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Nuclear Fuel Services Corrective Action Program
NQA-1-2008-16A-1 Gap Analysis

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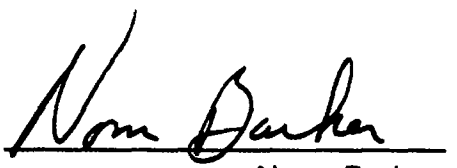

Norm Barker
Assessor

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Executive Summary

An assessment of the NFS Corrective Action Program (CAP) was performed by doing a gap analysis against NQA-1-2008 Appendix 16A-1. This included a comparison between ASME NQA-1-2008 Appendix 16A-1 and the NFS Corrective Action Program as described in NFS programs and procedures. In addition an assessment of the CAP program implementation was performed by observation, review of documentation, and interviews with individuals involved in leading and managing the program.

General Perspective on NQA-1 Corrective Action Requirements

The application and use of NQA-1-2008 Appendix 16A-1 is built upon the NQA-1 Quality Assurance Standard basic requirement 16 of NQA-1 2008. Integrating corrective action into all aspects of the quality assurance program is expected as stated in section 200 of 16A-1. In addition, NQA-1 basic requirement 16 is linked to basic requirement 15 in Controlling Nonconforming Items. Clearly the corrective action program needs to be well connected and compatible with the NFS QA program and consistent with the principles of NQA-1-2008.

Results

The assessment concludes that although much of the content of NQA-1 Appendix 16A-1 is covered in the NFS Problem Identification, Resolution and Correction System (PIRCS), it is necessary to adjust, tailor, and better align the NFS QAP identified process and NQA-1 terminology with the NFS PIRCS system to fully meet the requirements of NQA-1-Appendix 16A as applied to NFS unique needs.

In general, the NFS CAP as generally described in NFS GH-922, Rev 11 and referenced procedures covers most of the elements of NQA-1 Basic Requirement 16 and the guidance in 16A-1. However, the PIRCS process is not well aligned with the NFS QAP and does not completely pick up all the specific details and terminology of 16A-1. Also the NFS QAP and procedures used in other aspects of NFS activities use different terms and applications for handling conformances and corrective action. In order to fully comply with the NRC commitment to NQA-1 2008 Appendix16A-1, the PIRCS system should reflect the flowdown from the NFS QAP and better describe how the basic principles of corrective action are applied to NFS operations and are built into or connected to PIRCS.

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. This must include the prompt classification and segregation of Significant Conditions Adverse to Quality and appropriate cause analysis, correction and follow up as soon as practical as required in sections 302, 303, 304, and 305 as well as provide appropriate and timely action to analyze and provide corrective action to Conditions Adverse to Quality.

Report

Scope of Assessment

An assessment of the Nuclear Fuel Services (NFS) Corrective Action Program (CAP) was performed by doing a gap analysis against NQA-1-2008 Appendix 16A-1. This included a comparison between ASME NQA-1-2008 Appendix 16A-1 and the NFS Corrective Action Program as described in NFS programs and procedures. In addition an assessment of the CAP program implementation was performed by observation, review of documentation, and interviews with individuals involved in leading and managing the program. The assessment was conducted February 7 to 10, 2011 by Mr. Norm Barker.

The assessment consisted of a review of the NFS QA Program with specific focus on the gap analysis of NQA-1-2008 Appendix 16A-1 that covers the corrective action procedures being used, along with discussions with management team members. over 20 interviews with both QA/QC and line organization personnel, and direct observations and review of evidence of corrective action implementation. The completed checklist included in Attachment 1 provides detailed evidence of the gap analysis and procedural coverage along with observations on implementation. It is noted that the gap analysis includes the NFS QA program as it pertains to identifying nonconformances and providing corrective action as required by criteria 1, 15 and 16 of NQA-1-2008 as well as the specific requirements of Appendix 16A-1.

General Observations

NFS has a Quality Assurance Program (QAP) described in NFS-M-48, R3 which is generally patterned consistent with NQA-1, although not committed to NQA-1-2008. The NFS QAP, however, does not referece the NFS Problem Identifcation, Resolution, and Correction System (PIRCS) as described in NFS GH-922, Rev 11. It references alternate QA/QC procedures to cover nonconformances and corrective action requirements.

The PIRCS System has been developed and has done a good job in providing a single automated system to create overall attention by the management and plant team to identify, report and manage problems. The nuclear and safety culture has been addressed by the screening and processing, evaluation and resolving problems by the joint multiple discipline mid-management participation in prescreening, screening. and participation in formal cause analysis. and corrective action processing. The PIRCS System is used to track all problems and follow-up. This system has become the primary method to deal with all Issue Management as well as Corrective Action processes.

The assessment concludes that although much of the content of NQA-1 Appendix 16A-1 is covered in PIRCS, it is necessary to adjust, tailor, and better align the NFS PIRCS system and the NFS QA Program process identified and the NQA-1 terminology to fully meet the requirements of NQA-1-Appendix 16A as applied to NFS unique needs.

In general, the NFS CAP as generally described in NFS GH-922, Rev 11, and referenced procedures covers most of the elements of NQA-1 Basic Requirement 16 and the guidance in

16A-1. However, the PIRCS process is not well aligned with the NFS QAP and does not completely pick up all the specific details and terminology of 16A-1. Also the NFS QAP and procedures used in other aspects of NFS activities use different terms and applications for handling conformances and corrective action. In order to fully comply with the NRC commitment to NQA-1 2008 Appendix16A-1, the PIRCS system should reflect the flow down from the NFS QAP and better describe how the basic principles of corrective action are applied to NFS operations and are built into or connected to PIRCS.

Specific Observations and Recommendations

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.

Attachment A provides a detailed matrix of the gap analysis between the NFS coverage of NQA-1 16A-1.

The following summarizes the issues identified and provides recommended actions:

- (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.
- NFS GH-922 uses the NQA-1 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.
- 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.
- 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.
- (NQA-1-16A-1-300) 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-1 terminology.

- (NQA-1-16A-1-305) Follow-up should include a method for escalating management attention to unresolved items. QA uses a CAR system but no process is described in PIRCS.

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Reference: NQA-1-2008

Assessor: Norm Barker

Attachment A: NQA-1-2008 16A-1 Assessment Checklist

NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
REQUIREMENT 1 ORGANIZATION 100 Responsibilities for the establishment and implementation of the QA program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented. 200 Structure & Responsibility 201 General The organizational structure and responsibility assignments shall be such that (a) Senior management establishes overall expectations for effective implementation of the QA program and is responsible for obtaining the desired end result. (b) Quality is achieved and maintained by those assigned responsibility for performing work (c) Quality achievement is verified by those not directly responsible for performing the work (d) Those responsible for assuring that an appropriate QA program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to	NFS-M-48, R3, *QA Program:* 1.1 Description 1.2 Requirements 1.3 Organization & Responsibilities NFS-M-48, R3, *QA Program:* 1.1 P2 NFS-GH-922, R11, *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* Section 6 Program Roles and Responsibilities	Evidence confirmed the existence of an NQA-1 QA program as covered in NFS-M-48, Rev 3. Although NFS has not commited to the NQA-1 2008 standard there is evidence that the organization structure, roles and responsiblities, are defined and being implemented for the corrective action activity to meet NQA-1-16A-1. Organization charts and details for roles and responsibilities are available in the QA Program and in the procedure that most completely covers the corrective action process. NFS-GH-922, R11 It is noted that there are separate systems for identification and corrective action that are used depending on the nature of contracts. The QA/QC procedures covering nonconformance and corrective action on some contracts are performed to different procedures with different roles and responsibilities than those in the primary system defined in NFS-GH-922 R11. The flowdown of the NFS QAP into the procedures being used needs to be better integrated as discussed further below. The QA organization was confirmed to be adequately independent of cost and schedule considerations.

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NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
safety function considerations.		
202 Delegation of Work The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefore.	NFS-M-48, R3, *QA Program:* 1.2.2	The critical QA system role for identifying nonconformaces, problems and providing corrective action is clearly an organization wide QA function and that part of the QA program has been delegated to the PIRCS Program Owner (NFS President) or the QA/QC Organization for some contracts and activities. As noted below, the NFS QAP does not clearly define this delegation, although implementing procedures and actual practice evidence is available.
300 Interface Control Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented. The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.	NFS-M-48, R3, *QA Program:* 1.2.4 NFS-GH-922, R11 and associated procedures	Interfaces are covered in procedures and the interaction and participation was observed by attending a Screening Committee meeting which included representation from all key functional groups including QA. This meets the interface requirements associated with NQA-1-16A-1 requirements.
REQUIREMENT 15: CONTROL OF NONCONFORMING ITEMS		
100 Basic Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items and for notification to affected	NFS-M-48, R3, *QA Program:* 15.1 NFS-Q-185, R4, *Control of Nonconforming Items* 4.3, 4.4	NQA-1 Critierion 15 is usually interpreted to cover both hardware nonconformance and conditions adverse to quality. The elements of identification of non conforming conditions and the process for communicating, screening, documenting, dispositioning and providing corrective action are well identified in the QA Procedures used by the QC

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NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
organizations.	NFS-GH-922 section 7.1 NFS-GH-65, R6, *Problem Identification*	organization. NFS-Q-176 R3. NFS-Q-185 NFS-Q-214 The coverage of problem identification included in the PIRCS system, NFS-GH-922 & NFS-GH-65, R6, *Problem Identification* does not discuss the handling of nonconforming conditions or discuss dispositioning of nonconforming conditions as required in NQA-1.
200 Identification Nonconforming items shall be identified by legible marking, tagging, or other methods not detrimental to the item, on the item, the container, or the package containing the item.	NFS-M-48. R3. *QA Program:* 15.2.1 NFS-Q-185, R4, *Control of Nonconforming Items* 4.1 NFS-GH-922, R11, *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* *7.1* NFS-GH-65, R6, *Problem Identification* 5.1, 5.2	The elements of identification for non conforming conditions and the process for communicating, screening, documenting, dispositioning and providing corrective action are well identified in the QA Procedures used by the QC organization. NFS-Q-176 R3. NFS-Q-185. NFS-Q-214. The coverage of problem identification included in the PIRCS system, NFS-GH-922 & NFS-GH-65, R6, *Problem Identification* does not discuss the handling of nonconforming conditions or discuss dispositioning of nonconforming conditions as required in NQA-1.
300 Segregation (a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. (b) When segregation is impractical or impossible due to physical conditions such as size, weight, o access	(a) NFS-M-48, R3, *QA Program:* 15.2.2 PI (b) NFS-M-48, R3, *QA Program:*	Covered for hardware in the QC procedures NFS-Q-185, R4, *Control of Nonconforming Items* 4.2

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NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.	15.2.2 P2 NFS-Q-185, R4, *Control of Nonconforming Items* 4.2	
400 Disposition 401 Control Nonconforming items shall be evaluated and recommended dispositions shall be proposed.	NFS-M-48, R3, *QA Program:* 15.2.3 P2 NFS-Q-185, R4, *Control of Nonconforming Items* 4.4	The elements of identification for non conforming conditions and the process for communicating, screening, documenting, dispositioning and providing corrective action are well identified in the QA Procedures used by the QC organization. NFS-Q-176 R3. NFS-Q-185. NFS-Q-214. The coverage of problem identification included in the PIRCS system, NFS-GH-922 & NFS-GH-65, R6, *Problem Identification* does not discuss the handling of nonconforming conditions or discuss dispositioning of nonconforming conditions as required in NQA-1.
402 Responsibility & Authority The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined. Responsibility for the control of further processing, deliver, installation, or use of nonconforming items shall be designated in writing.	NFS-M-48, R3, *QA Program:* 15.2.3 P1	Generall covered in NFS-Q-185, R4, but not as clear in NFS-GH-922
403 Personnel Personnel performing evaluations to determine a disposition shall have (a) demonstrated competence in the specific area	NFS-M-48, R3, *QA Program:* 15.2.3 P4	The elements of identification for non conforming conditions and the process for communicating, screening, documenting, dispositioning and providing corrective action are well identified in the QA Procedures used by the QC organization. NFS-Q-176

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NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
they are evaluating (b) an adequate understanding of the requirements (c) access to pertinent background information	NFS-Q-185, R4, *Control of Nonconforming Items* 4.4.2	R3. NFS-Q-185. NFS-Q-214. The coverage of problem identification included in the PIRCS system, NFS-GH-922 & NFS-GH-65, R6, *Problem Identification* does not discuss the handling of nonconforming conditions or discuss dispositioning of nonconforming conditions as required in NQA-1.
404 Disposition A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented. Technical justification for the acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required as-built records shall reflect the use-as-is or repair condition.	NFS-M-48, R3, *QA Program:* 15.2.3 P5 NFS-Q-185, R4, *Control of Nonconforming Items* 4.4.1; 4.4.3	The elements of identification for non conforming conditions and the process for communicating, screening, documenting , dispositioning and providing corrective action are well identified in the QA Procedures used by the QC organization. NFS-Q-176 R3. NFS-Q-185. NFS-Q-214. The coverage of problem identification included in the PIRCS system, NFS-GH-922 & NFS-GH-65, R6, *Problem Identification* does not discuss the handling of nonconforming conditions or discuss dispositioning of nonconforming conditions as required in NQA-1.
405 Reexamination Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria. Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate	NFS-M-48, R3, *QA Program:* 15.2.3 P5 NFS-M-48, R3, *QA Program:* 15.2.3 P5	The elements of identification for non conforming conditions and the process for communicating, screening, documenting , dispositioning and providing corrective action are well identified in the QA Procedures used by the QC organization. NFS-Q-176 R3. NFS-Q-185. NFS-Q-214.

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acceptance criteria.	NFS-Q-185, R4, *Control of Nonconforming Items* 4.4.4	The coverage of problem identification included in the PIRCS system, NFS-GH-922 & NFS-GH-65, R6, *Problem Identification* does not discuss the handling of nonconforming conditions or discuss dispositioning of nonconforming conditions as required in NQA-1.
REQUIREMENT 16 CORRECTIVE ACTION 100 Basic 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. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* NFS-M-48, R3, *QA Program:* NFS-Q-176, R3 *Corrective Action Procedure* NFS-GH-65 R6 *Problem Identification* NFS-GH-918, R9 *Directed Investigation Program* NFS-CAP-001, R0 *Differing Professional Opinions* NFS-CAP-002, R0 *Problem Resolution: Developing Effective Corrective Actions* NFS-CAP-003, R0 *Apparent Cause Analysis* NFS-CAP-004, R0 *Common Factors Analysis* NFS-CAP-005, R0 *Safety Culture Implications Review* NFS-CAP-006, *R0 Generic Implications Determination by Performing Extent of Conditions and Cause Reviews* NFS-CAP-007, R0 *Trend Analysis* NFS-CAP-EFFECT-EVAL, R0 *Corrective Actions Program Guidance Document, Assigning and Performing Effectiveness Evaluations*	In general the NFS Corrective Action Program (CAP) as generally described in NFS GH-922, Rev 11 and referenced procedures covers most of the elements of NQA-1 Basic Requirement 16 and the guidance in 16A-1. However, the PIRCS process is not well aligned with the NFS QAP and does not completely pick up all the specific details and terminology of 16A-1. Also the NFS QAP and procedures used in other aspects of NFS activities uses different terms and applications for handling conformances and corrective action. In order to fully comply with the NRC commitment to NQA-1 2008 Appendix16A-1, the PIRCS system should reflect the flowdown from the NFS QAP and better describe how the basic principles of corrective action are applied to NFS operations and are built into or connected to PIRCS. Currently NFS-GH-922 does not address the clear separation between "Conditions Adverse to Quality" from "Significant Conditions Adverse to Quality." The definitions of (CAQ) and (Non CAQ) in NFS-GH-922 and the screening (problem classification) logic in NFS-GH-922, and NFS-GH-65 do not correlate to the NQA-1 screening for "Significant Conditions Adverse

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NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
		to Quality" even though the risk tables and logic provide risk considerations.
NONMANDATORY APPENDIX 16A-1 GUIDANCE ON CORRECTIVE ACTION 100 General This Appendix provides nonmandatory guidance on corrective action as specified in Requirement 16 of Part I.		See below.
200 Corrective Action Corrective action should be integrated into all aspects of the QA program and consist of 5 basic elements: (a) identification & documentation (b) classification (c) cause analysis (d) corrections (e) follow-up Corrective action activities should be prescribed in written form that provides adequate control over the basic elements above and should be documented in a manner that permits reviewing, evaluating, and verifying the results of the activities. Responsibilities should be prescribed.	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* (See above listing of procedures coverage) NFS-M-48, R3, *QA Program:*	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. In addition, the NFS-M-48, R3, *QA Program*, needs to be revised to flowdown the NQA-1, 16 and 16A-1 requirements to define the PIRCS process and to describe when the other QA/QC systems will be used (NFS-Q-185 & NFS-Q-176).

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NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
300 Basic Elements of Corrective Action 301 Identification and Documentation Conditions adverse to quality should be identified and documented. 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. Conditions adverse to quality should be reviewed to determine the existence of trends. Significance of identified trends should be classified. Other information that could indicate conditions adverse to quality should be reviewed and evaluated.	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* NFS-GH-65 R6 *Problem Identification* NFS-GH-918, R9 *Directed Investigation Program* NFS-CAP-007, R0 *Trend Analysis*	The identification of problems is documented on a problem report within the PIRCS system. Problem reports were reviewed along with the documentation packages for closing out the issues. Documentation of problems within the PIRCS system is observed to be in place. This meets NQA-1-16A-1
302 Classification 302.1 Criteria for classifying conditions adverse to quality as to significance should be established, and as a minimum, should consider the following aspects: (a) impact on health and safety of the public or environment (b) impact on reliability, availability, or maintainability of the equipment or facility (c) importance in meeting regulatory commitments (d) consequence of recurrence (e) the extent to which the adverse condition may apply to other items or activities beyond the specific occurrence	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* NFS-GH-65 R6 *Problem Identification* NFS-GH-918, R9 *Directed Investigation Program*	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. A better correlation is needed to demonstrate compliance to NQA-1- 16A-1.

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where it may have greater impact.		
302.2 Conditions adverse to quality identified under para. 301 of this Appendix should be classified according to significance using the established criteria. Examples of conditions that may be significant under certain conditions include (a) deficiencies in design, manufacturing, construction, testing, or process requiring substantial rework, repair, or replacement (b) damage to a structure, system, component, or facility requiring substantial repairs (c) a nonconservative error detected in a computer program after it has been released for use (d) loss of essential data (e) repeated failure to implement a portion of an approved procedure.	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* NFS-GH-65 R6 *Problem Identification* NFS-CAP-006, R0 *Generic Implications Determination by Performing Extent of Conditions and Cause Reviews*	See above.
302.3 In classifying conditions adverse to quality, the review should consider repetition of specific conditions adverse to quality, as well as the relationship or similarity between different conditions, in a manner and at a frequency that ensures significant quality trends are identified and evaluated for appropriate correction.	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* 1. NFS-CAP-004, R0 *Common Factors Analysis*	See above.
303 Cause Analysis For significant conditions adverse to quality, the root cause(s) should be determined and documented, and the impact of such conditions on completed and /or related	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* NFS-CAP-006, R0 *Generic Implications Determination by*	The cause analysis, extent of condition, and root and apparent cause processes were reviewed and considered appropriate to meet NQA-1-16A-1.

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NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
items and activities should be evaluated. Measures should be developed for determining the root cause(s) of significant conditions adverse to quality. The root cause is the main underlying source of a condition adverse to quality that, when corrected, eliminates recurrence of the condition. Typical root cause categories might include (a) inadequate management or supervision (b) inadequate human performance capability or skill (c) procedure inadequacy or error (d) inadequate training or qualification of personnel performing work (e) equipment or processing malfunction or inadequacy (f) impractical requirements or acceptance criteria (g) unrealistic schedules (h) worker fatigue	*Performing Extent of Conditions and Cause Reviews* NFS-CAP-003, R0 *Apparent Cause Analysis*	
304 Corrections The action(s) necessary to correct conditions adverse to quality should be determined and implemented. For significant conditions adverse to quality, action(s) necessary to correct the root cause(s) should also be included so as to prevent recurrence. The analysis to determine the action(s) to be taken to prevent recurrence of significant conditions adverse to quality may include studies, simulations, investigations, experimentation, trending, and interviewing personnel. The analysis should be documented and include (a) identification of preventive action to be taken	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)* NFS-CAP-006, R0 *Generic Implications Determination by Performing Extent of Conditions and Cause Reviews*	The cause analysis, extent of condition, and root and apparent cause processes were reviewed and considered appropriate to meet NQA-1-16A-1.

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NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
(b) a determination that generic implications have been considered (c) a determination that action taken will preclude recurrence		
305 Follow-Up The implementation of corrective action for significant conditions adverse to quality should be verified and should be assessed to determine its effectiveness. Corrective action status should be monitored. Corrective action should be verified as complete only when the actions to correct the condition adverse to quality, including, where appropriate, the actions to prevent recurrence, are complete and documented. When completion of corrective action cannot be verified due to a delay for an extended period of time, modification of the delay should be made to management of the affected organizations. After verification of completion of corrective action, follow-up reviews, surveillance, or auditing should e performed to determine whether actions taken have been and continue to be effective. When corrective actions have not been effective, further analysis should be performed to identify and correct the cause. In addition, the problem should receive escalated management attention.	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)*	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.
400 Management Involvement 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	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)*	Management involvement was observed to be in place by procedure and in practice to meet NQA-1-16A-1.

ENERGYSOLUTIONS

NQA-1-2008- 16A-1
Assessment Checklist

Audit Title: Nuclear Fuel Services Assessment
Reference: NQA-1-2008
Assessor: Norm Barker

NQA-1-2008 Requirement(s) (by section)	Implementing Procedures	Evidence of Implementation
management to be notified immediately when conditions adverse to quality are determined to be significant.	NFS-Q-176, R4. *Corrective Action Procedure* 4.1; 4.2	
500 Flow Chart Figure 16A-1.1 provides a pictorial illustration of the flow of activities through the basic element described in section 300 of this Appendix. The logic process illustrates a typical corrective action program and is provided for guidance and illustration only.	NFS-GH-922, R11 *The NFS Problem Identification, Resolution, and Correction System (PIRCS)*	PIRCS system generally follows this logic and meets NQA-1-16A-1.

Attachment B: Personnel Contacted

Name	Last	Title
Nick	Brown	Criticality Safety
Rocky	Crowe	Engineering & Former Corrective Actions Program Manager
John	Day	Quality Assurance Manager
Rik	Droke	Licensing & Regulatory/Safety Review Board
Mark	Elliott	Quality, Safety & Safeguards Director
Roddie	Fleming	Fuel Supervision
Dave	Hatcher	Quality Engineering
Jim	Hutton	Quality Engineering
Frank	Kerns	Work Control/Plant Superintendent
John	Kramer	Project Engineering Section Manager
Richard	Markland	Fuel Supervision
Jerry	May	BPF Supervision
John	Nagy	Assurance Director
Vanessa	Peterson	Corrective Actions Program Manager
Heather	Petterson	BPF Process Engineering Section Manager
Ronnie	Pierce	BPF Supervision
Jeff	Quillen	Process Engineering Section Manager
Charles	Street	Plant Superintendent
Mike	Tester	Radiation Protection Unit Manager

Attachment C: Documents Reviewed

Document Number	Document Title
1. NFS-PUR-A-054, R4	Control of Purchased Items and Services
2. NFS-Q-185, R4	Control of Nonconforming Items
3. NFS-Q-176, R3	Corrective Action Procedure
4. NFS-M-48, R3	Quality Assurance Program
5. NFS-Q-214, R1	Nonconformance and Corrective Action Trend Analysis Reporting for the Fuel Program
6. NRC Office of Investigation Report No. 2-2010-001	Letter dated November 16, 2010 to Mr. David Amerine, from Victor McCree, Deputy Regional Administrator for Operations, NRC, Subject: Confirmatory Order
7. 25296; 20566; 20984; 28317; 27756; 26114; 27627; 27756; 25576; 26775; 28187; 23971	Problem Reports
8. NFS-CAP-EFFECT-EVAL, R0	Corrective Actions Program Guidance Document, Assigning and Performing Effectiveness Evaluations
9. NFS-GH-65, R6	Problem Identification
10. NFS-GH-918, R9	Directed Investigation Program
11. NFS-GH-922, R11	The NFS Problem Identification, Resolution, and Correction System (PIRCS)
12. NFS-CAP-001, R0	Differing Professional Opinions
13. NFS-CAP-002, R0	Problem Resolution: Developing Effective Corrective Actions
14. NFS-CAP-003, R0	Apparent Cause Analysis
15. NFS-CAP-004, R0	Common Factors Analysis
16. NFS-CAP-005, R0	Safety Culture Implications Review
17. NFS-CAP-006, R0	Generic Implications Determination by Performing Extent of Conditions and Cause Reviews
18. NFS-CAP-007, R0	Trend Analysis