed within the four years specified for reasons that are beyond the control of the licensee. Accordingly, the rule language has been changed to accommodate these instances by adding a provision under which the period for implementing can be extended by the NRC if the delay is necessary for reasons beyond the licensees' control.

6. Other issues.

In the Federal Register Notice that contained the proposed rule, the Commission requested public comment on the flexibility permitted in the ISA methodology to be able to accommodate a wide range of technologies, and on other options for accomplishing the NRC-OSHA interface with respect to regulation of chemical hazards. With respect to the first issue, one comment was received which stated that "...the proposed rule offers sufficient flexibility in selecting ISA methodologies so that a broad spectrum of facilities can be addressed." Further, no comments were received on the ISA guidance document (Attachment 7). Consequently, no change to the rule or guidance is necessary to resolve this issue.

With respect to the second issue, one comment was received which stated that the proposed rule incorporates the current terms of the MOU between NRC and OSHA and that "this should result in more effective implementation for all concerned parties." The NRC staff agree with this assessment. Consequently, no changes are required to address the second issue.

According to some comments, the provisions in the existing rule for facilities that process plutonium are not needed because they are superseded by the new Part 70 requirements in subpart H. The subpart H requirements to the rule do not supersede the plutonium requirements, i.e., there are different timing requirements for submission of information. Furthermore, the Commission specifically established these requirements for plutonium facilities in recognition of the greater radiological hazards and the need for containing releases associated with plutonium processing.

Some commenters were concerned that the use of the term “ensure” in the definition of *available and reliable* implied a level of certainty that was unrealistically high. However, the staff believes that the use of the term is appropriate and consistent with its usage throughout NRC regulations. Retention of this term in the definition means that licensees are required to implement the necessary management measures to “ensure” that items relied on for safety will be available and reliable as necessary to protect workers and the public in accordance with the performance requirements.

Given the new licensing regime which, in effect, requires the maintenance of a “living license,” some commenters stated that a license term of twenty years or more for fuel cycle facilities was justified and should be included in the rule. While the staff agrees that a longer time period for license terms may be appropriate, it currently has the flexibility to increase the duration of licenses (as it has done in the past) and does not believe a change in the rule language is needed. Indeed, the staff is considering this issue for fuel cycle and other licensees as part of the FY02 budget development.

ANNEX TO
ATTACHMENT 6

PART 70 RULEMAKING
10 CFR 70.72(d) - 90 DAY CHANGE REPORTING REQUIREMENT

The proposed Part 70 rule (published in the FRN in July 1999) includes the following provision:

“for any changes that affect 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, within 90 days of the change.”

The staff’s reasoning for the 90-day update, as described in the Statement of Considerations (SOC) that accompanied the proposed rule, was as follows:

“Past incidents at fuel cycle facilities have often resulted from changes not fully analyzed, not authorized by licensee management, or not adequately understood by facility personnel. Therefore, effective control of changes to a facility’s site, structures, systems, equipment, components, and activities of personnel is a key element in assuring safety at that facility. This section would require the licensee to establish and use a system to evaluate changes and the potential impacts of those changes before implementing them. By using this system to evaluate, implement and track changes to the facility, the licensee can make certain changes without NRC pre-approval. If the change affects information contained in the ISA summary, the licensee would be required to notify NRC within 90 days of the change by submitting updated ISA summary pages in that time... . This update frequency would allow NRC staff to review the changes being made to the facility in enough time to ensure that the licensee’s evaluations of potential impacts to health and safety were accurate. It also allows NRC staff to maintain relatively current facility and safety information on the docket at all times. In addition, maintaining the license and ISA summary so that they reflect the current configuration of the facility would facilitate a relatively simple, cost-effective license renewal process... .

...Option 1 [the option reflected in the proposed rule] is consistent with the types of changes that have required pre-approval at Part 70 licensees in the past, and which the staff believes would require NRC pre-approval for only a relatively few significant changes... . *Since Option 1 would permit more changes without NRC pre-approval [as compared to option 2, which is based on 10 CFR 50.59 language], a relatively short timeframe (90 days) for submitting updated ISA summary pages is required in order for NRC to have information that reflects the current status of the facility and to be confident that adequate protection is still provided with the changes, as reflected in the ISA summary.*“ [italics added]

As reflected in the SOC, the change provision in the proposed rule differed significantly from the change provision used for reactors (i.e., option 2 in the proposed rule) in that the staff believes that it would allow more changes without NRC pre-approval than permitted by the change provision used for reactors. Accordingly, since the §70.72 provision in the proposed

rule was less restrictive, that is, more changes would be permitted without NRC pre-approval, the staff felt that a shorter timeframe for reporting these changes to NRC after the change was made would be appropriate, especially in light of the NRC's experience in regulating the fuel cycle facilities.

In the SRM dated July 8, 1999, the Commission commented that "the reporting frequency for the ISA summary updates needs to be reconsidered. It appears that the 90-day frequency proposed by the staff is inconsistent with comparable requirements placed on 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." Comments received on the proposed rule supported the view that the 90-day reporting is burdensome and recommended that the frequency 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.

To satisfy all of these needs, the §70.72 language was revised 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 close of the calendar year quarter in which the changes occurred."

"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 close of the calendar year in which the changes occurred."

The revised language (shown in italics) retains the 90-day reporting only for changes related to the items relied on for safety; all other changes which were required in the proposed rule to be reported in 90 days would now be reported to NRC annually.² 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 indicated. 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. The nature of technical specifications and the items relied on for safety is as follows:

² This would include information other than that relating to items relied on for safety contained in the ISA summary, such as information demonstrating compliance with performance requirements, including a description of the management measures, and descriptions of: the site; the facility; each process analyzed in the ISA; criticality monitoring and alarms; ISA team qualifications and methods; and the proposed standards for chemical exposure.

- With respect to technical specifications, §50.36 states that technical specifications include safety limits; limiting safety system settings; limiting control settings; limiting conditions for operation; surveillance requirements; design features, which if altered or modified, would have a significant effect on safety; and other items. Essentially, the technical specifications establish the safety envelope of the facility.
- 70.4 defines “items relied on for safety as “...structures, systems, components, and activities of personnel that re relied on to prevent potential accidents at a facility that could exceed the performance requirements in §70.61 or to mitigate their potential consequences....” Since the items relied on for safety are what maintains operation of the facility within the performance requirements, they too establish the safety envelope of the facility.

Considering the parallel between technical specifications and items relied on for safety, the revised rule language is viewed as less onerous than the reporting requirements for reactors, when considering the differences in the respective change control processes. In particular, for reactors, all changes to technical specifications must be pre-approved by NRC, effectively requiring the reporting of all changes to technical specifications before the change is made. The revised Part 70 language is not as restrictive -- it allows some changes to items relied on for safety to be made without NRC pre-approval and subsequently reported to NRC quarterly.

In conclusion, the revised 10 CFR 70.72 reporting would allow licensees flexibility yet still enable the staff to be knowledgeable of the changes within a reasonable amount of time, and if necessary, discuss the basis for the change with the licensee. The change from the proposed rule language is responsive to the Commission direction, responsive to the comments received, and permits the staff to know, in a reasonably timely manner, facility changes that have been made to the safety envelope without staff pre-approval.

Examples

The following describes four examples of how the change control process described in the final rule would work and shows how the licensee would report those changes to the NRC. Figure 1 is a flow diagram for the §70.72 change process and graphically represents the decisions which need to be made to determine if a change to the facility must be pre-approved by the NRC. Table 1 is an example list of the items relied on for safety which would be included in an ISA summary. (This is only an example for the purposes of this paper, and is not intended to represent the only way a list of items relied on for safety can be formatted). By using the figure and the table the staff has developed a few examples of changes at a facility³.

³ It is important to note that changes which are required to be reported are dependent on the content and description of the licensee’s list of items relied on for safety. The examples assume items relied on for safety as described in Table 1.

Example #1 - New Calciner

The first example of a change to a facility is the installation of a new calciner (a furnace used to heat and oxidize or reduce uranium). The licensee is considering adding a new larger calciner in a portion of a building which is currently being used for storage. This change would require new piping, electrical, and safety equipment, all of which needs to be scaled up from the equipment which is currently at the facility because of the increased size of the calciner.

Based on the flow diagram in Figure 1, this change could create new types of accident sequences which would then require pre-approval by NRC. If it does not create new types of accident sequences, then pre-approval would still be needed if the change involved equipment or technology for which the licensee does not have prior experience. This is an example of a change that most likely would require pre-approval by NRC.

Example #2 - New Ammonium Hydroxide Storage Tank.

Table 1 contains an item relied on for safety which states that a worker is required to check the level in the tank before receiving a load of uranium contaminated ammonium hydroxide. In this example, the size of the tank is increased to the extent that it could hold two full loads of ammonium hydroxide. Based on the frequency of reprocessing of the material and the shipment schedule, it is not considered possible to overfill the tank. With this change, the action of checking the tank level is considered to be no longer needed and is removed from the list of items relied on for safety.

On the flow diagram this change would not create new types of accident sequences, it is not a new technology, it does not remove an item relied on for safety without an equivalent replacement (the operator action is replaced by the larger tank) and it does not replace a sole item relied on for safety. Therefore, it passes the §70.72 change process requirements and does not require pre-approval. However, the change does result in a change to the list of items relied on for safety and a revised page would have to be submitted as part of the quarterly report.

Example #3 - Changes to the Fire Sprinkler System.

The licensee is considering erecting a wall in building A which would separate the main area of a processing room, which requires fire suppression, from a small storage area which will not contain any flammable material. The sprinkler system is not considered necessary to be present in the storage area, and would be removed.

As in the previous example, this change would pass the §70.72 requirements and would not require NRC pre-approval. Because on the list of items relied on for safety, this particular item relied on for safety is so broad (i.e., "fire sprinkler system") this change would not change the actual list. Therefore this would not have to be included in the quarterly report. This change could change some of the documentation required by §70.62. If it does change this documentation, then NRC would be notified of the change in the next annual report. If not, no reporting would be required.

Example #4 - Changes in Monitoring Action Levels.

The licensee is considering raising their monitoring action levels because the current action levels are very close to the lower limit of detection. This type of change would not require NRC pre-approval. It is not on the list of items relied on for safety so it would not have to be reported quarterly. It also most likely would not change the records required by §70.62 - ISA, management measures, or process safety information. Therefore, this is a change that would not be reported to NRC on any time frame.

Table 1
EXAMPLE LIST OF ITEMS RELIED ON FOR SAFETY

ITEMS RELIED ON FOR SAFETY	Function
Bulk chemical storage tanks # 12, 13, 14, & 15 in Building A	Storage tanks are made of chemically resistant materials.
Bulk chem transfer piping for tanks # 12, 13, 14, & 15 in Building A.	Transfer materials are made of chemically resistant materials.
Bulk Chem Operator sight gauge at station X in building A	During loading and unloading the operator watches fill gauge.
Operator checks level in tank and will not take load unless tank level is less than 64". (4500 gal)	To ensure that the tank is not overfilled.
Fire sprinkler system in building A	To extinguish a fire by providing suppression

Figure 1 Flow Diagram for 70.72 Change Process

Does the change:

