Nuclear Fuel Services, Inc.
1205 Banner Hill Road
Erwin, TN 37650

(423) 743-9141

www.atnfs.com

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GOV-01-55-04
ACF-07-0353
December 14, 2007

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 William D. Travers to Dwight B. Ferguson, Confirmatory Order for Program Improvements, dated February 21, 2007
3) Letter from B. Marie Moore to NMSS NRC, License Amendment Request To Make Changes to Part I, Chapter 2, of SNM-124 Regarding the Configuration Management Program, dated April 20, 2007 (21G-07-0053)
4) Letter from Kevin M. Ramsey to B. Marie Moore, Request for Additional Information Concerning Configuration Management Program Amendment (TAC L32632), dated October 17, 2007

Subject: **Response to Request for Additional Information Concerning Configuration Management Program Amendment**

Dear Sir:

Attached is the Nuclear Fuel Services, Inc. (NFS) response to the subject Request for Additional Information (RAI). As part of this submittal, we have included revisions to the previous April 20, 2007, amendment request for the Configuration Management (CM) Program which we believe better describe our overall CM policy and program elements. There are several reasons that these revisions are warranted:

1) Section 2.11, Configuration Management, of SNM-124 which was submitted in April and existing Section 2.12.2, also entitled Configuration Management, both discuss CM in detail, but are somewhat different in several areas. It was our intent that Section 2.11 should describe the overall NFS CM Program while Section 2.12.2 focused on the application of CM to IROFS as part of the Management Measures. However, based on prior discussions with you in August concerning our April 20 license amendment request and the items included in your October 17 RAI, it is obvious that these license sections are confusing as written and could imply that NFS has two separate CM programs. Thus, we have revised both sections so that Section 2.11 clearly addresses the overall CM Program

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and Section 2.12.2 specifically addresses how the CM Program is applied to IROFS. Additionally, we believe these modifications align with our latest revision to the CM Program document.

2) Although it was stated in the April 20 submittal that the NFS CM Program is based on the ANSI/NIRMA CM 1.0-2000 standard, NFS has incorporated key CM concepts and program structure from several other documents and standards, chiefly DOE-STD-1073-2003, *Configuration Management,* which we believe provides the best approach for the NFS CM Program. We have rewritten our CM Program document to reflect these concepts and program structure, and it is in final management review and approval. It should be noted that ANSI/NIRMA CM 1.0-2000 has been reissued as ANSI/NIRMA CM 1.0-2007. Because this new revision more closely represents the guidelines on which NFS has based the CM Program, NFS has referenced this document in the license submittal.

3) We have elected to incorporate several of our responses to the items in your RAI in order to provide a more comprehensive description of our revised CM Program in the license and to better address NUREG-1520.

We believe the revisions to our CM Program, which are reflected in the attached documents, fully address the requirements set forth in the Confirmatory Order for Program Improvements issued February 21, 2007.

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-07-0165) in any correspondence concerning this letter.

Sincerely,

NUCLEAR FUEL SERVICES, INC.

for B. Marie Moore
Vice President, Safety and Regulatory

RPS/pdj
Attachments

21G-07-0165
GOV-01-55-04
ACF-07-0353

copy:
Regional Administrator
U.S. Nuclear Regulatory Commission
Region II
Atlanta Federal Center
61 Forsyth Street, SW
Suite 23T85
Atlanta, GA 30303

Mr. Manuel Crespo
Project Inspector
U.S. Nuclear Regulatory Commission
Region II
Atlanta Federal Center
61 Forsyth Street, SW
Suite 23T85
Atlanta, GA 30303

Mr. Steve Burris
U.S. Nuclear Regulatory Commission
Senior Resident Inspector

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ACF-07-0353

ATTACHMENT A

Response to Request for Additional Information
Concerning Configuration Management Program Amendment

25 pages

RESPONSE TO RAI

1. **Describe which features of the revised Configuration Management (CM) program would have prevented the spill of high-enriched uranium in March 2006 or a related event.**

   Section 2 of the Confirmatory Order dated February 21, 2007, requires revision of the CM program by license amendment. The requirement to revise the CM program is based on concerns associated with the spill of high-enriched uranium event.

   Response

   A weakness identified in the existing CM functions was a lack of rigorous control of design change documents and information during the change process. Although there are a number of thorough reviews during the development and implementation of changes, and post-implementation verification and validation reviews to assure physical changes match the change documents, there was inadequate control to prevent potentially unreviewed changes from being made to change documents (e.g., drawings, instructions, procedures, etc.). The investigation into the March 2006 event found that an isolation valve that may have prevented transfer of high-enriched uranium from the process line to the glove box where the spill occurred appeared on one revision of a drawing, but did not appear on another version of the same revision. This latter version, without the valve, was used to conduct the field verification of the installation.

   The revised CM Program addresses this problem in several ways:

   1) A more rigorous Design Control function is being implemented to better control development, review, approval, and revision of design documents. Once approved, changes to design documents are not permitted without undergoing a review and approval process in the engineering organization in accordance with design process procedures.

   2) An enhanced Change Control process utilizing both a change request process and a change control package process is being implemented. The change request process requires that all affected documents and information be identified as part of the request documentation. The change request receives both a review by the CM organization and by a Change Control Board to assure that the proposed change addresses the requirements of 10 CFR 70.72 as a minimum prior to development of detailed design and change documents. Once approved, the change documents (e.g., drawings, analyses, procedure revisions, installation instructions, test procedures, etc.) must be prepared in accordance with the approved change request.

      Change documents are subsequently prepared in accordance with their respective governing procedures and assembled as a Change Control Package (CCP) for technical, safety, and management reviews. This affords reviewers the ability to look at the change in detail in its entirety and assure consistency among the documents and information. Once the CCP is approved, the change, including all document revisions, must be accomplished in accordance with the approved CCP.

      If a modification is required during implementation of the CCP, a change request must be utilized to assure that the modification is appropriately reviewed and approved, and all affected documents are identified, revised, reviewed and approved before the modification can be implemented.

3) NFS is implementing the LINC System utilizing third party software which will be used with the revised CM Program. Several key features of the LINC System are its capabilities to cross-reference configuration items and their associated documents and information and to electronically control revisions to documents and information (i.e., documents cannot be changed without proper authorization). Implementation of change requests, CCPs, and CCP modifications will be done electronically to assure further control of design and change implementation documents.

   As part of the implementation of the revised CM Program, all configuration items (CIs) and associated facility configuration information or FCI (e.g., IROFS, drawings, design requirements and design bases, engineering calculations and analyses, procedures, specifications, safety bases, etc.) will be located in the LINC System. To date, all drawings have been entered.

   As FCI is entered into the LINC System, it will become no longer available except through LINC in accordance with procedures to control its use and revision.

2. Describe how the CM system accounts for changes made to the facility or processes (e.g., changes to the site, operating procedures, or control systems). Explain how the CM system is used to evaluate any facility changes or changes in the process safety information that may alter the parameters of an accident sequence by means of the facility's ISA methods as required by 10 CFR 70.72(d)(1) and (3).

10 CFR 70.72(a) requires that changes to the site, structures, systems, components, computer programs, and activities of personnel are evaluated, implemented, and tracked.

Response

1) Changes to facilities, SSCs, and associated FCI (e.g., drawings, procedures, tests, analyses, etc.) must go through the NFS CM Program Change Control Process which utilizes a change request, preparation of change control packages, and implementation of the changes in accordance with the approved change request/packages.

   a) The LINC System is used to account for changes to FCI by keeping a readily available status of change requests (pending changes that are active), change history (what changes have occurred and the associated change implementing vehicles), and work orders (current status of changes in progress).

   b) The CM Manager is responsible for assuring that physical change status is tracked and that changes are completed in accordance with the approved CCPs. The CM Manager is also responsible for tracking the changes to associated FCI to assure they are completed and documents are updated.

   2) The NFS CM Program Change Control Process requires that all proposed changes to Configuration Items (CIs) and Facility Configuration Information (FCI), which includes process safety information (ISAs), utilize a change request process. The change request process requires that sufficient information be provided to properly evaluate the proposed change which includes:

      - a description of the proposed change
      - the technical basis for the change [10 CFR 70.72(a)]

- potential impacts or modifications to the ISA, ISA Summary, or other program information developed in accordance with 10 CFR 70.62 [10 CFR 70.72(a)]
- impact of the change on safety and health or control of licensed material [10 CFR 70.72(a)]
- a description or list of the potentially affected CIs and associated documentation which includes modifications to existing operating procedures including any necessary training [10 CFR 70.72(a)]
- for temporary changes, the approved duration (e.g., expiration date) of the change [10 CFR 70.72(a)]
- authorization requirements for the change[10 CFR 70.72(a)]
- any other information needed to review, track, approve, or process the proposed change

Each change request is reviewed for completeness and accuracy by the CM Group. For other than certain administrative changes, the change request is subsequently reviewed by a Change Control Board (CCB). One of the review criteria is to determine if a license amendment should be submitted as discussed in 10 CFR 70.72. Proposed changes to process safety information (including those that may alter the parameters of an accident sequence), the ISA or ISA Summary go through the same rigorous change request preparation, review and approval process.

3. Describe the functional interfaces between the new CM program in Section 2.11 and the existing configuration management program in Section 2.12.1. Explain how functional interfaces between the two CM programs will be managed to prevent a loss of configuration control.

The intent of the Confirmatory Order for Program Improvements issued on February 21, 2007, is to require a more comprehensive and robust program that will prevent the loss of configuration control experienced during the spill of high-enriched uranium in March 2006. NUREG-1520, Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Section 11.4.3.1 states that an acceptable CM program should describe functional interfaces.

Response

There is only a single CM Program to manage the configuration of all CIs (which includes all IROFS) and FCI. To assure that configuration control is maintained, the revised CM Program requires the following:

- All changes to CIs and FCI must go through the same Change Control Process which requires that all changes use a change request to identify all impacts of the change.
- All proposed changes must go through a rigorous review process that involves the CM Manager and the CM organization and a Change Control Board (CCB) involving all affected organizations.
- Implementation of approved change requests involves the development of change control packages (CCPs) which include drawings, analyses, procedure changes, work instructions, and/or other documents needed to properly review, implement, and verify the proposed change. The CCPs also define the methods and acceptance criteria for applicable post-implementation testing.
- CCPs receive technical, safety, and management reviews and approvals by appropriate NFS disciplines and organizations.

- CCPs must be implemented as approved and any necessary changes are reviewed and approved through a modification process which includes technical, safety, and management reviews (as required) commensurate with those of the original CCP.
- All key operating procedures and documents are updated and any training needed to perform safe operations is conducted prior to returning a system or process to service after implementation of a change.
- The status of FCI (e.g., as-built, pending changes and active, current status of changes in progress) is always available.
- All CIs and FCIs that are subject to alternate and/or temporary configurations for operational or testing purposes must have these alternate configurations reviewed, approved and implemented through the Change Control Process so that operational configuration is maintained.
- A CM Assessment function establishes a system of reviews and audits to detect, document, determine the cause of, and initiate corrections of inconsistencies among design requirements, FCI, and physical configuration, as well as assure CM functions are properly integrated to maintain configuration control
- Any discrepancies between CIs and associated FCI, or among FCI, are identified and processed through the Problem Identification, Resolution and Correction System (PIRCS) in which technical evaluations and safety reviews are conducted to determine the correct configuration. Any required changes are processed through the Change Control Process.

4. **Identify the managers with key responsibility for the CM Program and specify whether the positions are independent of production responsibilities. If the positions are not independent of production responsibilities, justify why no conflict of interest exists between production responsibilities and configuration control responsibilities.**

   The intent of the Confirmatory Order for Program Improvements issued on February 21, 2007, is to require a more comprehensive and robust program that will prevent the loss of configuration control experienced during the spill of high-enriched uranium in March 2006. NUREG-1520, Section 11.4.3.1, states that an acceptable configuration management program should describe its organizational structure. In addition, NUREG-1520, Section 11.5.2.1, states that the reviewer should consider whether the application acceptably defines key responsibilities.

   Response

   The revised NFS CM Program clearly defines the NFS positions with associated responsibilities in implementation of the CM Program. A CM Manager has been designated in the Engineering organization with responsibility to implement and manage the CM Program. The Engineering Director is the designated Design Authority responsible for establishing and maintaining the design requirements and design bases for CIs. These positions are independent of the Production organization.

5. **Provide a description of areas where the proposed program differs from the guidance in American National Standards Institute/Nuclear Information and Records Management Association, Inc. (ANSI/NIRMA) CM 1.0-2000 "Guidelines for Configuration Management of Nuclear Facilities." Explain the reason for the differences and why the alternative provides reasonable assurance that configuration control will be maintained. The application states that**

the new program is "modeled" after the standard. Clarification is necessary to determine if there are differences. In addition, the Forward Section of the standard states that it does not address configuration management of items that NRC regulations require the configuration management program to address. The impact of this statement on the CM program is unclear.

10 CFR 70.64(a)(1) requires quality standards and records to be developed and implemented in accordance with management measures in order to provide adequate assurance that items relied on for safety (IROFS) will be available and reliable.

10 CFR 70.72(a) requires the establishment of a configuration management system that will evaluate, implement and track each change to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel.

ANSI/NIRMA CM 1.0-2000, "Foreword" states that the standard does not address configuration management for computer software, product acquisition or management, design basis reconstitution, or the process or requirements for maintaining authorization basis or license for operation of a facility.

Response

The revised NFS CMP is based not only on the ANSI/NIRMA CM 1.0-2007[1] standard, but also relies heavily on the guidance contained in DOE-STD-1073-2004, *Configuration Management,* and NUREG-1520 sections on CM. Since there is not a specific guideline for nuclear fuel processing facilities, NFS believes this combination provides the best guidance to establish an effective CM Program for its facilities.

The revised NFS CMP generally implements the guidelines of the ANSI/NIRMA CM standard with the following exceptions and clarifications:

1) ANSI/NIRMA CM 1.0-2007, "Foreword" and Section 1.0 SCOPE state that the standard does not address configuration management for computer software.

   The revised NFS CM Program includes Programmable Logic Controller (PLC) software as CIs to be managed in accordance with the Program requirements. Other software requiring CM such as the software running on the NFS Computer Network is managed under the NFS Software Quality Assurance Program (SQAP) based on ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications,* which includes software CM.

2) ANSI/NIRMA CM 1.0-2007, "Foreword" and Section 1.0 SCOPE state that the standard does not provide configuration management related guidance for product acquisition or management.

   The revised NFS CM Program includes specifications and vendor/supplier information as FCI. Specification and procurement requirements are derived from the design requirements information which is controlled in accordance with CMP requirements. The NFS CMP Change Control Process requires that all FCI associated with proposed changes be reviewed and evaluated for impact, and used in the acquisition of replacement and equivalent equipment and parts.

[1] For clarification, ANSI/NIRMA CM 1.0-2000 (R2006) has been approved as ANSI/NIRMA CM 1.0-2007, since the RAI was received.

3) ANSI/NIRMA CM 1.0-2007, "Foreword" states that it only addresses facility authorization or licensing processes only in the context of facility configuration changes; Section 1.0 SCOPE states that the standard does not provide guidance regarding facility authorization or licensing processes.

   The revised NFS CMP considers the facility license, ISA, and ISA Summaries to be FCI and therefore subject to the Change Control Process. These documents are evaluated for impact when facility or CI changes are requested and proposed revisions are included as part of the overall change. Likewise, requested changes to these documents go through the Change Control Process and other affected FCI and CIs are evaluated for impact and changed accordingly.

4) ANSI/NIRMA CM 1.0-2007, "Foreword" and Section 1.0 SCOPE state that the standard does not provide guidance regarding reconstitution of design basis information.

   As discussed in response to item 6 below, the revised NFS CMP requires that the design requirements and associated design bases for CIs be identified and documented. This information will be included in design requirements/design basis (DRB) documents prepared on a facility, process, system, or major equipment basis. Whenever the design bases for the design requirements of existing CIs may not be fully documented or readily available, the reconstruction (i.e., reconstitution) of the design bases will be determined on a case-by-case basis in accordance with a graded approach which will consider the identified need, safety implications, type and complexity of change, and/or the type of CI (e.g., IROFS, non-safety, or other).

   A full adjunct design basis reconstitution program to the CMP is not considered necessary by NFS. However, development and/or assembly of design basis information using a graded approach will follow much of the guidance provided in DOE-STD-1073-2003 and IAEA-TECDOC-1335, *Configuration Management in Nuclear Power Plants.*

5) ANSI/NIRMA CM 1.0-2007, Section 3.2.6 Margin Information states that knowing what margins exist for the design is important in assuring conformance with the design basis, and that margin information should be documented, maintained, and kept current with the configuration.

   The revised NFS CMP does not address margins as a specific class of FCI to be managed under the CMP. As discussed in the response to item 6 below, the CMP requires that the design requirements and associated design bases for CIs be identified and documented. NFS follows the DOE CM Standard definition for design margin which is the conservatism between the specified design requirement and the minimum requirement that could be developed from the design basis.

   The Change Control Process requires a design basis/design requirements review for proposed CI changes to confirm the changes are within the current applicable design basis and design requirements. If a proposed change is not within the design basis, then a design analysis is performed to either support a change to the design basis or to determine the change cannot be implemented as proposed. The design analysis process is used to document the design assumptions and identify the available design margin. Design margin information is therefore identified and becomes part of the DRB documents as they are developed and revised. Since DRB documents are FCI, they are maintained and controlled under the CMP.

6. State where the structures, systems, and components (SSCs) subject to the new configuration management program are declared and identified. Describe how the baseline design requirements are established for the existing facility (i.e., all SSCs and IROFS subject to

configuration control). Describe how the design requirements are translated into a fixed baseline design basis and measured against subsequent changes. Also, describe how conformity is verified between the design requirements, actual configuration, and the as-built facility documentation.

10 CFR 70.64(a) requires that the baseline design criteria for new processes at existing facilities be evaluated. The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities. ANSI/NIRMA CM 1.0-2000, "Foreword," states that the standard does not provide guidance on how to perform design basis reconstitution.

NUREG-1520, Section 11.4.3.1, states that an acceptable program should have the current design bases for existing facilities, including design requirements, supporting analyses, and documentation. A verification process, including walkdowns, is complete and has verified that the configuration is consistent with as-built facility documentation.

Response

State where the structures, systems, and components (SSCs) subject to the new configuration management program are declared and identified.

The revised NFS CM Program (CMP) Scope states that the CMP specifically applies to Items Relied on for Safety (IROFS) contained in the Integrated Safety Analysis (ISA) Summary and SSCs and administrative controls (ACs) that are necessary:

- To physically process, store or transfer more than 350 grams of U-235 as Special Nuclear Material (SNM) contained within an SSC at any given time. Specifically included are the SSCs and administrative controls associated with active SNM processing facilities, the SNM storage vaults, the Waste Water Treatment Facility, associated Process Off-Gas Ventilation systems, bulk chemicals and gases.
- To protect off-site and on-site personnel from nuclear and other hazards, as defined by the facility Integrated Safety Analyses (ISA);
- To meet regulatory requirements for the physical protection of SNM;
- To protect the environment from significant damage or to satisfy environmental requirements or permits;
- To avoid substantial unplanned interruption of Production operations having significant cost or product quality impact.

The SSCs and ACs that are managed and controlled under the CMP are identified as Configuration Items (CIs) which includes all IROFS as a minimum. CIs are identified by the following methods:

- Depicted on drawings designated in the ISA process (or process hazard evaluations) and nuclear criticality safety evaluations (NCSEs).
- IROFS are maintained on a controlled list by the ISA Group.
- Safety Related Equipment (SRE) are maintained on a controlled list by the ISA Group.
- Listed in the LINC System as a CI.

The LINC System will ultimately contain and be used to maintain all CIs.

Describe how the baseline design requirements are established for the existing facility (i.e., all SSCs and IROFS subject to configuration control).

The design requirements for many CIs for existing facilities and SSCs are identified and documented both in electronic databases and in hard copy files. Design requirements and safety bases for existing IROFS are contained in the ISA Files, ISA Summaries, Nuclear Criticality Safety Evaluations (NCSEs), etc., which are being introduced into and controlled by the LINC System. Design requirements for both IROFS and other SSCs may also be contained in Engineering Design Files (EDFs), Engineering Design Philosophy Documents, and also in the LINC System.

The revised NFS CMP requires that the design requirements and associated design bases for CIs be identified and documented. A design requirements and design basis implementing procedure is being developed for development of new and/or assembly of existing design requirements and associated design basis information whenever changes are made to CIs, or where there are other identified needs. This information will be included in design requirements/design basis (DRB) documents prepared on a facility, process, system, or major equipment basis. DRB documents will be formally prepared, reviewed, approved, and controlled in the LINC System as facility configuration information (FCI). As a minimum, the ten (10) Baseline Design Criteria (BDC) of 10 CFR 70.64(a) are required to be addressed for IROFS, as applicable, for new facilities at NFS or new processes at existing NFS facilities.

Whenever the design bases for the design requirements of existing CIs may not be fully documented or readily available, the reconstruction (i.e., reconstitution) of the design bases will be determined on a case-by-case basis in accordance with a graded approach which will consider the identified need, safety implications, type and complexity of change, and/or the type of CI (e.g., IROFS, non-safety, or other).

Describe how the design requirements are translated into a fixed baseline design basis and measured against subsequent changes.

As discussed above, the revised NFS CMP requires the development of design requirements and associated design bases for CIs which will be accomplished in the formal development and approval of DRB documents that will be controlled in the LINC System. Once approved, a DRB document becomes the baseline set of design requirements and associated design bases for its subject facility, process, system or major equipment, and is considered FCI.

The Change Control Process of the revised NFS CMP requires that all proposed changes be evaluated for potential impacts to the associated design requirements and design basis. If a proposed change causes a need to revise a design requirement, the potential design requirement change is technically evaluated against the associated design basis. If the design requirement change will be within the design basis (i.e., no change to the design basis required), then the DRB document will be revised to reflect the revised design requirement and processed as part of the change. If the proposed change is not within the design basis, then a design analysis is performed to either change the design basis or to determine the change cannot be implemented as proposed. The DRB document is revised to reflect the revised design basis (and associated design requirement) and processed as part of the change. For changes involving IROFS, the IROFS List is also updated if the design basis is revised.

Also, describe how conformity is verified between the design requirements, actual configuration, and the as-built facility documentation.

There are several methods which address the verification of conformity:

1) The revised NFS CMP Change Control Process uses both a Change Request process and a Change Control Package (CCP) process to assure that all affected FCI including design requirements, drawings, procedures, etc., associated with a CI change are appropriately reviewed for impact and proposed revisions are developed and reviewed as part of the change. After physical changes are made in the facility, an independent review and walkdown is performed to assure the physical as-implemented configuration is in accordance with the CCP documentation (plus any approved change modifications). Any corrections needed to the installation and/or the documentation (including design requirements) are reviewed and approved, and documents are then updated to reflect the as-built configuration.

2) The revised NFS CMP includes periodic audits and assessments as defined in approved procedures and commitments which include:

   - Periodic review that configuration controlled drawings accurately reflect the equipment configuration.

   - Periodic review of set point analyses to confirm an IROFS performs the function assigned by the ISA process to verify that the identified system boundary, assumptions and process, utility and environmental variables still accurately reflect current conditions and that no changes to the setpoint analysis is necessary.

   - Periodic review of SRE tests to verify that the SRE test continues to fully test the controls required by the applicable IROFS.

3) The revised NFS CMP also requires that any identified discrepancies between CIs and associated FCI be processed through the PIRCS system. Resolution includes a review of the design requirements and FCI to resolve the identified differences which may include rework in the field as well as updating FCI to reflect the as-built configuration.

7. **Describe how "operational configuration information" is maintained in the new program. Figure 1 of ANSI/NIRMA CM 1.0 indicates that operational configuration information is part of the information to be maintained. However, the discussion in Section 2.11.1 does not appear to address operational configuration information.**

   10 CFR 70.72(a) requires the establishment of a configuration management system that will evaluate, implement and track each change to the site, structures, processes, systems, equipment, components, computer programs and activities of personnel. The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000, Figure 1, provides an illustration depicting objectives of configuration management at a nuclear facility, which includes operational configuration information.

   Response

   Operational configuration is defined in the revised NFS CMP as the "state" (e.g., on/off, open/closed, operating/not operating) of facility SSCs and processes at a particular point in time. Operational configuration information is that FCI which describes the acceptable SSC or process configurations when variable configuration conditions may exist based on operational or other needs. The CMP requires that all variable SSC and process configurations (e.g., allowable "states") together with their

associated FCI be reviewed and approved prior to use or implementation to assure they are within approved design requirements at all times.

Typically operating, maintenance/calibration, and test procedures (together with any other supporting FCI such as drawings and checklists) are used to change the configuration of SSCs and processes without requiring additional review and approval. Any configuration changes, whether temporary or permanent, not covered by procedures (i.e., not pre-approved) are treated as changes which must go through the CMP Change Control Process. Technical, independent, and safety reviews of the change including procedures and other FCI specifically assure:

- The facility SSC or process will continue to operate safely and provide adequate protection to workers, the public, and the environment;
- IROFS are not prevented from performing their expected safety functions and/or sufficient compensatory measures are established;
- Performance criteria are not negatively affected;
- The change will not create unacceptable maintenance problems;
- The change will not create unacceptable problems if periodic tests are required to verify the safety function; and
- System interactions are appropriately considered.

Examples of variable configurations include:

- adjustment of PLC operating band within the range allowed by system or process design
- installation and removal of jumpers as part of surveillance or performance testing
- use of alternate process equipment or flow paths
- temporary operation of automatic systems or components in a manual or bypass mode
- isolation of equipment and/or process subsystems for testing or maintenance

The Operational Readiness Review (ORR) and Readiness Assessment processes are used as appropriate to further validate operating and test procedures to safely operate equipment, systems and processes. The formalized Verification and Validation process is used to assure that operating and test procedures, equipment alignment information, drawings and other supporting operating configuration information is current, accurate, clear and unambiguous, and usable by operations and maintenance/test personnel. Verification is also required after re-configuring SSCs and processes to normal or preferred operating configurations after completion of maintenance, tests, or alternate process/system operating configurations.

8. Describe how the configuration management program addresses computer software in the following areas:

a. acquisition process;
b. design requirements;
c. verification and validation process;
d. implementation;
e. acceptance testing;
f. documentation requirements;
g. access control specifications;
h. problem reporting;
i. corrective action system;

j. in-use tests; and
k. configuration change control process.

10 CFR 70.72(a) requires that a configuration management system shall evaluate, implement and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.

ANSI/NIRMA CM 1.0-2000, "Foreword" states that the standard does not address configuration management for computer software.

Response

The LINC System is discussed in the response to Item 14. For all other software and programs, CM is accomplished, when applicable, through the NFS Software Quality Assurance Program (SQAP) which is based on the software applicable sections of ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications.* Software CM is applied to those computer programs and applications that manage, monitor, or report against configuration items (CIs) within the scope of the CM program, such as scheduling and testing/calibrating of Safety Related Equipment (SRE) and IROFS List. The SQAP is implemented through procedures which assure that:

- software design requirements are identified, documented, reviewed, and approved;
- software design is documented to meet the software requirements;
- software design is implemented in accordance with approved NFS programming standards;
- software is verified through approved methods and documented;
- software is tested in accordance with approved test procedures to confirm adherence to the design/functional requirements and results documented; and
- software configuration management is applied that:
  - identifies applications that are software configuration items
  - formally documents, evaluates, and approves changes
  - controls and statuses changes until incorporated into the applications

Because Programmable Logic Controllers (PLCs) have the unique nature of directly controlling process CIs, the software/logic associated with PLCs is controlled in accordance with the CM Program. With regard to the specific items a-k, PLC software is addressed as follows:

a. A PLC Software Configuration Control File (SCCF) is created for each PLC that contains (as applicable) software specification documents such as a Functional Design Specification (FDS) (as discussed below), Interlock Narrative, Sequence Diagrams, Operator Interface Descriptions, Acquisition Plan (if applicable), Verification Plan, Verification Test Results, Validation Plan, Validation Results, and Release to Operations memo. The SSCF and its contents are FCI controlled under the CM Program requirements. If required, Acquisition Plans specify whether the required PLC software is to be acquired by new development, lease or purchase, or by modification to existing software. Acquisition plans can only be revised through approved changes in accordance with the CM Program Change Control Process.

b. PLC Code Specification Documents are prepared which include the FDS, Interlock narratives, sequence diagrams, and other information as needed to define the form and function of the PLC code required for a specific application. The FDS provides design information of what is expected from the PLC software (i.e., performance expectations, user characteristics, user objectives, and possible constraints); and the functionality that the software is to perform (i.e.,

examples of outputs required). The interlocks active in each operational phase are defined in accordance the interlock descriptions on the process P&IDs and are contained in the FDS and/or may be shown in Interlock Narrative tables. The controls and indicators needed for operator interface or human machine interface (HMI) in accordance with operating procedure requirements, safety requirements, and good ergonomic practices are also defined in the FDS. The Code Specification Documents are considered as FCI and changes are processed in accordance with the CM Program Change Control Process.

c. Formal Validation and Verification Plans are developed for use in verifying the PLC software code and its implementation meet the Code Specification Documents. Validation includes PLC program testing using the actual hardware and systems to the extent safety allows. Verification includes the process of determining whether or not the products of a given phase of the PLC software development cycle fulfill the requirements of that phase, and can include Walk-throughs and similar "Tabletop" exercises. Validation and Verification Plans and their results are considered FCI and managed in accordance with the CM Program requirements (e.g., Change Control and Information Control Processes).

d. The approved FDS is translated by a programmer into a workable PLC program code. Any changes which may be needed during implementation are processed in accordance with the CM Change Control Process, and the FDS is updated with approved changes.

e. Test programs are structured by the PLC software programmer to test the implemented code against the software design. Simulation is the preferred method of testing which mimics the process on a basic level as required to test various software functions. Testing is documented via a checklist derived from the FDS. All tests and test data is maintained as FCI.

f. As stated in item a above, the FDS, Interlock Narrative, Sequence Diagrams, Operator Interface Descriptions, Acquisition Plan (if applicable), Verification Plan, Verification Test Results, Validation Plan, Validation Results, and Release to Operations memos are considered as FCI maintained in accordance with the Information Control function of the CM Program.

g. Where the hardware and/or software support it, PLC programs include an access password for routine change control. The routine access password is stored in the SCCF and is accessible only to designated programmers. A master password is also specified for all programs. The master password is controlled by the Engineering Director and used as needed to reset a lost or compromised routine password. Access to PLCs which are not connected to a network is performed by the use of handheld programmers and laptops. This hardware is maintained by Engineering and/or Electronics Engineering and, to the extent possible, the use of this equipment is restricted to designated programmers only. Where the hardware/software does not support the use of a password, access is controlled by password and user sign-on to the gateway PC used for a system of PLC and Human Machine Interface (HMI) devices. Access to the SCCF and archive files is controlled by means of an access list provided to the NFS IS department. Access is granted to qualified users only and is read only or read/write depending on the need. Access to the NFS network is controlled by user name and password.

h. Any PLC software user or programmer that determines or believes that an error exists in released PLC computer code notifies the Program owner to report the problem. If an error occurs during verification, it is corrected and the verification step is repeated. When testing is complete and correct, the PLC code is formally released for validation. If errors occur during validation, they are corrected and validation cycle is repeated until validation testing is successfully completed. Upon completion of the validation process, the user submits the validation documentation to the

cognizant manager for review and release of the software. All changes, thereafter, are controlled in accordance with the CM Program Change Control Process.

i. Needed corrections to PLC software during verification and validation testing are performed as discussed in item h above. Errors discovered after the PLC software has been tested and the PLC software is under change control are required to go through the PIRCS system.

j. As discussed previously, simulation testing is the preferred method of testing PLC software to mimic a process on a basic level. All simulation tests are documented and controlled as FCI. However, during troubleshooting or to gather information on process and PLC functions, it may become necessary to go on-line with the PLC to observe the program in actual operation. No changes of any type are permitted during this procedure. Observation may be performed by a programmer at the request of the Process Owner at any time. Documentation of such on-line or in-use tests are considered FCI managed under the CM Program.

k. Approved PLC software is controlled in accordance with the CM Program Change Control Process which requires use of a Change request (CR), review and approval by the Change Control Board (CCB), development of a Change Control Package (CCP), technical and safety review of the CCP, implementation in accordance with the CCP including verification/validation and testing, and update of the associated FCI (applicable SSCF items).

9. Identify the policy or directive that proclaims management support for CM, and provides the criteria for the scope for CM, and establishes key terminology and definitions.

10 CFR 70.72(a) requires each licensee to establish a configuration management system.

The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.1.1, "Program Planning," states that a CM program should include a policy or directive that proclaims management support for CM, provides criteria for the scope, and establishes key terminology and definitions.

NUREG-1520, Section 11.4.3.1, states that an acceptable configuration management program includes a comprehensive Configuration Management Policy.

Response

NFS-MGT-03-005, *Configuration Management Policy,* states management support for CM, provides the criteria for CIs and FCI to be included in the scope of the CM Program, identifies organizational roles and responsibilities in CM, describes the CM Program functions, and establishes key high-level terminology and definitions.

10. Identify the mechanism for review and disposition of weaknesses discovered during CM assessments.

10 CFR 70.61(e) and 10 CFR 70.64(a)(1) requires that management measures are to be applied to ensure their availability and reliability to perform their function when needed.

The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.1.1, "Program Planning," states that a CM program should include a mechanism for review and disposition of weaknesses discovered during CM assessments. In addition, NUREG-1520, Section 11.4.3.1, states that an acceptable configuration management program documents all assessments and follow-up actions.

Response

The revised NFS CM Program includes an assessment function to evaluate CMP objectives and processes, and a formal audit of the CMP is performed biennially by the Quality Assurance (QA) department. Where practicable, CM related reviews and assessments are combined with other periodic assessments of facilities, processes, and activities for efficiency and cost-effectiveness. All or part of the assessment of the adequacy of CM for an activity or process may be integrated into broader management and performance assessments.

The assessment function also includes various types of assessments to detect, document, determine the cause of, and initiate correction of inconsistencies among design requirements, FCI, and physical configuration. The assessments help identify inconsistencies between these areas, evaluate the root causes for these problems, and prescribe improvements to avoid similar inconsistencies in the future. The five types of assessments used include:

- Construction/Installation Assessments – ensure configuration is managed throughout the construction or installation process for new construction or major modifications.
- Physical Configuration Assessments – evaluate the consistency between the physical configuration and the associated FCI.
- Design Assessments – ensure that design documents and information have been updated to reflect changes and accurately reflect the physical configuration of the nuclear facility.
- Post-Implementation inspections, calibrations, and tests – verify operation of modified SSCs and processes are as expected.
- Periodic Performance Assessments – verify that SSCs and processes continue to meet design and performance requirements in their current configurations.

Assessment findings are documented as open items in the Problem Identification, Resolution and Correction System (PIRCS) as CM issues. The PIRCS process involves identification, screening for importance/risk, root cause investigation and analysis, development and approval of corrective actions, and "cradle-to-grave" tracking to assure corrective actions are completed.

NFS resolves identified physical configuration and FCI discrepancies entered into PIRCS by determining the actual physical configuration that exists at a point in time, identifying any discrepancies with the FCI, and technically resolving those discrepancies. Technical resolution is based on the Design Authority determining if the existing physical configuration is the desired configuration within the approved design requirements. If the existing configuration is not within the design requirements, the design requirements are either changed through the Design Control Process, or the existing configuration is changed through the Change Control Process. This assures that

documentation has been both field-verified and design-verified to be consistent with the "as-built" or actual physical configuration.

11. Describe how the organization(s) responsible for construction, operation, maintenance, modification, and decommissioning of the facility will implement the CM program.

10 CFR 70.64(a) requires that baseline design criteria must be addressed in the design of a new facility.

The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.1.1, "Program Planning," states that a CM program should include documents detailing how the organization(s) responsible for construction, operation, maintenance, modification, and decommissioning of the facility will implement the CM program.

NUREG-1520, Section 11.4.3.1, states that an acceptable configuration management program should address functional interfaces and describe acceptable methods for document control and change control.

Response

The revised NFS CM Program is applicable to all NFS organizations including contractors who perform construction, operation, maintenance, modification, and decommissioning activities associated with NFS facilities, SSCs and processes. Implementation of the NFS CM Program is accomplished through procedures and instructions that delineate the responsibilities and actions of personnel to effectively implement the CM Program elements.

The Production or operations discipline is responsible for production related activities involving the handling and processing of SNM, including developing operating procedures and maintaining facilities and equipment in a safe operating condition and in accordance with the CMP. Functional areas include activities associated with facility equipment installation and start-up. This discipline also performs functional testing on CIs (as applicable) after changes are made to CIs prior to their return to service to provide reasonable assurance that the CIs perform or meet their designated functions. Production is a member of the Change Control Board (CCB) which reviews change requests, and is also a member of the Safety and Safeguards Review Council (SSRC) which reviews and approves certain Change Control Packages.

The Maintenance discipline includes maintenance activities (corrective maintenance, predictive maintenance, testing, and surveillance/monitoring) performed on CIs to ensure continued reliability and functional acceptability. Maintenance is in accordance with written instructions and procedures, and performed by trained and qualified personnel. Changes to CIs by maintenance activities must be in accordance with the CMP Change Control process. Maintenance is within the Engineering discipline which is a member of the CCB and the SSRC.

The Decommissioning discipline develops plans for the decommissioning of facilities and equipment, writes and obtains approval of procedures to conduct decommissioning, obtains any special equipment and/or facilities needed for decommissioning, and assures that decommissioning activities are conducted in accordance with approved documents. Decommissioning is a member of the SSRC and reviews proposed substantial facility and activity changes for potential impacts to the SSCs and ACs.

Reviews to verify compliance with the baseline design criteria are conducted in accordance with approved procedures during the change approval process.

12. Describe how the graded approach will be applied to implementing the CM criteria. Section 2.11.1 states that a graded approach will be used.

10 CFR 70.62(a) states that the safety program may be graded such that management measures applied are graded commensurate with the reduction of risks. The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.1.1, "Program Planning," states that a CM program should include a graded approach to implementing the CM criteria.

NUREG-1520, Section 11.4.3.1, states that an acceptable configuration management program should define the specific attributes of the reduced level or levels of configuration management that would be applied to selected items, and identify those items that will be assigned the lesser level or levels of configuration management.

Response

The revised NFS CMP utilizes a graded approach to apply a level of resources and CMP functions that are appropriate to the degree of risk to safety goals and objectives. Grading is used in the CMP for two purposes: (1) to help define which SSCs, facilities, processes, and activities will be subject to CM, and (2) to define the extent to which the CMP will be applied, e.g. the degree, rigor and extent to which applicable CM functions and requirements are applied to SSCs, ACs, facilities, processes, and work activities.

Application of the graded approach is based on:

- magnitude of any hazards involved
- magnitude of risks and consequences associated with design basis events
- relative importance of an IROFS to safety (risk and consequence reduction) and security
- importance of an SSC (or AC) to product quality
- type and technical characteristics of a facility or process (e.g., separation, tank farm, glove box, solvent extraction, etc.)
- facility or process operational status
- programmatic and technical issues
- existing programs and procedures

Grading is used to determine the extent of application of CM required to assure that IROFS can be relied upon to perform their safety function(s), or for other CIs to meet their operational and/or functional requirements. As stated in the NFS License SNM-124, Section 2.12, IROFS credited with a high level of Risk Reduction for High or Intermediate consequence events require a higher level of control than IROFS credited with a moderate level of Risk Reduction for Intermediate consequence events. The type of IROFS, e.g., Active Engineered Control, Passive Engineered Control, Administrative Control (AC), or Enhanced Administrative Control, also determines the extent of configuration control required. Application of CM may involve, for example, periodic testing versus

inspection, post-maintenance verification, critical versus non-critical document updates, and the degree of training and qualification requirements required for maintenance and operations.

The application of the Change Control Process is applied in a graded manner which categorizes changes as administrative, minor, and major changes in accordance with approved procedures. Administrative changes include inconsequential changes to FCI and pre-approved equivalent replacements of CIs. Minor changes include addition, deletion, and modification of CIs in existing process systems where the design bases or approved accident sequences are not affected. Major changes include new facilities, new processes, substantial changes to existing process systems, changes impacting the design bases/accident sequences, and changes requiring license amendments. A Change Control Board (CCB) is used to review minor and major change requests. The application of safety reviews (e.g., radiological, nuclear criticality safety, industrial, fire, and environmental safety) for a proposed change is also directly dependent on the type of CI(s) involved, associated risks, and type and extent of proposed change.

13. Describe how facility configuration information (FCI) is distinguished from other information such as special drawings, document numbers, or designators.

10 CFR 70.64(a)(1) requires quality standards and records to be developed and implemented in accordance with management measures. 10 CFR 70.72(a) requires documentation of facility changes and the change process. The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.1.3, "Facility Configuration Information Scope Criteria," states that the FCI to be included in the program should be identified.

Response

FCI to be managed under the NFS CM Program includes information that reflect the design requirements, performance criteria, physical characteristics, and regulatory requirements of CIs, as applicable. This information represents the minimum number of documents, drawings, and database information that are essential to operate, maintain, test, modify, repair and/or replace, and substantiate the safety function(s) or operation/functional requirements of a CI. There are no special drawings, numbering, or indicators on documents to indicate which are FCI. However, the revised NFS CM Program identifies the following as the most typical FCI documents and information:

- ISAs and ISA Summaries
- Process Hazard Analyses (PHAs)
- Documents that identify or define design requirements
- Documents that demonstrate compliance with design and licensing requirements
- Design specifications and/or calculations
- Safety analyses (ACE, FHA, NCSE, etc.)
- Physical item databases
- Change process documentation (change requests, reviews)
- Software logic and manuals for operation and maintenance of critical software (e.g., Programmable Logic Controllers or PLCs)
- Key operating and test procedures
- Key drawings (P&IDs, flow diagrams, electrical schematics, logic diagrams, wiring interconnects)
- Vendor technical information (parts lists, installation and operating manuals, test instructions)

FCI is captured in the LINC System and associated with CIs so that whenever a CI is viewed in the system, all associated documents and information, e.g. FCI, can also be obtained. The Change Control Process also identifies FCI to be updated or as-built as part of a proposed change. As FCI is identified, the following information is typical for FCI documents:

- Document Type
- Document number (document control number)
- Document Title
- Effective and Obsolescence dates
- Status information (document, revision, and change)
- Cross references (with full text recognition to facilitate searching and retrieval of information)
- Attributes specific to document type (e.g., drawing type, review period)
- Associated SSC
- Associated key documents (e.g., P&IDs, flow diagrams, logic diagrams, electrical schematics, etc.)
- Associated processes
- Document owner
- Other information needed for control and tracking, such as:
  - Pending change requests
  - Change history
  - Electronic approvals
  - Security to control document access and associated information
  - Distribution lists and document holders

14. With regards to the eB CM information management tool program, describe:

a. How the system will be used in conjunction with the current CM program and whether the system development and implementation complies with an industry standard;
b. How the system will ensure that all aspects of the CM program are properly captured and executed;
c. How the system will address any programming errors, or logic errors as they occur;
d. How the system will be maintained so that it remains available and reliable;
e. The qualifications or training that a person would be required to complete in order to be able to enter information into the system;
f. The qualifications or training that a person would be required to complete in order to be able to become the system administrator;
g. How the data will be backed up in case of a software/hardware malfunction or loss of power.
h. How the system will be tested.

10 CFR 70.62(a) requires that a safety program, including management measures, has to be established and maintained. The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.1.6, "Configuration Control Information System" states an information system for configuration control should be established and policies and appropriate procedures should be defined and organized.

NUREG-1520, Section 11.4.3.1, states that an acceptable configuration management program should describe acceptable methods for document control and change control.

Response

a. The LINC System (eB software) will be used to support implementation of the revised NFS CM Program. LINC will be the controlled repository of all CIs (SSCs and equipment lists) and associated FCI (information directly entered into LINC database or storage of electronic versions of documents and drawings). Specific support of the CM Program functions/elements is discussed in item b below.

   The eB software is designed, implemented, and managed in accordance with vendor internal development standards. Source code control is done using Visual SourceSafe and eB.

b. The key elements of the NFS CM Program include:

   1) Program Management - no LINC interface required

   2) Design Requirements - The NFS CMP requires that the design requirements (and bases) for CIs be identified and documented. Design requirements for IROFS are contained in the ISA Files, ISA Summaries, Nuclear Criticality Safety Evaluations (NCSEs), etc., which are being introduced into and controlled by the LINC System. Design requirements for other CIs are contained in Engineering Design Files (EDFs) and also in the LINC System. The LINC System will ultimately become the official repository for all design requirements.

      The results of design requirements (and bases) reviews, including resolution of comments and issues, are documented and maintained in a retrievable manner in the LINC System. Design requirements (and bases as applicable) are also reviewed during the Change Control process to assure technical adequacy of design requirements for proposed changes, and during periodic assessments and reviews. The results of reviews and assessments of design requirements (and bases) associated with changes, including resolutions of issues and comments, are maintained as part of the change documentation in LINC.

   3) Change Control - Requests for proposed changes to CIs and FCI are required to be effectively documented. This is accomplished by use of formal Change Requests (CRs) which are generated in LINC and provides basic information including the change criteria of 10 CFR 70.72(a) to evaluate the proposed change. The LINC System is used to identify associated CIs and FCI that may be impacted by a proposed change so that the full extent of an approved change is captured. All rejected and approved CRs are stored in LINC.

      Upon approval of a CR, a Change Control Package (CCP) is prepared based on the approved CR. LINC is used to issue change notices to the various FCI owners to revise their documents and information in accordance with the approved CCP. The CCP is prepared consistent with the design process (if applicable) and controls for the proposed change, and includes the approved CR. The CCP includes proposed FCI (e.g., drawings, analyses, procedure changes, etc.) changes, instructions, and/or other documents needed to properly review, implement, verify, and validate the proposed change. The FCI changes are processed though LINC in accordance with their respective governing procedures so that the status of FCI is maintained.

Each CCP will be formally reviewed which may include a technical review, a safety review, and a management review. The review results are documented and stored in LINC as well as the approval.

Approved changes to CIs and their associated FCI are implemented in a manner consistent with the approved CCPs. Should any modifications be needed to the CCPs after work has begun, the CR process is utilized through LINC including maintenance of the review and approval documentation. The status of approved changes including physical changes and associated FCI is tracked through LINC

Drawings and procedures associated with changes to CIs are updated as part of the work processes to implement the change. All affected drawings, procedures, and documents are updated in a timely manner, and drawings and procedures necessary to support operations are either updated, "red-lined", or "pen and ink" changed before the SSC or process is returned to operation. All FCI affected by the CCP will be updated to reflect the "as-built" configuration. The status of drawing and document updates to reflect the as-built conditions are tracked by the LINC System. Closeout of all completed CCPs is documented in LINC.

4) Information Control

Only the most recently approved versions of FCI are used in the process of operating, maintaining, and modifying the SSCs, facilities, and processes. The LINC System is used for information control to help ensure that:

- important facility documents and information are properly stored
- revisions to FCI are controlled, tracked, and completed in a timely manner
- revised documents and information are formally distributed or made available to designated users
- information concerning pending revisions is readily available

As controlled information is updated in LINC to reflect changes to the requirements and/or physical installation, the LINC System ensures that:

a) Updated FCI documents are uniquely identified and includes a revision number and/or date, and
b) Any outdated documents and information are replaced by the latest revisions.

The following information is typical for FCI documents in LINC:

- Document Type
- Document number (document control number)
- Document Title
- Effective and Obsolescence dates
- Status information (document, revision, and change)
- Cross references (with full text recognition to facilitate searching and retrieval of information)
- Attributes specific to document type (e.g., drawing type, review period)
- Associated SSC
- Associated key documents (e.g., P&IDs, flow diagrams, logic diagrams, electrical schematics, etc.)
- Associated processes
- Document owner

- Other information needed for control and tracking, such as:
  - Pending change requests
  - Change history
  - Electronic approvals
  - Security to control document access and associated information
  - Distribution lists and document holders

Secure master files of original and/or master copies of FCI documents such as design analyses, calculations, specifications, drawings, procedures, etc., are maintained in the LINC System. Master copies are not released from master files and are used to provide copies either on a regular distribution schedule or in response to specific requests. Access and security precautions are implemented to ensure that master files are controlled and kept current.

The LINC System and other systems containing FCI are maintained on secure servers and access is controlled to prevent unauthorized access or use. Capability to add, delete or modify information is controlled to prohibit such changes without going through appropriate reviews and approvals. Appropriate controls are established to ensure that all electronic files are backed up and the appropriate versions are available electronically.

5) Assessments
The five types of assessments used by NFS for CM are:

- Construction/Installation Assessments – ensure configuration is managed throughout the construction or installation process for new construction or major modifications.
- Physical Configuration Assessments – evaluate the consistency between the physical configuration and the associated FCI.
- Design Assessments – ensure that design documents and information have been updated to reflect changes and accurately reflect the physical configuration of the nuclear facility.
- Post-Implementation inspections, calibrations, and tests – verify operation of modified SSCs and processes are as expected.
- Periodic Performance Assessments – verify that SSCs and processes continue to meet design and performance requirements in their current configurations.

All CM assessment results and reports are captured in the LINC System and traceable to facilities, processes, systems and CIs.

6) Training
At present, Training does not utilize LINC. However, future plans are to have training plans, modules, records, and other supporting training documentation included in LINC. Training modules and tests as a minimum will be configuration controlled in accordance with the CM Program.

7) Program Metrics
The LINC System tracks CI and FCI changes in progress, and is used to periodically report the status and associated change information to determine CM Program efficiency and effectiveness. Information tracked and reported by LINC typically includes such items as:

- Identification of the approved changes,

- Major SSCs, ACs, and processes affected by the changes,
- Impacts or constraints on current operations,
- Modifications that have been approved to originally approved changes,
- Status of the implementation and verification of the changes,
- Numbers of drawings and documents updated per selected time frame (daily, weekly, monthly, etc.)
- Backlog numbers of drawing and document updates

c. Any problems encountered by NFS are identified, documented, and sent to the software vendor. A priority system has been established with the vendor to assure that any problems that would have a significant business impact (e.g., process shutdown) would be fixed immediately. Problems affecting data integrity are typically addressed by "hot fixes" provided by the vendor within several business days. Problems that do not affect data integrity or cause business downtime are addressed by work arounds and/or in subsequent software product releases.

d. NFS uses a dedicated team to maintain the servers the LINC System and associated databases are located on. All maintenance activities that would require application downtime are performed after normal working hours. Hot fixes and new releases are loaded into a software test system independent of the software production or normal operating system, and validated to assure there are no problems. Upon successful validation testing in the test system, the fixes or new releases are migrated to the production system and tested. NFS users are involved in testing in both systems. Full LINC System backups are performed before any maintenance activities or updates are done. Daily backups of the LINC System database are performed and transaction logs are recorded so that the system and data can be quickly restored if needed.

e. An NFS user must have an active User ID in the NFS network and have been trained on the LINC System processes. These processes may include adding virtual items, adding physical items, adding documents, adding serial items; add & review change requests, implement change requests, create work orders, manage documents, manage physical items, etc. A graded approach is used with regard to training based on the work function(s) of the user.

f. System Administrative (SA) functions are only granted to a core group of personnel within the CM Group. Training is provided on SA functions including adding users & permissions; adding persons, organizations & projects; and data administration. SA personnel must be experienced in PC applications (e.g., databases, word processing, spreadsheets, etc.) and have some understanding of networks and servers.

g. See response to item d above. Daily backups of data are performed and transaction logs are recorded. Full server backups of application and data are performed prior to any maintenance or update activities.

h. System (application) testing is performed on three levels:

1) A basic test is performed for application availability which includes all services/modules and transactions.
2) The execution of each business or application process is tested.
3) Integration and interface testing between application services/modules and between the LINC System and other software applications, e.g., Microstation CAD and Microsoft Word.

A graded approach is used in testing hot fixes and product updates. Testing of hot fixes is done only for the application service/module and/or functional area where the hot fix is applied. For product updates, full application testing is done. As discussed in item d above, a test system is used prior to placing a hot fix or product update in the production or user system. Testing in the production system is also done after the test system.

15. Describe how CM boundaries are established, maintained, and recorded.

10 CFR 70.65(b)(1)-(9) requires that the Integrated Safety Analysis (ISA) document shall contain a general description of the facility with emphasis on the areas that could affect safety, including controlled area boundaries e.g., (piping and instrumentation drawings, engineered IROFS, boundary descriptions, criticality safety analysis, dose calculations, process hazards analysis, process safety information ISA work sheets etc.) and that this information will be maintained at the facility site.

The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.2.2, "System and Process Boundaries," states that the boundaries of each system and process should be established and identifiable through controlled documentation or information system.

NUREG-1520, Section 11.4.3.1, states that an acceptable configuration management program should define the scope of items to be included in the configuration management function.

Response

In general, all facilities, processes, and systems which fall within the scope of the revised NFS CM Program are managed under the Program as Configuration Items (CIs). This includes Items Relied on for Safety (IROFS) contained in the Integrated Safety Analysis (ISA) Summary and facilities and SSCs used:

- To physically process, store or transfer more than 350 grams of U-235 as Special Nuclear Material (SNM) contained within an SSC at any given time. Specifically included are the SSCs and administrative controls associated with active SNM processing facilities, the SNM storage vaults, the Waste Water Treatment Facility, associated Process Off-Gas Ventilation systems, bulk chemicals and gases.
- To protect off-site and on-site personnel from nuclear and other hazards, as defined by the facility Integrated Safety Analyses (ISA);
- To meet regulatory requirements for the physical protection of SNM;
- To protect the environment from significant damage or to satisfy environmental requirements or permits; and
- To avoid substantial unplanned interruption of Production operations having significant cost or product quality impact.

CIs are contained in the LINC System and controlled in accordance with the CM Program requirements. Processes and systems are contained on Piping and Instrumentation Diagrams (P&IDs) and/or Process Flow Diagrams. All piping, components and instrumentation shown on these P&IDs or flow diagrams are under CM by scope definition. Process or system components and piping are no longer used (i.e., not under CM) that appear on P&IDs or flow diagrams are clearly marked to

indicate they are not under CM. These components and piping are also physically marked (tagged) in the facilities.

The functional boundaries of IROFS are identified during the identification and documenting of IROFS in the process hazards and risk assessment processes. The functional boundary consists of all structures and components relied upon for an IROFS to fulfill its safety requirements when required. These boundaries are identified in a controlled IROFS list which is FCI and will be maintained in the LINC System. The ISA Summary documents contain (or reference) process and system descriptions and associated Process Flow Diagrams which identify boundaries.

16. Describe the measures that have been taken to eliminate or minimize redundant FCI.

10 CFR 70.72(c)(1)(I) requires that changes to the site, structures, processes, systems, equipment, computer programs and activities of personnel do not create new types of accident sequences. 10 CFR 70.72(f) requires that records of changes shall be maintained. The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.3.6, "Minimization," states that redundant FCI need to be minimized or eliminated.

Response

As stated in ANSI/NIRMA CM 1.0-2007 Section 3.3.6, the minimization or elimination of redundant FCI is needed to reduce or eliminate:

- potential risk of error in facility, process and system operations,
- conflicts between sources of information,
- unnecessary costs, and
- reduced worker efficiency.

The revised NFS CM Program supports this standard requirement in the following ways:

1) The use of the LINC System to become the repository of all FCI helps to identify and eliminate duplicate or redundant information. As documents and information are input into LINC and interrelationships among FCI and CI are established, discrepancies and conflicts are identified and resolved. Duplicate and redundant data and information are eliminated to the extent practicable as part of normal "cleanup". Additionally, lists of CIs and FCI that contain redundant information and are managed by NFS organizations in various locations will be consolidated into LINC so that the potential of conflicting information will be eliminated.

2) A number of procedure revisions and several new procedures have been identified to effectively implement Design Control and Change Control processes of the revised CM Program. During this identification effort, various procedures and procedure steps were identified that produced redundant and duplicate FCI. As these procedures are revised and/or developed, procedures and steps will be eliminated and/or consolidated to reduce or eliminate production of redundant FCI.

3) The Change Control Process of the revised CM Program requires that all affected FCI and CIs associated with a proposed change be identified and evaluated for impact. Redundant and/or discrepant FCI identified during this review and evaluation will be eliminated or corrected as part of the change control package developed to implement approved changes.

4) The Assessment function of the revised CM Program has an objective of correcting inconsistencies among design requirements, FCI, and physical configuration. Key sources of inconsistencies among FCI are redundant information. CM assessments help identify inconsistencies among information sources, evaluate the root causes, and prescribe improvements to avoid similar inconsistencies in the future.

17. Describe how the configuration management system is used to defend against common mode failure of IROFS on a process that lead to a high consequence or intermediate consequence events.

10 CFR 70.61(e) requires that IROFS are available and reliable to perform its intended function when needed. The amendment commits to model the CM program after ANSI/NIRMA CM 1.0-2000, "Guidelines for Configuration Management of Nuclear Facilities." ANSI/NIRMA CM 1.0-2000 Section 4.3.7, "Operational Configuration Information Status Control," specifies that appropriate method(s) should be available to facility operators that enable them to be aware of the current operational configuration and relate it to the configuration presumed by the design bases.

Response

Common mode failure is addressed in the Design Control Process of the CM Program as a design requirement and/or design basis. To the extent practicable, NFS avoids reliance on an IROFS that is the sole item preventing or mitigating an accident sequence. Redundancy and alternate preventive or mitigative measures are utilized in designs such that common mode failures are negated by locating IROFS where accident environments are avoided, independency of redundant IROFS is maintained, and/or alternate independent essential utilities are provided. NFS also identifies IROFS susceptible to common mode (or common cause) failures with the initiating event(s) or other IROFS during the risk assessment process. If it is determined that a common mode failure scenario exists, then IROFS are re-evaluated and re-assigned. The design requirements, design bases, design documents, and safety analyses associated with CIs including IROFS are FCI managed under the CM Program.

In the Change Control Process of the revised NFS CM Program, all proposed changes go through a change request and change control package process. These include technical, safety, and management reviews as appropriate to assure that changes meet design requirements and are within design bases. If design requirements must be changed, technical analyses are performed to assure that IROFS can still perform their expected safety function(s) and meet design basis requirements.

As discussed in the response to Item 7, the revised CM Program requires that all variable SSC (including IROFS) and process configurations together with their associated FCI be reviewed and approved prior to use or implementation to assure they are within approved design requirements at all times. This includes facility, process, and system operating procedures so that operational configuration is maintained. The review and approval process helps assure that removal of a redundant, alternate, or a single IROFS from service for testing or other purposes does not result in a condition that would allow common mode failure to occur without proper compensatory or other measures being established to maintain required safety function(s).

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ATTACHMENT 1

Page Changes to SNM-124

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ORGANIZATION AND ADMINISTRATION

2.1 General Safety Policy and Responsibilities

It is NFS' policy that radiation exposures to employees and the general public be kept as low as reasonably achievable (ALARA). Responsibility for safety in the various production lines, processes, and services is delegated to the lowest practical level of supervision. Safety is the responsibility of each supervisor within his own area. Through training and periodic retraining, each individual, regardless of position, shall be made aware that safety in his work area is ultimately his responsibility.

2.2 Key Positions with Safety- and Quality-Related Responsibilities

The positions described in this section are intended to be generic in nature and do not reflect specific organizational titles or jobs. The responsibilities of the positions described may be discharged by one or more different organizational positions so long as the minimum position qualifications specified in this chapter are met.

2.2.0 President and/or CEO

The president and/or CEO has overall responsibility for all activities conducted at NFS. This includes safety, security, and quality assurance, as well as all other disciplines on site.

2.2.1 Discipline Vice-President/Directors

The discipline vice-presidents/directors together have the delegated responsibility for plant safety and for compliance with conditions of SNM licenses and NRC regulations in order to maintain a safe work place for all employees.

The operative discipline vice-president is responsible for the overall management and efficient operation of the manufacturing facilities of the Erwin plant. The position has been delegated authority to direct all operations within the broad guidance of assigned management objectives.

The safety discipline vice-president is responsible for insuring that plant operations comply with all regulatory requirements of governmental agencies and good practice in the area of safety and material control.

2.2.2 Discipline Manager

The discipline manager is the designated individual who is responsible for ensuring that all activities in his area are performed in a safe and effective manner. The discipline manager manages and directs operations within his discipline. The position ensures that all operations under its guidance comply with safety and license conditions, requirements for quality-related safety activities, and safety-related configuration management requirements. The discipline managers are responsible for the formation, approval, and implementation of procedures that incorporate safety and quality controls and limits commensurate with the particular operation involved. The discipline managers work together to assure the plant is operated in a safe and efficient manner, and in compliance with federal, state, and local regulations and laws governing operation of a nuclear facility. The disciplines with safety-related responsibilities include;

- Production;
- Decommissioning;
- Engineering;
- Safety;
- Material Control and Accountability;
- Security.

2.2.3 Safety Discipline Manager

The safety discipline manager is responsible for planning, directing, and controlling the overall activities associated with all aspects of the safety discipline. The safety discipline is the administrative area that governs the following functions: criticality safety function, radiation safety and protection function, environmental protection function, and the industrial safety function. The safety discipline manager is authorized to suspend operations or require additional safety precautions when he believes such measures are necessary in the interest of plant safety. The position is administratively independent of production responsibilities.

The safety function is responsible for analyzing safety risk and providing barriers to unacceptable risk. This function is also responsible for the following areas:

- Planning for radiological emergencies;
- Preparation and issuance of ALARA plans and reports;

- License compliance activities as it relates to radiation and environmental safety;

- Technical advice on shipment of radioactive material

2.2.3.1 Criticality Safety Function Manager

The criticality safety function manager is administratively independent of production responsibilities and has the authority to shut down operations believed to threaten the health and safety of employees or the public. The criticality safety function provides authoritative professional advice and counsel to discipline managers on matters of control against accidental criticality. These functions include at least the following:

- Establishment of a criticality safety control program including criteria, procedures, and training,

- Analysis and approval of proposed changes in process conditions and processing equipment involving criticality safety,

- Measurement of the effectiveness of the criticality control program.

Measurement of the effectiveness of the criticality control program is determined through inspection and audit programs to assure that nuclear safety criteria are met for the protection of employees, the public, and the environment.

2.2.3.1.1 Criticality Safety Function Senior Member

The criticality safety function senior member is administratively independent of production responsibilities and performs criticality safety analyses of proposed facility, process, or equipment changes. The senior member has the authority to shut down operations which involve criticality safety practices believed to threaten the health and safety of employees or the public. The position provides authoritative professional advice and counsel to discipline managers and their staffs on matters of control against accidental criticality. The senior member performs inspections and audits of operations to determine compliance with the limitations and controls established for criticality safety, including procedural compliance. The position reviews criticality safety analyses which have been performed by a junior member of the function and instructs other members of the safety discipline on methods used in criticality safety audits and inspections.

2.2.3.1.2 Criticality Safety Function Junior Member

The criticality safety function junior member is administratively independent of production responsibilities and performs criticality safety analyses of proposed facility, process, or equipment changes. The position provides authoritative professional advice and counsel to discipline managers and their staffs on matters of control against accidental criticality. The junior member performs inspections and audits of operations to determine compliance with the limitations and controls established for criticality safety, including procedural compliance.

2.2.3.2 Health Physics Function Manager

The health physics function manager manages the health physics function, is administratively independent of production responsibilities, and has the authority to shut down an operation believed to threaten the health and safety of employees or the public. The health physics function provides authoritative professional advice and counsel to discipline managers on matters of radiation safety and measures the effectiveness of the radiation safety program. The health physics function has the responsibility of establishing and maintaining the radiation safety program necessary to ensure the protection of employees at NFS and the community. The manager of the health physics function shall review and approve the radiation safety programs which shall include at least the following:

- The radiation protection and radiation monitoring program;
- The radiation protection criteria, procedures, and training programs to control contamination and exposure to individuals,
- Analysis and approval of proposed changes in the process conditions and processing equipment involving radiological safety.

2.2.3.2.1 Health Physicist

The health physicists are administratively independent of production responsibilities and perform radiation safety analyses and evaluations of proposed changes in facility, process, or equipment changes. In addition, the health physicists: (1) provide authoritative professional advice and counsel to discipline managers and their staffs on matters of radiation safety and the control of radiation exposure; (2) perform inspections and audits of operations to determine compliance with the limitations and controls established for radiation safety purposes, including procedural compliance; (3) review radiation safety analyses which have been performed by other members of the safety function and instruct other members of the safety discipline on methods used in radiation safety audits and inspections; and (4) write and sign Radiation Work Permits.

2.2.3.2.2 Radiation Monitoring Function Manager

The manager of the radiation monitoring function is administratively independent of production responsibilities. He has the authority to shut down an operation believed to threaten the health and safety of employees or the public. The radiation monitoring function manager: (1) reviews, approves, and supervises the conduct of the radiation monitoring program; (2) provides advice and counsel to discipline managers and their staffs on matters of radiation safety, monitoring, and the control of radiation exposure during all shifts of operation; (3) perform walk-through inspections of operations to determine compliance with the limitations and control established for radiation safety purposes, including procedural compliance.

The radiation monitoring function is designated the responsibility to provide support to operations requiring radiation monitoring services, and shall include at least the following:

- Conduct of radiation monitoring programs,
- Measurement of airborne radionuclide concentration, contamination level, and external radiation levels,
- Evaluation of the operational integrity and reliability of radiation detection instruments,
- Maintenance of records related to the radiation monitoring program

2.2.3.2.3 Radiation Technician Supervisor

The radiation technician supervisor is administratively independent of production responsibilities and is responsible for the assignment of technicians on each shift to conduct radiation measurements and surveys and to perform scheduled safety inspections. The radiation technician supervisor is responsible for overseeing routine instrument maintenance and calibration checks of radiation survey meters and counting instruments. The radiation technician supervisor reports to the radiation monitoring function manager.

2.2.3.3 Environmental Protection Function Manager

The environmental protection function manager is administratively independent of production responsibilities and has the authority to shut down an operation believed to threaten the health and safety of employees or the public. The environmental protection function provides authoritative professional advice and counsel to discipline managers on

matters of environmental protection and measures the effectiveness of the environmental protection program. The environmental protection function has the responsibility of establishing and maintaining the environmental protection program necessary to ensure the protection of employees at NFS and the community. It is defined as that function of NFS with designated responsibilities that include at least the following:

- Emergency planning;
- Identification of environmental requirements of federal, state, and local regulations governing NFS' operation.
- Establishment of systems and methods to measure and document NFS' adherence to regulatory, environmental requirements, and license conditions;
- Assurance of proper federal and state permits, licenses, and registrations for nonradiological discharges from the facility.

2.2.3.3.1 Environmental Protection Analyst

The environmental protection analyst is administratively independent of production responsibilities and performs analyses and evaluations of proposed changes in facility, process, or equipment changes as they relate to environmental protection. The position provides authoritative professional advice and counsel to discipline managers and their staffs on matters of environmental protection. The environmental protection analyst performs reviews of environmental monitoring data to determine compliance with the limitations and controls established for regulatory compliance purposes.

2.2.3.4 Industrial Safety Function Manager

The industrial safety function is administratively independent of production responsibilities and has the authority to shut down an operation believed to threaten the health and safety of employees or the public. The industrial safety function provides authoritative professional advice and counsel to discipline managers on matters of industrial safety/industrial hygiene and measures the effectiveness of the industrial safety program. The industrial safety function has the responsibility of establishing and maintaining the industrial safety program necessary to ensure the protection of employees at NFS and the community. It is defined as that function of NFS with designated responsibilities that include at least the following:

- Industrial hygiene (chemical safety);
- Industrial safety;

- Respiratory protection;

- Fire protection;

- Establishment of systems and methods to measure and document NFS' adherence to regulatory safety requirements and license conditions, as they relate to industrial safety/hygiene.

2.2.3.4.1 Industrial Safety Specialist

The industrial safety specialist is administratively independent of production responsibilities and supervises the conduct of the respiratory protection, fire protection, and industrial safety surveys, audits, inspections, and measurements. The position provides advise and counsel to discipline managers and their staffs on matters of industrial safety and control. The industrial safety specialist performs inspections and audits of operations to determine compliance with the limitations and controls established for industrial safety purposes.

2.2.4 Quality Assurance Function Manager

The quality assurance function manager has overall responsibility for the development, management, oversight, and evaluation of the quality assurance program. The quality assurance program is based on, but not limited to, applicable requirements and guidance such as ASME NQA-1, MIL-Q-9858A, or other guidance. The quality assurance function manager is administratively independent of operations, and has no other duties or responsibilities unrelated to quality assurance that would interfere with carrying out the duties of this position. The quality assurance function manager has direct access to the President and/or CEO.

2.3 Personnel Education and Experience Requirements

2.3.1 Discipline Vice-President

The qualifications for the discipline vice-president are a BS/BA degree in engineering or physical science and ten years of experience in industry or nuclear reactor operations – five of which have been in a supervisory position in the nuclear industry or reactor operations.

2.3.2 Discipline Manager

The qualifications for the discipline managers vary for each discipline; however, the minimum qualifications shall be a BS/BA degree and at least five years experience in the discipline under his control, two years of which shall have been nuclear fuel cycle.

Each discipline manager shall be knowledgeable of the safety procedures and programs as they relate to their area of responsibility.

2.3.3 Safety Discipline Manager

The qualifications for the safety discipline manager are a BS/BA degree in science or engineering with a minimum of eight years experience in applied health physics and/or nuclear safety. A MS degree in radiological physics or nuclear engineering may be substituted for two years of the experience.

2.3.3.1 Criticality Safety Function Manager

The qualifications for the criticality safety function manager are a BS/BA degree in nuclear science or engineering with a minimum of three years experience in nuclear criticality safety.

2.3.3.1.1 Criticality Safety Function Senior Member

The qualifications for the criticality safety senior member are a BS/BA degree in nuclear science or engineering with at least three years experience in criticality safety work.

2.3.3.1.2 Criticality Safety Function Junior Member

The qualifications for the criticality safety junior member are a BS/BA degree in nuclear science or engineering with at least one year of experience in criticality safety work.

2.3.3.2 Health Physics Function Manager

The qualifications for the manager of the health physics function are a BS/BA degree in science or engineering with at least three years of experience in applied health physics in a program dealing with radiation safety problems similar to the one managed.

2.3.3.2.1 Health Physicist

The qualifications for the health physicist are a BS/BA degree in science, or engineering, or equivalent experience. In addition, the position requires at least one year of experience

in health physics. A Master's degree in health physics or related discipline may be substituted for one year experience.

2.3.3.2.2 Radiation Monitoring Function Manager and Radiation Technician Supervisor

The qualifications for the radiation monitoring manager function and the radiation technician supervisor are a minimum of two years of college or equivalent experience and one year of experience in applied health physics.

2.3.3.3 Environmental Protection Function Manager

The qualifications for the manager of the environmental protection function are a BS/BA degree in a scientific field or equivalent experience and at least three years experience in applied health physics or environmental protection.

2.3.3.3.1 Environmental Protection Analyst

The qualifications for an environmental protection analyst are a BS/BA degree in a scientific field or equivalent experience. Additionally, the position requires at least one year of applied health physics or environmental protection experience.

2.3.3.4 Industrial Safety Function Manager

The qualifications for the manager of the industrial safety function are a BS/BA degree in industrial hygiene, or safety, or other appropriate field with three years industrial experience in fire protection, respiratory protection, industrial hygiene, or other closely related areas.

2.3.3.4.1 Industrial Safety Specialist

The requirements for advanced industrial safety specialist positions are a BS/BA degree with specialized training in environmental health, fire protection, industrial safety/hygiene, or closely related field and at least three years of industrial safety experience. Lower level positions require at least two years of industrial safety or equivalent plant experience. Only personnel knowledgeable in hazards evaluation and control methods for chemical process safety will perform chemical process safety reviews. The necessary training and qualifications for persons conducting these reviews will be documented and maintained.

2.3.4 Quality Assurance Manager

The qualifications for the quality assurance manager are a BS/BA degree and at least five years experience in quality assurance, two years of which shall have been in the nuclear fuel cycle.

2.4 Safety Review Committee

The safety review committee membership includes senior representatives of the following disciplines:

- Production;
- Decommissioning;
- Engineering;
- Safety;
- Material Control and Accountability; and,
- Security.

The safety director position shall be a member of the safety review committee.

The chair, other members, and their alternates, are appointed by the president or the vice-president authorized to be his alternate and, at a minimum, have the qualifications specified for a discipline manager (Section 2.3.2). Members of the safety review committee, identified above, shall have documented training on possible error modes of management control systems, such as the Management Oversight and Risk Tree (MORT) method.

The committee is responsible to the president, or the vice-president authorized to be his alternate, who retains overall authority for the approval or disapproval of committee actions.

The authority and responsibilities of the full safety review committee include the following:

- Reviewing proposed changes having safety significance and that require license changes before the associated license amendment applications are submitted to the NRC.

- Reviewing and approving physical changes to the facility or facility operations having safety implications at NFS which do not require approval of a license amendment. Changes to the facility or facility operations which affect material control and accountability or physical security and have safety significance shall also be reviewed.

- Deciding what practices are an acceptable or unacceptable risk.

- Reviewing the results of license-required safety audits and any follow-up actions recommended.

- Reviewing the ALARA program for at least the following:

  (a) Trends in air activity,

  (b) Cumulative exposure,

  (c) Engineering design and personnel work practices.

- Working with the safety discipline to implement the ALARA program.

- Reviewing reports of safety inspections, audits, and investigations which the license requires be conducted.

- Reviewing all violations of regulations or license conditions having safety significance, as well as any unusual occurrences (see Section 2.8) having safety significance.

The chair of the safety review committee is authorized to select individual committee members to review and approve new or revised operating, general safety, decommissioning, and emergency procedures. However, the review and approval of such procedures, as described herein, shall include at a minimum the initiating discipline manager, the safety discipline manager, and the appropriate safety review committee members, as selected by the safety review committee chair. In addition, the chair of the safety review committee may also select individual committee members to review existing operating procedures for accuracy and for being current at least every two years.

The committee will meet at the following frequencies:

- to discuss topics such as facility modifications – as needed;

- to discuss ALARA considerations – at least semiannually;

- to review safety audits, inspections, reports, and violations of regulations or license conditions – at least quarterly.

Its proceedings, findings, and recommendations will be reported in writing to the discipline vice-presidents and to the appropriate discipline managers. Such reports shall be retained for at least five years. Records pertaining to the facility modification projects shall be retained until the termination of the license. Records of procedural changes will be maintained for a minimum of five years.

Review of matters by the committee may be conducted by either individual review or collectively at a meeting, provided that individual members of the committee have the authority to request a meeting of the entire committee on any given matters.

2.5 Approval Authority for Personnel Selection

When a vacancy occurs at NFS in a safety related position, the responsible manager will make a recommendation to fill the vacancy. Approvals must be obtained from the next higher level of management.

2.6 Training

The objective of NFS' safety training program is to provide employees, contractors, and visitors the knowledge and expertise needed to carry out their job function while assuring the safety and well-being of all personnel on the NFS site. The NFS program is flexible and adaptive to current safety needs. Its aim is to train employees to be aware of and respect the hazards they encounter in their daily work and to respond to emergencies promptly and properly.

Objectives and requirements for training programs are jointly agreed upon by NFS management based upon plant needs and input provided by the training function and the appropriate discipline. The content of safety training is evaluated continually to ensure current relevance.

The NFS Training Program requires that all personnel who are granted unescorted access to the protected area 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 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 and radiological and nuclear criticality safety controls specific to the particular work assignment. Work training also includes appropriate reinstruction 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 also participate in periodic procedure review training sessions designed to allow them time to re-review the operating procedures applicable to their particular work assignment. Those individuals are also required to undergo a re-qualification process for applicable work assignments every three years (maximum internal not to exceed 42 months). Additional details of the work training program are provided in approved written 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. Such training records will be maintained for a minimum of two years.

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.

The effectiveness of all required training is evaluated with appropriate measurement tools (e.g., written tests, demonstrations of skills, questionnaires, etc.).

2.7 Procedures

SNM operations and safety function activities are conducted in accordance with written procedures as defined in Section 1.7.4 and 1.7.5. Compliance with these procedures is mandatory.

2.7.1 Adopting and Issuing Procedures

Operating procedures (see Section 1.7.4 for definitions) will be prepared by the appropriate discipline manager and approved by the safety discipline manager. These operating procedures will incorporate limits and controls established by the safety functions. Operating procedures will be made readily available to foremen, operators, and other affected personnel. Additionally, work place posting of limits and controls, training, and other communication devices will be used to enhance comprehension and understanding of operating procedures. The operating procedures are reviewed and approved by the safety review committee. Review, to assure they reflect current practice, is performed by the safety review committee at least every two years.

Criticality safety controls, radiation safety and protection controls, environmental protection controls, and industrial safety controls, as appropriate for workers in uranium processing areas, are described in operating procedures.

The general safety program is designed to establish and maintain a comprehensive set of safety function procedures for health and safety practices so as to maintain occupational radiation exposures at levels as low as reasonably achievable (ALARA). Procedural review is done every two years by the appropriate safety function manager.

Safety function procedures, as defined in Section 1.7.5, are prepared by the safety function and approved by the safety discipline manager.

2.7.2 Operating Procedure Changes

Whenever facility or equipment changes occur, the operating and, if appropriate, the safety procedure will be modified or amended to reflect such changes. Criticality safety, radiation safety, industrial safety, and environmental protection aspects of the changes will be considered and incorporated into the revised procedures as necessary. The modified or amended procedures are prepared by the appropriate discipline manager and reviewed and approved by the safety review committee. The safety analyses, required reviews and testing, required training, and distribution of procedure revisions will be completed before procedural changes are implemented.

2.7.3 Safety Reviews

A request for safety analysis is prepared by or at the direction of the discipline manager for any proposed new activity or change in activity which involves the handling, processing, or storage of SNM and which may require a change in criticality safety, radiological safety and protection, environmental protection, or industrial safety controls.

The safety analysis thus performed will be done, as a minimum, by a person possessing the minimum qualifications for the criticality safety function junior member, radiation safety analyst, industrial safety specialist, or environmental protection analyst. Criticality safety analyses performed by the criticality safety function junior member will be reviewed by an individual with qualifications equivalent to the criticality safety function senior member. The change will not be implemented until the analysis demonstrating safety of the activity has been completed, approval has been granted by the safety review committee, a pre-operational inspection or test has been conducted to verify that the installation is in accordance with the safety analysis, and appropriate procedures and/or instructions are in place.

Hazards associated with operations shall be analyzed and documented as part of any safety analysis for new processes or for changes to existing process systems requiring approval of the safety review committee. Acceptable analysis methodologies may include but are not limited to the following techniques:

- Operational Hazards Analysis (OHA)
- What-If/Checklist Reviews
- Management Oversite and Risk Tree (MORT)
- Hazard and Operability Study (HAZOP)
- Failure Modes and Effects Analysis (FMEA)
- Process Hazards Characterization and Analysis (PHCA)
- Fault Tree Analysis
- Event Tree Analysis

The hazard analysis shall be commensurate with the complexity of the process and with the types of hazards present.

The results of these analyses are documented and maintained until the termination of the license.

2.8 Audits and Inspections

Operating procedures are based on NFS' practices, applicable regulations, and license conditions.

Audits are performed to assure plant operations are conducted in accordance with established regulatory requirements and standard industry practice. Inspections are performed to assure that operations are conducted according to approved procedures. The objective of these audits and inspections is a critical self-assessment of the safety program and the continuous improvement of the safety program.

2.8.1 Internal Safety Audits

Members of each safety function conduct formal safety audits of nuclear manufacturing and support areas on a quarterly basis and in accordance with written procedures which have been approved by the appropriate safety function manager. Such audits are performed to determine that actual operations conform to the safety requirements. The quarterly safety audit will be conducted by an individual who has, as a minimum, the qualifications required for the radiation safety analyst, environmental protection analyst, industrial safety specialist, or the senior member in the criticality safety function as appropriate for the area to be audited.

Monthly criticality safety, radiation safety and protection, environmental protection, and industrial safety inspections of operating manufacturing and support areas are conducted in accordance with procedures which have been reviewed and approved by the applicable safety manager of the safety function. The inspection is performed by persons appointed by the appropriate safety function manager and have qualifications of the criticality safety junior member, the radiation safety analyst, the environmental protection analyst, or the industrial safety specialist as appropriate for the area being inspected.

Safety training programs are audited annually by a member of the safety discipline as appropriate for the subject of the training.

Inspection reports documenting discrepancies shall be submitted to the responsible discipline managers. Where items of nonconformance are identified, they shall be brought directly to the attention of the responsible supervisor. Copies of audit reports shall be sent to the discipline vice-president and appropriate discipline managers for corrective action. Audits and inspection reports, as well as any subsequent reviews, investigations, corrective actions, etc., shall be documented and shall be maintained for a period of at least two years.

Findings of required audits and inspections and the corrective actions are reviewed by the safety review committee. Corrective action items are tracked until their closure.

2.8.2 External Audits

The NFS safety programs are audited at a frequency of at least every three years by an appropriate function outside the NFS Erwin organization. The audit team is composed of individuals whose qualifications are approved by the safety discipline vice-president.

Audit results are reported in writing to the safety discipline vice-president. The discipline vice-president will assure that necessary response actions are taken.

Audit results in the form of corrective action recommendations are reported to the safety discipline vice-president and his staff for tracking until their closure.

2.9 Investigations and Reporting

Upon discovery and reporting of an unusual occurrence, the appropriate function vice-president will appoint an appropriate investigation team from his staff with representation from the disciplines necessary to conduct a thorough inquiry with the goal of identifying the root cause and recommending appropriate corrective action. The purpose of this inquiry is to insure that lessons learned are identified and incorporated into plant procedures and/or systems to prevent a recurrence.

2.9.1 Classification of Unusual Occurrences

Unusual occurrences which potentially threaten or less then effectiveness of health, safety, and environmental protection are classified by the appropriate safety function manager. Each incident is considered in terms of its severity.

2.9.2 Investigation of Unusual Occurrences

The safety function manager is responsible for preparing, reviewing, and approving the procedures for conducting investigations of unusual occurrences. Responsibility for initiating and conducting the investigation is assigned to the team chairperson appointed by the appropriate function vice-president. The investigation will be initiated and completed as soon as practical after the discovery of the occurrence. These investigations are conducted in accordance with approved safety procedures. The goal of the investigation will be to identify root causes of the incident and to identify corrective actions to prevent recurrence.

The individual(s) representing the safety discipline on the team conducting investigations of unusual occurrences will have, as a minimum, the qualifications of a criticality safety function senior member, radiation safety analyst, industrial safety specialist, or environmental protection analyst as appropriate for the area or incident to be investigated.

The investigation will be documented in a written report which shall include a statement regarding the probable cause(s) of the event, include recommendations for immediate and long-term corrective actions taken to prevent recurrence, contain provisions for tracking and following of corrective actions and be retained for a minimum of five years.

(Table 2.1 - Reserved)

2.10 Records

Records appropriate to safety activities, 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 Commission license conditions and regulations. Records of criticality safety analyses are maintained in sufficient detail and form to permit independent review and audit of the method of calculation and results. Records associated with personnel radiation exposures and environmental activities are generated and retained in such a manner as to comply with the relevant requirements of 10 CFR 20.

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

2.11 Configuration Management

Nuclear Fuel Services (NFS) maintains a Configuration Management (CM) Program to ensure the following objectives are met for selected structures, systems, and components (SSCs), processes, and activities managed by NFS:

- To establish consistency among design and regulatory requirements, physical configuration, and facility configuration information (FCI);
- To maintain this consistency throughout the life of the facilities and activities, particularly as changes are made, until the point that configuration management (CM) is no longer needed, and
- To help assure ongoing protection of the safety and health of workers, the public and the environment.

The NFS CM Program meets the requirements of 10 CFR 70.62(d), 10 CFR 70.64, and 10 CFR 70.72, the objectives and expectations of NUREG-1520, *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,* and incorporates key programmatic concepts recommended in ANSI/NIRMA CM 1.0-2007, *Configuration*

Management of Nuclear Facilities, and DOE-STD-1073-2003, *Configuration Management.*

After June 30, 2008, new processes covered under this Configuration Management program will meet the applicable requirements of this program prior to being placed into operation. Remaining processes and SSCs (i.e., those that are designed, installed or in operation prior to June 30, 2008), will meet the applicable requirements of this program per the schedule agreed upon between NFS and the NRC.

2.11.1 CM Policy

The NFS CM Policy requires establishment of an effective CM Program with clear objectives, defines the scope of the CM Program, documents NFS senior management commitment to CM, designates key NFS organizations with responsibility for implementing the CM Program, and describes the key CM Program functions.

The CM Program applies to Items Relied on for Safety (IROFS) contained in the Integrated Safety Analysis (ISA) and other structures, systems and components (SSCs) that are required to:

- Physically process, store or transfer more than 350 grams of U-235 as Special Nuclear Material (SNM) contained within the SSC at any given time. Specifically included are the active SNM processing facilities, the SNM storage vaults, the Waste Water Treatment Facility, associated Process Off-Gas Ventilation systems, and bulk chemical and gas storage and supply systems.
- Protect off-site and on-site personnel from nuclear and other hazards, as defined by the facility's ISA;
- Meet regulatory requirements for the physical protection of SNM;
- Protect the environment from significant damage or to satisfy environmental requirements or permits;
- Avoid substantial unplanned interruption of operations having significant cost or quality impact.

CM of computer programs and software applications is not within the scope of the CM Program with the exception of software contained in Programmable Logic Controllers (PLCs). CM of computer programs and software are addressed through the NFS Software Quality Assurance Program (SQAP) which is based on the sections of ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications,* applicable to software.

The IROFS and SSCs that are managed and controlled under the CM Program are identified as Configuration Items (CI). FCI to be managed under the CM Program includes information that reflects the design bases and requirements, performance

criteria, physical characteristics, and regulatory requirements (as applicable) of IROFS and SSCs. FCI represents documents, drawings, procedures, and database information that are essential to operate, maintain, test, modify, repair and/or replace, and substantiate the safety function(s) or operational/functional requirements of IROFS and SSCs.

The CM Program utilizes a graded approach to apply a level of resources and CM Program functions that are appropriate to the degree of risk to safety. Grading is used: (1) to help define which SSCs, facilities, processes, and activities will be subject to CM, and (2) to define the extent to which CM will be applied, e.g. the degree, rigor and extent to which applicable CM functions and requirements are applied to IROFS, SSCs, facilities, processes, and work activities. Application of the graded approach is based on:

- magnitude of any hazards involved
- magnitude of risks and consequences associated with design basis events
- relative importance of an IROFS to safety (risk and consequence reduction) and security
- importance of an SSC (or AC) to continued production operations
- type and technical characteristics of a facility or process
- facility or process operational status
- programmatic and technical issues
- existing programs and procedures

The engineering discipline manager is responsible for the NFS CM Program and a CM function manager is designated with direct responsibility for implementation and ongoing management of the program. All NFS employees, contractors, and organizations including Engineering, Safety, Production, Maintenance, Security, Quality Assurance, Training & Qualification, and Decommissioning are responsible for complying with the CM Program objectives and implementing Program requirements as an integral part of their respective areas of operation.

2.11.2 CM Program

The NFS CM Program includes the following seven (7) elements that are addressed in the following sections:

- Program Management
- Design Requirements
- Change Control
- Information Control
- Assessments
- Training
- Program Metrics

2.11.2.1 Program Management

The Program Management function identifies the NFS organizations and associated responsibilities for implementing and managing the CM Program. Engineering has overall responsibility for the program. A CM function manager has been designated to assure the program is effectively implemented and maintained. The CM management function is independent of the Production organization.

The CM Program is applicable to all NFS organizations including contractors who perform construction, operation, maintenance, modification, and decommissioning activities associated with NFS facilities, SSCs and processes. Implementation of the CM Program is accomplished through procedures and instructions that delineate the responsibilities and actions of personnel to effectively implement the CM Program functions.

The production or operations discipline is responsible for production related activities involving the handling and processing of SNM, including developing operating procedures and maintaining facilities and equipment in a safe operating condition and in accordance with the CM Program. Production is a member of the Change Control Board (CCB) which reviews change requests, and is also a member of the safety review committee which reviews and approves certain Change Control Packages.

The Maintenance discipline includes maintenance activities (corrective maintenance, preventive maintenance, testing, and surveillance/monitoring) performed on CI to ensure continued reliability and functional acceptability. Maintenance is in accordance with written procedures, and performed by trained and qualified personnel. Changes to CI by maintenance activities must be in accordance with the CM Program Change Control process (section 2.11.2.3).

All other disciplines and organizations such as Safety, Material Control and Accountability (MC&A), Decommissioning, and Security are members of the CCB and the safety review committee either as core or ad hoc members, and are charged with review of change requests and Change Control Packages for potential impact to FCI and CI within their areas of expertise.

2.11.2.2 Design Requirements

The objectives of the Design Requirements function of the CM Program are to: 1) establish, document, maintain and communicate the design requirements and design bases associated with the CI managed under the CM Program, and 2) establish a Design Control Process that effectively translates design inputs (design requirements and bases) into design outputs to implement approved changes and controls changes to design requirements and bases.

The CM Program defines design requirements as engineering or technical requirements reflected in design output information (documents and/or data) that define the form, fit and function of CI (including capabilities, capacities, physical sizes and dimensions, limits, setpoints, etc.) specified and/or approved by the Design Authority and derived from the design bases. The design bases are the set of high-level functional requirements, interfaces and expectations of a facility or CI that are based on regulatory requirements, performance requirements and/or analyses. Each design requirement has a design basis whether documented or not.

The design requirements for CI for existing facilities are identified and documented both in electronic databases and/or in hard copy files, and will ultimately reside in a single electronic database. Where the design bases for the design requirements of existing CI may not be fully documented or readily available, the development and/or assembly (reconstitution) of the design bases is determined on a case-by-case basis in accordance with the graded approach discussed in Section 2.11.1 above.

For new facilities, processes/systems, and new CI, design requirements (and design bases) are required to be developed, reviewed, approved, and documented before start of construction or installation activities. As a minimum, the baseline design criteria identified in 10 CFR 70.64 is addressed.

Design requirements for CI are reviewed for adequacy (completeness, accuracy, and level of documentation available) when initially established or during changes when design requirements information must be developed. Design requirements (and bases) are approved by the engineering discipline manager as the Design Authority after completion of review and resolution of comments, as applicable, and concurrence by affected stakeholders, e.g., applicable Safety organizations. Review and approval of changes to design requirements (and bases) is in accordance with the CM Program Change Control process (Section 2.11.2.3).

The level of review for design basis changes assures that all safety and technical aspects of proposed changes do not adversely affect the credited safety functions of IROFS or the operating and/or functional requirements of other CI. Where a change in design requirements does not affect the safety or design basis, the CMP does not require a new design analysis to be performed; however, the affected design requirements are required to be updated, and the associated design bases must support any changes.

2.11.2.3 Change Control

The objective of the Change Control Process is to maintain consistency among design requirements, the physical configuration, and the related FCI, even as changes are made. The Change Control Process is used to ensure CI and FCI changes are properly reviewed, approved and implemented to assure that all impacts of proposed changes are identified

and evaluated, design requirements (and bases) are maintained or appropriately revised, and changes are coordinated across the various NFS organizations and personnel responsible for activities and programs at NFS facilities.

Requests for proposed changes to CI and FCI are required to be effectively documented. This is procedurally accomplished by use of formal Change Requests (CRs) which include the following information as a minimum:

1. Description and reason for the change
2. The technical basis for the change;
3. Identification of all CI and FCI impacted by the proposed change;
4. Modifications to existing operating procedures including any necessary training or retraining before operation;
5. Impact of the change on safety and health, or control of licensed material;
6. Authorization requirements for the change;
7. For temporary changes, the requested duration (e.g., expiration date) of the change;
8. The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other program information developed in accordance with 10 CFR 70.62; and
9. Whether or not a license amendment must be prepared, submitted in accordance with 10 CFR 70.34 and 10 CFR 70.65, and approved by the Nuclear Regulatory Commission (NRC).

The application of the Change Control Process is applied in a graded manner which categorizes changes as administrative, minor, and major changes. Administrative changes include inconsequential changes to FCI and pre-approved equivalent replacements of CI. Minor changes basically include initial equivalent replacements of CI, and addition, deletion, and modification of CI in existing process systems where the design requirements and process function(s) are not affected. Major changes include new facilities, new processes, substantial changes to existing process systems, changes impacting design requirements/bases, and changes requiring license amendments.

Each CR is reviewed for completeness and accuracy by the CM Group. A Change Control Board (CCB) is used to review and approve (or reject) minor and major change requests. The board is chaired by the CM function manager and is comprised of Engineering, ISA Group, and Production. The board may request review by other organizations as required, e.g., Security, QA, Decommissioning, MC&A, etc., depending on the level (minor or major) of change(s) to assure appropriate reviews are obtained. The application of safety reviews, e.g., radiological, nuclear criticality safety, industrial, fire protection, and environmental for a proposed change is also directly dependent on the type of CI(s) involved, associated risks, and type and extent of proposed change. The CM function manager has approval authority for administrative CRs.

Upon approval of a CR, a Change Control Package (CCP) is prepared based on the approved CR. The CCP is prepared consistent with the Design Control Process (as applicable) and includes the approved CR, drawings, analyses, procedure changes, instructions, and/or other documents needed to properly review, implement, verify, and validate the proposed change. The CCP also defines the methods and acceptance criteria for applicable post-implementation testing. CCPs are revised, updated, and supplemented as necessary during the review process, and contain a copy of all approvals.

Each CCP is formally reviewed which includes a technical review, a safety review, and a management review. Other reviews may be performed as needed for such items as meeting regulatory or contractual requirements, cost/benefit, or schedule impact.

The safety review committee reviews and approves major changes, the CM function manager/designee approves administrative changes, and the engineering discipline manager/designee has authority to approve minor changes.

The CM function manager is responsible for assuring that physical change status is tracked and that changes are completed in accordance with the approved CCPs. The CM function manager is also responsible for tracking the changes to associated FCI to assure they are completed and documents are updated.

Operational configuration is defined in the NFS CM Program as the "state" (e.g., on/off, open/closed, operating/not operating) of facility SSCs and processes at a particular point in time. Operational configuration information is that FCI which describes the acceptable SSC or process configurations when variable configuration conditions may exist based on operational or other needs. The CM Program requires that all variable SSC and process configurations (e.g., allowable "states") together with their associated FCI be reviewed and approved prior to use or implementation to assure they are within approved design requirements at all times. Any configuration changes, whether temporary or permanent, not covered by procedures (i.e., not pre-approved) are treated as changes which must go through the Change Control Process. Technical, independent, and safety reviews of the change including procedures and other related FCI specifically assure that the facility SSC or process will continue to operate safely and provide adequate protection to workers, the public, and the environment, and that IROFS are not prevented from performing their expected safety functions and/or sufficient compensatory measures are established.

2.11.2.4 Information Control

The objective of the Information Control function is to identify and manage FCI (both electronic and documents) related to the physical configuration and design requirements. Information control helps ensure that:

- important facility documents and information are properly stored
- revisions to FCI are controlled, tracked, and completed in a timely manner
- revised documents and information are formally distributed or made available to designated users
- information concerning pending revisions is readily available

The most typical FCI documents and information include:

- ISAs and ISA Summaries
- Process Hazard Analyses (PHAs)
- Documents that identify or define design requirements
- Documents that demonstrate compliance with design and licensing requirements
- Design specifications and/or calculations
- Safety analyses (ACE, FHA, NCSE, etc.)
- Physical item databases
- Change process documentation
- Software logic and manuals for operation and maintenance of critical software (e.g., Programmable Logic Controllers or PLCs)
- Key operating and test procedures
- Key drawings
- Audit and assessment results
- Vendor technical information

An information control system is established to create, control, and track documents within the CM Program. Only the most recently approved versions of FCI are used in the process of operating, maintaining, and modifying the SSCs, facilities, and processes. As controlled information is updated to reflect changes to the requirements and/or physical installation, the CM Program ensures that updated FCI documents are uniquely identified and includes a revision number and/or date, and any outdated documents and information are replaced by the latest approved versions.

FCI documents, drawings, and copies are maintained in accordance with procedures that facilitate retrievability and use, control classified information, and meet record keeping requirements. Electronic versions of classified and unclassified FCI are maintained on secure servers and made available to authorized users.

2.11.2.5 Assessments

The objective of the CM Program Assessment function is to detect, document, determine the cause of, and initiate correction of inconsistencies among design requirements, FCI, and physical configuration. The assessments help identify inconsistencies between these areas, evaluate the root causes for these problems, and prescribe improvements to avoid similar inconsistencies in the future.

Assessments of the NFS CM Program are performed to evaluate CM Program objectives and processes, and a formal audit of the CM Program is performed biennially by the Quality Assurance (QA) department. The effectiveness of different aspects of the CM Program is assessed through physical configuration assessments, design assessments, post-implementation inspections and tests, and periodic performance assessments. Where practicable, CM related reviews and assessments are combined with other periodic assessments of facilities, processes, and activities for efficiency and cost-effectiveness. All or part of the assessment of the adequacy of CM for an activity or process may be integrated into broader management and performance assessments.

CM assessments will be conducted in accordance with the NFS facility audit and assessment program as specified in Section 2.12.5. The results of these assessments shall be documented and maintained in accordance with Sections 2.12.5, "Audits and Assessments," and 2.12.7, "Records Management." An assessment conducted by an individual(s) outside NFS will be conducted within 1 year of the approval of this license amendment and then once every three years thereafter.

NFS assures that the persons performing the assessments activities are qualified, and that any NFS personnel performing assessments have sufficient authority and freedom from line management to objectively conduct the assessments.

Assessment findings are documented as open items in the Problem Identification, Resolution and Correction System (PIRCS) as CM issues if they are validated to involve contradictory information among different FCI, unanswered technical questions, and/or missing, undocumented or inaccurate information.

2.11.2.6 Training

The objective of the CM Program Training function is to provide adequate assurance that facility personnel are aware of the CM concepts, terminology, definitions and procedures. Training will ensure that workers have an understanding of how their actions impact CM and that they are able to properly carry out their work in a way that helps NFS achieve its objective to maintain consistency between the design requirements, the FCI and the physical configuration.

2.11.2.7 Performance Metrics

The CM function manager tracks CI and FCI changes in progress, and periodically reports the status and associated change information to determine CMP efficiency and effectiveness. Information reported typically includes such items as:

- Identification of the approved changes,
- Major SSCs, ACs, and processes affected by the changes,

- Impacts or constraints on current operations,
- Modifications that have been approved to originally approved changes,
- Status of the implementation and verification of the changes,
- Numbers of drawings and documents updated per selected time frame (daily, weekly, monthly, etc.)
- Backlog numbers of drawing and document updates

The CM-related issues entered into PIRCS (Section 2.11.2.5) are reviewed to determine trends and CM Program effectiveness.

2.12 Management Measures for Items Relied On For Safety

Management measures, as described in Section 2.12, shall be implemented prior to startup of operations for which an ISA has identified a need for Items Relied On For Safety (IROFS). 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.

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
ACTIVE ENGINEERED CONTROLS		
Periodic Functional Test	X	
Maintenance	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	
PASSIVE ENGINEERED CONTROLS		
Maintenance	X	
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	
ADMINISTRATIVE CONTROLS		
Procedural or Posting Identification	X	X
Pre-operational Audits	X	X
Periodic Audits	X	X
Training and Qualifications	X	
Testing of Training Effectiveness	X	
Records Management, Investigations, and other quality assurance elements	X	

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**
ENHANCED ADMINISTRATIVE CONTROLS		
Periodic Functional Test	X	
Maintenance	X	
Verification After Maintenance	X	
Calibration	X	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 Qualifications	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. IROFS will be maintained as described in Section 2.12.2.		

2.12.1 Configuration Management

The NFS Configuration Management (CM) Program is discussed in Section 2.11, and is applicable to IROFS which are included as Configuration Items (CI) in the Program. The scope of the IROFS that are under CM, 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 are specified in the ISA Summary in accordance with 10 CFR 70.62. The NFS CM Program is implemented through procedures, and specific application of the CM Program to IROFS is discussed in the following sections.

2.12.1.1 CM Policy

The NFS CM Policy specifically includes IROFS within the scope of CI to be managed by the CM Program. Additionally, the NFS CM Policy requires establishment of an effective CM Program with clear objectives, documents NFS senior management commitment to CM, designates key NFS organizations with responsibility for implementing the CM Program, and describes the key CM Program functions. The Policy requires that, prior to implementation, changes to IROFS must be evaluated in accordance with the requirements of 10 CFR 70.72(a)(1)-(5), to determine if a license amendment is required in accordance with 10 CFR 70.72(b), and to determine if NRC approval is required in accordance with 10 CFR 70.72(c)(1)-(4).

2.12.1.2 Program Management

The Program Management function identifies the NFS organizations and responsibilities for implementing and managing the CM Program. The ISA function manages the ISA process which includes identification and analysis of IROFS including those associated with the Industrial, Radiation (Health Physics), and Environmental Safety functions. This function also includes identification of the safety bases for IROFS. The Nuclear Criticality Safety function identifies IROFS which include those used to implement the Double Contingency Principle of criticality safety as Configuration Control Equipment (CCE) maintained in accordance with the CM Program. The engineering discipline manager is the designated Design Authority responsible for establishing and maintaining the design basis for SSCs (including IROFS), ensuring that design requirements reflected in design output documents accurately reflect the design basis, and maintaining design control and ultimate technical adequacy of the design process.

2.12.1.3 Design Requirements

The design (safety) bases and requirements for IROFS are derived from the NFS Integrated Safety Analysis (ISA) process and are categorized as Facility Configuration Information (FCI). As a minimum, the Baseline Design Criteria (BDC) of 10 CFR

70.64(a) are addressed for IROFS, as applicable, for new facilities at NFS or new processes at existing NFS facilities. Design bases and requirements are developed and reviewed by a multi-disciplined team comprised of engineering and safety personnel and are approved by the safety discipline manager and the engineering discipline manager as the Design Authority.

Changes to IROFS design requirements (and bases) are processed through the CM Program Change Control Process. The level of review for design basis changes assures that all safety and technical aspects of proposed changes do not adversely affect the credited safety functions of IROFS.

2.12.1.4 Change Control

A Change Control Process is established as part of the NFS CM Program that complies with requirements specified in 10 CFR 70.72. Proposed changes to IROFS and/or potentially affecting IROFS are processed through a formal Change Request (CR) which addresses as a minimum the items in 10 CFR 70.72(a). CRs for minor and major changes are reviewed by a Change Control Board (CCB) which authorizes a Change Control Package (CCP) to be prepared (as required), reviewed and approved that includes all the design documents, proposed FCI changes (ISA Summary, design basis, procedures, analyses, etc.), change implementation and test documents necessary to fully implement the IROFS change. The safety review committee reviews and approves the CCP for major changes.

Approved CCPs for IROFS are implemented as approved. Any changes to the approved CCP that may be required are prepared, reviewed and approved at the same level as the original CCP. Any required post-modification testing and operation/maintenance training must be completed prior to returning the IROFS to service. Procedures required to operate the revised IROFS must also be updated before return to service.

The CM function manager is responsible for assuring that physical change status of IROFS is tracked and that changes are completed in accordance with the approved CCPs. The CM function manager is also responsible for tracking changes to the associated FCI including the design bases and requirements, ISA Summary, License, procedures, drawings, and analyses.

With regard to operational CM, all variable IROFS configurations (e.g., allowable "states") together with the associated FCI must be reviewed and approved prior to use or implementation to assure IROFS remain within approved design requirements at all times. Any configuration changes, whether temporary or permanent, not covered by procedures (i.e., not pre-approved) are treated as changes which must go through the Change Control Process. Technical, independent, and safety reviews of such changes including procedures and other related FCI specifically assure that IROFS are not

prevented from performing their expected safety functions and/or sufficient compensatory measures are established.

2.12.1.5 Information Control

The Information Control function of the NFS CM Program assures that FCI associated with IROFS is properly stored, controlled, and tracked. The function also assures that revisions are formally distributed or available to designated users, and information concerning pending revisions is readily available. The information control function maintains control of procedures that are IROFS, change control documents associated with IROFS, ISA and ISA Summary, safety analyses, and hazards analyses.

Information control utilizes an electronic information management system to store and control IROFS information and documents, provide change status and pending change information, and facilitates the Change Control Process for FCI through electronic work flow of the Change Request process.

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

2.12.1.6 Assessments

As discussed in Section 2.11, assessments shall be performed in a systematic and planned manner and shall include physical configuration assessments, design assessments, post-implementation inspections and tests, and periodic performance assessments. Types of assessments that include or may include IROFS and associated FCI are identified in Section 2.11.2.5.

Assessment findings involving IROFS are documented as open items in the Problem Identification, Resolution and Correction System (PIRCS) as CM issues if they are validated to involve contradictory information among different FCI, unanswered technical questions, and/or missing, undocumented or inaccurate information.

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 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 facilities or 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 and 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 require 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 include 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 reinstruction 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 ever 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 retraining, 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 walk-down 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 and 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 function 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 and Qualifications,
- 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, qualification, 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 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 and 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.

ATTACHMENT 2

Implementation Plan for CM Program Enhancements

3 pages

Attachment 2
Implementation Plan for CM Program Enhancements

PROGRAM AREA	ACTIVITY
Program Management	
	Establish CM Function Complete. CM group established and a manager assigned.
	Revise CM Program Documents • Revise the CM policy. Original Target Completion: June 2007; **Status**: Complete. Revised CM Policy published July 2007. • Revise CM program (NFS-GH-901) and related documents. Original Target Completion: September 2007; **Status**: The revision to NFS-GH-901 is currently routing for approval. During the revision process, several new and required revisions to existing procedures were identified. Work to complete these procedures is ongoing. Because many of these procedures must be effective on the same day to ensure continuity of the CM function, full revision of the program documentation will not be completed until March, 2008. Revised Completion Date: March 2008.
Design Requirements	
	Revise Engineering Procedures • Revise Engineering procedure(s) to identify what design information will be included within the CM program and where/how this information will be stored. Original Target Completion: December 2007; **Status:** Complete rewrite to NFS-GH-901 precipitated broader changes to affected documents than previously estimated. Procedures to be written or revised have been identified. Revised Completion Date: March 2008.
Information Control	
	Complete Mini-prototype (BPF U-Al Bowl Cleaning) • Establish an initial set of capabilities for the system. Collect, validate and enter into the information system needed design data, physical configuration information and FCI. Original Target Completion: June 2007. **Status**: Complete July 2007.

PROGRAM AREA	ACTIVITY
	Complete Prototype (BPF U-Metal Operation) • Expand the information in the system to include information for the U-Metal operation. Original Target Completion: September 2007; **Status**: Through **lessons learned** with the U-Aluminum prototype, the strategy forward was changed. In lieu of a phased roll out of capabilities through the various facilities, it was decided to enter all engineering drawings managed under the CM program into the LINC system before proceeding. This effort was completed. Next, the MEL (Master Equipment List) footprint data for ALL Configuration Items within the BPF, Navy Fuel Operations, Wastewater Treatment Facility (WWTF) and Bulk Chemical will be entered into the LINC system. The MEL footprint data consists of the Component Identification from the Process and Instrumentation Diagrams (P & ID). To date, the WWTF and Bulk Chemical footprints have been entered. Once the footprint data is complete, teams will deploy through each affected operating facility to identify the MEL Equipment data and associate it with the appropriate component. The combination of MEL footprint data and the MEL Equipment data will constitute the MEL data record. Equipment data to be entered will include manufacturer, vendor, type, model, etc. This will allow change control capabilities within the LINC system against each component. Dates for completing this effort in the various NFS facilities are discussed below.
	Roll Capabilities throughout BPF • Expand the information in the system to include information for the entire BPF operation. A phased approach will be developed and schedule adjusted based upon "lessons learned" from the prototype deployment. Original Target Completion: March 2008; **Status**: Based on "lessons learned" explained above, completion of the MEL data record: September 2008.
	Roll Capabilities throughout Navy Fuel Operations • Expand the information in the system to include information for Navy Fuel Operation. A phased approach will be developed and schedule adjusted based upon "lessons learned" from the BPF deployment. Original Target Completion: June 2009; **Status**: Based on "lessons learned" explained above, completion of the MEL data record: June 2009.
	Roll Capabilities throughout NFS • Expand the information in the system to include information for all NFS activities included within the CM program. A phased approach will be developed and schedule adjusted based upon "lessons learned" from the earlier deployments. Target Completion: December 2010; **Status**: Based on "lessons leaned" explained above, completion of the MEL data record: December 2010.
	Develop Procedures for Control and Storage of CM Information • Develop and revise procedures to identify data storage requirements for deployment of the new information system. Target Completion: August 2007; **Status**: Based on "lessons learned", completion of the procedure for control and storage of CM information within the LINC system: March 2008.
Change Control	
	Revise/Develop Change Control Procedures • Develop/revise procedures to incorporate electronic approval of change requests. Target Completion: August 2007; **Status**: Based on "lessons learned", and complete rewrite of the CM program document, NFS-GH-901, completion of the procedure for submitting electronic change request: March 2008.

PROGRAM AREA	ACTIVITY
Assessments	
	Conduct CM Assessment by Outside Individual(s) • To be conducted within 1 year after approval of this license amendment. **Status**: No change.
	Identify and Track CM Performance Indicators • Develop criteria to report and trend CM discrepancies. Original Target Completion: August 2007. **Status**: Problem identification categories and the criteria for entering the discrepancies have been developed and are in use in the PIRCS system. Complete November 2007.
Training	
	Personnel Training • Provide training to NFS personnel so that they are able to carryout their work in a way that helps NFS achieve its CM objectives. Original Target Completion: September 2007; **Status**: Complete December 2007.