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March 21, 2012

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

References: 1)

- 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)

Subject:

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)

Dear Sir:

Nuclear Fuel Services, Inc (NFS) hereby submits the attached responses to the request for additional information for the request to amend SNM-124 regarding the Corrective Action Program (Reference 5). Some of the responses include proposed revisions to certain sections within SNM-124. Red text has been used to show the changes as previously proposed in Reference 3. Green text has been used to show additional changes proposed to address the RAI questions. 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-12-0053) in any correspondence concerning this letter.

Sincerely,

NUCLEAR FUEL SERVICES, INC.

Mark P. Elliott, Director

Quality, Safety, and Safeguards

JKW/pdj

Attachment: Response to Request for Additional Information for the Request to Amend

SNM-124 Regarding the Corrective Action Program

Copy:

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Attachment

Response to Request for Additional Information for the Request to Amend SNM-124 Regarding the Corrective Action Program

(16 pages to follow)

Response to Request for Additional Information 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, riskbased 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.

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.

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

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

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

NFS Response

The first sentence of Section 11.6.1 will be revised as follows to clarify that the scope of Section 11.6 is not limited to only "events" required to be reported under 10 CFR 70.50, 70.62, and 70.74. In addition, your comment requesting clarification of our commitment to maintain written procedures is also addressed.

NFS maintains implements, through written procedures, a corrective action program to investigate, and document, and report events for operations involving special nuclear materials, including those as required by to be reported under 10 CFR 70.50, 70.62, and 70.74 for operations involving special nuclear materials.

With the change proposed above, RAI 2.1(b) no longer applies.

- 2.2. 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."
- 2.3. 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.

NFS Response

After the first paragraph of Section 11.6.1, the section will be revised as follows to more clearly describe the process used to classify 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 (i.e., IROFS failure or degradation, customer product quality); and impacts to regulatory commitments.

A multi-disciplinary committee reviews these events in accordance with written guidance to determine the safety significance of the event provides further review to ensure proper classification, and based on the significance of the issue, may initiate an investigation to determine the root cause of the condition. A graded, risk-based approach is applied to the assignment of the level of investigation; and, based on severity or potential severity of the event, the investigation may be conducted by one or more individual(s). Levels of investigation, as well as reviews and approvals, are assigned for events in accordance with written procedures. Corrective actions are developed, approved, and implemented. Measures to prevent recurrence and/or to control affected work in progress may also be taken.

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.

4. 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 CAP on the following criteria: "CAQ shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence."

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

NFS Response

NFS trains employees to promptly report problems. Safety Conscious Work Environment (SCWE) training is provided to new employees and management as part of General Employee Training. SCWE training includes a module on "Reporting Concerns" that emphasizes prompt reporting and the avenues that are available to employees for reporting problems. This training is also periodically refreshed through the Annual Safety Refresher training module, which includes sections on safety culture, SCWE, and reporting of problems. NFS implementing procedure, NFS-CAP-009, *The NFS Corrective Action Program*, states "NFS employees and contractors are encouraged to identify and report events and unsafe conditions through their management and/or the PIRCS." This philosophy is also covered in NFS-GH-65, *Problem Identification*.

Section 2.5.1 will be revised for clarity as follows to address RAI 4(a).

2.5.1 Reporting of Potentially Unsafe Conditions or Activities

A problem identification system is available for any person at the NFS site to report potentially unsafe conditions or activities to the Safety Discipline. Prompt reporting is expected so that conditions adverse to safety can be corrected as soon as practicable. The concern is entered in the system, and processed through a screening committee with Safety Discipline representation. The screening committee assigns the issue to an owner and defines follow-up investigation/evaluation requirements. Corrective actions are assigned and tracked to completion. The Corrective Action Program is discussed further in Chapter 11.

For RAI 4(b), see the response for RAI 2.2 and 2.3.

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

Describe how this portion of the CAP has been incorporated into Chapter 11 of the LA.

NFS Response

See the response to RAI 2.2 and 2.3 above for measures to control affected work in progress. In addition, consideration of generic implications (i.e., the extent to which other items and activities may be affected) is already included in Section 11.6.1, paragraph 1, last sentence; and Section 11.6.2, item 5.

- 6. The NFS Corrective Action Program Gap Analysis (See Section 301, "Identification and Documentation") assessed the NFS CAP on the following criteria: "Conditions adverse to quality should be reviewed to determine the existence of trends. The significance of identified trends should be classified."
 - Section 11.6.2 of SNM-124 states that, "A database of events, investigations, and corrective actions is maintained for tracking, trending, and documentation purposes. Trends involving failure of IROFS are reviewed to determine effectiveness of safety systems and to provide feedback to management for establishment of actions to minimize and/or prevent recurrence."
- 6.1. Clarify Chapter 11 of the LA to identify whether trending determination activities will include trending of CAQ (i.e., loss of essential data, repeated failure to implement procedures, failures in record management, etc.); in addition to the evaluation of trends involving failure of IROFS. In addition, clarify if trending as described in Section 11.6.2, will be limited to investigations initiated for events specified in 10 CFR Parts 70.50, 70.62, or 70.74.
- 6.2. Clarify in Chapter 11 of the LA what measures are implemented by NFS for the classification of the significance of trends.

NFS Response

The last paragraph of Section 11.6.2 will be revised as follows to clarify trending of conditions adverse to safety and the process used to classify the significance of those trending results.

Trends involving <u>conditions</u> adverse to <u>safety</u>, <u>including</u> 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. <u>Adverse trends are entered in the system as events and are classified using the same graded, risk-based approach used to classify events.</u>

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

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

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

NFS Response

The second to last paragraph of Section 11.6.2 will be revised for clarity as follows to address RAI 7.1.

Auditable records and documentation related to events, investigations, and root cause analysis are maintained as described in written procedures. For each event utilizing a team investigation, the incident report will include a description of the event, contributing factors, a root cause analysis, and findings and recommendations. Relevant findings are communicated to affected personnel, including appropriate levels of management. A database of events, investigations, and corrective actions is maintained for tracking, trending, and documentation purposes.

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

NFS Response

Section 2.2 will be revised for clarity as follows to address RAI 7.2.

2.2 Site Organization

The NFS corporate 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. This responsibility is implemented through the functional disciplines of production, decommissioning, engineering, safety, material control and accountability, security, and quality assurance, as described in the sections below, all of which have safety-related responsibilities. Figure 2-1 shows the current NFS functional organization.

The management positions for each discipline together have the delegated responsibility for plant safety and for compliance with conditions of SNM licenses and with federal, state, and local regulations and laws governing operation of a nuclear facility in order to maintain a safe work place for all employees. Each discipline management team is responsible for

- ensuring that all activities in their area are performed in a safe and effective manner;
- managing and directing operations within their discipline;
- ensuring that all operations under its guidance comply with safety and license conditions, requirements for quality-related safety activities, and safety-related configuration management requirements;
- being knowledgeable of the safety procedures and programs as they relate to their area of responsibility; and
- developing, approving, and implementing procedures that incorporate safety and quality controls and limits commensurate with the particular operation involved; <u>and</u>
- 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.

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

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

Section 200 of NQA-1-2008 Nonmandatory Appendix 16A-1 states that "Corrective action should be integrated into all aspects of the quality assurance program. It consists of five basic elements:

- (a) identification and documentation
- (b) classification
- (c) cause
- (d) corrections
- (e) follow-up"

Describe how these assessment recommendations were addressed, identifying specific program changes that were made to better describe the overall CAP to specifically address each of the criteria in Section 200 (a) through (e) and how those changes were incorporated into Chapter 11 of the LA (see RAI 9 for further questions regarding how follow-up is or will be described in the license).

NFS Response

The CAP implementing procedures cover the five basic elements of NQA-1-16A-1-200, however, they are not formatted exactly as NQA-1 presents the elements. The CAP provides an integrated system for identification and documentation of events; these events are classified using a graded, risk-based approach. The more significant events are investigated for cause, and corrective actions are assigned, executed, and followed by management. These corrective actions are also evaluated for effectiveness. If they are deemed effective, the issue is closed. If they are not effective, the issue cycles back through the investigative corrective action process.

The following provides an outline of the CAP program and the implementing procedures associated with Section 200 (a) through (e).

(a) Identification and Documentation

Conditions adverse to safety are identified and documented through the QAP and CAP.

Conditions adverse to safety may include:

- Failures
- Malfunctions
- Deficiencies
- Defective items

Other information that could indicate conditions adverse to safety:

- Audits
- Inspections
- Assessments
- Individual observation
- Adverse trends
- Operational events
- Maintenance activities

CAP and QAP implementing procedures are as follows:

- NFS-CAP-009, The NFS Corrective Action Program
- NFS-GH-65, Problem Identification
- NFS-CAP-008, Directed Investigation Program
- NFS-CAP-007, Trend Analysis
- NFS-M-48, QA Program
- NFS-Q-176, Corrective Action Procedure Quality
- NFS-CAP-002, Problem Resolution: Developing Effective Corrective Actions
- NFS-CAP-003, Apparent Cause Analysis
- NFS-CAP-004, Common Factors Analysis
- NFS-CAP-005, Safety Culture Implications Review
- NFS-CAP-006, Generic Implications Determination by Performing Extent of Conditions and Cause Reviews
- NFS-CAP-EFFECT-EVAL, Corrective Actions Program Guidance Document, Assigning and Performing Effectiveness Evaluations

(b) Classification

Conditions adverse to safety are reviewed and classified utilizing a graded, risk-based approach. There is a process for classifying these conditions that determines whether or not they are significant.

When classifying conditions adverse to safety, a multi-disciplinary group, as well as management, considers the repetition of conditions adverse to safety, and the

relationship/similarity to different conditions, to determine when significant safety trends should be identified and evaluated for appropriate correction.

CAP implementing procedures are as follows:

- NFS-CAP-009, The NFS Corrective Action Program
- NFS-GH-65, Problem Identification

(c) Cause

For significant conditions adverse to safety, the root cause(s) are determined and documented within the CAP. NFS utilizes several methodologies for determination of cause.

CAP implementing procedures are as follows:

- NFS-CAP-009, The NFS Corrective Action Program
- NFS-CAP-008, Directed Investigation Program
- NFS-CAP-006, Generic Implications Determination by Performing Extent of Conditions and Cause Reviews

(d) Corrections

For significant conditions adverse to safety:

For significant conditions adverse to safety, the action(s) necessary to correct the root cause(s) are included so as to prevent recurrence.

CAP implementing procedures are as follows:

- NFS-CAP-009, The NFS Corrective Action Program
- NFS-CAP-008, Directed Investigation Program
- NFS-CAP-006, Generic Implications Determination by Performing Extent of Conditions

For conditions adverse to safety:

Corrective actions are determined, entered into PIRCS, and implemented per CAP procedure NFS-CAP-009. If applicable, effectiveness evaluations of corrective action(s) are conducted.

(e) Follow-Up (for significant conditions adverse to safety)

Corrective actions for significant conditions adverse to safety are implemented, documented, and evaluated for effectiveness per the CAP implementing procedure, NFS-CAP-009. Management monitors the status of corrective actions through completion. If they are deemed effective, the issue is closed. If they are not effective, the issue cycles back through the investigative corrective action process.

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

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

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

NFS Response

See the response to RAI 7.2 for proposed revisions to Section 2.2 to clarify management's involvement.

In addition, the following paragraph from Section 11.6.2 will be revised for clarity as follows.

Corrective actions are documented and monitored through completion. A graded, risk-based approach is applied to prioritize completion of corrective actions so that conditions adverse to safety are corrected as soon as practicable. 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. Corrective actions generated from investigations are used to make corrections and improvements (i.e., "lessons learned") necessary to prevent or minimize single or commonmode failures. Details of the accident event sequence(s) will be compared with accident sequence(s) already considered in the ISA, and the ISA Summary will be modified to include evaluation of the risk associated with accidents of the type actually experienced.