

# Attachment 2

## Discussion Points NRC/NFS Meeting January 31 – February 1, 2012

### Background

By letter dated November 16, 2010, the NRC issued a Confirmatory Order to NFS. 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 against the requirements of NQA-1-2008, Part III, Subpart 3.1, "Non-Mandatory Appendix 16A-1." Based on this assessment, NFS will submit a license amendment (LA) request within nine months of the date of issuance of this Confirmatory Order incorporating into the license its current corrective action program including the additional enhancements made to the program as a result of the assessment." NFS submitted a request for a license amendment (LA) in letter dated August 5, 2011, in order to satisfy the requirements of the order.

### Points

The NRC staff has reviewed the LA and has identified areas in which further information is required to demonstrate compliance with the Order. Provide the following information (and any revised Chapter 11 text) to support the staff's review of the LA:

1. Section 3(4)(f) of the November 16, 2010, Confirmatory Order requires that "NFS will complete an assessment of its current corrective action program against the requirements of NQA-1-2008, Part III, Subpart 3.1, "Non-Mandatory Appendix 16A-1." Based on this assessment, NFS will submit a license amendment request within nine months of the date of issuance of this Confirmatory Order incorporating into the license its current corrective action program including the additional enhancements made to the program as a result of the assessment."

The letter dated August 5, 2011, submitted to the NRC by NFS in order to satisfy the requirements of the order states, in part, that as currently approved, SNM-124 contains information on the CAP in Section 2.9, "Investigations and Reporting;" Section 2.12.6, "Incident Investigations and Corrective Actions;" and Section 2.12.8, "Other Quality Assurance Elements."

The letter further states that as currently under review for License Renewal, SNM-124 contains information on the CAP in Section 2.5.1, "Reporting of Potentially Unsafe Conditions or Activities;" Section 11.6, "Corrective Action Program;" and Section 11.8, "Other QA Elements."

Verify that the references provided to Chapters 2 and 11 of SNM-124, as submitted in letter dated August 5, 2011, provide a complete description of the NFS corrective action program, including enhancements made as a result of the assessment.

2. The NFS Corrective Action Program Gap Analysis states "The NFS Corrective Action Program (PIRCS) is not completely connected to the terms and application of Appendix 16A-1 of NQA-1-2008 nor to the NFS QAP and needs to be better aligned and described." The assessment identified the following issues and recommended actions:

- 2.1. (NQA-1-16A-1-200) Corrective action should be integrated into all aspects of the QA Program---Handling of Nonconformances (NCR's), Conditions Adverse to Quality (CAQ) and Significant Conditions Adverse to Quality (SCAQ) needs to be reconciled with handling of problems as described by the PIRCS system and by the NFS QAP.
- 2.2. NFS GH-922 uses the NQA-I basic requirement 16 concept for Conditions Adverse to Quality (CAQ) but not Significant Conditions Adverse to Quality (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 QC procedures (NFS-Q-176, NFS-Q-185 and NFS-Q-214) but not completely translated in NFS GH- 922.
- 2.3. 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.
- 2.4. 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&QC are used. This should focus on the identification of nonconformances and the disposition of the issues identified.
- 2.5. (QA- I-16A-I-300) Conditions Adverse to Quality should be reviewed for Significance- The classification of those items that are Significant Conditions Adverse to Quality 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.

3. NRC's Confirmatory Order to NFS, requires NFS to complete an assessment of its current corrective action program against the requirements of NQA-1-2008, Part III, Subpart 3.1,

“Non-Mandatory Appendix 16A-1” and to include additional enhancements made to the program as a result of the assessment.

In addition, NFS Corrective Actions Program Gap Analysis states “Based on observations, interviews, and review of documentation of the implementations of the PIRCS, the system can be adjusted to meet the requirements of the NQA-1-16A-1. Action to address the above issues is needed. These changes to better align the PIRCS system with the NFS QA program should adequately cover the requirements of NQA-1-16A-1 for a timely and effective corrective action system.” Describe actions taken by NFS in response to this recommendation and provide supplemental documentation as needed.

4. Section 11.6 of SNM-124 states, “NFS maintains a corrective action program to investigate, document, and report events as required by 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 corrective action program.”

In letter dated August 5, 2011, NFS stated that Section 11.6 “Corrective Action Program,” of the License Renewal applies as a management measure to activities involving the handling of SNM, in addition to IROFS.

- 4.1. Clarify the scope of Section 11.6 of the LA. Specifically, identify in Chapter 11
    - (a) if the corrective action program described in Section 11.6.1 of SNM-124 applies 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.
  - 4.2. Describe what types of conditions are considered as conditions adverse to safety in Chapter 11 of the LA. Include the criteria used for classifying conditions as “conditions adverse to safety”.
  - 4.3. Describe in Chapter 11 of the LA, 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”.
  - 4.4. Clarify if the investigations described in Section 11.6.2 of the LA are applicable only to events or if they are also applicable to conditions adverse to quality and/or safety.
5. The NFS Corrective Action Program Gap Analysis states “The classifications of those items that are Significant Conditions Adverse to Quality 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 screening problems is not aligned with the NQA-1 terminology for separating Conditions Adverse to Quality and those 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. 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.

6. Section 11.6.2 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 (See Section 100, "Basic") assessed the NFS Corrective Action Program on the following criteria: "Conditions adverse to quality 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 to specify if conditions adverse to safety are identified promptly and corrected as soon as practicable. Identify if the cause of conditions adverse to safety will be determined and if corrective actions will be taken to preclude recurrence.

7. The NFS Corrective Action Program Gap Analysis (See Section 301, "Identification and Documentation") assessed the NFS Corrective Action Program on the following criteria: "Where conditions adverse to quality 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 Corrective Action Program has been incorporated into Chapter 11 of the LA.

8. The NFS Corrective Action Program Gap Analysis (See Section 301, "Identification and Documentation") assessed the NFS Corrective Action Program 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.”

- 8.1. Clarify Chapter 11 of the LA to identify whether trending determination activities will include trending of conditions adverse to quality (i.e. loss of essential data, repeated failure to implement procedures, failures in record management, etc) in addition of evaluation of trends involving failure of IROFS. 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.
- 8.2. Clarify in Chapter 11 of the LA what measures are implemented by NFS for the classification of the significance of trends.
9. The NFS Corrective Action Program Gap Analysis (See Section 400, “Management Involvement”) assessed the NFS Corrective Action Program 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 conditions adverse to quality 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.]

- 9.1. Section 11.6.2 of SNM-124 states, “Relevant findings are communicated to affected personnel.” Clarify Chapter 11 of the LA to specify whether “affected personnel” includes appropriate levels of management.
- 9.2. Incorporate guidance in Chapter 11 of the LA to describe management involvement in the corrective action process, including provisions for management notification of significant conditions adverse to quality and management responsibilities for corrective actions.
10. The NFS Corrective Action Program Gap Analysis (Assessment) 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 corrective action program 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 corrective action program 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.

11. The NFS Corrective Action Program Gap Analysis states that "The follow up and close out 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 close out to meet NQA-1-16A-1."

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

Provide a description of the process used to monitor the status of corrective actions in Chapter 11 of the LA. 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.