DOCKET NO.: 70-143

LICENSEE: NUCLEAR FUEL SERVICES, INC.

SUBJECT: SAFETY EVALUATION REPORT: SUBMITTAL DATED AUGUST 5, 2011—ENHANCEMENT OF CORRECTIVE ACTION PROGRAM (TAC L33127)

BACKGROUND

An Order (Ref. 1) was issued to Nuclear Fuel Services, Inc. (NFS), effective immediately, directing the licensee to incorporate the Corrective Action Program (CAP) into the license. Section V, Paragraph 6, of the Order imposes the following requirement:

> 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.

By letter dated August 5, 2011, NFS requested an amendment to incorporate its enhanced corrective action program into the license. The request was supplemented by letters dated February 7, March 21, May 14, and October 10, 2012.

DISCUSSION

The NRC staff evaluated the extent to which the licensee met the elements of the Order:

- complete an assessment
- submit a request to amend SNM-124 within 9 months of the Order
- incorporate into the license the current CAP, including enhancements

The NRC staff reviewed the application for a license amendment (LA), responses to requests for additional information (RAIs), and the assessment. The NRC staff did not review implementing procedures; the NFS procedures will be reviewed during NRC inspections. The NRC staff evaluated the assessment based on its own merits and determined it was unnecessary to independently audit the assessment by comparing the findings of the assessment with information sources used to perform the assessment.

COMPLETE AN ASSESSMENT

NFS completed an assessment (Ref. 2), comparing the Non-Mandatory Appendix 16A-1 of ASME NQA-1-2008 (Ref. 3) and the NFS CAP as described in NFS programs and procedures. Issues were identified and recommendations were made.

The assessment was completed at the NFS site by reviewing the CAP, supplementing the review with observations, reviews of document, and interviews with individuals involved in both leading and managing the program.

The assessment was done by completing a checklist, where applicable sections of NQA-1-2008-16A-1 were related to implementing procedures at NFS. The assessment also documented evidence of the implementation.

The NRC staff reviewed the assessment on its own merits. The assessment is clearly documented and organized. Issues were systematically identified by comparing the NFS CAP to applicable sections of NQA-1-2008-16A-1 (Ref. 3), element by element and offering supporting evidence in applicable program procedures. Issues are listed and clearly summarized.

The staff finds that the assessment addresses the relevant aspects of NQA-1-2008-16A-1, and clearly documents the findings in an organized and clear manner.

SUBMIT A LICENSE APPLICATION

The Order directed NFS to submit a LA within 9 months from the date of the Order. The Order, which became effective immediately, was issued on November 16, 2010. Thus, NFS was required to submit a LA by August 16, 2011. NFS submitted a LA dated August 5, 2011 (Ref. 4).

The NRC staff finds that NFS submitted the LA within 9 months of the Order.

ENHANCEMENTS AS A RESULT OF THE ASSESSMENT

Recommendation 1. The NFS assessment (Ref. 2) recommended that the corrective actions should be integrated into all aspects of the Quality Assurance (QA) Program.

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 and responsibilities associated with this program and CAP will improve the consistency between the two programs. Although NFS did not change terminology they use, to better define the CAP elements, the licensee added a definition of Condition Adverse to Safety (CAS) to Section 2.2, 2.5.1, and 11.6 of the license application.

The NRC staff acknowledges that the process used to correct safety-related issues and product quality issues are similar but with different functions. The NRC staff is not aware of any significant problems caused by a lack of coordination between the programs. Therefore, the NRC staff finds both that the NFS response to the recommendation is acceptable and that NFS has adequately incorporated its CAP into the commitments in the LA. Therefore, the NFS response to the recommendation is acceptable.

Recommendation 2. The NFS assessment (Ref. 2) stated that NFS implementing procedure GH-922 uses the NQA-1 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 implementing procedure NFS GH-922.

Even though this recommendation was related to specific NFS implementing procedures, NFS made changes to its LA to its own definition. In its RAI responses, NFS stated that it uses the term "conditions adverse to safety," in lieu of "conditions adverse to quality" as used in NQA-1. As a result, NFS added the following definition to Section 1.2.7 of the LA:

> **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.

In addition, NFS stated that the CAP implementing procedures classify the risk of conditions adverse to safety. The classification can range from low risk (little to no safety significance) to high risk (significant risk to the health and welfare of the public or plant personnel).

The NRC staff finds that the definition added to the LA to classify the risk significance of conditions using procedural control is an adequate response to the recommendation, and is acceptable.

Recommendation 3. The NFS assessment (Ref. 2) stated that implementing procedure NFS-GH-922 should be customized to reflect the overall NFS process for addressing QAP sections 15 and 16 flow down of implementing control of nonconforming conditions, CAQ, SCAQ, and providing corrective action. This would include how the Problem Identification, Resolution, and Correction System (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.

The assessment made this recommendation based on implementing procedure NFS-GH-922. However, NFS revised Chapter 1, Chapter 2, and Chapter 11 of its LA to clarify several areas of their CAP. In RAIs responses, NFS stated that its CAP, and in particular the PIRCS software program used to document plant-wide corrective action activities, provides a comprehensive system as follows:

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

As stated above, NFS acknowledges that there is room for improvement between its Quality Assurance Program and CAP implementing procedures, but this level of detail is not typically included in the application. NFS believes that the practices being implemented are adequate to ensure quality-related issues that have the potential to impact the safety of licensed activities are properly identified and classified within the CAP.

The NRC staff agrees that it is acceptable for the detail on how PIRCS provides a comprehensive system for corrective action activities to be addressed in procedures instead of in the LA. The NRC staff evaluated the LA by identifying the elements of an acceptable CAP as defined in the NQA-1-2008-16A-1 guidance. Section 11.6 of the LA describes the elements of the CAP, as provided in NQA-1-2008-16A-1 for:

- identification and documentation
- classification
- causal analysis
- corrections
- follow-up
- management involvement

Following is the NRC staff's review of the changes made by NFS each of the above CAP elements.

Identification and documentation: As described in NQA-1-2008-16A-1, conditions adverse to safety should be identified and documented. The extent to which other items and activities may be affected should be evaluated so that appropriate actions may be taken, including measures to control any affected work in process, if necessary. Conditions should be reviewed to determine the existence of trends. The significance of trends should be determined. Other information that could indicate CAQ should be reviewed and evaluated. Corrective actions should be documented in a manner that permits reviewing, evaluating, and verifying the results of the activities.

In its RAI responses (Ref. 5), NFS stated that they use software known as PIRCS, to document and track both conditions adverse to safety and corrective actions. PIRCS is the software program used to document plant-wide corrective action activities to identify and track events, employee identified safety items, audit findings, customer-related quality issues, inspections, surveillances, investigations, and corrective actions from initiation to completion and follow-up.

On January 31, 2012, during a site visit, (Ref. 6), the NRC staff were told by the licensee that any employee can enter an issue into PIRCS. Once an issue is entered, the first phase is to separate issues into personnel matters and procedures/hardware issues. Personal information is redacted for tracking purposes. Minor issues (e.g., light bulb burned out in office hallway) are addressed, but separate from significant issues involving hardware and procedures. Once an issue is entered, the PIRCS is access controlled such that only a limited number of NFS staff can modify the entries.

As part of the enhancements to the CAP as a result of the assessment, Section 2.5., "Reporting of Potentially Unsafe Conditions or Activities," of the LA was revised to indicate that prompt reporting is expected so that conditions adverse to safety can be corrected as soon as practicable.

Section 11.6 of the LA included commitments for documentation of corrective actions, generic implications of events, and trending. Section 11.6.2 of the LA states that corrective actions are documented and monitored to final resolution risk. However, the licensee revised both Section 11.6.1 and Section 11.6.2 to add further clarifications in some areas. Section 11.6.1 of the LA was revised to clarify that NFS implements, through written procedures, a CAP to investigate and document events for operations involving special nuclear material, in addition to those required to be reported under 10 CFR 70.50, 70.61, and 70.74. In addition, this section was revised to include that measures to prevent recurrence and/or to control affected work in progress may also be taken.

The LA was also revised to include further clarification on trending evaluation activities. Section 11.6.2 was revised to (1) clarify that relevant findings are communicated to the appropriate levels of management in addition to affected personnel, (2) clarify that trending involving conditions adverse to safety will also be reviewed, in addition to trending involving failure of IROFS, and (3) include that adverse trends are entered in the system as events and are classified using the same graded, risk-based approach used to classify events.

Classification: As described in NQA-1-2008-16A-1, the criteria for classifying conditions CAQ should be established, considering the impact on health and safety of the public or environment; the impact on reliability, availability, or maintainability of the equipment or facility; the importance in meeting regulatory commitments; the consequence of recurrence; and the extent to which the adverse condition may apply to other items or activities.

As mentioned above in the discussion for recommendation 2, the licensee defined conditions adverse to safety in Section 1.2.7, and it parallels the definition of CAQ provided in NQA-1.

Section 11.6.1 of the LA (Ref. 4) was revised to clearly describe the process used for classifying events. Events are reviewed and classified using a graded, risk-based approach that is guided by risk-tables in implementing documents. The criteria for classifying conditions adverse to safety takes into consideration safety significance and regulatory compliance, including the impact on the health and safety of the public and the environment (i.e., for a chemical spill - type of chemical, spill volume, spill location): impact on reliability or availability of equipment/facilities (e.g., IROFS failure or degradation, customer product quality): and impacts to regulatory commitments. In addition, the licensee clarified that (1) a multi-disciplinary committee provides further review of issues to ensure proper classification, and based on the significance of the issue, may initiate an investigation to determine the root cause of the condition and (2) corrective actions are developed, approved, and implemented for conditions adverse to safety; and (3) measures to prevent recurrence and/or to control affected work in progress may also be taken.

The licensee revised Section 11.6.2 of the LA to include commitments on prioritization of corrective actions. It was clarified that a graded, risk-based, approach is used to prioritize the corrective actions so that conditions adverse to safety are corrected as soon as practicable. The process used to monitor corrective actions also includes verification and completion of those corrective actions and as applicable, reviews of effectiveness and management attention for those corrective actions deemed ineffective.

In addition, the licensee responded that the CAP implementing procedures discuss how the graded, risk-based approach is applied 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.

Section 11.6.2 included the commitment to ensure prompt investigation of an event, commensurate with ensuring the safety of the investigator(s), after the event has been brought under control. As described in the LA, team investigations will be performed by individuals that include at least one individual knowledgeable of the area being investigated and at least one team member trained in root cause analysis.

Cause Analysis: As described in NQA-1-2008-16A-1, measures to determine the root cause of SCAQ should be developed. The impact of such conditions on completed and/or related items and activities should be evaluated and the results of the evaluation of root cause analysis should be documented.

Section 11.6.2 included a commitment to determine specific or generic root cause(s) and generic implication of events such as having at least one individual knowledgeable of the area being investigated (as applicable), and at least one team member trained in root cause analysis for team investigations. In addition, this section included commitments for documentation of root cause analysis evaluations. The LA states that "auditable records and documentation related to events, investigations, and root cause analysis are maintained as described in written procedures." However, the licensee revised Section 11.6.1 to clarify that a graded, risk-based approach is used to establish the requirements for such determination.

The licensee also responded that the PIRCS system provides a standardized process to track the corrective action process, including investigation of root cause, implementation of corrective actions and assessment of effectiveness, and management follow-up for significant conditions adverse to safety.

Corrections: As described in NQA-1-2008-16A-1, the action(s) necessary to correct conditions adverse to quality should be determined and implemented. For SCAQ, actions necessary to correct the root cause should also prevent recurrence. The analysis should be documented, including the preventive action taken, the generic implications, and measures to prevent recurrence

As stated above, Section 11.6.1 of the LA was revised to clarify that NFS implements, through written procedures, a CAP to investigate and document events for operations involving special nuclear material, including to those required to be reported under 10 CFR 70.50, 70.61, and 70.74. In addition, this section was revised to clarify that corrective actions are developed, approved, and implemented. Measures to prevent recurrence and/or to control affected work in progress may also be taken. As revised by the licensee, section 11.6.2 states that a graded, risk-based, approach is used to prioritize the corrective actions so that conditions adverse to safety are corrected as soon as practicable. The process used to monitor corrective actions also includes verification and completion, and as applicable, reviews of effectiveness and management attention for those corrective actions deemed ineffective.

Follow-up: As described in NQA-1-2008-16A-1, the implementation of corrective actions for significant CAQ should be verified and its effectiveness should be determined. Corrective actions should be monitored through completion and verification of effectiveness of corrective actions should be performed. When corrective actions are found to be ineffective, further analysis should be performed correct the cause and escalated attention by management should be given.

The licensee indicated that when an entry is made in PIRCS by an NFS employee, the entry is reviewed to ensure that the entry is properly classified and to determine its safety significance using risk tables in procedures. As stated in Section 11.6 of the LA, the assignment of the level of investigation of events, as described in written procedures, is determined based on the significance of the issue. As previously discussed, corrective actions are eventually developed, approved, implemented, and monitored to completion. The more significant events are investigated for root cause, and these corrective actions are also evaluated for effectiveness. If the corrections are effective, the issue is closed. If the issue is not completely resolved, additional investigations and corrective actions are assigned.

Section 11.6.2 of the LA was revised to clarify both the trending of conditions adverse to safety and the process used to classify the significance of the trending results. The licensee clarified that the process used to monitor corrective actions also includes verification of completion, and as applicable, reviews of effectiveness and management attention for those corrective actions deemed ineffective. In addition, the licensee clarified that trending involving conditions adverse to safety will also be reviewed, in addition to trending involving failure of IROFS, to provide feedback to management for minimizing and preventing recurrence. The licensee stated that adverse trends are entered into PIRCS as events and are classified using the same graded, risk-based approach used to classify events.

Management Involvement: As described in NQA-1-2008-16A-1, the responsibilities of management in the corrective action process should be specified. Corrective action activities should allow cognizant management to be notified immediately when CAQ are determined to be significant.

As described in the LA, the NFS organization provides the management, administrative, and technical capabilities for ensuring that NFS site operations utilizing SNM are conducted in a manner that is protective of its workers, the public, and the surrounding environment; and remain in compliance with applicable Federal, State, and local regulations, licenses, and permits. Section 2.2 of the LA was revised to clarify the role of NFS management in addressing events. It was revised to include a commitment that each management team will be responsible for ensuring that conditions adverse to safety are reported and investigated promptly and that corrective actions are tracked to completion and, as applicable, monitored for effectiveness. In addition, section 11.6.2 was revised to include a commitment to provide management attention for corrective actions deemed ineffective and to clarify that those relevant findings will be communicated to appropriate levels of management.

The NRC staff finds that the changes made to each of the above elements in Chapter 1, Chapter 2, and Chapter 11 do not represent a reduction in commitment and adequately describe the overall NFS CAP. In addition, the staff has determined that the

commitments presented in the license for a CAP satisfy the requirements of NQA-1-2008, Part III, Subpart 3.1, "Non-Mandatory Appendix 16A-1" for identification and documentation, classification cause analysis, corrections, follow-up, and management involvement. Therefore, the NFS response to the assessment recommendations is acceptable.

Recommendation 4. The NFS assessment (Ref. 2) stated that the NFS QA Program should identify when PIRCS is used as the system to handle identification of nonconforming conditions and corrective action, and where and when other processes are used. This should focus on the identification of non-conformances and the disposition of the issues identified.

Recommendation 4 is addressed in the discussion of Recommendation 1.

Recommendation 5. The NFS assessment (Ref. 2) stated that the 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.

As discussed above, the LA defines "conditions adverse to safety," and commits to a risk-based approach for assessing the significance of conditions adverse to safety. The terminology is similar, but not identical to the NQA-1 terminology. The definition of "condition adverse to safety," as provided in the license application, parallels the definition of "condition adverse to quality" as described in NQA-1. Therefore, the NRC staff finds the commitment in the LA to be adequate. As such, the NFS response to this recommendation is acceptable.

Commitments on classification of CAQ are covered in discussion to recommendation 3 above.

Recommendation 6. The NFS assessment (Ref. 2) stated that follow-up for CAQ should include a method for escalating management attention to unresolved items. QA uses a CAR[1] system but no process is described in PIRCS.

As discussed under Recommendation 3, the revised license application includes commitments to ensure management involvement in the CAP.

Therefore, the NRC staff finds that the commitments are adequate.

[1] Corrective Action Report. A report initiated by Quality Control detailing conditions and significant conditions adverse to quality and requesting corrective action by the responsible person or organization.

ENVIRONMENTAL REVIEW

A proposed action is excluded from an Environmental Review under Title 10 of the *Code of Federal Regulations* (10 CFR) 51.22(c)(11) if it is procedural in nature and satisfies the following requirements:

i. There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite.
ii. There is no significant increase in the individual or cumulative occupational radiation exposure.
iii. There is no significant construction impact.
iv. There is no significant increase in the potential for or no consequences from radiological accidents.

Changing the LA commitments for the CAP meets the requirements listed above. No significant change in effluents is expected. The proposed action makes no changes to the existing environmental monitoring program. No significant change in exposures is expected because worker exposures will continue to be monitored, and the exposures will continue to be evaluated by the existing program. There is no construction associated with the action and no change to operating equipment which would increase the potential for or consequences from an accident.

The NRC staff determined that the proposed action does not adversely impact public health and safety or the environment, and is categorically excluded from the requirement to prepare a site-specific Environmental Assessment (EA). Therefore, in accordance with 10 CFR 51.22(c)(11), neither an EA nor an Environmental Impact Statement is warranted for this action.

CONCLUSION

As stated above, the NRC staff finds that the revised LA (Ref. 7) adequately defines the overall process for the CAP and the changes made do not represent a reduction in commitment. The NRC staff concludes that NFS has fulfilled Paragraph 6 in Section V of the Order. The licensee completed an assessment; submitted a request to amend SNM-124 within 9 months of the Order; and incorporated into the license the current CAP, including enhancements made as a result of the assessment.

The licensee submitted an updated LA, incorporating the above mentioned changes, as Reference 7.

The Region II inspection staff have no objection to this action.

PRINCIPAL CONTRIBUTORS
Kevin Ramsey
Christopher Ryder
Soly Soto

REFERENCES

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

2. Letter from Mark P. Elliott, NFS, "Supplemental Information [Assessment] Supporting the Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-10-076)," February 7, 2012. ADAMS Accession Number ML120460946.

3. The American Society of Mechanical Engineers, "Quality Assurance Requirements for Nuclear Facility Applications," ASME NQA-1–2008.

4. Letter from Mark P. Elliott, NFS, "Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-10-076)," August 5, 2011. ADAMS Accession Number ML11228A082.

5. Letter from M. Elliott, NFS, 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), May 14. 2012. ADAMS accession number ML12143A313.

6. "Meeting Summary January 31, 2012, with Nuclear Fuel Services," ADAMS accession number ML120380446.

7. Nuclear Fuel Services, Inc., "Revised Request to Amend SNM-124 Regarding Corrective Action Program," October 10, 2012. ADAMS accession number ML12296A156.