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*AIRBORNE EXPRESS*

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April 16, 2003

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

- References:
- 1) Docket No. 70-143; SNM License 124
  - 2) Letter from B.M. Moore to NRC, License Amendment Request to Support the Uranyl Nitrate Building at the BLEU Complex, dated February 28, 2002 (21G-02-0051)
  - 3) Letter from B.M. Moore to NRC, Revised License Amendment Request Regarding Management Measures for IROFS at the UNB, dated March 6, 2003 (21G-03-0053)
  - 4) Letter from NRC to B.M. Moore, Nuclear Fuel Services, Inc., Request for Additional Information (TAC No. L31739) Revised License Amendment Request Regarding Management Measures for IROFS, dated March 26, 2003

**Subject: Response to NRC Request for Additional Information Regarding Management Measures for IROFS at the UNB**

Dear Sir:

Nuclear Fuel Services, Inc. (NFS) hereby provides its response to the subject Request for Additional Information (RAI), regarding management measures for IROFS (Reference 4).

The response to the RAI is contained in Attachment I. Revised pages to the referenced license are contained in Attachment II. Due to the extensive changes to the license pages, Attachment II replaces the attachment to Reference 3 in its entirety. The NFS Safety and Safeguards Review Council has reviewed and approved these changes. For your convenience, vertical lines in the right-hand margin of affected license pages denote changes.

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If you or your staff have any questions, require additional information, or wish to discuss this, please contact me, or Mr. Rik Droke, Licensing and Compliance Director at (423) 743-1741. Please reference our unique document identification number (21G-03-0084) in any correspondence concerning this letter.

Sincerely,

**NUCLEAR FUEL SERVICES, INC.**

A handwritten signature in black ink, appearing to read 'BMM' with a stylized flourish.

B. Marie Moore  
Vice President  
Safety and Regulatory

JSK/lsn

cc:  
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**Attachment I**

NFS Response to NRC Request for Additional Information (RAI)  
Dated March 26, 2003

(15 pages to follow)

## **NFS Section 2.12.1 Configuration Management**

***NRC Comment No. 1: Revise Section 2.12.1.3 to include a commitment that the configuration management (CM) function will maintain strict consistency among the design requirements, the physical configuration, and the facility documentation as listed under the acceptance criteria in SRP Section 11.4.3.1 Item 4.***

***NFS Response:*** Section 2.12.1.4 *Change Control* has been revised to institute programmatic commitments to ensure that the configuration management (CM) function provides consistency among the design requirements, the physical configuration, and the facility documentation as follows:

### ***2.12.1.4 Change Control***

*Staff members from individual safety functions are required to review, in accordance with written procedures, proposed changes that may affect design requirements, physical configurations and facility documentation. The safety review committee reviews and approves all proposed changes involving IROFS credited in the ISA Summary. Other committee responsibilities are set forth in Sections 2.4, 11.4 and 11.7, and License Condition S-25. In addition, a review of approved changes (IACs) that may affect an ISA Summary are reviewed by the safety discipline annually in support of requirements specified in 10 CFR 70.72 and License Condition S-25. Oversight of the change control process by the safety discipline manager and the safety review committee ensures consistency with these configuration management elements.*

***NRC Comment No. 2: Per the acceptance criteria of SRP Section 11.4.3.1 Item 1, revise Section 2.12.1 to include a subsection that describes the configuration management organization, including design requirements staff, design staff (engineering), safety analysts, safety discipline manager(s), safety review committee, procurement staff, construction supervision staff, construction and installation verification staff, pre-operational auditors, periodic auditors, and others in the CM function. Describe how they interface with each other. A CM function flow chart may be useful to illustrate decision points and CM function chronologies and sequences. Also include the objectives of each CM activity.***

***NFS Response:*** Acceptance criteria in SRP Section 11.4.3.1 Item 1 addresses the need to describe the organizational structure and staffing interfaces related to designing new facilities or processes. This guidance also states that the functional interfaces with maintenance and training and qualification are of particular importance and should be addressed individually. In addition, the IROFS under CM should include all IROFS listed in the ISA Summary.

At NFS, the CM organization that ensures the design requirements are effectively implemented in new facilities and process operations includes input from the engineering and safety staff early in the design process. In addition, recommendations from safety personnel, as part of the Integrated Safety Analysis (ISA) process, may necessitate further refinement of the process design.

NFS uses the following methodology to design and complete a project.

- Define the project and establish a multi-disciplined design team to review the project and provide design requirements to the design engineers
- Prepare a project definition per NFS procedure and obtain management approval
- Obtain SSRC preliminary approval for the project
- Develop preliminary drawings relative to the project
- Perform a multi-disciplined ISA review and provide feedback to the design team including a list of IROFS.
- Complete detailed design with ISA review of changes from the preliminary design
- Construct the project consistent with detailed design
- Compare installation with P&IDs and approve the drawings
- Field test operating procedures to the extent possible
- Establish configuration control on drawings and operating procedures
- Obtain final approval of Internally Authorized Change (IAC) by the SSRC
- Perform final safety discipline inspection of installed equipment
- Perform equipment testing with water, chemicals, and/or non-special nuclear materials as appropriate
- Verify operating procedures during cold tests
- Obtain senior NFS management approval to proceed with startup

NFS has revised Section 2.12.1.1 *Configuration Management Policy* to reflect the organization and staffing interfaces that will be used for designing new facilities or process operations as follows:

#### *2.12.1.1 Configuration Management Policy*

*The design process shall rely on information supplied from a multi-disciplined team of engineers and safety personnel. This design process is initiated with a project definition wherein the baseline and safety design criteria are established and concludes with a detailed design wherein the safety criteria are incorporated. Information provided by the multi-disciplined team shall be used, as appropriate, to establish and implement the following configuration management functions for new facilities to ensure a baseline design meets the requirements specified in 10 CFR 70.64:*

- *Design Requirements,*
- *Document Control,*
- *Change Control, and*
- *Assessments.*

Functional interfaces with maintenance and training and qualification are addressed in the following sections: Section 2.12 *Management Measures for IROFS*; 2.12.2 *Maintenance of*

*IROFS*; and 2.12.3 *Training and Qualification*. In addition, the IROFS under CM include all IROFS listed in the ISA Summary, as specified in Section 2.12.1.1 *Configuration Management Policy*.

***NRC Comment No. 3: Per the acceptance criteria of SRP Section 11.4.3.1 Item 3, revise Section 2.12.1 to include a description of an acceptable method to create and control documents within the CM function. In addition to the list of records to be maintained, describe how the document database is catalogued, how documents are maintained and distributed, and how documents are retrieved. Describe how the document control function tracks document changes and avoids access by facility personnel to outdated design and specification documents for IROFS.***

*NFS Response:* Section 2.12.1.3 *Document Control* was added to specifically describe a method to create and control documents within the CM function. This section also cross-references Section 2.12.7 *Records Management* that provides additional information regarding the list of records that shall be maintained. Commitments and information contained in these referenced sections are commensurate with the regulatory guidance cited in SRP Section 11.4.3.1 Item 3.

***NRC Comment No. 4: Revise Section 2.12.1.3 to describe how the CM function will address the acceptance criteria in SRP Section 11.4.3.1 Item 4.***

*NFS Response:* Section 2.12.1.4 *Change Control* was revised commensurate with the acceptance criteria in SRP Section 11.4.3.1 Item 4.

***NRC Comment No. 5: Revise Section 2.12.5.2 to describe the scope of the biennial CM function audit. The audit should include both documents assessments and physical assessments (system walkdowns) as discussed in SRP Section 11.4.3.1 Item 5.***

*NFS Response:* NFS has committed to perform an initial and a biennial assessment of the CM function, as discussed in the SRP Section 11.4.3.1 Item 5, as follows:

#### *2.12.1.5 Assessments*

*An initial and a biennial assessment of the configuration management function shall be conducted to determine the program's effectiveness and to correct documented deficiencies. These assessments shall be performed in a systematic and planned manner and shall include both document assessments and physical assessments (i.e., facility walkdowns). The results of these assessments may provide a basis for future changes and shall be documented; the records shall be maintained in accordance with Sections 2.12.5 "Audits and Assessments" and 2.12.7 "Records Management".*

*The assessments shall be performed in accordance with the facility audit and assessment program as specified in Section 2.12.5 "Audits and Assessments".*

## **NFS Section 2.12.2 Maintenance of IROFS**

***NRC Comment No. 1: Revise Section 2.12.2 to describe the surveillance/monitoring of IROFS as discussed in the acceptance criteria of SRP Section 11.4.3.2 Item 1.***

**NFS Response:** Section 2.12.2 *Maintenance of IROFS* was revised to address surveillance and monitoring of IROFS as follows:

### *2.12.2.1 Maintenance of Active and Passive Engineered Controls*

*The maintenance program consists of several key program elements including a maintenance management system that provides the scheduling and documentation of the following maintenance elements when applied to IROFS:*

- *Surveillance and Monitoring,*
- *Corrective Maintenance,*
- *Preventive Maintenance, and*
- *Functional Testing.*

*Maintenance activities will be performed on IROFS in a manner to minimize the recurrence of unacceptable performance deficiencies. Maintenance, preventive maintenance, calibration, testing, and surveillance/monitoring of IROFS, to ensure continued reliability and functional acceptability of IROFS, will be authorized in accordance with written procedures and at frequencies approved by the safety review committee.*

***NRC Comment No. 2: Revise Section 2.12.2.1 to describe preventive maintenance, corrective maintenance and functional testing as discussed in the acceptance criteria of SRP Section 11.4.3.2, Items 2, 3, and 4. Also describe how a maintenance function is identified as not being applicable. Discuss whether a technical evaluation is performed and if such an evaluation is reviewed by a multi-disciplinary team of experts with review and approval by the safety review committee.***

**NFS Response:** Section 2.12.2.1 *Maintenance of Active and Passive Engineered Controls* was revised to describe preventive maintenance, corrective maintenance and functional testing of IROFS.

This section was also revised by deleting the specific reference that maintenance functions would be performed (as applicable) to ensure that equipment performs its functions effectively. In addition, a statement in the footnote below Table 2.2 *Management Measures for IROFS* that maintenance functions will be performed, if applicable, provides general guidance for which management measures will be applied to IROFS. This clarification is needed because in some instances a management measure listed in Table 2.2 is not practical or physically possible. However, in these instances, documentation is required to provide justification regarding the reason for deviating from a management measure identified in Table 2.2 *Management Measures*

for IROFS. To reflect this commitment, Section 2.12 *Management Measures for IROFS* was revised as follows:

### *2.12 Management Measures for IROFS*

*The applicable management measures identified in Table 2.2 are applied based on the type of control to ensure that the credited IROFS failure index meets the risk index specified or the design-based thresholds for events associated with natural phenomena. Information to justify a deviation from a management measure contained in Table 2.2 associated with a specific IROFS shall be documented by the ISA team.*

***NRC Comment No. 3: Revise Section 2.12.2.2 to discuss in detail management measures applied to administrative controls. The words “as applicable” in the footnote to Table 2.2 should be described in detail, including when, who, and what are involved in a decision to apply or not apply management measures to an administrative control. Also discuss when a management measure is applicable and what analysis (which should be part of the safety analysis) is made to determine that a management measure is not applicable. The ISA Summary should be revised to identify any IROFS that has less management measures applied than that fully specified for its corresponding risk reduction level. Section 2.12.2.2 should also be revised to include a description of maintenance for administrative (especially when the administrative control includes an active component) and enhanced administrative controls.***

NFS Response: As stated in response to NRC Comment No. 2 (above), NFS committed to document the justification for deviating from any of the management measures listed in Table 2.2 *Management Measures for IROFS*. Moreover, a commitment and description of means to maintain administrative or enhanced administrative controls (e.g., Training & Qualification and Periodic Audits) are discussed in the relevant sections throughout Section 2.12 *Management Measures for IROFS*. Section 2.12.2.2 *Maintenance of Administrative Controls* now reads as follows:

#### *2.12.2.2 Maintenance of Administrative Controls*

*NFS ensures that Administrative and Enhanced Administrative Controls designated as IROFS are functional and reliable over extended periods of operation by applying the Management Measures described throughout this section and in Table 2.2 “Management Measures for IROFS”.*

***NRC Comment No. 4: The first sentence in Section 2.12.2.3 includes the words “as applicable.” Revise Section 2.12.2.3 to specify or define “as applicable.” List who is notified before repairs/maintenance are conducted and why are they notified. Also explain why the phrase “to ensure compliance with 10 CFR Part 21” was not included in the requirements for replacement of like-kind parts and control of new or replacement parts.***

NFS Response: The words “as applicable” have been retained in 2.12.2.3 *Maintenance Information Contained in Written Procedures* because some of the information that needs to be included in procedures may not be applicable or germane to the actual circumstance (e.g., a parts list may not exist for a sight-glass that is listed as an IROFS). In addition, SRP Section 11.4.3.2 Item 4 *Functional Testing* allows such flexibility with respect to the applicability of the type of information that needs to be captured in procedures or authorized work instructions.

Additional information was added to Section 2.12.2.3 *Maintenance Information Contained in Written Procedures* regarding the need to provide instructions and who should be notified when work is to be performed on IROFS as follows:

*2.12.2.3 Maintenance Information Contained in Written Procedures*

*The following methods/practices, as applicable, are incorporated into programs, systems or written procedures regarding maintenance of IROFS:*

*...Notification before conducting repairs/maintenance or removing an IROFS from service, including notification instructions and the functional discipline(s) that shall be notified;*

Section 11.4.3.2 of the SRP states that information should be provided, as applicable, regarding replacement of like-kind parts and control of new or replacement parts to ensure compliance with 10 CFR Part 21. However, NFS committed to replacing “like-kind parts and control of new or replacement parts” under the requirements of its Quality Assurance Program, as described in Section 2.12.8 *Other QA Elements*. In addition, Section 2.12.2.1 *Maintenance of Active and Passive Engineered Controls* was revised requiring reports of failures involving IROFS to be maintained.

*2.12.2.1 Maintenance of Active and Passive Engineered Controls*

*Records for failures of IROFS shall be maintained in accordance with 10 CFR 70.62(a)(3).*

Also, Section 2.12.6 *Incident Investigations and Corrective Actions* was revised to require reporting of IROFS failures:

*2.12.6 Incident Investigations and Corrective Actions*

*NFS shall maintain a corrective action program to investigate, document and report events as required by 10 CFR Parts 70.50, 70.62, and 70.74 for operations involving special nuclear materials.*

For the reasons stated above, reference to 10 CFR Part 21 as noted in the SRP was not included in Section 2.12 because similar means are used to control procurement of new or replacement parts related to IROFS and to report failures of IROFS as required by 10 CFR 70.62(a)(3)).

### **NFS Section 2.12.3 Training and Qualification**

***NRC Comment No. 1: Revise Section 2.12.3 to clearly make commitments regarding organization and management of training as discussed in the acceptance criteria of SRP Section 11.4.3.3 Item 1.a-g.***

***NFS Response:*** Section 2.12.3 *Training and Qualification* has been revised as follows to clarify that site management is responsible for approving the requirements and methods of the training and qualification programs and for providing an ongoing evaluation of the effectiveness of the programs:

#### *2.12.3 Training and Qualification*

*The NFS Training and Qualification Program (as described in Section 2.6 "Training") shall provide all personnel on site with the knowledge and skills to safely perform their job function, effectively deal with the hazards of the workplace, and properly respond to emergency situations. The qualification aspect of this program ensures that operations are performed only by properly trained personnel. Requirements and methods for the training and qualification programs are approved by site management, who also provide ongoing evaluation of the effectiveness of the programs.*

### **NFS Section 2.12.4 Procedures**

***NRC Comment No. 1: Revise Section 2.12.4 to describe the management measures controlled by procedures: design, configuration management, procurement, construction, radiation safety, maintenance, quality assurance, training and qualification, audits and assessments, incident investigations, records management, criticality safety, fire safety, chemical process safety, and reporting requirements as discussed in the acceptance criteria of SRP Section 11.4.3.4.***

***NFS Response:*** Section 2.12.4 *Procedures* was revised, as follows, to clarify the management measures that are controlled by procedures. Please note that other sections of SNM-124 that are applicable to current site operations are cross-referenced.

#### *2.12.4 Procedures*

*NFS uses several systems of operating and safety function procedures, as defined in Sections 1.7.4 "Operating Procedures" and 1.7.5 "Safety Procedures" to conduct SNM operations and related support functions, including operations related to IROFS and their supporting management measures. NFS procedures address the following: design, configuration management, procurement, construction, radiation safety, maintenance, quality assurance, training and qualification, audits and assessments, incident investigations, records management, nuclear criticality safety, fire safety, chemical process safety, and*

*reporting requirements. Procedures are further described in Section 11.7 "Procedures".*

***NRC Comment No. 2: Revise Section 2.12.4 to add a commitment that procedures are required for operator actions that are necessary to prevent or mitigate accidents defined in the ISA Summary as discussed in the acceptance criteria of SRP Section 11.4.3.4 Item 6.***

NFS Response: Section 2.12.4 *Procedures* was revised to address this commitment as follows:

*2.12.4 Procedures*

*Procedures shall be required for operator actions that are necessary to prevent or mitigate accidents defined in an ISA Summary.*

***NRC Comment No. 3: Revise Section 2.12.4 to add a commitment that procedures are reviewed after unusual incidents as discussed in the acceptance criteria of SRP Section 11.4.3.4 Item 7.***

NFS Response: To address this comment, Section 2.12.4.2 *Procedure Approval/Reviews* has been revised as follows:

*2.12.4.2 Procedure Approval/Reviews*

*...In addition, applicable procedures are reviewed as a corrective action after abnormal events.*

***NRC Comment No. 4: Revise Section 2.12.4 to add a commitment that temporary procedures are controlled by a formal procedure, do not involve a change to the ISA, and have a documented review and approval process as discussed in the acceptance criteria of SRP Section 11.4.3.4 Item 10.***

NFS Response: The last paragraph of Section 2.12.4 *Procedures* was revised to address this comment as follows:

*2.12.4 Procedures*

*Temporary procedures are controlled, reviewed, and approved as specified by a written procedure and shall not change an ISA except as authorized in License Condition S-25. The review and approval process required for temporary procedures is the same as for all other procedures.*

***NRC Comment No. 5: Revise Section 2.12.4 to add a commitment to perform periodic reviews of procedures to ensure their continued accuracy and usefulness including assurance that, as a minimum, all operating procedures are reviewed every 5 years, and emergency procedures are reviewed every year as discussed in the acceptance criteria of SRP Section 11.4.3.4 Item 12.***

NFS Response: To address these criteria, Section 2.12.4.2 *Procedure Approval/Reviews* was revised as follows:

#### *2.12.4.2 Procedure Approval/Reviews*

*The operating procedures (including active temporary procedures) are reviewed at least every five years to assure they reflect current practice. Emergency procedures are reviewed annually. In addition, applicable procedures are reviewed as a corrective action after abnormal events.*

#### **NFS Section 2.12.5 Audits and Assessments/Inspections**

***NRC Comment No 1: SRP Section 11.4.3.5 Item 1 states that the application should describe the guidance for conducting an audit or assessment. SRP Section 11.3.5 states that the reviewer should examine the application for the general structure of typical audits and assessments. Revise Section 2.12.5 to describe the general structure of typical audits and assessments specified in written procedures.***

NFS Response: Section 2.12.5 *Audits and Assessments* was revised to reflect the acceptance criteria cited in SRP Section 11.4.3.5 Item 1 that states the applicant should describe policy directives covering audits and assessments. Individual examples of the types of information that should be included in the policy directive should also be referenced.

Section 2.12.5 *Audits and Assessments* was revised to reflect the acceptance criteria cited in SRP Section 11.4.3.5 Item 1 as follows:

#### *2.12.5 Audits and Assessments*

*Guidance and procedures used to perform these audit and inspection functions contain the following information:*

- *Activity to be audited,*
- *Audit frequency,*
- *Applicable guidance to be used in conducting the audit,*
- *Responsibilities for each phase of the audit and/or inspection,*
- *Procedure for recording the results, recommending and approving actions to be taken, and*
- *Required distribution list of functional disciplines.*

Please note that inspections that are performed at NFS are analogous to assessments described in the context of SRP Section 11.4.3.5 *Audits and Assessments*.

***NRC Comment No. 2: SRP Section 11.4.3.5 states that the application should describe the assigned responsibilities for each phase of the work. The staff positions and committees responsible for audits and assessments should be specified. Revise Section 2.12.5 to specify, by***

***title, the staff positions and committees responsible for each phase of the audit and assessment function.***

NFS Response: The acceptance criteria (cited in SRP Section 11.4.3.5 Item 1) encourages the applicant to describe in policy directives the “assigned responsibilities for each phase of the work”.

As noted in response to NRC Comment No. 1 above, Section 2.12.5 *Audits and Assessments* was revised to describe the information that shall be included in guidance or procedures used to perform these audit and inspection functions; information regarding the “responsibilities for each phase of the audit and/or inspection” is included in the commitment. Additional information concerning the staff positions and committees responsible for audits and assessments will be described in the implementing guidance and procedures.

***NRC Comment No. 3: SRP Section 11.4.3.5 states that the application should describe the procedures for recording the audit/assessment results and recommending the actions to be taken. The levels of management to which results are reported, and the systems to provide corrective actions should be described. Revise Section 2.12.5 to specify the levels of management to which the audit/assessment results are reported and describe the features of the corrective action program (i.e., assign actions, prioritize work, track progress, etc.).***

NFS Response: Item 1 of SRP Section 11.4.3.5 states that the applicant should describe the policy directives covering the audits and assessments function relative to “recording the results and recommending actions to be taken”.

As noted in response to NRC Comment No. 1 above, Section 2.12.5 *Audits and Assessments* was revised to commit to including in guidance or procedures the information necessary for recording the results of audits/assessments and recommending and approving actions to be taken.

The levels of management to which results are reported is described in Section 2.12.5.3 *Audit and Inspection Reports* as follows:

#### ***2.12.5.3 Audit and Inspection Reports***

***Results of the audits and inspections are documented in written reports and distributed to NFS management as specified in Section 2.8 “Audits and Inspections”. These written reports are maintained in accordance with Section 2.12.7 “Records Management”.***

Section 2.12.5.2 *Audits of Management Measures and the Emergency Plan* was revised, as follows, to commit to evaluating audit results as part of NFS’ corrective action program. Additional details concerning the corrective action program are described in Section 2.12.6 *Incident Investigations and Corrective Actions*.

### *2.12.5.2 Audits of Management Measures and the Emergency Plan*

*Audit results are evaluated as part of the NFS corrective action program.*

***NRC Comment No. 4: SRP Section 11.4.3.5 states that audits and assessments should be conducted for several areas, including maintenance and procedures. Revise Section 2.12.5 to specify that audits and assessments will be performed in the areas of maintenance and procedures, including management measures.***

NFS Response: Section 2.12.5 *Audits and Assessments* was revised to include these two functional areas.

***NRC Comment No. 5: SRP Section 11.4.3.5 states that qualified personnel without direct responsibility for the function or area being audited or assessed will be used. In addition, independent assessments (i.e., external audits) will be conducted by offsite groups or individuals not involved in the licensed activity. Proposed Section 2.12.5 specifies these requirements with respect to quarterly audits, but fails to specify these requirements with respect to monthly assessments and external audits. Revise Section 2.12.5 to clarify that personnel performing any of the audits or assessments shall be qualified and without direct responsibility for the function or area being reviewed.***

NFS Response: Section 2.12.5.1 *Safety Function Audits and Inspections* was revised to clarify that staff performing inspections and external audits are qualified and do not have direct responsibility for the area being inspected or audited.

Section 2.12.5 *Audits and Assessments* was revised to cross-reference applicable and existing sections of SNM-124 regarding personnel qualifications:

#### *2.12.5 Audits and Assessments*

*A description of each of the functional safety and quality-related disciplines and associated qualifications are described in Sections 2.2 “Key Positions with Safety and Quality-Related Responsibilities” and 2.3 “Personnel Education and Experience Requirements”.*

### **NFS Section 2.12.6 Incident Investigations and Corrective Actions**

***NRC Comment No. 1: SRP Section 11.4.3.6 states that a process shall be established to investigate abnormal events. The investigations should begin within 48 hours, or sooner, depending on the safety significance of the event. Also details of the event sequence will be compared with the accident sequences considered in the ISA with modifications made to the ISA and ISA Summary as needed to evaluate the risk associated with the event. Revise Section 2.12.6 to address these acceptance criteria in SRP Section 11.4.3.6.***

NFS Response: Section 2.12.6 *Incident Investigations and Corrective Actions* was revised, as follows, to address this acceptance criteria:

*2.12.6 Incident Investigations and Corrective Actions*

*...An investigation shall be initiated for those events specified in 10 CFR Parts 70.50, 70.62 and 70.74, as well as Unusual Occurrences (as described in Section 2.9.2 "Investigation of Unusual Occurrences") within 48 hours of discovery, or sooner, based on the safety significance of the event.*

This section was also revised, as follows, to address the acceptance criteria related to reviewing and revising the ISA Summary to include accident sequences evaluated as a result of abnormal events.

*2.12.6 Incident Investigations and Corrective Actions*

*...Details of the accident event sequence(s) shall be compared with accident sequence(s) already considered in the ISA. The ISA Summary will be modified to include evaluation of the risk associated with accidents of the type actually experienced.*

***NRC Comment No. 2: SRP Section 11.4.3.6 states that incident investigation policy or procedures should describe the functions, qualifications, and responsibilities of the team manager and team members along with the scope of the team's authority and responsibilities and assurance of cooperation from management. Also procedures should require documentation relating to abnormal events be maintained for 2 years or for the life of the operation, if longer, and a system for monitoring completion of appropriate corrective actions. Guidance should also be provided on how to apply a reasonable, systematic, structured approach to determine the specific or generic root cause(s) and generic implications of the event. Revise Section 2.12.6 to describe incident policy or procedures in terms of these acceptance criteria from SRP Section 11.4.3.6.***

NFS Response: SRP Section 11.4.3.6 *Incident Investigations* specifies acceptance criteria regarding the types of information that should be included in a formal policy or procedure necessary for conducting investigations. Section 2.12.6 *Incident Investigations and Corrective Actions* has been revised to address each of these criteria.

In addition, Section 2.12.6 *Incident Investigations and Corrective Actions* was revised to reflect the commitment to maintain records for a minimum period of two years.

This section was also revised to address applying "a reasonable, systematic, structured approach to determine the specific or generic root cause(s) and generic implications of the event" as follows:

### *2.12.6 Incident Investigations and Corrective Actions*

*NFS shall maintain a corrective action program to investigate, document and report events as required by 10 CFR Parts 70.50, 70.62, and 70.74 for operations involving special nuclear materials. Events are reported, investigated, tracked and corrective actions are assigned through a formal corrective action program. A systematic and structured approach is used to determine the specific or generic root cause(s) and generic implications of events.*

***NRC Comment No. 3: SRP Section 11.4.3.6 states that a documented plan for abnormal incident investigation should be an element of the incident investigation policy or procedures and should be separate from any required emergency plan. Revise Section 2.12.6 to describe the contents of that plan in terms of the acceptance criteria listed as the last items in SRP Section 11.4.3.6.***

**NFS Response:** Section 2.12.6 *Incident Investigations and Corrective Actions* has been revised to address this comment as follows:

*The guidance for conducting an investigation shall contain the following elements:*

- 1. A documented plan for investigating an event. This plan is separate from any required Emergency Plan...*

### **NFS Section 2.12.7 Records Management**

***NRC Comment No. 1: SRP Section 11.4.3.7 states that records should be verified, legible, identifiable, and retrievable for their designated lifetimes. Records should be protected against tampering, theft, loss, unauthorized access, damage, and deterioration. Procedures should be established to specify the requirements and responsibilities for record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition. Also an organization and procedures should be in place to promptly detect and correct deficiencies in the records management system. Revise Section 2.12.7 to describe the records management system capabilities in terms of these acceptance criteria in SRP Section 11.4.3.7.***

**NFS Response:** Section 2.12.7 *Records Management* was revised to address each of these acceptance criteria as follows:

#### *2.12.7 Records Management*

*Records management procedures shall (a) assign responsibilities for records management, (b) specify the authority needed for records retention or disposal, (c) specify which records must have controlled access and provide the controls needed, (d) provide for the protection of records from loss, damage, tampering, theft or during an*

*emergency, and (e) specify procedures for ensuring that the records management system remains effective.*

*A functional organization shall be in place to ensure prompt detection and correction of deficiencies in the records management system or its implementation. The records management procedures shall provide the following instructions to ensure that:*

- *Records are prepared, verified, characterized, and maintained;*
- *Records are legible, identifiable, and retrievable for their designated lifetimes;*
- *Records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage; and*
- *Procedures are established and documented specifying the requirements and responsibilities for record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition.*

*Records shall be categorized by their relative importance to safety and/or regulatory compliance to identify record protection and storage needs and to designate the retention period for individual kinds of records.*

***NRC Comment No. 2: SRP Section 11.4.3.7 states that records management procedures should categorize records by the safety importance; assign responsibilities for records management; specify the authority needed for records retention or disposal; specify which records need access control and provide the needed controls; protect records from loss, damage, tampering, theft, or during an emergency; and ensure the records management system remains effective. Revise Section 2.12.7 to describe the records management system procedures in terms of these acceptance criteria in SRP Section 11.4.3.7.***

NFS Response: These acceptance criteria are addressed as noted in response to NRC Comment No. 1 above.

***NRC Comment No. 3: SRP Section 11.4.3.7 states that for computer codes and data used for safety related activities, procedures should be developed for maintaining the usefulness of older computer codes and data as technology changes. Also records of IROFS failures must be kept up to date in accordance with 10 CFR 70.62(a)(3). Revise Section 2.12.7 to address these acceptance criteria from SRP Section 11.4.3.7.***

NFS Response: These criteria are addressed in Section 2.12.7 *Records Management* as follows:

#### *2.12.7 Records Management*

*For computer codes and computerized data used for activities relied on for safety, as specified in the ISA Summary, procedure(s) shall be established for maintaining readability and usability of older codes and data as computing technology changes. The procedures should include transfer of the older forms of information (e.g., punched cards or paper tapes) and codes for older computing equipment to contemporary computing media and equipment.*

*In addition, records of IROFS failures must be kept and updated in accordance with 10 CFR 70.62(a)(3). Record revisions necessitated by post-failure investigation conclusions should be made within 5 working days of the completion of the investigation.*

**NFS Section 2.12.8 Quality Assurance Elements**

***NRC Comment No. 1: Proposed Section 2.12.8 states that individual elements of American Society of Mechanical Engineers (ASME) NQA-1, "Quality Assurance Requirements for Nuclear Facility Application" will be applied "as deemed appropriate on individual projects." Revise Section 2.12.8 to add a stronger commitment to ASME NQA-1-1994 or to address the itemized acceptance criteria of SRP Section 11.4.3.8.***

**NFS Response:** Section 2.12.8 *Other Quality Assurance Elements* has been revised to strengthen the commitment with respect to using individual elements of American Society of Mechanical Engineers (ASME) NQA-1, "Quality Assurance Requirements for Nuclear Facility Application."

**Attachment II**

Page Changes to SNM-124

**Part I**

Page Index  
Pages 1 through 5

Table of Contents  
Pages v – viia

List of Tables  
Page ix

Chapter 2  
Pages 29 – 46

## SPECIAL NUCLEAR MATERIAL LICENSE

SNM-124

(04/16/03) |

PAGE INDEX (Submitted)

<u>Part</u>	<u>Section</u>	<u>Page(s)</u>	<u>Revision</u>	<u>Date</u>
I	Introduction	i	1	08/15/89
		ii	1	08/15/89
I	Table of Contents	iii	6	08/07/98
		iv	8	04/28/00
		v	8	04/16/03
		vi	8	04/16/03
		vii	6	04/16/03
		vii-a	3	04/16/03
I	List of Figures	viii	9	10/11/02
I	List of Tables	ix	3	04/16/03
I	Chapter 1	1	6	04/28/00
		2	7	04/28/00
		3	9	12/10/99
		4	6	11/24/98
		5	6	11/15/01
		6	13	04/03/02
		7	2	10/15/90
		8	2	05/15/91
		9	1	08/15/89
		10	1	05/15/91
		11	1	05/18/95
		12	2	01/11/01
I	Appendix A	1	1	11/06/98
		2	1	11/06/98
		3	1	11/06/98
		4	1	11/06/98
I	Appendix B (NRC)	1	0	10/06/95
		2	0	10/06/95
		3	0	10/06/95
		4	0	10/06/95
I	Appendix C	1	0	09/25/98
		2	0	09/25/98
		3	0	09/25/98
		4	0	09/25/98
I	Appendix D	1	1	10/11/02
		2	1	10/11/02
		3	1	10/11/02

SPECIAL NUCLEAR MATERIAL LICENSE

SNM-124

(04/16/03) |

PAGE INDEX (Submitted)

<u>Part</u>	<u>Section</u>	<u>Page(s)</u>	<u>Revision</u>	<u>Date</u>
I	Chapter 2	1	4	09/15/98
		2	4	09/15/98
		3	3	05/15/91
		4	1	08/15/89
		5	1	08/15/89
		6	2	03/13/98
		7	3	03/13/98
		8	2	03/13/98
		9	2	03/13/98
		10	2	10/15/90
		11	1	08/15/89
		12	3	09/15/98
		13	3	03/13/98
		14	2	03/13/98
		15	4	03/13/98
		16	8	07/30/99
		17	5	12/20/00
		18	4	12/20/00
		19	5	10/19/98
		20	5	10/19/98
		21	4	06/18/93
		22	5	07/30/93
		23	3	08/07/92
		24	2	10/15/90
		25	2	10/15/90
		26	2	10/15/90
		27	3	11/16/98
		28	3	01/11/01
		29	0	04/16/03
		30	0	04/16/03
		31	0	04/16/03
		32	0	04/16/03
		33	0	04/16/03
		34	0	04/16/03
		35	0	04/16/03
		36	0	04/16/03
		37	0	04/16/03
		38	0	04/16/03
		39	0	04/16/03
		40	0	04/16/03
		41	0	04/16/03
		42	0	04/16/03
		43	0	04/16/03
		44	0	04/16/03
		45	0	04/16/03
		46	0	04/16/03
I	Chapter 3	1	2	05/15/91
		2	4	05/18/95

## SPECIAL NUCLEAR MATERIAL LICENSE

SNM-124

(04/16/03) |

PAGE INDEX (Submitted)

<u>Part</u>	<u>Section</u>	<u>Page (s)</u>	<u>Revision</u>	<u>Date</u>		
I	Chapter 3	3	5	03/13/98		
		4	3	05/18/95		
		5	6	03/13/98		
		6	1	08/15/89		
		7	5	03/13/98		
		8	3	05/18/95		
		9	3	05/18/95		
		10	2	05/15/91		
		11	4	05/20/92		
		12	3	05/18/95		
		13	6	01/23/03		
		14	4	03/13/98		
		15	6	12/10/99		
		16	2	05/18/95		
		17	3	05/15/91		
		18	2	05/15/91		
		19	4	12/10/99		
		20	7	01/23/03		
		21	10	01/23/03		
		22	5	04/28/00		
		23	5	04/28/00		
		24	7	04/28/00		
		25	6	03/13/98		
		I	Chapter 4	1	4	10/23/98
				2	4	10/23/98
3	3			10/23/98		
4	5			10/23/98		
5	2			10/23/98		
6	4			10/23/98		
7	4			10/23/98		
8	2			10/23/98		
9	2			10/23/98		
10	4			10/23/98		
11	4			10/23/98		
12	4			10/23/98		
13	2			10/23/98		
14	2			10/23/98		
15	3			10/23/98		
16	2			10/23/98		
17	2			10/23/98		
18	4			10/23/98		
19	3			10/23/98		
20	3			10/23/98		
21	3			10/23/98		
22	5			10/23/98		
23	3			10/23/98		
24	2			10/23/98		
25	2			10/23/98		

SPECIAL NUCLEAR MATERIAL LICENSE

SNM-124

(04/16/03) |

PAGE INDEX (Submitted)

<u>Part</u>	<u>Section</u>	<u>Page(s)</u>	<u>Revision</u>	<u>Date</u>
I	Chapter 4	26	2	10/23/98
		27	3	10/23/98
		28	3	10/23/98
		29	5	05/21/99
		30	4	05/21/99
		31	3	10/23/98
		32	5	10/23/98
		33	4	10/23/98
		34	3	10/23/98
		35	4	10/23/98
		36	4	10/23/98
		37	6	04/23/99
		38	6	04/23/99
		39	3	10/23/98
		40	5	04/23/99
		41	2	10/23/98
		42	2	10/23/98
		43	2	10/23/98
		44	5	04/23/99
		45	2	10/23/98
		46	4	10/23/98
		47	4	10/23/98
		48	3	10/23/98
		49	2	10/23/98
		50	2	10/23/98
		51	2	10/23/98
		52	2	10/23/98
		53	4	10/23/98
		54	2	10/23/98
		55	2	10/23/98
		56	2	10/23/98
		57	2	10/23/98
		58	2	10/23/98
		59	2	10/23/98
60	4	10/23/98		
I	Chapter 5	1	3	08/09/00
		2	6	04/14/03
		3	3	08/28/98
		4	3	08/28/98
		5	2	08/28/98
		6	3	10/11/02
		7	4	10/11/02
		8	8	04/14/03
		9	5	10/11/02
		10	6	08/18/00
		11	3	08/28/98
		12	2	08/28/98
		13	2	08/28/98
		14	3	08/28/98

## SPECIAL NUCLEAR MATERIAL LICENSE

SNM-124

(04/16/03) |

PAGE INDEX (Submitted)

<u>Part</u>	<u>Section</u>	<u>Page (s)</u>	<u>Revision</u>	<u>Date</u>
I	Chapter 5	15	3	08/28/98
		16	2	08/28/98
		17	3	08/28/98
		18	7	10/11/02
		19	5	08/28/98
		20	2	08/28/98
		21	2	08/28/98
		22	2	08/28/98
		23	0	08/28/98
		I	Chapter 6	1
2	3			11/13/98
3	7			05/21/99
4	7			09/04/98
5	3			02/14/03
6	3			10/11/02
7	1			08/14/01
8	1			10/11/02
9	2			08/14/98
10	1			11/29/94
I	Chapter 7	1	8	11/16/98
		2	5	10/08/93
		3	4	10/08/93
		4	2	11/16/98
		5	2	11/16/98
		6	2	11/16/98
I	Chapter 7			
	Appendix A	deleted		
I	Chapter 7			
	Appendix B	deleted		
I	Chapter 8	1	2	08/28/98

TABLE OF CONTENTS

Part I

<u>Section</u>	<u>Title</u>	<u>Chapter-Page</u>
CHAPTER 2 - (Continued)		
2.8	AUDITS AND INSPECTIONS	2-22
2.8.1	Internal Safety Audits	2-23
2.8.2	External Audits	2-24
2.9	INVESTIGATIONS AND REPORTING	2-25
2.9.1	Classification of Unusual Occurrences	2-25
2.9.2	Investigation of Unusual Occurrences	2-25
2.9.3	Reporting of Unusual Occurrences	2-27
2.10	RECORDS	2-27
2.11	SPECIAL PROGRAMS	2-28
2.11.1	Configuration Management	2-28
2.11.2	Maintenance	2-28
2.12	MANAGEMENT MEASURES FOR ITEMS RELIED ON FOR SAFETY	2-29
2.12.1	Configuration Management	2-30
2.12.2	Maintenance of IROFS	2-33
2.12.3	Training and Qualification	2-35
2.12.4	Procedures	2-37
2.12.5	Audits and Assessments	2-39
2.12.6	Incident Investigations and Corrective Actions	2-41
2.12.7	Records Management	2-43
2.12.8	Other Quality Assurance Elements	2-45
CHAPTER 3 - <u>RADIATION PROTECTION</u>		
3.1	SPECIAL ADMINISTRATIVE REQUIREMENTS	3-1
3.1.1	ALARA Policy	3-1
3.1.2	Radiation Work Permit (RWP) Procedure	3-3
3.1.3	Safety Procedures	3-4
3.1.4	Fire, Welding, Cutting Permit System	3-4
3.2	TECHNICAL REQUIREMENTS	3-5
3.2.1	Plant Protected Areas - Personnel Contamination Control	3-5
3.2.2	Ventilation	3-6
3.2.3	Work-Area Air Sampling	3-12
3.2.4	Radioactivity Measurement Instruments	3-15
3.2.5	Radiation Exposure Assessment	3-19
3.2.6	Surface Contamination	3-22
3.2.7	Personnel Contamination	3-24

TABLE OF CONTENTS

Part I

<u>Section</u>	<u>Title</u>	<u>Chapter-Page</u>
CHAPTER 4 - <u>NUCLEAR CRITICALITY SAFETY</u>		4-1
4.1 ADMINISTRATIVE CONDITIONS		4-1
4.1.1	Nuclear Criticality Safety Philosophy	4-1
4.1.1.1	Engineered Controls	4-3
4.1.1.2	Procedural/Administrative Controls	4-5
4.1.2	Responsibilities for Nuclear Safety	4-6
4.1.3	Documentation and Records Retention	4-7
4.1.4	Procedures	4-8
4.1.5	Posting of Nuclear Criticality Safety Limits	4-8
4.1.6	Approval of New or Modified Equipment	4-9
4.1.7	Nuclear Safety Procedures	4-10
4.2 TECHNICAL CRITERIA		4-10
4.2.1	Individual Units	4-10
4.2.1.1	Internal Moderation	4-10
4.2.1.2	Reflection	4-11
4.2.1.3	Mass	4-13
4.2.1.4	Concentration	4-15
4.2.1.5	Density	4-17
4.2.1.6	Enrichment	4-18
4.2.1.7	Heterogeneity	4-19
4.2.1.8	Geometry	4-20
4.2.1.8.1	Diameter	4-21
4.2.1.8.2	Thickness	4-21
4.2.1.8.3	Volume	4-22
4.2.1.8.4	Intersection of Pipes	4-22
4.2.1.9	Fixed Neutron Absorbers	4-25
4.2.2	Multiple Units or Arrays	4-26
4.2.2.1	Areal Density	4-27
4.2.2.2	Spacing (Interaction)	4-28
4.2.2.3	Interspersed Moderation	4-30
4.2.2.4	Array Reflection	4-30
4.2.3	Technical Data and Analytical Methods	4-31
4.2.3.1	Technical Data	4-31
4.2.3.2	Analytical Methods	4-38
4.2.4	Special Controls	4-45
4.2.4.1	Criticality Control by Boron	4-45
4.2.4.1.1	Borosilicate-Glass Raschig Rings	4-45
4.2.4.1.2	Soluble Boron	4-47
4.2.4.2	Heat Exchangers	4-47
4.2.4.3	Insulation or Jackets on Geometrically Favorable Equipment	4-49

TABLE OF CONTENTS

Part I

<u>Section</u>	<u>Title</u>	<u>Chapter-Page</u>
4.2.4.4	Siphon Breaks	4-49
4.2.4.5	Presence of Vessels of Unfavorable Geometry and Volume	4-51
4.2.4.5.1	Solution-Bearing Vessels	4-51
4.2.4.5.2	Normally-Empty Vessels	4-53
4.2.4.6	Ventilation Systems	4-54
4.2.4.6.1	High Enriched Uranium Fuel Recovery Facility	4-55
4.2.4.6.2	Low Enriched Uranium Fuel Recovery Facility	4-55
4.2.4.6.3	R&D Laboratories (Buildings 110A, B, D, and 131)	4-55
4.2.4.6.4	Building 105 Laboratory Facility	4-55
4.2.4.6.5	Fuel Development Facility	4-55
4.2.4.6.6	High Enriched Uranium Fuel Production Facility	4-55
4.2.4.6.7	Other Sections of the Ventilation Systems	4-55
4.2.4.7	Release to Unfavorable Geometry and Volume	4-55
4.2.4.8	Neutron Isolation Controls	4-57
4.2.4.9	Packaging and Transportation Regulations	4-58
4.3	ACCIDENT ANALYSIS	4-59
CHAPTER 5	- <u>ENVIRONMENTAL PROTECTION</u>	5-1
5.1	EFFLUENT CONTROL SYSTEMS	5-1
5.1.1	Airborne Effluents	5-3
5.1.2	Liquid Effluents	5-6
5.1.3	Solid Wastes	5-10
5.1.4	Effluent Controls Responsibilities	5-11
5.2	ENVIRONMENTAL MONITORING PROGRAM	5-12
5.2.1	Location Criteria for Environmental Sampling Stations	5-12
5.2.2	Air Monitoring	5-13
5.2.3	Soil Sampling	5-14
5.2.4	Vegetation Sampling	5-16
5.2.5	Silt/Sediment Sampling	5-16
5.2.6	Surface Water Sampling	5-17
5.2.7	Ground Water Monitoring	5-18
5.3	QUALITY ASSURANCE OF RADIATION MEASUREMENTS	5-21
5.3.1	Organizational Structure: Managerial and Operational Responsibilities	5-21
5.3.2	Specification of Personnel Qualification	5-21
5.3.3	Operating Procedures/Instructions	5-22
5.3.4	Records	5-22

TABLE OF CONTENTS

Part I

<u>Section</u>	<u>Title</u>	<u>Chapter-Page</u>
5.3.5	Quality Control in Sampling	5-22
5.3.6	Quality Control in Laboratory	5-22
5.3.7	Data Analysis and Review	5-23
5.3.8	Audits	5-23
CHAPTER 6 - <u>SPECIAL PROCESSES</u>		6-1
6.1	PROPRIETARY INFORMATION	6-1
6.2	OCCUPATIONAL SAFETY	6-1
6.3	EMERGENCY UTILITIES	6-4
6.4	RADIOACTIVE WASTE MANAGEMENT	6-5
6.5	SPECIFIC LICENSE CONDITIONS	6-5
6.5.1	Intermediate Treatment Furnace in the Fuel Development Facility	6-5
6.5.2	Special Processing Unit in the Fuel Development Facility	6-6
6.5.3	Sprinkler System in Building 233	6-6
6.5.4	Enrichment Blending System	6-6
6.5.5	UNH Blend/Hold Tanks	6-9
CHAPTER 7 - <u>DECOMMISSIONING PLAN</u>		
7.1	General Information	7-1
7.2	Financial Assurance Information	7-1
7.2.1	U. S. Government Funding	7-1
7.2.2	NFS Financial Assurance for KAST/BAST Equipment	7-2
7.2.3	Additional NFS Financial Assurance	7-3
7.2.4	NFS Escrow Agreements	7-4
7.2.5	"Getty Notes" Commitments	7-4
7.2.6	Financial Statements	7-5
7.3	Planned Decommissioning Activities	7-6
7.4	Schedules	7-6
7.5	Cost Estimates	7-6
Appendix A	deleted	
Appendix B	deleted	
CHAPTER 8 - <u>EMERGENCY PLAN</u>		8-1

LIST OF TABLES

<u>Table</u>	<u>Title</u>	<u>Chapter-Page</u>
Chapter 2 - ORGANIZATION AND ADMINISTRATION		
2.1	Classification of Unusual Events	2-26
2.2	Management Measures for IROFS	2-46
Chapter 3 - RADIATION PROTECTION		
3.1	Action Limits for Alpha Contamination	3-7
3.2	Types and Uses of Available Instruments (Typical)	3-17
3.3	Routine Smear Survey Frequencies	3-23
3.4	Action Limits for Alpha Contamination	3-24
Chapter 4 - NUCLEAR CRITICALITY SAFETY		
4.1	Inside Pipe Diameter Limits for Intersections	4-23
4.2	Central Column Diameter and Intersection Area Per Quadrant Limits	4-25
4.3A	Single Parameter Limits for Fully Reflected Units of Homogeneous Low Enriched Materials	4-32
4.3B	Single Parameter Limits for Fully Reflected Units of Heterogeneous Low Enriched Materials	4-32
4.4A	Single Parameter Limits for Fully Reflected Units of Homogeneous 100.0 Wt.% <sup>235</sup> U Compounds and Water	4-33
4.4B	Single Parameter Limits for Fully Reflected Units of Uranium Metal at 100.0 Wt.% <sup>235</sup> U for all Values of H/X	4-33
4.5	Critical and Safe Concentrations in Aqueous Solutions	4-34
Chapter 5 - ENVIRONMENTAL PROTECTION		
5.1	Environmental Radiological Monitoring Program	5-2
Chapter 6 - SPECIAL PROCESSES		
6.1	Limiting Conditions of Operations for UNH Blend/Hold Tanks	6-10

## 2.12 Management Measures for Items Relied On For Safety

Management Measures, as described in Section 2.12, shall be implemented for Items Relied On For Safety (IROFS) upon approval of an ISA Summary which is required to be contained in a license application (or amendment application), as specified under 10 CFR 70.65(b). Management Measures are applied to IROFS to ensure the IROFS are available and reliable to perform their required function when needed, as specified in 10 CFR 70.62(d).

Management measures are defined (10 CFR 70.4) as functions performed, generally on a continuing basis, that are applied to IROFS, to ensure they are available and reliable to perform their functions when needed. Management measures shall include the following elements:

- Configuration Management,
- Maintenance,
- Training and Qualifications,
- Procedures,
- Audits and Assessments,
- Incident Investigations,
- Records Management, and
- Other Quality Assurance Elements.

The type of IROFS control, along with the risk reduction level credited to the IROFS in the ISA Summary, will determine the level of management measures applied to each IROFS. The four types of IROFS controls are Active Engineered, Passive Engineered, Administrative, and Enhanced Administrative. The management measures appropriate for each type of control are shown in Table 2.2. The management measures applied to a particular IROFS may be graded commensurate with the level of risk reduction credited for that IROFS in the ISA Summary. High or Intermediate consequence events depend on IROFS to reduce the overall risk to an acceptable level. High consequence events must be justified as highly unlikely, and intermediate consequence events justified as unlikely, after implementation of credited IROFS. Table 2.2 identifies how management measures are applied in a graded approach based on risk reduction levels (Level A or B) credited in the ISA Summary. IROFS credited with a high level (those corresponding to "High" and/or "Intermediate" consequence accident sequences (Level A)) of risk reduction will require application of more management measures to ensure a high level of reliability. IROFS credited with a moderate level (those corresponding to "Intermediate" consequence accident sequences (Level B)) of risk reduction, or intermediate failure likelihood, may have a reduced level of management measures applied.

The applicable management measures identified in Table 2.2 are applied based on the type of control to ensure that the credited IROFS failure index meets the risk index specified or the design-based thresholds for events associated with natural phenomena. Information to justify a

deviation from a management measure contained in Table 2.2 associated with a specific IROFS shall be documented by the ISA team.

## 2.12.1 Configuration Management

### 2.12.1.1 Configuration Management Policy

NFS maintains a configuration management program for IROFS in a manner consistent with Chapter 11 of NUREG-1520 (issued March 2002). The scope of the IROFS that are under configuration management, and management measures that shall be applied to maintain these safety controls reliable, are contained in Table 2.2. In addition, each IROFS and its associated management measures is specified in the ISA Summary in accordance with 10 CFR 70.62.

The design process shall rely on information supplied from a multi-disciplined team of engineers and safety personnel. This design process is initiated with a project definition wherein the baseline and safety design criteria are established and concludes with a detailed design wherein the safety criteria are incorporated. Information provided by the multi-disciplined team shall be used, as appropriate, to establish and implement the following configuration management functions for new facilities to ensure a baseline design meets the requirements specified in 10 CFR 70.64:

- Design Requirements,
- Document Control,
- Change Control, and
- Assessments.

Changes to IROFS are managed and controlled as described in written procedures developed in conformance with guidance specified in NUREG-1520. IROFS are identified in the ISA Summary, a controlled document.

### 2.12.1.2 Design Requirements

NFS has documents establishing requirements for design of new facilities where Special Nuclear Material is handled. Designs based on these requirements are reviewed in a graded manner through the NFS Internally Authorized Change (IAC) process and the NFS Integrated Safety Analysis (ISA) process.

The design bases are established in accordance with procedures to meet regulatory requirements and to ensure that process operations perform the desired function in accordance with requirements from individual safety functions. These design bases are developed by a multi-disciplined team comprised of engineering and safety personnel and

are approved by the safety discipline manager (See Section 2.2.3). Procedures used to establish design bases shall incorporate engineering, maintenance, and safety review interfaces used in support of the IAC and ISA processes. Through the IAC process, written approval of the recommended design bases shall be required from the safety review committee before startup of operations is permissible.

#### 2.12.1.3 Document Control

In accordance with procedures, a document control system shall be established for new facilities to create, control and track documents within the configuration management function. The document control system shall maintain control of procedures that are IROFS and those procedures related to training, quality assurance, maintenance, audits and assessments, emergency operations, emergency response, and change control documents associated with IROFS.

Other documents that shall be maintained under the document control system when relied on for safety include:

- Design Requirements,
- Engineering drawings and/or sketches, and
- Specifications for IROFS; and
- The ISA Summary

The document control system will address cataloging the document databases, the informational content of the document databases, means to maintain and distribute documents, and document retention/retrieval policies. The document databases are used to control documents and track the document change status.

Documents are controlled in accordance with procedures developed by the appropriate functional disciplines (i.e., departments) until such time that the documents are transferred to Records Management for retention.

Additional information concerning the document databases and records management system that shall be used to capture documents that are relevant and relied on for safety is provided in Section 2.12.7 "Records Management".

#### 2.12.1.4 Change Control

A change control process shall be established, as part of configuration management, that complies with requirements specified in 10 CFR 70.72. Proposed changes involving site structures, equipment, processes, systems, components, or procedures related to SNM operations and potentially affecting an IROFS are submitted to the safety discipline manager for review to determine if a license amendment is required or if the change requires using the NFS Internally Authorized Change (IAC) process. The criteria for exemption from a license amendment are specified in License Condition S-25 which implements the requirements of 10 CFR 70.72(a). The change control process, including requirements to update the necessary supporting safety basis documents (e.g., NCSE and ISA Summary), is specified in written procedures. This change control process provides the means to document and disseminate changes to the affected engineering, operations, maintenance, training and safety disciplines.

Staff members from individual safety functions are required to review, in accordance with written procedures, proposed changes that may affect design requirements, physical configurations and facility documentation. The safety review committee reviews and approves all proposed changes involving IROFS credited in the ISA Summary. Other committee responsibilities are set forth in Sections 2.4, 11.4 and 11.7, and License Condition S-25. In addition, a review of approved changes (IACs) that may affect an ISA Summary are reviewed by the safety discipline annually in support of requirements specified in 10 CFR 70.72 and License Condition S-25. Oversight of the change control process by the safety discipline manager and the safety review committee ensures consistency with these configuration management elements.

The records management program described in Section 2.12.7 shall also be used to track and document IACs that are implemented.

#### 2.12.1.5 Assessments

An initial and a biennial assessment of the configuration management function shall be conducted to determine the program's effectiveness and to correct documented deficiencies. These assessments shall be performed in a systematic and planned manner and shall include both document assessments and physical assessments (i.e., facility walkdowns). The results of these assessments may provide a basis for future changes and shall be documented; the records shall be maintained in accordance with Sections 2.12.5 "Audits and Assessments" and 2.12.7 "Records Management".

The assessments shall be performed in accordance with the facility audit and assessment program as specified in Section 2.12.5 "Audits and Assessments".

## 2.12.2 Maintenance of IROFS

### 2.12.2.1 Maintenance of Active and Passive Engineered Controls

NFS has established a program to ensure that Active and Passive Engineered Controls designated as IROFS are maintained in a manner so as to ensure the IROFS are capable of performing their intended function when called upon. An essential element of the maintenance program requires that all maintenance activities, including functional testing of IROFS during startup of new process operations, are authorized by written procedures and/or written instructions.

The maintenance program consists of several key program elements including a maintenance management system that provides the scheduling and documentation of the following maintenance elements when applied to IROFS:

- Surveillance and Monitoring,
- Corrective Maintenance,
- Preventive Maintenance, and
- Functional Testing.

Maintenance activities will be performed on IROFS in a manner to minimize the recurrence of unacceptable performance deficiencies. Maintenance, preventive maintenance, calibration, testing, and surveillance/monitoring of IROFS, to ensure continued reliability and functional acceptability of IROFS, will be authorized in accordance with written procedures and at frequencies approved by the safety review committee. These frequencies will be established based on manufacturer and industry guidance, risk assessment, feedback from surveillance and maintenance activities, or recommendations from NFS' corrective action program (See Section 2.12.6 "Incident Investigations and Corrective Actions").

Corrective maintenance shall be performed in a planned, systematic, integrated and controlled approach for the repair and replacement activities associated with identified unacceptable performance deficiencies of IROFS. Functional testing of the IROFS shall be performed to provide reasonable assurance that the safety control performs as designated and provides the safety action expected.

Preventive maintenance shall be performed in a preplanned and scheduled manner to refurbish or overhaul IROFS to ensure that they perform their intended function. Functional testing of the IROFS shall be performed to provide reasonable assurance that the safety control performs as designated and provides the safety action expected. Preventive maintenance will be appropriately balanced against the objective of

minimizing unavailability of IROFS. A schedule for performing preventive maintenance on IROFS is maintained as specified in written procedures.

Functional testing of IROFS shall be performed prior to startup of new facilities or new process operations involving IROFS to provide reasonable assurance that the safety control performs as designated. Functional testing of IROFS shall be performed, prior to restart, if the process operation has been inactive for more than 120 days. During process operations, compensatory measures will be used as appropriate while functional testing is performed on IROFS. The results of functional testing shall be documented and maintained as specified in Section 2.12.7 "Records Management".

The maintenance system also provides instructions for specifying and documenting maintenance work activities and approvals. Maintenance skills training for mechanics involved in maintenance activities regarding IROFS is also required. Maintenance skills' training is addressed in Section 2.12.3 "Training & Qualifications". Contractors that perform work on IROFS will meet the same guidelines for IROFS training or will be under direct supervision by NFS-trained personnel that are qualified for the particular IROFS and knowledgeable of that IROFS.

Records for failures of IROFS shall be maintained in accordance with 10 CFR 70.62(a)(3). Maintenance records shall be maintained in accordance with written procedures as specified in Section 2.12.7 "Records Management".

#### 2.12.2.2 Maintenance of Administrative Controls

NFS ensures that Administrative and Enhanced Administrative Controls designated as IROFS are functional and reliable over extended periods of operation by applying the Management Measures described throughout this section and in Table 2.2 "Management Measures for IROFS".

#### 2.12.2.3 Maintenance Information Contained in Written Procedures

The following methods/practices, as applicable, are incorporated into programs, systems or written procedures regarding maintenance of IROFS:

- Authorized maintenance instructions with identification of the IROFS;
- Parts list for IROFS;
- As-built or red-lined drawings;
- Pre-maintenance review of work to be performed on unique and complex IROFS including procedure reviews to ensure accuracy and completeness;

- Notification before conducting repairs/maintenance or removing an IROFS from service, including notification instructions and the functional discipline(s) that shall be notified;
- Radiation Work Permit;
- Safe Work Practices (e.g., lock-out/tag-out; confined space entry; nuclear, radiation, environmental, fire, and chemical safety issues);
- Requirements for replacement of like-kind parts and control of new or replacement parts;
- Compensatory measures while performing work on IROFS;
- Procedural control of removal of components from service for maintenance and for return to service;
- Ensuring safe operations during removal of IROFS from service; and
- Notification to operations personnel that repair has been completed.

### 2.12.3 Training and Qualification

The NFS Training and Qualification Program (as described in Section 2.6 “Training”) shall provide all personnel on site with the knowledge and skills to safely perform their job function, effectively deal with the hazards of the workplace, and properly respond to emergency situations. The qualification aspect of this program ensures that operations are performed only by properly trained personnel. Requirements and methods for the training and qualification programs are approved by site management, who also provide ongoing evaluation of the effectiveness of the programs.

The NFS Training and Qualification Program requires that all personnel who are granted unescorted access to the restricted area(s) receive formal Safety Orientation Training. Safety Orientation Training covers plant safety rules, radiological, nuclear criticality, industrial, and environmental safety topics as appropriate to the job function of the individuals being trained. In addition, this training covers proper response to emergencies. Previously trained employees receive formal refresher training in Safety on an annual basis.

The NFS Training and Qualification Program provide a means to ensure that only qualified personnel are assigned to specific process operations involving handling of special nuclear materials (as described in Section 11.6). Exemptions from training are only authorized as described in written procedures.

The NFS Training and Qualification Program includes Work Training for operating personnel and others who directly handle greater than laboratory sample quantities of special nuclear material. Work Training typically includes classroom, on-the-job and guided-work-experience training necessary to provide the desired knowledge and/or skill. It covers the operating procedures, alarms, emergency response actions, and radiological, nuclear criticality, industrial, and environmental safety controls and limits specific to the particular

work assignment. NFS lesson plans and other training guides (for both class room and on-the-job training) developed for activities relied on for safety are based on learning objectives developed from specific job performance requirements. As such, information provided by various safety disciplines is included in the content of training elements with clearly defined objectives. The lesson plans also provide reasonable assurance that training is conducted in a reliable and consistent manner. The Configuration Management program (See Section 2.12.1.4 "Change Control) provides a means to assure that design changes and modifications to IROFS are accounted for in the training.

Work Training also includes appropriate re-instruction for previously qualified individuals prior to implementation of a process change or procedural modification. In addition, special "tool-box" training sessions are conducted when necessary to reinforce a particular requirement of the safety program or the operating procedure. Previously qualified individuals are required to undergo a re-qualification process for applicable work assignments every three years (maximum interval not to exceed 42 months). Additional details of the Work Training Program are provided in approved written procedures as described in Section 2.7 "Procedures."

The NFS Training Program provides for the instruction and training of mechanics involved in maintenance activities at NFS. Maintenance skills training may include such topics as basic math/precision instrument reading, laser alignment/vibration analysis, basic programmable logic controller (PLC), welding, industrial electricity (basic, intermediate, and advanced), and machine tool operation, as appropriate. The type and level of training will be commensurate with the job assignments.

The training records system includes a means to document training objectives, individuals trained, course content and other data necessary to satisfy requirements. Training records related to IROFS will be maintained for a minimum of two years in accordance with 2.12.7, "Records Management."

All training is conducted by, or under the supervision of, individuals recognized by NFS management as possessing the necessary knowledge and skills to conduct the training. As such, information provided by various safety disciplines is included in the content of training elements with clearly defined objectives.

The effectiveness of the training program and the individual comprehension of the subject matter are measured by appropriate assessment tools (e.g., written and/or oral examination, demonstration of skills, questionnaire, and feedback from NFS' corrective action program, etc.). Results from these assessment tools will be used to identify individuals that require special re-training, and to further enhance future training efforts and systems.

#### 2.12.4 Procedures

NFS uses several systems of operating and safety function procedures, as defined in Sections 1.7.4 "Operating Procedures" and 1.7.5 "Safety Procedures" to conduct SNM operations and related support functions, including operations related to IROFS and their supporting management measures. NFS procedures address the following: design, configuration management, procurement, construction, radiation safety, maintenance, quality assurance, training and qualification, audits and assessments, incident investigations, records management, nuclear criticality safety, fire safety, chemical process safety, and reporting requirements. Procedures are further described in Section 11.7 "Procedures".

Procedures shall be required for operator actions that are necessary to prevent or mitigate accidents defined in an ISA Summary. As such, operating procedures involving IROFS contain the following information, as applicable, to ensure that process activities and steps involving special nuclear materials are conducted safely and in compliance with regulatory and licensing requirements: initial and normal start-up; normal and off-normal operations; temporary operations; emergency operations or shutdown; startup following an emergency or extended downtime; type of hazards that may be encountered; operating limits (such as mass limits, double contingency measures and associated set points); precautions to prevent exposure to hazardous materials, and timeframe for which the procedure is valid. These procedures are applicable to workers, visitors, contractors, and vendors.

Verification of procedures involving IROFS is required to provide reasonable assurance that information is technically correct. In addition, procedures are validated through walk-downs. The verification/validation process provides reasonable assurance that the technical information, including formulas, set points, and acceptance criteria, is all there and is correct, and includes either a walkdown of the procedure in the field, or a tabletop walkthrough. The review process includes technical, cross-disciplinary reviews by affected organizations. This process includes both new procedures and revised procedures. The review provides reasonable assurance that the operating limits and IROFS are specified in the procedures and that QA requirements related to IROFS are identified and included in operating procedures.

Approved temporary procedures (an example is LOAs; See Section 11.7) are used when permanent procedures do not exist to:

- Direct operations during testing, maintenance, and modifications;
- Provide guidance in unusual situations not within the scope of permanent procedures; and
- Provide assurance of orderly and uniform operations for periods of short duration when the plant, a system or a component is performing in a manner not covered by existing permanent procedures, or has been modified or extended in such a manner that portions of existing procedures do not apply.

Temporary procedures are controlled, reviewed, and approved as specified by a written procedure and shall not change an ISA except as authorized in License Condition S-25. The review and approval process required for temporary procedures is the same as for all other procedures.

#### 2.12.4.1 Developing Procedures

Procedures for operations involving IROFS are prepared by the appropriate functional discipline. The operating procedures will incorporate criticality safety controls, radiation safety controls, environmental protection controls, and industrial safety controls as defined by the results contained in the ISA or ISA Summary. In addition, these operating procedures include provisions to place process operations in a safe condition if a step of the procedure cannot be performed as written. Procedures are also developed for all management measures supporting the IROFS (See Section 2.12.4 above).

#### 2.12.4.2 Procedure Approval/Reviews

The safety review committee is responsible for reviewing and approving operating and emergency procedures. Procedures developed to support management measures shall be approved by the appropriate functional discipline manager and the safety discipline manager.

The operating procedures (including active temporary procedures) are reviewed at least every five years to assure they reflect current practice. Emergency procedures are reviewed annually. In addition, applicable procedures are reviewed as a corrective action after abnormal events.

#### 2.12.4.3 Personnel Qualification for Procedures

Each NFS position involving personnel assigned to SNM process operations is evaluated to determine the specific procedures that apply to the defined job function. The procedural qualifications are defined in an on-line computer database. Personnel are notified of procedure revisions or new procedures and must update their qualification records within a defined time period. Personnel must remain current on the defined set of procedures to maintain job qualifications.

#### 2.12.4.4 Issuance of Procedures

Operating procedures are controlled and made readily available to foremen, operators and other affected personnel. Additionally, work place posting of limits and controls, training and other communication devices are used, if appropriate, to enhance comprehension and understanding of operating procedures.

Once approved, new or revised operating procedures are distributed for personnel training and qualification, and outdated procedures are removed from use.

#### 2.12.5 Audits and Assessments

NFS conducts audits and inspections (referred to as assessments in NUREG-1520) as specified in Section 2.8 "Audits and Inspections. In addition, audits and inspections will be performed to determine that site operations, as well as off-site operations, involving activities related to the IROFS are conducted in compliance with regulatory requirements, license conditions, and written plans and/or procedures.

Guidance and procedures used to perform these audit and inspection functions contain the following information:

- Activity to be audited,
- Audit frequency,
- Applicable guidance to be used in conducting the audit,
- Responsibilities for each phase of the audit and/or inspection,
- Procedure for recording the results, recommending and approving actions to be taken, and
- Required distribution list of functional disciplines.

Audits and inspections will be performed in the following areas by qualified personnel for activities and operations involving IROFS:

- Radiation Safety,
- Nuclear Criticality Safety,
- Industrial Safety (Chemical and Fire),
- Environmental Safety,
- Emergency Preparedness,
- Quality Assurance,
- Maintenance,
- Procedures,
- Configuration Management,
- Training & Qualification,
- Incident Investigations, and
- Records Management.

A description of each of the functional safety and quality-related disciplines and associated qualifications are described in Sections 2.2 “Key Positions with Safety and Quality-Related Responsibilities” and 2.3 “Personnel Education and Experience Requirements”.

#### 2.12.5.1 Safety Function Audits and Inspections

Qualified members of the Radiation Safety, Nuclear Criticality Safety, Industrial Safety, and Environmental Safety functions perform quarterly audits in accordance with written plans and/or procedures. Personnel responsible for performing these audits shall be qualified and shall not have direct responsibility for the area being audited. Guidance required to perform audits is specified in written procedures.

Monthly inspections for compliance with safety requirements are performed by personnel appointed by the appropriate safety functional manager in accordance with written procedures. Personnel responsible for performing these inspections shall be qualified and shall not have direct responsibility for the area being inspected (i.e., safety is independent of operations).

In addition, external audits of these safety programs are performed at least every three years by an appropriate function outside of the NFS Erwin organization as specified in Section 2.8.2 “External Audits”. Personnel responsible for performing these external audits shall be appropriately qualified and shall not have direct responsibility for the program being audited.

Results from the audits and inspections are integral to ensuring that IROFS are available and reliable to perform the required functions when needed. As such, these results are evaluated (See Section 2.8 “Audits and Inspections”) to determine the effectiveness of the associated management measures as part of the NFS corrective action program described in Section 2.12.6 “Incident Investigations and Corrective Actions.”

#### 2.12.5.2 Audits of Management Measures and the Emergency Plan

Members of the Quality Assurance function conduct audits of management measures in accordance with written procedures to determine compliance with license requirements and NFS procedures. Reviews of operating procedures and equipment are performed as part of these audits to determine that approved procedures and equipment are available to the users. The Emergency Plan is audited on an annual basis. Audits of the following management measures elements are audited on a biennial basis:

- Quality Assurance,
- Maintenance,
- Procedures,

- Configuration Management,
- Training & Qualification,
- Incident Investigations, and
- Records Management.

Audit results are evaluated as part of the NFS corrective action program. Members of the Quality Assurance function periodically audit safety programs as directed by the NFS President and/or Vice President of Safety & Regulatory.

#### 2.12.5.3 Audit and Inspection Reports

Audit and inspection results, including findings and observations, are captured in the NFS corrective action program. Personnel assigned the responsibility for preparing corrective action responses are identified. Corrective actions to prevent recurrence will be documented and tracked to completion in accordance with the requirements specified in the corrective action program.

Results of the audits and inspections are documented in written reports and distributed to NFS management as specified in Section 2.8 "Audits and Inspections". These written reports are maintained in accordance with Section 2.12.7 "Records Management".

#### 2.12.6 Incident Investigations and Corrective Actions

NFS shall maintain a corrective action program to investigate, document and report events as required by 10 CFR Parts 70.50, 70.62, and 70.74 for operations involving special nuclear materials. Events are reported, investigated, tracked and corrective actions are assigned through a formal corrective action program. A systematic and structured approach is used to determine the specific or generic root cause(s) and generic implications of events.

A multi-disciplinary committee shall review these events in accordance with written guidance to determine the safety significance of the event. A graded, risk-based approach is applied to the assignment of the level of investigation based on severity or potential severity of the event. The following levels of investigation are assigned for events in accordance with written guidance:

- No investigation required,
- Apparent cause investigation,
- Small team investigation, and
- Full team investigation.

Full team investigations shall be approved by a discipline vice president position and be independent from the function involved in the event. Apparent cause investigation corrective actions shall be reviewed by the owner of the program related to events. Small team and full team investigation corrective actions shall be reviewed and approved by a discipline vice president position. Full team investigation corrective actions shall also be reviewed and approved by the safety review committee which may impose additional, or modify corrective actions.

The guidance for conducting an investigation shall contain the following elements:

1. A documented plan for investigating an event. This plan is separate from any required Emergency Plan. The investigation of an event should begin as soon as possible, commensurate with ensuring the safety of the investigative team, after the event has been brought under control.
2. A description of the functions, qualifications, and responsibilities of the individual who would lead the investigative team and those of the other team members; the scope of the team's authority and responsibilities; and assurance of cooperation of management.
3. Assurance of the team's authority to obtain all the information considered necessary and its independence from responsibility for or to the functional area involved in the incident under investigation.
4. Procedures requiring maintenance of all documentation relating to events for two years (or for the life of the operation), whichever is longer.
5. Guidance for personnel conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the specific or generic root cause(s) and generic implications of the problem. The level of investigation shall be based on a graded approach relative to the severity of the event.
6. Requirements to make available original investigation reports to the NRC on request.
7. A system for monitoring the completion of appropriate corrective actions.
8. Direction for ensuring that documented corrective actions are taken within a reasonable period to resolve findings from event investigations.

The team shall include at least one individual knowledgeable of the area being investigated (as applicable) and at least one team member shall be trained in root cause analysis. In addition, the investigation process and investigating team shall be independent of the line management, and participants are assured of no retaliation for participating in investigations.

An investigation shall be initiated for those events specified in 10 CFR Parts 70.50, 70.62 and 70.74, as well as Unusual Occurrences (as described in Section 2.9.2 "Investigation of Unusual Occurrences") within 48 hours of discovery, or sooner, based on the safety significance of the event.

Corrective actions generated from investigations shall be used to make corrections and improvements (i.e., "lessons learned") necessary to prevent or minimize single or common-mode failures. Corrective actions are monitored and documented through completion. Details of the accident event sequence(s) shall be compared with accident sequence(s) already considered in the ISA. The ISA Summary will be modified to include evaluation of the risk associated with accidents of the type actually experienced.

Auditable records and documentation related to these events, investigations, and root cause analysis are maintained as described in Chapter 2.12.7 "Records Management". For each event utilizing full team and small team investigations, the incident report shall include a description of the event, contributing factors, a root cause analysis, and findings and recommendations. Relevant findings are communicated to affected personnel. A database of events, investigations, and corrective actions shall be maintained for tracking, trending, and documentation purposes.

Trends involving failure of IROFS shall be reviewed to determine effectiveness of safety systems and to provide feedback to management for establishment of actions to minimize and/or prevent recurrence.

#### 2.12.7 Records Management

A records management system, as applied to safety (nuclear criticality, radiation, chemical, fire and environmental safety), decommissioning, emergency preparedness and quality assurance activities, shall be maintained in accordance with written procedures. Information related to occupational exposure of personnel to radiation, releases of radioactive materials to the environment, and other pertinent activities, are maintained in such a manner as to demonstrate compliance with license conditions and regulatory requirements. Specific requirements of the records management system are provided in Section 2.10, "Records," and as cited in applicable regulations.

All records pertaining to safety will be retained for at least two years unless longer retention is required by other regulatory or license specifications.

Records relevant to IROFS that shall be maintained include the following:

- Construction specifications,
- Facility and equipment descriptions and drawings,
- Design criteria requirements,

- Records of facility changes,
- Safety Analysis Reports, including ISA/ISA Summary,
- Procurement, including specifications for IROFS,
- Configuration Management (physical configuration of process designs, validation records for computer software, as appropriate),
- Maintenance (calibration, preventive/corrective maintenance (including schedules, test data for IROFS),
- Training & Qualification,
- Procedures,
- Audits and Assessments/Inspections,
- Incident Investigations (investigation reports), and
- Failures of IROFS

Records management procedures shall (a) assign responsibilities for records management, (b) specify the authority needed for records retention or disposal, (c) specify which records must have controlled access and provide the controls needed, (d) provide for the protection of records from loss, damage, tampering, theft or during an emergency, and (e) specify procedures for ensuring that the records management system remains effective.

A functional organization shall be in place to ensure prompt detection and correction of deficiencies in the records management system or its implementation. The records management procedures shall provide the following instructions to ensure that:

- Records are prepared, verified, characterized, and maintained;
- Records are legible, identifiable, and retrievable for their designated lifetimes;
- Records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage; and
- Procedures are established and documented specifying the requirements and responsibilities for record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition.

Records shall be categorized by their relative importance to safety and/or regulatory compliance to identify record protection and storage needs and to designate the retention period for individual kinds of records.

For computer codes and computerized data used for activities relied on for safety, as specified in the ISA Summary, procedure(s) shall be established for maintaining readability and usability of older codes and data as computing technology changes. The procedures should include transfer of the older forms of information (e.g., punched cards or paper tapes) and codes for older computing equipment to contemporary computing media and equipment.

In addition, records of IROFS failures must be kept and updated in accordance with 10 CFR 70.62(a)(3). Record revisions necessitated by post-failure investigation conclusions should be made within 5 working days of the completion of the investigation.

### 2.12.8 Other Quality Assurance Elements

The NFS quality system consists of the organizational structure, procedures, processes, and resources needed to implement quality management. The system is structured on ASME NQA-1 (*Quality Assurance Program Requirements for Nuclear Facilities*) under the overall responsibility of the Quality Assurance function manager (See Section 2.2.4 "Quality Assurance Manager"). The following elements, as appropriate, are applied on individual projects:

1. Organization and Responsibilities
2. Quality Assurance Program
  - Quality Planning
  - Test and Inspection Personnel Requirements
  - Graded Quality Assurance
3. Design Control
4. Procurement Document Control
5. Instructions, Procedures, and Drawings
6. Document Control
7. Control of Purchased Items and Services
8. Identification and Control of Items
9. Control of Special Processes
10. Inspection
11. Test Control
12. Control of Measuring and Test Equipment
13. Item Handling, Storage, and Shipping
14. Inspection, Test, and Operating Status
15. Control of Nonconforming Items
16. Corrective Action
17. Quality Assurance Records
18. Audits
19. Updates of QA Documents

The quality system for the design, construction and operation of IROFS is described in a quality assurance program document and is implemented by functionally specific procedures and/or specific quality assurance project plans. These procedures and plans outline quality measures that are applicable to the entire facility, upon approval of an ISA Summary as specified in 10 CFR 70.65(b), including implementing the requirements of the license.

**Table 2.2  
Management Measures for IROFS**

CONTROL TYPE / Measures	Risk Reduction Level	
	A IROFS credited with a high level of Risk Reduction for High or Intermediate consequence events	B IROFS credited with a moderate level of Risk Reduction for Intermediate consequence events
<b>ACTIVE ENGINEERED CONTROLS</b>		
Periodic Functional Test	x	
Verification After Maintenance	x	
Calibration	x	x
Controlled Listing Identification	x	
Drawing Identification	x	
Procedural Identification	x	x
Pre-operational Audits or Tests	x	x
Periodic Audits	x	x
Training and Qualifications	x	
Records Management, Investigations, and other quality assurance elements	x	
<b>PASSIVE ENGINEERED CONTROLS</b>		
Verification After Maintenance	x	
Controlled Listing Identification	x	
Procedural Identification	x	x
Pre-operational Audits or Tests	x	x
Independent Installation Verification	x	
Periodic Audits or Inspections	x	x
Vendor Specifications	x	
Training and Qualifications	x	
Records Management, Investigations, and other quality assurance elements	x	
<b>ADMINISTRATIVE CONTROLS</b>		
Procedural or Posting Identification	x	x
Pre-operational Audits	x	x
Periodic Audits	x	x
Training and Qualification	x	
Testing of Training Effectiveness	x	
Records Management, Investigations, and other quality assurance elements	x	
<b>ENHANCED ADMINISTRATIVE CONTROLS</b>		
Periodic Functional Test	x	
Verification After Maintenance	x	
Controlled Listing Identification	x	x
Drawing Identification	x	x
Procedural or Posting Identification	x	x
Pre-operational Audits	x	x
Periodic Audits	x	x
Training and Qualification	x	
Testing of Training Effectiveness	x	
Records Management, Investigations, and other quality assurance elements	x	

Note: The Management Measures identified for each risk reduction level are minimum if applicable. For example, it is not possible to calibrate certain types of active engineered controls. The controls may be increased based on the specific IROFS involved, the credited risk reduction, industry standards, vendor specifications, or engineering recommendations.