NUCLEAR FUEL SERVICES, INC.
a subsidiary of The Babcock & Wilcox Company

▪ 1205 banner hill road ▪ erwin, tn 37650 ▪ phone 423.743.9141
▪ www.nuclearfuelservices.com

21G-11-0153
GOV-01-55-04
ACF-11-0240

August 5, 2011

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-124
2) Letter from NRC to David B. Amerine, Confirmatory Order, dated November 16, 2010

Subject: Request to Amend SNM-124 Regarding Corrective Action Program to Fulfill Confirmatory Order, Section V, Paragraph 6 (EA-10-076)

Dear Sir:

As required by Reference 2 above, Nuclear Fuel Services, Inc (NFS) hereby submits a license amendment request regarding its Corrective Action Program (CAP). Please note that SNM-124 is currently in timely renewal, and the Licensing Review is estimated for completion in September, 2011. Thus, NFS requests that this license modification be considered for incorporation into the renewed version of the license, rather than the version that is currently effective.

The Order also required NFS to complete an assessment of its current CAP against the requirements of NQA-1-2008, Part III, Subpart 3.1, "Non-Mandatory Appendix 16A-1." The assessment is complete, and it was performed by an external NQA-1 subject matter expert. In summary, the assessment concluded that the overall requirements of Appendix 16A-1 are met with the existing CAP, and no major gaps were identified. The assessment did recommend that the Problem Identification, Resolution, and Correction System (PIRCS), the Quality Assurance (QA) Plan, and related procedures should contain NQA-1 like terminology so that they are easily traceable to the standard. The assessment is available for review at the NFS site.

NMSS01

As currently approved, SNM-124 contains the following information on the CAP:

- Section 2.9 – "Investigations and Reporting"
- Section 2.12.6 – "Incident Investigations and Corrective Actions." As written, this section only applies to IROFS, as required by NUREG-1520.
- Section 2.12.8 – "Other Quality Assurance Elements." This section includes a list of elements required by NUREG-1520 that are the same as 10 CFR 50, Appendix B – "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

As currently under review for License Renewal, SNM-124 contains the following information on the CAP:

- Section 2.5.1 – "Reporting of Potentially Unsafe Conditions or Activities"
- Section 11.6 – "Corrective Action Program." As a Management Measure, this section applies to "activities involving the handling of SNM," in addition to IROFS, as stated in the first sentence of Chapter 11.
- Section 11.8 – "Other QA Elements." This section includes a list of elements required by NUREG-1520 that are the same as 10 CFR 50, Appendix B – "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." A short description of each element is also included. Two elements of note are #2, "Quality Assurance Program," which is "structured on ASME NQA-1..."; and #16, "Corrective Action," where "reports of conditions adverse to safety are promptly identified and entered into the CAP (see Section 11.6)... ."

The assessment did not identify any major gaps, and the terminology observations relate specifically to the NFS CAP implementing procedures and systems, rather than the higher-level description in the License. The level of detail for the CAP description in the License is consistent with other Management Measure programs discussed in Chapter 11 (e.g., Configuration Management, Training and Qualification, Audits and Assessments). However, a few enhancements have been made to Section 11.6 to reference Appendix 16A-1 being used as guidance, and to clarify a few other elements of the program. Although only Section 11.6 has been changed, Chapter 11 has been provided in its entirety to maintain revision control. Changes are denoted by lines in the right margin of the revised pages.

If you or your staff have any questions, require additional information, or wish to discuss this matter further, please contact me at (423) 743-1705, or Ms. Jennifer Wheeler, Licensing and ISA Manager, at (423) 735-5429. Please reference our unique document identification number (21G-11-0153) in any correspondence concerning this letter.

Sincerely,
NUCLEAR FUEL SERVICES, INC.

Mark P. Elliott, Director
Quality, Safety, and Safeguards

JKW/pdj
Attachment: *SNM-124, Chapter 11, Revision 2*

Copy:

Mr. Victor M. McCree, Regional Administrator
U.S. Nuclear Regulatory Commission, Region II
245 Peachtree Center Avenue NE, Suite 1200
Atlanta, GA 30303-1257

Mr. Steven Vias, Branch Chief
Division of Fuel Facility Inspection
U.S. Nuclear Regulatory Commission, Region II
245 Peachtree Center Avenue NE, Suite 1200
Atlanta, GA 30303-1257

Mr. Kevin Ramsey
Fuel Manufacturing Branch
Fuel Facility Licensing Directorate
Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Mr. Anthony Gody, Director
Division of Fuel Facility Inspection
U.S. Nuclear Regulatory Commission, Region II
245 Peachtree Center Avenue NE, Suite 1200
Atlanta, GA 30303-1257

Mr. John Pelchat
Project Inspector
U.S. Nuclear Regulatory Commission, Region II
245 Peachtree Center Avenue NE, Suite 1200
Atlanta, GA 30303-1257

Mr. Galen Smith
Senior Resident Inspector
U.S. Nuclear Regulatory Commission

Attachment

SNM-124, Chapter 11, Revision 2

(28 pages to follow)

MANAGEMENT MEASURES
Table of Contents

MANAGEMENT MEASURES

Management measures are applied to activities involving the handling of SNM, generally on a continuing basis, to ensure protection of the safety and health of workers, the public, and the environment. As specified in 10 CFR 70.62(d), management measures are also applied to items relied on for safety (IROFS) to provide reasonable assurance that they remain available and able to perform their functions when needed.

The ISA Summary identifies IROFS applied to plant operating systems to assure those systems function within the performance requirements of 10 CFR 70.61. IROFS may be engineered controls (passive or active), enhanced administrative controls (active features that prompt a person to take an action), or administrative controls (actions of people). Management measures are applied to IROFS using a graded approach based on the type of control and the reduction of risk credited to that control. Methods used to select and assign management measures to IROFS are documented in written procedures.

11.1 Configuration Management

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 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.*

11.1.1 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 Policy requires that, prior to implementation, changes to IROFS must be evaluated in accordance with the requirements of 10 CFR 70.72(a)(1)-(6), 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). Per 10 CFR 70.72(d)(2), a brief summary of major changes that required revision of the applicable safety or environmental bases will be submitted within 30 days after the end of the calendar year during which the changes occurred.

The CM Program applies to 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 elements 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 elements 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 administrative control) 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 CM function manager is responsible for the NFS CM Program and has 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.

11.1.2 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

11.1.3 Program Management

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

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 elements.

The Change Control Board (CCB) reviews change requests (CRs) to ensure that proper review and identification of items affected by changes have occurred. Typically the CCB serves as a "go/no go" decision maker and may approve, reject, defer or require alternative solutions for changes. The board is chaired by a senior manager and is comprised of other managers representing the Engineering, Safety, and Production disciplines. The chairman, other CCB members, and their alternates, are designated in writing. All CCB members, including the chairman, are required to have the qualifications specified for a discipline manager, as described in Chapter 2.

Other disciplines and organizations such as Material Control and Accountability (MC&A), Decommissioning, and Security are members of the CCB as ad hoc members, and are charged with review of change requests for potential impact to FCI and CI within their areas of expertise.

11.1.4 Design Requirements

The objectives of the Design Requirements element 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 to control 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 11.1.1 above.

For new facilities, processes/systems, and new CI, design requirements (and design bases) are required to be developed, reviewed, approved, and documented before input of SNM. As a minimum, the baseline design criteria (BDC) identified in 10 CFR 70.64(a) are addressed for IROFS.

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 conducted in accordance with the CM Program Change Control process (Section 11.1.5).

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 CM Program 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.

11.1.5 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.

The Change Control Process assures that the following items are addressed prior to implementing the change:

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 ISA, ISA Summary, or other safety program information developed in accordance with 10 CFR 70.62; and
9. An evaluation per 10 CFR 70.72 as to whether or not a license amendment must be approved by the NRC prior to implementation of the change.

Requests for proposed changes to CI and FCI are required to be effectively documented, and this is procedurally accomplished by use of formal change requests (CRs). 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 include initial equivalent replacements of CI, and addition, deletion, and modification of CI in existing process systems where the design requirements, safety bases, and process function(s) are not affected. Major changes include substantial modifications to existing licensed facilities and/or processes, new licensed facilities, or new processes in existing licensed facilities. Any change requiring a license amendment is also considered a major change. Each CR is reviewed for completeness and accuracy, and a review is conducted to assure it is properly categorized. Non-CM and administrative CRs are approved by the CM function and do not require CCB review. The Engineering discipline manager/designee may approve minor CRs on behalf of the CCB, provided the change does not impact the safety or design bases. All major CRs are reviewed by the CCB.

The CCB 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 need for safety reviews, e.g., radiological, nuclear criticality, industrial, fire, and environmental, for a proposed change is determined using a graded approach based on the type of CI(s) involved, associated risks, and type and extent of the proposed change.

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-modification testing. CCPs are revised, updated, and supplemented as necessary during the review process, and contain a copy of all approvals. Any changes to the approved CCP that may be required are prepared, reviewed, and approved at the same level as the original CCP.

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 CM function manager is responsible for ensuring that CCPs are completed and stored in an information control system. 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 IROFS, 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.

11.1.6 Information Control

The objective of the Information Control element 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; and

- 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.)
- IROFS
- 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, include 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.

11.1.7 Assessments

The objective of the CM Program Assessment element 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.

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 practical, 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 results of these assessments are documented and maintained in accordance with written procedures.

NFS assures that the persons performing the assessment 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 corrective action program as CM issues if they are validated to involve contradictory information among different FCI, unanswered technical questions, and/or missing, undocumented or inaccurate information.

11.1.8 Training

The objective of the CM Program Training element 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.

11.1.9 Performance Metrics

The CM function manager tracks CI and FCI changes in progress. The status, rate of change, and backlogs are periodically reviewed to demonstrate CM Program efficiency and effectiveness.

CM-related issues entered into the corrective action program are also reviewed to determine trends and CM Program effectiveness.

11.2 Maintenance

NFS has a maintenance program designed to ensure that IROFS are maintained in a manner so as to ensure they 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, are authorized by written procedures and/or written instructions to which appropriate personnel have

been trained. Steps are included within the maintenance procedures for the notification of all affected parties before and at the completion of all maintenance activities.

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

1) Surveillance and Monitoring,

2) Corrective Maintenance,

3) Preventive Maintenance, and

4) Functional Testing.

Maintenance skills training for mechanics performing maintenance activities involving IROFS is also required. Maintenance skills training is further addressed in Section 11.3. Contractors that perform work on IROFS will meet the same guidelines for IROFS training or will be under direct supervision of NFS-trained personnel that are qualified and knowledgeable of the particular IROFS involved.

11.2.1 Surveillance and Monitoring

NFS utilizes established surveillance activities to monitor the current and long-term performance of IROFS. These activities include preventive maintenance (11.2.3), functional testing (11.2.4), and follow-up to corrective maintenance (11.2.2). IROFS found to be out-of-tolerance or unable to perform their intended function are reported in a timely manner to the safety discipline through the corrective action program.

Reports of IROFS failures are entered into the corrective action program which provides a means to evaluate the failure of IROFS, identify the cause of failure, and assign appropriate corrective actions to be initiated. Records of IROFS performance issues and corrective actions are maintained within the maintenance and corrective action programs, as applicable. Records for failures of IROFS are maintained in accordance with 10 CFR 70.62(a)(3) within the corrective action program.

11.2.2 Corrective Maintenance

Corrective maintenance is performed using a planned, systematic, integrated, and controlled approach to ensure that IROFS and other systems necessary for the safe operation of the facility are properly repaired and restored to service in a manner that maintains facility safety and the function of the safety system. Maintenance

activities are performed on IROFS in a manner that minimizes or eliminates the recurrence of unacceptable performance deficiencies.

Corrective maintenance is authorized, initiated, and documented through a formally established process that includes steps requiring coordination between the maintenance and operating organizations. The process also includes an evaluation to determine if IROFS have been, or may be, affected by the equipment failure/malfunction or the ensuing maintenance and whether post-modification functional testing of IROFS is required.

11.2.3 Preventive Maintenance

Preventive maintenance (PM) is performed in a preplanned and scheduled manner to refurbish or overhaul IROFS to ensure that they continue to perform their intended function. PM activities are appropriately balanced against the objective of minimizing unavailability of IROFS. After conducting PM, and before returning a safety control to service, a functional test may be required to provide reasonable assurance that the safety control performs as designed and provides the safety action expected.

A schedule for performing PM on IROFS is maintained as specified in written procedures, and frequencies are established based on operating history, manufacturer and industry guidance, feedback from surveillance and maintenance activities, and/or recommendations from the corrective action program.

11.2.4 Functional Testing

Functional testing of IROFS under the Safety Related Equipment program is performed using approved, written instructions prior to startup of facilities or process operations involving IROFS and at periodic intervals during operations to provide reasonable assurance that the safety control performs as designed and provides the desired safety action. Functional testing of IROFS will be performed prior to restart if the process operation has been inactive for more than 120 days.

Functional test instructions and frequencies are approved by, and cannot be modified without the approval of, the safety review committee, and are based on operating history, manufacturer and industry guidance, risk assessment, feedback from surveillance and maintenance activities, and/or recommendations from the corrective action program. Minor changes to functional test instructions, as defined in a written procedure, are allowed to be approved by the safety review committee chairman on behalf of the entire committee. During process operations, compensatory measures are used as appropriate while functional testing is performed on IROFS. The results of functional testing are documented and the

documentation is maintained as "records pertaining to safety" as specified in Section 11.7.

11.3 Training and Qualification

The NFS Training and Qualification Program provides workers with the knowledge and skills to safely perform their job function, recognize the importance of IROFS, effectively deal with the hazards of the workplace, and properly respond to emergency situations. The qualification aspect of this program ensures that operations and maintenance are performed only by properly trained personnel.

Requirements and methods for the training and qualification programs are approved by NFS site management, who also provide ongoing evaluation of the effectiveness of the programs. Training records, including those related to IROFS, are maintained for a minimum of two years.

This training typically falls into one of two categories:

1) General safety training not specific to a particular work station or activity; and
2) Training to assure proper performance for positions and work activities that are relied on for safety, in particular those designated as IROFS.

11.3.1 General Safety Training

The NFS Training and Qualification 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 content of safety training is evaluated biennially by a member of the safety discipline, as appropriate for the subject of the training, to ensure it remains current and relevant. Additional details regarding periodic evaluation of the Radiation Protection Training Program is discussed in Chapter 4.

11.3.2 Training and Qualification for Activities Involving the Handling of SNM

The Training and Qualification Program includes work training for operating personnel and others who directly handle greater than laboratory sample quantities

of special nuclear material. Work training typically includes classroom, on-the-job, and guided-work-experience training necessary to provide the desired knowledge and/or skill. It covers the operating procedures, alarms, emergency response actions, and radiological, nuclear criticality, industrial, and environmental safety controls and limits specific to the particular work assignment.

Work training includes appropriate reinstruction for previously qualified individuals prior to implementation of a process change or procedural modification. When changes are made relative to safety or emergency response requirements, provisions are made to assure that affected employees are appropriately informed and instructed on the changes. Previously qualified individuals are required to undergo a re-qualification process for applicable work assignments every three years (maximum interval not to exceed 42 months). Additional details about the work training program are provided in approved written procedures.

The Training and Qualification 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, basics of programmable logic controllers (PLC), welding, industrial electricity (basic, intermediate, and advanced), and machine tool operation, as appropriate. The type and level of training is commensurate with the job assignments.

Organization and Management of Training

The responsibility for the assurance of properly trained and qualified personnel resides with the discipline management team and pertinent line management. Support to line management for the development, implementation, and administration of the facility Training and Qualification Program is provided by the Training function. Implementation of the Training and Qualification Program is accomplished in accordance with written procedures.

All training is conducted by, or under the supervision of, individuals recognized by management as possessing the necessary knowledge and skills to conduct the training. Exemptions from training are only authorized as described in approved written procedures.

Identification of Activities Requiring Training

Positions impacting the availability/reliability of IROFS are assessed, based on a graded approach that considers the hazards and the safety responsibilities associated with each position. Input from subject matter experts, with support from the training function, is utilized as appropriate.

Position Training Requirements

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.

Each NFS position involving personnel assigned to SNM process operations is evaluated to determine the specific requirements that apply to the defined job function. The requirements are defined in an on-line computer database. Personnel must remain current on the defined set of requirements to maintain job qualifications.

Bases for Training

The objective of training is to ensure safe and efficient operation of the facility and compliance with applicable established regulations and requirements. Learning objectives are established for those positions/activities impacting the safety of licensed material operations, and in particular the availability/reliability of designated IROFS. Objectives include, as applicable, the knowledge, skills, and abilities the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity.

Training Materials

Lesson plans and other training guides (for both classroom and on-the-job training) developed for activities relied on for safety are based on learning objectives developed from specific job performance requirements. 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 provides a means to assure that design changes and modifications to IROFS are accounted for in the training.

Evaluation of Trainee Accomplishment

Trainee understanding and command of learning objectives are evaluated. The evaluation may be accomplished through a combination of observation/skills demonstration, written tests, or oral examinations. The results of trainee evaluations are documented.

On-the-Job Training (OJT)

OJT requirements for activities relied on for safety and listed in the ISA Summary, if applicable, are specified as part of pertinent position training requirements.

Completion of OJT may be demonstrated by actual task performance (preferred) or task simulation. Completion of OJT requirements are documented.

Training Program Review

The effectiveness of the Training and Qualification Program is assessed on a periodic basis. Work assignments involving the handling of SNM are evaluated for needed re-current training and/or re-evaluation of qualification activities.

11.4 Procedure Development and Implementation

Activities involving the handling of SNM and/or IROFS are conducted in accordance with written procedures as defined in this section. NFS procedures also address the following activities: 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.

The process for the development and implementation of procedures is defined in written procedures. These procedures address how procedures are developed, reviewed, approved, distributed, revised, and deleted. The system ensures that the most current revisions of procedures are readily available to workers within their work areas (operating procedures), or in a centralized location accessible to all affected personnel (general safety and support group procedures), that any necessary training and qualification requirements are identified, and that the timeframe for which the procedure is valid is defined.

The safety review committee is responsible for reviewing and approving new and revised operating and general safety procedures, as defined below, and per Section 2.4 requirements. Support group procedures, including those developed to support management measures, are approved by the discipline manager for the originating group and by the appropriate safety function manager(s) if the procedure contains safety-related information.

Changes and/or revisions to procedures covering licensed material operations and/or IROFS are reviewed by the safety functions, as appropriate, in accordance with the requirements of the CM program, as discussed in Section 11.1, to ensure that all associated activities and documentation (safety analyses, reviews, testing, training, etc.) are completed before procedural changes are implemented.

11.4.1 Operating Procedures

Operating procedures are documents written to authorize a) the processing of radioactive material or b) a decommissioning activity; and, within these documents, detailed instructions for operation of equipment used in the process or activity, instructions for disposition of radioactive wastes, and limits and controls established for safety purposes, including IROFS, are identified. Operating procedures may take various forms (e.g., standard operating procedures, special work instructions, etc.).

Operating procedures include provisions to place process operations in a safe condition if a step of the procedure cannot be performed as written. Work place posting of limits and controls, training, and other communication devices are used, if appropriate, to enhance comprehension and understanding of operating procedures.

During operating procedure development, the technical accuracy is verified. Changes to existing operating procedures are evaluated to determine if the scope of the change warrants a walk-down and/or an independent verification/validation. New operating procedures are validated by operations staff through walk-downs to ensure that they can be performed as written. An independent verification/validation review may also be performed to provide additional assurance that the technical information, including formulas, set points, and acceptance criteria, is all there and is correct, and may include a tabletop walkthrough or a walk-down of the procedure in the field.

11.4.2 General Safety Procedures

General safety procedures outline health and safety practices that help maintain occupational radiation exposures at levels as low as reasonably achievable (ALARA). These procedures are generally applicable on a plant-wide basis such as those governing the collection of bioassay samples, contamination control, emergency evacuation, and other similar matters. Included in this category are the Emergency Plan implementing procedures and the Criticality control procedures. General safety procedures are reviewed and approved by the safety review committee and such other discipline managers as deemed necessary by the safety discipline vice president.

11.4.3 Support Group Procedures

Support group procedures are documents written to authorize the conduct of activities that are not directly involved in the processing of radioactive material or a decommissioning activity, but may involve radioactive material (e.g., laboratory analytical procedures, safety monitoring procedures, material control and

accountability procedures, etc.); and, within these documents, the activities are described and any special safety precautions are identified.

11.4.4 Maintenance Procedures

Significant maintenance activities are conducted under formal work packages (FWPs) which are reviewed by the safety functions, as appropriate, prior to initiation of the work. Each FWP prescribes the controls necessary to provide for safety. Items such as the release of airborne radioactivity; unusual exposure of personnel; draining, disassembling, modifying, or routing of lines to equipment that may contain special nuclear material are considered during the review.

Although FWPs are not considered to be operating procedures as defined in this section, a written and safety review committee approved procedure is in place to give instructions when an FWP is required and whose approval is required.

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 or 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 will be notified;
- Safe Work Practices/Permits (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 repairs have been completed.

11.4.5 Temporary Procedures

Approved temporary procedures (i.e., Letter of Authorization (LOA)) are used when permanent procedures do not exist to:

1) Direct operations during testing, maintenance, and modifications;

2) Provide guidance in unusual situations not within the scope of permanent procedures; or,

3) 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 will not change an ISA except as authorized under 10 CFR 70.72. The review and approval process required for temporary procedures is the same as for other procedures, and a timeframe is defined for which the procedure is valid.

11.4.6 Periodic Reviews of Procedures

If an active operating or general safety procedure has not been revised within a three-year period, the procedure will be reviewed to ensure it remains current and relevant. The chairman of the safety review committee may select individual members to perform the review, rather than the entire committee. The selection process is described in Section 2.4. Any general safety procedure meeting this condition will also be reviewed by the appropriate safety function manager(s). Support group procedures are periodically reviewed in accordance with the Audits and Assessments program (see Section 11.5). Emergency procedures are reviewed per the Emergency Plan required in Chapter 8.

The corrective action program includes provisions to assess the role of procedures in adverse conditions or events evaluated within the program. Corrections of procedural deficiencies are tracked to completion within the system.

11.5 Audits and Assessments

NFS has a program for conducting audits and assessments of activities significant to facility safety and environmental protection that identifies responsibility for:

1) Determining the appropriate utilization of internal and/or external personnel for particular audit and assessment activities;
2) Assuring audit and assessment personnel have the expertise and background sufficient to successfully conduct audit and assessment activities;
3) Assuring audit and assessment personnel are sufficiently independent of the area being reviewed; and,

4) Verifying the utilization of an effective corrective action program to address findings of audits and assessments.

Written guidance and procedures used to perform the audits and assessments contain the following information:

- Activities to be reviewed;
- Frequency of reviews;
- Applicable guidance to be used in conducting the reviews;
- Responsibilities for each phase of the reviews;
- Instructions for recording the results, and recommending and approving actions to be taken; and,
- The levels of management to which results are reported.

Results, including findings and observations, are captured in the corrective action program. Corrective actions to prevent recurrence are assigned to owners, documented, and tracked to completion in accordance with the requirements specified in the corrective action program.

11.5.1 Audits

Audits are compliance-based evaluation activities with an objective of verifying compliance of operations with established regulatory requirements, license commitments, and standard industry practice. As a minimum, audits apply to the programs presented below.

Members of each safety function perform audits of activities involving the handling of SNM, including support areas, on a quarterly basis.

The Emergency Preparedness Program is audited by the Quality Assurance discipline on an annual basis. The following management measures are audited on a biennial basis by the Quality Assurance discipline:

- Maintenance;
- Procedures;
- Configuration Management;
- Training and Qualifications;
- Incident Investigations;
- Records Management; and
- Quality Assurance elements for IROFS.

Members of the Quality Assurance discipline periodically audit safety programs as directed by the president and/or a discipline vice-president/director.

11.5.2 Assessments

Assessments are performance-based evaluation activities conducted to assess the effectiveness of health, safety, and environmental compliance functions in achieving their designated purpose, particularly in providing reasonable assurance of the availability and reliability of IROFS.

As a minimum, assessments apply to each of the safety function programs and configuration management. Assessments in these areas are performed on a triennial basis. The need for assessments of maintenance, procedures, training and qualifications, incident investigations, records management, and Quality Assurance elements for IROFS will be determined at the discretion of the president and/or a discipline vice-president/director after considering plant activities and the results of periodic audits of these areas.

11.6 Corrective Action Program

11.6.1 Corrective Action Program

NFS maintains a corrective action program to investigate, document, and report events as required by 10 CFR 70.50, 70.62, and 70.74 for operations involving special nuclear materials. The corrective action program is based on, but is not limited to, guidance provided in NQA-1-2008, Part III, Subpart 3.1, "Non-Mandatory Appendix 16A-1," or other similar guidance. Events, including those with conditions adverse to safety, are reported, investigated, tracked, and corrective actions are assigned through a formal corrective action program. A graded, risk-based approach is used to establish the requirements for determining specific or generic root cause(s) and generic implication of events.

A multi-disciplinary committee reviews 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; and, based on severity or potential severity of the event, the investigation may be conducted by one or more individual(s). Levels of investigation, as well as reviews and approvals, are assigned for events in accordance with written procedures.

11.6.2 Incident Investigations

The guidance for conducting an investigation contains the following elements:

1. A documented approach for investigating an event, separate from any required Emergency Plan. The investigation of an event should begin as soon as possible, commensurate with ensuring the safety of the investigator(s), 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 investigator(s)' authority and responsibilities; and assurance of the cooperation of management.

3. Assurance of the investigator(s)' authority to obtain all the information considered necessary and 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 graded, risk-based approach using reasonable, systematic, structured methods to determine, as warranted by the risk, the specific or generic root cause(s) and generic implications of the problem. The level of investigation is based on a graded approach relative to the severity of the event.

6. Requirements to make available original investigation reports to 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.

An investigation will 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.

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

Corrective actions are documented and monitored through completion. Corrective actions generated from investigations are used to make corrections and improvements (i.e., "lessons learned") necessary to prevent or minimize single or common-mode failures. Details of the accident event sequence(s) will be compared

with accident sequence(s) already considered in the ISA, and the ISA Summary will be modified to include evaluation of the risk associated with accidents of the type actually experienced.

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

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

11.7 Records Management

A records management system, as applied to safety (i.e., ISA, radiation protection, nuclear criticality safety, chemical process safety, fire safety, emergency preparedness, and environmental protection), decommissioning, and quality assurance activities, is 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 the relevant regulatory 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. For example, records of major changes implemented under 10 CFR 70.72 will be maintained until termination of the license. Major changes are defined in 11.1.5.

Records relevant to IROFS that are maintained include the following:

- Construction specifications,
- Facility and equipment descriptions and drawings,
- Design criteria requirements,
- Records of facility changes,
- Safety analyses, reports, and assessments, including the ISA and 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 (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 is 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 are 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) are 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.

11.8 Other QA Elements

The NFS quality system consists of the organizational structure, procedures, processes, and resources needed to implement quality management. The following elements, as appropriate, are applied on individual projects using a graded approach based on the degree of importance to safety.

1. Organization and Responsibilities
   Chapter 2 provides the commitments associated with the organizational structure, authority, and responsibilities to ensure that activities involving the handling of SNM and/or IROFS are performed safely and in compliance with license and regulatory requirements.

2. Quality Assurance Program
   NFS maintains a QA Program that is structured on ASME NQA-1 (*Quality Assurance Program Requirements for Nuclear Facilities*) under the overall responsibility of the Quality Assurance discipline. Aspects of this program may be applied to IROFS using a graded approach based on the degree of importance to safety.

3. Design Control
   Design control is an element of the Configuration Management Program as described in Section 11.1. Information control of items such as design inputs, analyses, and other design documentation and records is discussed in Section 11.1.6.

4. Procurement Document Control
   The Purchasing Program has provisions to ensure that applicable design bases and other requirements necessary to provide reasonable assurance of quality are included or referenced in documents for procurement of items or services relied on for safety. To the extent necessary, suppliers are required to have QA consistent with the quality level of the item or service to be procured.

5. Instructions, Procedures, and Drawings
   Section 11.4 includes the commitment that "activities involving the handling of SNM and/or IROFS are conducted in accordance with written procedures". This section also describes the process for developing and implementing procedures. Drawings are controlled under the Configuration Management Program as described in Section 11.1.6.

6. Document Control
A process is in place for developing, implementing, and revising documents to provide reasonable assurance that the appropriate documents are in use (refer to Sections 11.1 and 11.4). Document changes are reviewed for adequacy and approved for implementation by authorized personnel.

7. Control of Purchased Items and Services
The Purchasing Program has provisions for purchase specifications that define the necessary requirements for controlling purchased material. The program provides reasonable assurance of conformance with specified requirements, and it also allows for appropriate receipt inspection, storage, and shelf life requirements for materials.

8. Identification and Control of Items
The Configuration Management and Purchasing Programs have provisions for identifying and controlling items, including IROFS, to provide reasonable assurance that incorrect or defective items are not used.

9. Control of Special Processes
Section 11.4 includes the commitment that "activities involving the handling of SNM and/or IROFS are conducted in accordance with written procedures". This commitment also applies to special processes such as welding, nondestructive testing, and chemical cleaning. Such activities are performed by qualified personnel using approved procedures and equipment.

10. Inspection
Acceptance testing and/or inspection is a part of the Configuration Management Program which ensures that IROFS meet specified requirements prior to initial use. The Surveillance and Monitoring, Preventive Maintenance, and Functional Testing functions, as described in Section 11.2, provide assurance that IROFS continue to meet specified requirements by assuring that these testing and inspection activities are scheduled and implemented.

11. Test Control
Acceptance testing and/or inspection is a part of the Configuration Management Program which ensures that IROFS meet specified requirements prior to initial use. The Surveillance and Monitoring, Preventive Maintenance, and Functional Testing elements, as described in Section 11.2, provide assurance that IROFS continue to meet specified requirements by assuring that these testing and inspection activities are scheduled and implemented.

12. Control of Measuring and Test Equipment
The Calibration Program has provisions to provide reasonable assurance that tools, gauges, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at appropriate intervals to maintain performance within required limits.

13. Item Handling, Storage, and Shipping
The spare parts program has provisions to ensure that items are stored in such a manner as to prevent damage, loss, or deterioration caused by environmental conditions. Testing conducted prior to initial use should detect potential damage incurred during shipping, handling, or storage.

14. Inspection, Test, and Operating Status
Acceptance testing and/or inspection is a part of the Configuration Management Program which ensures that IROFS meet specified requirements prior to initial use. The Surveillance and Monitoring, Preventive Maintenance, and Functional Testing elements, as described in Section 11.2, provide assurance that IROFS continue to meet specified requirements by assuring that these testing and inspection activities are scheduled and implemented. The Configuration Management and Purchasing Programs have provisions for identifying and controlling items, including IROFS, to provide reasonable assurance that incorrect or defective items are not used.

15. Control of Nonconforming Items
The Configuration Management and Purchasing Programs have provisions for identifying, segregating, and controlling items, including IROFS, to provide reasonable assurance that incorrect or defective items are not used.

16. Corrective Action
Reports of conditions adverse to safety are promptly identified and entered into the Corrective Action Program (see Section 11.6), which provides a means to evaluate the problem, identify the cause of the problem, assign appropriate corrective actions to be initiated, and track the corrective actions to closure. Prompt identification and effective corrective actions should provide reasonable assurance that repetition of the problem will be minimized.

17. Quality Assurance Records
The Records Management Program, as described in Section 11.7, has provisions for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality of IROFS.

18. Audits
Section 11.5 includes the commitments for scheduling and implementing audits and assessments.

19. Updates of QA Documents
The management positions for each discipline are responsible for reviewing and updating quality program documents, as applicable, based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other quality program changes.