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21G-12-0096
GOV-01-55-04
ACF-12-0144

May 14, 2012

Director, Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555

References:
1) Docket No. 70-143; SNM-124
2) Letter from NRC to David B. Amerine, Confirmatory Order, dated November 16, 2010
3) Letter from Mark P. Elliott to NRC, Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-10-076), dated August 5, 2011, (21G-11-0153)
4) Letter from Mark P. Elliott to NRC, Supplemental Information Supporting the Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-10-076), dated February 7, 2012, (21G-12-0025)
5) Letter from NRC to Mark P. Elliott, Request for Additional Information Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-10-076), dated February 16, 2012, (TAC No. L33172)
6) Letter from Mark P. Elliott to NRC, Response to the Request for Additional Information for the Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-10-076), dated March 21, 2012

Subject: **Supplemental Response to the RAI for the Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-10-076)**

Dear Sir:

Nuclear Fuel Services, Inc (NFS) hereby submits a supplement to the RAI responses submitted on March 21, 2012 (Reference 6). The responses to RAI 1 and RAI 3 have been revised, and the versions contained in the Attachment supersede the corresponding responses in Reference 6. Some of the responses include proposed

NMSSD1

revisions to certain sections within SNM-124, as shown with green text. Once agreement is reached on the proposed changes, revised pages for SNM-124 will be submitted.

If you or your staff have any questions, require additional information, or wish to discuss this matter further, please contact me at (423) 743-1705, or Ms. Jennifer Wheeler, Licensing and ISA Manager, at (423) 735-5429. Please reference our unique document identification number (21G-12-0096) in any correspondence concerning this letter.

Sincerely,

NUCLEAR FUEL SERVICES, INC.

Mark P. Elliott, Director
Quality, Safety, and Safeguards

JKW/pdj

Attachment: Supplemental Response to RAI for the Request to Amend SNM-124 Regarding the Corrective Action Program

Copy:

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Attachment

Supplemental Response to RAI for the
Request to Amend SNM-124 Regarding the Corrective Action Program

(4 pages to follow)

**Supplemental Response to RAI for the
Request to Amend SNM-124 Regarding the Corrective Action Program**

RAI 1

1. **The NFS Corrective Action Program Gap Analysis 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-1 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-1-16A-1-300) 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-1 terminology.

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

NFS Response

NFS' CAP, and in particular the PIRCS (the software program used to document plant wide corrective action activities), emerged from the necessity to combine numerous organizational programs into one comprehensive system to identify and track events, employee identified safety items, audit findings, customer related quality issues, inspections, surveillances, investigations, and corrective actions from "cradle to grave."

This comprehensive system provides consistency to the CAP as follows:

- provides common/standardized language and structure to reporting events;
- allows each entry to be screened and prioritized using the same graded, risk-based approach;
- assignment of problem priority levels based on significance;
- rapid notification of significant events;
- provides a standardized process to investigate for root cause, implementation of corrective actions and assessing their effectiveness, and management follow-up for significant conditions adverse to safety; and
- trending capabilities.

Although this comprehensive program provides consistency across varying disciplines at NFS, there is room for improvement as the CAP assessment states. The QAP and CAP maintain consistency as discussed above; however, the implementing procedures use differing terminology which can make it difficult to link the programs on the implementation level. The QAP implementing procedures (NFS-M-48, *QA Program* ; NFS-Q-185, *Control of Nonconforming Items*; NFS-Q-176, *Quality Control – Corrective Action Procedure;* and NFS-Q-214, *Nonconformance and Corrective Action Trend Analysis Reporting for the Fuel Program*) were written using NQA-1 as guidance, along with customer contract requirements. The CAP implementing procedures (NFS-CAP-009, *The NFS Corrective Action Program;* and NFS-GH-65, *Problem Identification*) were based on regulatory requirements and guidance. Utilizing the CAP assessment observations, these differences can be evaluated more closely to further improve program consistencies. This level of detail is typically not included in SNM-124, thus allowing for continued program improvements.

The Quality Control Program is administered by trained and qualified individuals who monitor the quality of NFS' product based on customer requirements. This includes the identification, disposition, and segregation of nonconforming items, as well as conditions adverse to quality and significant conditions adverse to quality. On a routine basis, these individuals monitor the events reported through the CAP for impact to product

quality. The QC implementing procedures provide direction for investigation, corrective actions, effectiveness of corrective actions, and follow-up with management. The QC program is well established and actions to align the roles/responsibilities associated with this program and CAP will improve the consistency between the two programs.

Although, as stated above, there is room for improving the consistency between the QAP and CAP, the practices being implemented today are adequate to ensure quality-related issues that could have the potential to impact the safety of licensed activities are properly identified and classified within the CAP.

Events that are not quality-related can also have the potential to impact safety and are entered into the CAP. In order to cover the broad range of events that have the potential to impact the safety of licensed activities, NFS chose to use the term "conditions adverse to safety" in lieu of "conditions adverse to quality." Quality-related issues with no impact on licensed activities are outside the scope of the SNM-124 license.

As defined in NQA-1, Part 1, Section 400, Terms and Definitions, "conditions adverse to quality" includes failures, malfunctions, deficiencies, defective items, and non-conformances. For events that have the potential to impact the safety of licensed activities, the CAP does address the full scope of "conditions adverse to quality," as shown in the NFS definition for "conditions adverse to safety" below.

The CAP implementing procedures discuss the "how to" in applying the graded, risk-based approach when conditions adverse to safety are identified. The assigned classification can range from a "low" risk (little to no safety significance) event to a "high" risk (significant risk to the health and welfare of the public or plant personnel) event.

To clarify what is meant by the term "conditions adverse to safety," a definition will be added to Chapter 1, Section 1.2.7, "Terminology/Definitions" as follows.

> **Conditions adverse to safety:** As used in Sections 2.2, 2.5.1, and 11.6, events that could have the potential to impact the safety of licensed activities, including equipment failures, malfunctions, or deficiencies; procedure problems, errors, or omissions; improper installations; non-conformances with regulatory requirements or commitments; quality-related issues; or a significant condition, such that if uncorrected, could have a serious effect on safety.

RAI 3

3. **The NFS Corrective Action Program Gap Analysis 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. 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 (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.

NFS Response

See the response to RAI 2.2 and 2.3 above for the criteria used for classifying events, including conditions adverse to safety. In addition, consideration of generic implications (i.e., repetition of conditions and the relationship or similarity between different conditions) is already included in Section 11.6.1, paragraph 1, last sentence; and Section 11.6.2, item 5. See the response to RAI 1 above for a description of the relationship between "conditions adverse to safety" and the NQA-1 terminology of "conditions adverse to quality" and "significant conditions adverse to quality."