Differing Professional Opinion (DPO)
on Management Policy on Licensing
New Fuel Cycle Facilities
(DPO-2006-005)

DPO Panel Report

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Enclosure 1

Introduction

The Differing Profession Opinion (DPO) concerns the acceptability of the staff's approach to licensing new fuel cycle facilities. Specifically, the concern is that the licensing approach described in an August 4, 2006, memorandum from Mr. Robert Pierson, Director, Division of Fuel Cycle Facility Safety and Safeguards (FCSS), Office of Nuclear Material Safety and Safeguards (NMSS), to FCSS staff, titled "United States Enrichment Corporation License Detail Regarding the Level of Information Needed for 10 CFR Part 70 Licensing," (the Memo) is inconsistent with the requirements of the licensing process contained in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and the staff review guidance in NUREG - 1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (ML020930033).

The DPO was submitted November 15, 2006. The DPO Panel was established on December 22, 2006, by a memorandum from Jack R. Strosnider, Director, NMSS, to the members of the DPO Ad Hoc Review Panel (the Panel). This tasking memorandum was later superseded by a memorandum from Jack R. Strosnider dated January 17, 2007, which removed reference to specific individuals identified in the earlier memorandum. These memoranda provided the tasking to the Panel to disposition the DPO in accordance with the requirements in Management Directive (MD) 10.159, "The NRC Differing Professional Opinions Program." For specific details, refer to the January 17, 2007, memorandum.

The Panel met with the Submitters on January 18 and February 8, 2007, to obtain a mutual understanding of the Submitters' concerns. The concerns were summarized in a February 16, 2007, email from Thomas Bergman to the Submitters and the Panel, and accepted by the Submitters in an email dated February 20, 2007.

The Panel performed its review: (1) by reviewing the DPO submittal, other relevant documents including correspondence provided by the submitters, selected portions of the USEC application, the USEC application Integrated Safety Assessment (ISA) Summary, the Staff Safety Evaluation Report, and the rulemaking history of Part 70; and (2) through interviews with the Submitters and other staff.

Statement of Concerns

The Panel and the Submitters reached mutual understanding on the Statement of Concerns, which are summarized as follows (a more complete description is provided in the Appendix):

1. The Memo is inconsistent with the requirements of the licensing process contained in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

2. The Memo is unclear and self-contradictory regarding the level of completeness required for the ISA Summary.

3. The Memo approach that the licensing review is programmatic in nature is an unacceptable interpretation of Part 70.

4. The approach allowed by the Memo would not ensure that all hazards, accident sequences and IROFS would be identified as required by 10 CFR 70.65(b).

5. A complete ISA cannot be developed without a sufficiently complete design.

6. A license issued in accordance with the Memo would result in a reduced assurance of safety as compared to a license issued in accordance with Part 70 and NUREG-1520.

7. The Safety Evaluation Report does not fully disclose the fact that the design is incomplete.

8. The Memo is inconsistent with the staff review guidance in NUREG-1520.

9. Evaluate whether an alternative set of criteria represent an acceptable definition for Integrated Safety Assessment (ISA) completeness.

10. Use of the Memo is inconsistent with the Agency's Strategic Goal of Openness.

Discussion

On August 4, 2006, the Director of the Division of Fuel Cycle Safety and Safeguards (FCSS), NMSS, issued a memorandum to staff outlining the FCSS application review approach with respect to the level of information needed for Part 70 licensing (the Memo). According to the Memo, the staff uses a reasonable assurance standard and focuses on the "programmatic provisions of the applicant's proposed activities." The Memo stated that the licensing review should focus on the applicant's programmatic commitments and that "consequently, the licensing decision is ultimately based on a sufficient level of detail to understand process system functions and functionally how items relied on for safety can perform their intended function and be reliable." The Memo concluded that a final facility design or an absolutely complete identification of all IROFS and accident sequences is not necessary. Instead, it is sufficient if the reviewer can understand the process and functions of the IROFS. This review approach was further clarified in the staff's response to ASLB questions. There the staff stated that the term "programmatic" refers to a description of safety and administrative programs as well as structure, system, and component designs at a functional, "programmatic" level, as opposed to detailed, final design-level construction specifications. The Panel uses the term programmatic level as the functional level of design information coupled with the administrative and safety programs used to control the quality and reliability of the design. This is how the term "programmatic" is used throughout this report and its appendix.

The concerns raised by the Memo are focused on two fundamental questions, is the programmatic review described in the Memo consistent with: (1) the requirements of Part 70, and (2) the review guidance contained in the Standard Review Plan (SRP), NUREG-1520? In addition, although not raised as a specific concern to be considered by the Panel, the Panel evaluated how the approach in the Memo could affect the inspection program and FCSS staff after the facility has been licensed and prior to operation.

Consistency With Part 70

A fundamental question is whether it is consistent with Part 70 licensing to only require a functional level of detail. The Panel performed an extensive review of Part 70, Subpart H requirements and the rulemaking history of the revisions to Part 70 to determine the scope and intent of Part 70. The Panel concluded from its research that a licensing review based upon a

functional level of design detail is consistent with Part 70. The following discussion provides the basis for this conclusion.

Part 70 is a risk-informed, performance-based regulation. Performance-based regulation provides applicants and licensees flexibility in meeting established performance criteria. Programs and processes used to achieve the established performance criteria are established at the applicant's or licensee's discretion. In most cases, performance criteria are expected to be set at the system level or higher (e.g., the "maintenance rule," 10 CFR 50.65)). Part 70, Subpart H contains additional requirements for a license for a fuel facility; specifically, Sections 70.61, 70.62, 70.64, and 70.65.

Section 70.62 requires applicants and licensees to conduct an integrated safety analysis (ISA) that is "of appropriate detail for the complexity of the process." The ISA must, among other things, identify each item relied on for safety (IROFS), including the characteristics of its preventative, mitigative, or other safety function. IROFS are those engineered or administrative controls or control systems necessary to comply with the performance requirements of section 70.61. A summary of the ISA must be submitted with an application. As described in section 70.65(b)(3), the ISA summary must describe each process (defined as a single, reasonably simple unit of operation within an overall production line) in sufficient detail to "understand the theory of operation; and for each process, the hazards that were identified in the integrated safety analysis." Further, under in section 70.65(b)(6), the summary must list, briefly, the IROFS in "sufficient detail to understand their functions in relation to the performance requirements." However, the regulations do not define what constitutes a sufficient or appropriate level of detail (i.e., whether the level of detail should be at the functional level or the component level).

The rulemaking history of Part 70, subpart H does not specifically address this issue, but it does provide some insight into the Commission's expectations. The Statements of Consideration (SOC) for the final revisions to Part 70 provide that there must be sufficient information in the ISA summary for the staff to make its determinations required by section 70.66. In the SOC, the Commission indicated that information at a systems level could be sufficient. Specifically, the Commission stated: "The current language permits the description of information at a systems level provided that there is enough detail to understand the function of the system in relation to the performance requirements. The degree of detail provided in the ISA Summary, with the other information available to NRC staff, must be sufficient for the NRC staff to make the determination specified in § 70.66."

The staff explained its position to the Commission in a meeting on June 20, 2000. There the staff made a number of statements indicating that the applicant (or licensee) had flexibility over how much detail it chose to submit in an ISA summary. For example, in discussing the change process of section 70.72, the staff stated that how often a licensee would need to submit a license amendment request would depend on the level of detail in the ISA summary. The staff stated that a licensee could come in at a "fairly" high level of information and still meet the rule. The staff explained further that licensees have that flexibility under the proposed rule. In response to Commissioner questions regarding the change process, the staff indicated that an applicant need only describe an IROFS at the functional level, and not at the component level. The staff explained: "If it's truly at a higher level, this is the system and these are the functions we want that system to do to meet the performance requirements, I would expect there to be less changes to that, because I think you can change components within the system. Not every component in a system would be a safety-related component. Even then, if you don't describe

on a component level in your application, changes can be made to components as long as the functions described in the application and the system don't change." (emphasis added). A review of the staff's comment resolutions for both the proposed rule and final rule express similar views. Thus, it appears that for the ISA summary, a description of the facility, processes, and IROFS could be at the functional level.

What is not fully discussed in the rulemaking history is the amount of design detail that is necessary for the staff to review the underlying ISA. Part 70 provides baseline design criteria that must be addressed in the design of new facilities. The baseline design criteria are a set of initial design safety considerations. The design of a facility is then to be further refined by the performance of the ISA. However, for fuel facilities, the NRC does not explicitly approve a design. The inference is that the design need not be final at license application.

Therefore, a reasonable interpretation of the Commission's expectation with respect to Part 70 licensing is that the applicant would perform an ISA and submit an ISA summary for staff review. That summary would, consistent with section 70.65(b), contain a "general description" of the facility, among other things. The staff would then review the summary, as well as other aspects of the license application and issue a license with certain commitments to design and operate the facility based on the information in the application and the ISA summary. Prior to operations, the staff would perform an operational readiness review to ensure that the facility had been constructed in accordance with the commitments in the license. Thus, under this scenario, it is not unreasonable for the staff to review the design of the proposed facility at the functional or programmatic level, and then follow up the functional-level review with design-level reviews before approving the facility for operation. Accordingly, following this process, the Memo is consistent with Part 70.

Consistency With NUREG-1520

A second fundamental issue is whether the Memo is consistent with the SRP (NUREG 1520). Ultimately, of course, although the SRP is an important tool for staff review in that the SRP provides the staff guidance on the areas of an application that require staff review, it is not a requirement. In the SRP itself, and in the regulatory history documents, it is clear that alternatives to the SRP review process are to be allowed. Therefore, if the Memo and the SRP are inconsistent, this issue in and of itself would not be problematic in terms of determining the acceptability of the USEC ACP license application, as the final determinant would be whether the application met the requirements in Part 70 (not the SRP).

However, the general expectation among reviewers is that they will evaluate an application against the SRP, and that deviations from the SRP will be explicitly noted and their bases for finding an application acceptable will be identified. The Panel has determined that the SRP could, in the areas reviewed (section 3.4.3.2 specifically), be interpreted from a programmatic level in terms of completeness, i.e., the Memo is not inconsistent with the SRP. This is, in general, the argument the staff has made to the Atomic Safety Licensing Board (ASLB) in the USEC American Centrifuge Plant (ACP) hearing. The Panel, however, did not reach this conclusion easily. Only after reviewing the regulatory history and the filings with the Board was the Panel able to reach this conclusion. The original review by the Panel, and arguably a simple reading of section 3.4.3.2, would not obviously lead to an understanding that the review was to be conducted at a programmatic level and not at a detailed design level.

In the staff's February 6, 2007, filing with the ASLB in the USEC ACP hearing, the staff stated that in future revisions to the SRP, the staff plans to provide clarifying guidance on the necessary level of detail for new facilities. Such a clarification to the SRP would be beneficial for future license application reviews and eliminate the apparent misunderstanding that occurred among staff in the USEC ACP review. The Panel does not believe this clarification should be limited to new facilities. Part 70 does not distinguish between new and existing facilities in terms of the level of detail necessary for applications, amendments and renewals. There is no apparent regulatory basis for having a different standard for reviews conducted for new versus existing facilities. If a programmatic review is sufficient for new applications, as the staff has argued and the Panel agrees, Part 70 allows then that a programmatic review is also sufficient for future licensing actions such as amendments to the license and future renewals of the license. If different acceptance standards persist for new and existing facilities, confusion as to the appropriate level of detail required for future reviews is more likely to recur. The Panel understands that an existing facility should be able to provide more detail than a new facility; however, that should not drive the acceptance criteria provided in guidance to the staff. That is, the standard for level of detail of information required should not change upon issuance of a license.

Impact on Inspection Program

Although the impact of the licensing approach allowed by the Memo was discussed in the DPO, it was not raised as a specific concern for the Panel to address. However, the Panel shares the concern expressed in the DPO that a performance-based approach to licensing allowed by Part 70 does represent a significant shift in responsibilities from the licensing review to the follow-up inspection review and operational readiness review for new facilities. The Panel does not take issue with this approach as Part 70, subpart H, was intended to be performance-based. The Agency's experience with performance-based regulation, at least in the case of the maintenance rule (10 CFR 50.65), is that performance-based reviews in general require more resources than prescriptive approaches, and need effective communication, development of guidance documents and inspection procedures, training and oversight. The staff has stated that additional resources are planned to support the construction and inspection of the USEC ACP. The Panel encourages the staff to ensure that sufficient resources, of the right technical capabilities, are available, and that inspection procedures be developed that are sufficient to address the special challenges of inspecting conformance with a license granted in accordance with a performance-based rule.

Conclusions

The Panel concludes that a programmatic review, as described in the August 4, 2006, memorandum, is consistent with the requirements of Part 70. The Panel also concludes that, for the reviewed portions, NUREG-1520 (the SRP) could be interpreted to allow a programmatic review although that conclusion is not readily reached by relying solely upon the language in the SRP. The Panel has concluded that it would be of benefit for the staff to modify the SRP to be clear that a programmatic review is acceptable, and establish this as the sole standard in the SRP for both new and existing facilities, as opposed to only applicable to new facilities as the staff indicated it planned to do in its filing with the USEC ACP Hearing Board.

Recommendations

1. The staff should modify the SRP (NUREG-1520) to be clear that a programmatic level of detail is sufficient for licensing reviews conducted in accordance with Part 70, for both new and existing facilities, and ensure that the acceptance criteria in the SRP are consistent with that approach.

2. The staff should ensure that sufficient staff with the requisite technical skills, and infrastructure is available to conduct post-licensing confirmatory inspections and reviews of IROFS, such that the reviews and inspections can be conducted prior to allowing the facility to commence operations.

Appendix: Panel Views on the Specific Concerns in DPO-2006-005

cc: DPOPM

Appendix: Panel Views on the Specific Concerns in DPO

This appendix provides a summary response to each individual concern raised in DPO-2006-005. The same terminology is used here as in the Panel's report (the report), for example:

- "The Memo" refers to the August 4, 2006, memorandum from Mr. Robert Pierson, Director, Division of Fuel Cycle Facility Safety and Safeguards (FCSS), Office of Nuclear Material Safety and Safeguards (NMSS), to FCSS staff, titled "United States Enrichment Corporation License Detail Regarding the Level of Information Needed for 10 CFR Part 70 Licensing."

- The term "programmatic review" when referring to the Memo and Part 70 means a functional level of design information coupled with the administrative and safety programs

Summary of Specific Concerns

1. *The Memo is inconsistent with the requirements of the licensing process contained in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." Specifically, the requirements contained in Sections 70.22 - 70.23, and 70.60 - 70.66.*

As noted in the report, Part 70 was intended to allow a programmatic level of detail for license reviews. Therefore, the Memo, which restated that a programmatic level of review was conducted for LES and should be conducted for the USEC ACP, was consistent with Part 70. The report dealt principally with subpart H of Part 70, which contains in part the requirements in Sections 70.60-70.66.

With respect to Section 70.22, "Contents of applications," and Section 70.23, "Requirements for the approval of applications," the relevant portions of these sections provide for a general description of the activity to be licensed or a description of equipment and facilities which will be used by the applicant to protect health and minimize danger to the public and the Commission finds that it has done so. These two regulations are "basic" regulations, with the requirements of subpart H (70.60-66) being the more specific regulations. As basic regulations, the description of the facility required to be submitted (Sections 70.22(a)(7) & (8)) and approved (Sections 70.23(a)(3) & (4)) is intended to be general and is not a requirement to describe the facility and all its equipment and procedures in detail. A cursory review of the USEC ACP application indicates that the level of description provided appears to address these requirements.

The Memo was not intended to be a detailed analysis of all of Part 70, or even Sections 70.22-23 and 70.60-66. Rather, the Memo was issued in response to staff concerns regarding the appropriate level of detail required in the USEC ACP license application. Therefore, the Memo was focused on the level of detail issue. Where the Memo is silent on the implementation of a specific requirement, it should not be viewed as a position that the requirement need not be met. Instead it appears that certain citations of regulations were omitted because there was not an apparent issue over the implementation of those requirements in the USEC ACP review.

2. *The Memo is unclear and self-contradictory regarding the level of completeness required for the ISA Summary. The Memo, in one paragraph, states "…reasonable assurance that the integrated safety analysis is complete… does not require a final facility design or an absolutely complete identification of all items relied on for safety and accident sequences … reasonable assurance that the integrated safety analysis summary is complete."*

Although the Memo could have been written more clearly, this paragraph is not self-contradictory, nor unclear if read from the perspective of the programmatic level of detail allowed by Part 70. To restate the paragraph,

> The ISA Summary must be complete at the programmatic level to make the reasonable assurance finding. In order to make this finding, there does not need to be a final facility design nor an identification of all IROFS at the detailed design level. What is necessary is to have reasonable assurance that the processes and functions for IROFS are identified at the programmatic level to conclude that the ISA Summary is complete. The Memo does not obviate the need for the staff to confirm that the functional level of detail is appropriate for approving a license application.

3. *The Memo approach that the licensing review is programmatic in nature is an unacceptable interpretation of Part 70, with an example being the level of information provided on instrumentation and control design being insufficient to make the required finding (i.e., the applicant's commitments to industry standards and inspections required by 10 CFR 70.32(k) to verify conformance to commitments were unacceptable in lieu of sufficient design detail).*

As noted in the report, Part 70 was intended to allow a programmatic level of detail for license reviews. The staff's review of the USEC ACP instrumentation and control design was not re-reviewed by the Panel to determine if the application was adequate, as the issue here is whether a more complete design than one described at the programmatic level is required. The staff, in Appendix E of the USEC ACP SER concluded that, with respect to this example, the application was acceptable at the programmatic level. Since this review was conducted in accordance with the level of information (programmatic) indicated necessary in the Memo, and the Memo is consistent with Part 70, the conclusion in Appendix E of the USEC ACP should be sufficient.

The inspections performed in accordance with section 70.32(k) are to confirm that the licensee has constructed the facility in accordance with the requirements of the license, including meeting the programmatic conditions imposed upon the instrumentation and control design. These inspections are not a new licensing review that results in a new licensing basis. The licensing basis is established at the time the license is issued, as modified by subsequent amendments to that license or through the section 70.72 change process. That is, the programmatic level of detail is not only sufficient for the initial license application, but for the duration of the license including construction, operation and any subsequent license amendments or renewals. This does not override the staff's responsibility to confirm that the facility is constructed in accordance with licensing commitments and applicable standards.

4. *The approach allowed by the Memo would not ensure that all hazards, accident sequences and IROFS would be identified as required by 10 CFR 70.65(b) (i.e., is the*

level of detail described in Chapter 3 of NUREG-1520 necessary to meet 10 CFR 70.65(a), or do equally acceptable alternatives exist?).

As noted in the report, Part 70 was intended to allow a programmatic level of detail for license reviews provided there is reasonable assurance that hazards, accident sequences and IROFS have been identified at the programmatic level. Any approach that meets this standard would be acceptable. As noted in the report, it is possible that as long as it is understood that a programmatic level of detail is required, the SRP could still be used as the basis for approving a license application.

5. A complete ISA cannot be developed without a sufficiently complete design.

As noted in the report, Part 70 was intended to allow a programmatic level of detail for license reviews. This would include the level of detail required for the ISA to support the application and the ISA summary submitted with the application. In the course of finalizing the design, whether that occurs during the license review or prior to the operational readiness review, the ISA (and summary) would be updated as required by section 70.72 to ultimately reflect the as-built design. It is possible that no changes to the ISA or ISA summary could result during this process. If changes were to occur as a result of finalizing the design (as may be expected), this would not invalidate the original licensing as the changes would be captured appropriately through the section 70.72 change control process.

6. *A license issued in accordance with the Memo would result in a reduced assurance of safety as compared to a license issued in accordance with Part 70 and NUREG-1520*.

As the Panel has concluded that the Memo is consistent with the requirements of Part 70, and Part 70 provides reasonable assurance of safety, licenses granted in accordance with the Memo provide sufficient assurance of safety, provided the staff confirms that the facility is constructed in accordance with licensing commitments and applicable standards.

7. *The Safety Evaluation Report does not fully disclose the fact that the design is incomplete and, as a result, does not ensure that all the requirements of 10 CFR 70.66(a) have been met.*

As noted in the report, Part 70 was intended to allow a programmatic level of detail for license reviews. This concern was raised in the context that the SER did not clearly disclose that portions of the SER were based on a programmatic level of detail rather than a more detailed design. As long as the SER relied on at least a programmatic level of detail, the SER should have reached the appropriate conclusions, including that all requirements of section 70.66(a) had been met. Implicit in this conclusion is that the staff will confirm that the facility is constructed in accordance with its licensing commitments and applicable standards.

8. *The Memo is inconsistent with the staff review guidance in NUREG-1520. Specifically, the guidance contained in Section 3.4.3.2, pages 3-13 through 3-21, and whether identification of all accident sequences and IROFS must be "absolutely complete."*

As noted in the report, the NUREG could be interpreted such that the Memo is consistent with the guidance in the NUREG. However, a simple reading of section 3.4.3.2 would not lead to that conclusion. The Panel has recommended that the SRP be modified to clearly indicate that a programmatic review is acceptable for license reviews, whether the applications are for new facilities, amendments to existing facilities, or license renewals.

9. *Evaluate whether the following criteria represent an acceptable definition for ISA completeness and, if not, what would.*
   a. *All credible accident sequences have been identified and evaluated.*
   b. *All IROFS needed to meet the performance requirements have been identified.*
   c. *The process is described in sufficient detail for the staff to understand the theory of operation and evaluate whether all credible sequences have been identified.*
   d. *The IROFS are described in sufficient detail for the staff to understand their safety function and to have reasonable assurance that they will perform their safety function commensurate with the level of likelihood assumed in the ISA Summary.*

The proposed criteria appear to represent an acceptable definition for ISA completeness. They are robust in that they require "all" credible accident sequences to be identified and evaluated, and "all" IROFS needed to meet the performance requirements. From an implementation standpoint, the definition has a number of weaknesses. If by "all" it means "absolutely all," in the sense that all components are known and all possible failure mechanisms known, then this exceeds the requirements of Part 70. An application meeting this definition should be able to include an ISA Summary (based on an ISA) that would meet the requirements of Part 70. However, it cannot be concluded that an application that does not meet this definition would be unacceptable. Both the SRP and the Memo were attempts to define what constitutes an acceptable level of detail. Therefore, while this definition may be an acceptable alternative definition of ISA completeness, it does not resolve the central concern of this DPO: "what is the necessary level of detail?" Neither does completeness of design information obviate the need for the staff to confirm that the facility is constructed in accordance with its licensing commitments and applicable standards.

10. *Use of the Memo is inconsistent with the Agency's Strategic Goal of Openness in that it did not allow stakeholder participation in the same manner provided for rulemaking or NUREG development.*

Since the Panel determined that a programmatic level of detail is consistent with Part 70 and appears to have been the intended approach when the Commission promulgated the revision to Part 70 in 2000, the use of the Memo would not be inconsistent with the Agency's Strategic Goal of Openness. The Memo is a restatement of the approach allowed by Part 70, to clarify the intent of Part 70 for staff involved in the USEC ACP review and, therefore, since new policy was not being proposed, did not need to seek additional stakeholder input.