**Request for Additional Information**
**Nuclear Fuel Services, Inc.**
**November 16, 2010, Order and August 5, 2011, License Application**

Background

By letter dated November 16, 2010, the U.S. Nuclear Regulatory Commission (NRC) issued a Confirmatory Order to Nuclear Fuel Services (NFS) (Ref. 0). The Order, which became effective immediately, included the following requirement in Paragraph 6 of Section V: "NFS will complete an assessment of its current Corrective Action Program (CAP) against the requirements of NQA-1-2008, Part III, Subpart 3.1, "Non-Mandatory Appendix 16A-1" (Ref. 0). Based on this assessment, NFS will submit a License Amendment (LA) request within 9 months of the date of issuance of this Confirmatory Order incorporating into the license its current CAP—including the additional enhancements made to the program as a result of the assessment." NFS submitted a request for an LA (Ref. 0) in the letter dated August 5, 2011, to satisfy the requirements of the Order.

Requests for Additional Information (RAIs)

The NRC staff has reviewed the LA (Ref. 0) and has identified areas in which further information is required to demonstrate compliance with the Order. Provide the following information (and any corresponding changes to the amendment request) to support the staff's review of the LA (Ref. 0):

1. The NFS Corrective Action Program Gap Analysis (Ref. 0) states, "The NFS CAP Problem Identification, Resolution, and Correction System (PIRCS) is not completely connected to the terms and application of Appendix 16A-1 of NQA-1-2008 or to the NFS Quality Assurance Program (QAP) and needs to be better aligned and described." The assessment identified the following issues and recommended actions:

    1.1. (NQA-1-16A-1-200) Corrective action should be integrated into all aspects of the QAP—Handling of Nonconformances (NCRs), Conditions Adverse to Quality (CAQ) and Significant Conditions Adverse to Quality (SCAQ) need to be reconciled with handling of problems as described by the PIRCS system and by the NFS QAP.

    1.2. NFS GH-922 uses the NQA-l Basic Requirement 16 concept for CAQ, but not SCAQ. This key concept of separating corrective actions into a classification system based on significance of impact on quality is picked up in Section 16 of the NFS QAP and in quality control (QC) procedures (NFS-Q-176. NFS-Q-185 and NFS-Q-214), but not completely translated in NFS GH- 922.

    1.3. NFS-GH-922 should be customized to reflect the overall NFS process for addressing QAP Sections 15 and 16 flowdown of implementing control of nonconforming conditions, conditions adverse to quality, significant conditions adverse to quality, and providing corrective action. This would include how PIRCS covers all of the acceptable methods being used throughout NFS and how they are handled or connected in the PIRCS process. The requirements for identifying, documenting, classifying, cause analysis, corrections, follow-up, effectiveness reviews, and trend analysis as outlined in 16A-1, Section 200, should be reconciled with the current process and language in PIRCS.

1.4. The NFS QAP should identify, when PIRCS is used as the system to handle identification of nonconforming conditions and corrective action and where and when other processes, such as QA and QC are used. This should focus on the identification of nonconformances and the disposition of the issues identified.

1.5. (QA- I-16A-I-300) CAQ should be reviewed for significance. The classification of those items that are SCAQ are not currently correlated to the risk-basis of the PIRCS process. There is a robust risk-based process included in PIRCS, but it needs to be correlated with the NQA-I terminology.

Clarify how the issues and recommendations have been addressed and how these program elements have been incorporated in the LA (Ref. 0).

2. Section 11.6 of Special Nuclear Material (SNM)-124 states, "NFS maintains a CAP to investigate, document, and report events as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 70.50, 70.62, and 70.74 for operations involving special nuclear materials." Section 11.6 also states, "Events, including those with conditions adverse to safety, are reported, investigated, tracked, and corrective actions are assigned through a formal CAP."

   In the letter (Ref. 0) dated August 5, 2011, NFS stated that Section 11.6, "CAP," of the License Renewal applies as a management measure to activities involving the handling of SNM, in addition to items relied on for safety (IROFS).

   2.1. Clarify the scope of Section 11.6 of the LA (Ref. 0). Specifically, identify in Chapter 11: (a) if the CAP described in Section 11.6.1 and the investigations described in Section 11.6.2 of SNM-124 apply only to "events" required to be reported under 10 CFR 70.50, 70.62, and 70.74; and (b) how corrective actions are applied to conditions that are not required to be reported under 10 CFR 70.50, 70.62, and 70.74.

   2.2. Describe what types of conditions are considered as conditions adverse to safety in Chapter 11 of the LA (Ref. 0). Include the criteria used for classifying conditions as "conditions adverse to safety."

   2.3. Describe in Chapter 11 of the LA (Ref. 0), what types of conditions, if any, are considered as significant conditions adverse to safety. If applicable, include the criteria used for classifying conditions as "significant conditions adverse to safety.

3. The NFS Corrective Action Program Gap Analysis (Ref. 0) states, "The classifications of those items that are SCAQ are not currently correlated to the risk basis of the PIRCS process. There is a robust risk-based process included in PIRCS, but it needs to be correlated with NQA-1 terminology." In addition, it also states, "The risk tables and logic for that are Significantly Adverse to Quality."

   The Analysis also states that "Currently NFS-GH-922 does not address the clear separation between "Conditions Adverse to Quality" and "Significant Conditions Adverse to Quality."

Identify any changes made to the NFS CAP as a result of these Analysis statements and describe how these changes were incorporated into the LA (Ref. 0). Further, describe the relationship between *conditions adverse to safety* and the NQA-1 terminology of *conditions adverse to quality* and *significant conditions adverse to quality*. Include the criteria used for classifying conditions adverse to quality and significant conditions adverse to quality in Chapter 11 of the LA (Ref. 0) (if these terms will be used in addition to or in lieu of "conditions adverse to safety"). In your discussion of the criteria used for classifying conditions adverse to quality, identify if the review considers repetition of conditions and the relationship or similarity between different conditions to ensure that quality trends can be identified.

4. Section 11.6.2 of Ref. 0 states, "Corrective actions are documented and monitored through completion. Corrective actions generated from investigations are used to make corrections and improvements necessary to prevent or minimize single or common-mode failures."

   The NFS Corrective Action Program Gap Analysis (Ref. 0) (See Section 100, "Basic") assessed the NFS CAP on the following criteria: "CAQ shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence."

   Clarify Chapter 11 of the LA (Ref. 0) to specify: (a) if conditions adverse to safety are identified promptly and corrected as soon as practicable, and (b) if the cause of conditions adverse to safety will be determined and corrective actions will be taken to preclude recurrence.

5. The NFS Corrective Action Program Gap Analysis (Ref. 0) (see Section 301, "Identification and Documentation") assessed the NFS CAP on the following criteria: "Where CAQ have been identified, the extent to which other items and activities may be affected should be evaluated so that appropriate action may be taken, including measures to control any affected work in process, if necessary."

   Describe how this portion of the CAP has been incorporated into Chapter 11 of the LA (Ref. 0).

6. The NFS Corrective Action Program Gap Analysis (Ref. 0) (See Section 301, "Identification and Documentation") assessed the NFS CAP on the following criteria: "Conditions adverse to quality should be reviewed to determine the existence of trends. The significance of identified trends should be classified."

   Section 11.6.2 of SNM-124 states that, "A database of events, investigations, and corrective actions is maintained for tracking, trending, and documentation purposes. Trends involving failure of IROFS are reviewed to determine effectiveness of safety systems and to provide feedback to management for establishment of actions to minimize and/or prevent recurrence."

   6.1. Clarify Chapter 11 of the LA (Ref. 0) to identify whether trending determination activities will include trending of CAQ (i.e., loss of essential data, repeated failure to

implement procedures, failures in record management, etc.); in addition to the evaluation of trends involving failure of IROFS. In addition, clarify if trending as described in Section 11.6.2, will be limited to investigations initiated for events specified in 10 CFR Parts 70.50, 70.62, or 70.74.

6.2. Clarify in Chapter 11 of the LA (Ref. 0) what measures are implemented by NFS for the classification of the significance of trends.

7. The NFS Corrective Action Program Gap Analysis (Ref. 0) (see Section 400, "Management Involvement") assessed the NFS CAP on the following criteria: "Appropriate levels of management should be involved in the corrective action process. The responsibilities of management should be specified. In addition, the corrective action activities should provide for cognizant management to be notified immediately when CAQ are determined to be significant."

   The Analysis found that "Management involvement was observed to be in place by procedure and in practice to meet NQA-1-16A-1." [The Assessment referenced NFS-GH-922, R11, as the implementing procedure that provides guidance for management involvement.]

   7.1. Section 11.6.2 of SNM-124 states, "Relevant findings are communicated to affected personnel." Clarify Chapter 11 of the LA (Ref. 0) to specify whether "affected personnel" includes appropriate levels of management.

   7.2. Incorporate guidance in Chapter 11 of the LA (Ref. 0) to describe management involvement in the CAP, including provisions for management notification of significant conditions adverse to quality and management responsibilities for corrective actions.

8. The NFS Corrective Action Program Gap Analysis (Ref. 0) states that "Review of the QAP and the PIRCS system implementation confirms that there is a system in place for identifying problems and providing appropriate corrective action. However, in reviewing the implementation of the PIRCS system as described in NFS-GH-922, R11, there needs to be changes in this description to better align it with NQA-1-2008-16A-1 requirements.

   Specifically, NFS-GH-922 needs to be revised to better describe the overall CAP to specifically address each of the 16A-1 criteria in Section 200 (a) through (e) and reference the additional procedures that support the overall description."

   Section 200 of NQA-1-2008 Nonmandatory Appendix 16A-1 states that "Corrective action should be integrated into all aspects of the quality assurance program. It consists of five basic elements:
   (a) identification and documentation
   (b) classification
   (c) cause
   (d) corrections
   (e) follow-up

   Describe how these assessment recommendations were addressed, identifying specific program changes that were made to better describe the overall CAP to specifically address

each of the criteria in Section 200 (a) through (e) and how those changes were incorporated into Chapter 11 of the LA (Ref. 0) (see RAI 9 for further questions regarding how follow-up is or will be described in the license).

9. The NFS Corrective Action Program Gap Analysis (Ref. 0) states that "The follow-up and closeout of problem reports was reviewed by sampling of items in specific Problem Reports. Although the problem report documentation packages were not always easy to review, there was evidence of follow-up, verification, and closeout to meet NQA-1-16A-1."

   Section 11.6.2, "Incident Investigations," of SNM-124 states that "Corrective actions are documented and monitored though completion."

   Provide a description of the process used to monitor the status of corrective actions in Chapter 11 of the LA (Ref. 0). In your description, include actions taken to alleviate significant delays in completion of corrective actions, verify completion of corrective action, determine effectiveness of corrective actions, and ensure further analysis and management attention for ineffective corrective actions.

References


1. Confirmatory Order (effective immediately) [NRC Office of Investigation Report No. 2-2010-001]. November 16, 2010. Agencywide Documents Access and Management Systems (ADAMS) Accession Number ML103210213.

2. The American Society of Mechanical Engineers, "Quality Assurance Requirement for Nuclear Facility Applications," ASME NQA-1-2008. March 14, 2008.

3. Letter from Mark P. Elliott, Nuclear Fuel Services, Inc., "Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-1 0-076)," August 5, 2011. ADAMS Accession Number ML11228A082.

4. Letter from Mark P. Elliott, Nuclear Fuel Services, "Supplemental Information Supporting the Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order," Section V, Paragraph 6 (EA-10-076). ADAMS Accession Number ML120460946.