EHS&L Document

SNM-1227 - Chapter 11
Management Measures

Nature of Changes

Item	Paragraph	Description	Justification
1.	Entire Document	Changed AREVA Inc. to Framatome Inc.	Company Name Change
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
List Below any Documents, including Forms & Operator Aids which must be issued concurrently with this document revision:			

This Document contains a total of 19 pages excluding the signature page.

DOCUMENT REVIEW/APPROVAL/DELETION CHECKLIST

All new and/or revised procedures shall be approved by the change author, cognizant manager(s) of areas affected by the changes, and by applicable manager(s) of any function that approved the previous revision of the document unless responsibility for such approval has been transferred to another organization. Also, the procedure shall be approved by manager(s) of functional organizations that provide technical reviews with the exception of the Training Department. Finally, Document Control shall verify that the required approvals have been properly obtained and that any documents that must be issued concurrently are ready to be issued.

Document Reviews			Document Approvals	
Purpose/Function of Review	Specify Reviewer(s) (Optional except for change author)	(Check all that apply)	Title of Approver	(Check all that Apply)
Document Control (Automatic)		☒	Document Control (Automatic)	☒
Change Author	CD Manning	☒	Author	☒
Independent Technical Review		☐		
Operability Review(s)			Mgr, Richland Operations[1]	☐
Conversion		☐	Mgr, Uranium Conversion & Recovery Operations[1]	☐
Recovery		☐		
Ceramics		☐	Mgr, Ceramic Operations[1]	☐
Rods		☐	Mgr, Rods & Bundles[1]	☐
Bundles		☐		
Components		☐	Mgr, Component Fabrication[1]	☐
Maintenance Review		☐	Mgr, Maintenance[1]	☐
Lab Review		☐	Mgr, Production Support[1]	☐
Transportation		☐	Mgr, Ops Strategy & Supply Chain	☐
EHS&L Review(s)			Mgr, EHS&L[2]	☒
Criticality	WL Doane	☒	Mgr, Nuclear Safety[2]	☐
Radiation Protection		☐		
Safety		☐	Mgr, Safety[2]	☐
Security/Emergency Prep.		☐	Mgr, Security & Emergency Preparedness[2]	☐
Fire Safety		☐		
MC&A		☐	Mgr, Licensing & Compliance[2]	☐
Transportation		☐		
Environmental		☐		
Mechanics Richland Review		☐	Mgr, Mechanics Richland	☐
Mechanics Lynchburg Review		☐		
Thermal-Hydraulics Richland Review		☐	Mgr, Thermal-Hydraulics Richland	☐
Thermal-Mechanics Richland Review		☐	Mgr, Materials & Therm-Mechs	☐
Project & Reliability Review		☐	Mgr, Project & Reliability Eng.	☐
Quality Review		☐	Mgr, Richland Site Quality	☐
Purchasing Review		☐	Mgr, PP&CPC	☐
Others:		☐	Mgr, Richland Site/Other	☐
Document Control		☐	Richland Records Management	☐
Training & Employee Dev.:[3]		☐	Training & Employee Dev.	☐

[1]Note: If approvals include 2 or more product center managers, the Operations manager can be substituted for the applicable product center managers.

[2]Note: If approvals include 2 or more EHS&L functional managers, the EHS&L manager can be substituted for the applicable EHS&L functional managers.

[3]Note: Training department review is required for all procedures that require or affect a Learning Plan and if additional training materials or curriculum must be revised before issuing procedure.

23371 (Rev. 001, 01/09/2018)

EHS&L CHANGE IMPACT EVALUATION FORM

The scope and content of this document have been determined by EHS&L to not impact the safety disciplines checked below. Future revisions do not require review by those EHS&L component(s) unless the scope changes such that a previously excluded safety discipline may be impacted.

☐ Criticality ☐ Radiation Protection ☐ Safety/Security ☐ Emergency Preparedness ☐ MC&A ☐ Transportation ☐ Environmental

DOCUMENT VERSION:	EHS&L REVIEW COMPONENT:	EVALUATION DATE:	CHANGE EVALUATOR*: 2ND PARTY APPROVAL*:

The scope and content of this document have been determined by EHS&L to not directly impact the safe handling of licensed materials (enriched uranium). Future revisions to this document do not require the **10CFR 70.72** change evaluation unless the scope of the document changes such that it directly impacts the handling of licensed materials. ☐

DOCUMENT / ECN NO**:	EVALUATION DATE:	CHANGE EVALUATOR:
E10-08-01100	**1/19/18**	**CD Manning**

Does the change potentially impact Criticality Alarm System (CAS) coverage?	☐ YES ☒ NO
EVALUATION OF NRC PRE-APPROVAL:	
IS NRC PRE-APPROVAL (LICENSE AMENDMENT) NEEDED? ➢ Based on "**YES**" answer to any of five questions below. ➢ Based on "**NO**" answer to all five questions below.	☐ YES ☒ NO
1. Does the change create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of **10 CFR 70.61** (create high or intermediate consequence events) and that have not previously been described in Framatome's ISA Summary?	☐ YES ☒ NO
2. Does the change use new processes, technologies, or control systems for which Framatome has no prior experience?	☐ YES ☒ NO
3. Does the change remove, without at least an equivalent replacement of the safety function an item relied on for safety **(IROFS)** that is listed in the ISA Summary?	☐ YES ☒ NO
4. Does the change alter any item relied on for safety, listed in the ISA Summary, that is the sole item preventing or mitigating an accident sequence of high or intermediate consequences?	☐ YES ☒ NO
5. Does the change qualify as a change specifically prohibited by NRC regulation, order or license condition?	☐ YES ☒ NO
Evaluation of Actions Required PRIOR TO OR CONCURRENT with Change Implementation:	
6. Modification / Addition to CAS system or system coverage documentation	☐ YES ☒ NO
7. Acquire NRC pre-approval (LICENSE AMENDMENT)	☐ YES ☒ NO
8. Conduct/modify ISA	☐ YES ☒ NO

9. Modify / update the following:	☒ None ☐ Other	☐ ISA Database ☐ Red-Line Drawings/P&ID	☐ NCSA ☐ NCSS	☐ NCSP ☐ PHA	☐ RHA ☐ FHA	☐ ChHA ☐ Procedures
Evaluation of Actions Required SUBSEQUENT TO Change Implementation:						
10. Modify / update the following:	☒ None ☐ Other	☐ ISA Database ☐ AS-Built Drawings/P&ID	☐ NCSA ☐ NCSS	☐ NCSP ☐ PHA	☐ RHA ☐ FHA	☐ ChHA ☐ Procedures

Justification Section for "YES" preceding Questions 1 – 8 or other for 9, 10: Being prepared as part of a License Amendment, however pre-approval of the amendment prior to issuing is not required.

(*) Only required if one or more of the boxes to exclude a particular safety discipline review is checked.

(**) If this form exists as a part of a document, the document number is not required.

Table of Contents

List of Tables

11.0 **Management Measures**

Management measures are applied to items relied on for safety (IROFS) to provide reasonable assurance that the IROFS are available and able to perform their functions when needed. Framatome Inc.'s (Framatome's) ISA Summary [see Chapter 3, Integrated Safety Analysis (ISA) and ISA Summary] identifies IROFS applied to plant operating systems to assure that those systems function within the performance criteria of 10 CFR 70.61. Those IROFS may be engineered features (passive or active) or administrative features (actions of people). Management measures are applied to IROFS as described in Section 11.8 of this chapter.

11.1 ***Configuration Management (CM)***

To ensure that configuration changes do not adversely impact currently implemented IROFS or add a new process or system which would pose an unacceptable risk, a formal review process will be used to assess new systems and components, or to modify existing systems or components. The CM function captures formal documentation governing the design and continued modification of the site structures, processes, systems, equipment, components, computer programs, personnel activities, and supporting management measures. The process for evaluating safety of configuration changes is discussed in Chapter 3.

11.1.1 CM Policy

It is management's policy to control facilities and processes so that the safety basis is maintained and that changes to facilities and processes are evaluated according to approved written procedures and consistent with 10 CFR 70.72. The CM process provides assurance that consistency is established and maintained between facility design, operational requirements, physical configuration, and facility documentation.

CM is applied uniformly to IROFS regardless of safety significance, i.e., a graded approach is not used.

Overall responsibility for configuration management resides with the Richland Site Manager. Key responsibilities within the configuration management program are delegated as follows:

- Plant Projects Component - overall ownership of the plant's configuration management system for facilities, equipment, and software. Includes control of plant projects (additions and modifications) from design to operational turnover.
- Environmental, Health, Safety and Licensing (EHS&L) Component - evaluation of safety and licensing impacts of plant additions/modifications.
- Fuel Operations (and Maintenance) Component - assurance that operational procedures and operator training are consistent with the equipment, process, and safety bases of the plant and that these bases are maintained over the course of maintenance activities.

The organizational relationships of these components are depicted in Chapter 2, Organization and Administration.

11.1.2 Configuration Control

Framatome shall maintain a configuration control program to ensure that proper reviews are undertaken prior to and after changes to facilities, equipment, or software systems, particularly with regards to facilities, equipment, and software involved in the handling or processing of

licensed material. The reviews will ensure that facility changes are properly evaluated with respect to:

- Impact on safety and health or the control of licensed material, and
- Impacts to the pre-existing integrated safety analysis, integrated safety analysis summary, or other safety program information developed in accordance with 10 CFR 70.62.

The evaluation determines, before the change is implemented, if an amendment to the site's NRC license is required to be submitted in accordance with 10 CFR 70.72(c).

The configuration control program shall be implemented via approved procedures to which appropriate personnel shall be trained. Those procedures shall define the overall process for change control, including as appropriate:

- establishment of technical design bases/criteria;
- design development, review, and control;
- project approval, initiation, and control;
- evaluation of safety/licensing implications, including the need for new or revised safety analyses;
- needs for post-modification testing;
- project readiness review/startup approval, operational turnover, and closeout (control points applicable to the projects, safety, and operations organizations are identified and documented); and
- maintaining/updating of safety basis documentation.

Relevant procedures and associated documentation shall be readily available for review onsite. Procedures are subject to the controls set forth in Section 11.4.

11.1.3 CM Program Review

The effectiveness of the CM Program shall be assessed on a periodic basis in accordance with 11.5.2, Assessments.

11.2 ***Maintenance***

Management will establish and maintain maintenance programs designed to ensure the availability and proper performance of features essential to the safe operation of the Richland facility.

11.2.1 Corrective Maintenance

Corrective maintenance will be conducted as required to ensure that IROFS and other systems or features necessary to 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/feature.

Corrective maintenance shall be authorized, initiated, and documented via a formally established procedure to which appropriate personnel have been trained. The procedure shall include steps to invoke appropriate coordination between the maintenance and operating organizations.

The corrective maintenance procedure shall include an evaluation step to determine if IROFS have been, or may be, affected by the equipment failure/malfunction or the ensuing maintenance. This evaluation step, performed using skill of the maintenance craft and operator, shall give appropriate consideration to the need for post-maintenance functional testing of IROFS.

11.2.2 Preventive Maintenance (PM)

Framatome conducts a preventive maintenance program covering equipment, facilities, systems and support activities with emphasis on safety items, including designated IROFS. The Richland program includes two components - preventive maintenance on equipment other than instruments (PM program) and instrument repetitive maintenance (IRM program). The PM program includes routine functional testing of IROFS.

PMs/IRMs for safety-related features, including IROFS, shall be managed within formal programs for scheduling, initiation, tracking, and documentation. These programs shall be governed by approved procedures.

IRMs and PMs shall be conducted by qualified personnel in accordance with written and approved instructions.

Safety-related IRMs/PMs shall be designated as such within the preventive maintenance management system. These IRMs/PMs are identified by a unique numbering system as well as appropriate precautionary statements on their respective data sheets.

Frequencies for safety-related IRMs/PMs are established with, and cannot be modified without, concurrence of the Environmental, Health, Safety and Licensing (EHS&L) function. Similarly, due dates for safety-related IRMs/PMs cannot be extended without concurrence of the EHS&L function.

Safety-related items, including IROFS, found to be non-functional or out-of-tolerance shall result in timely notification of the safety organization.

11.2.3 Functional Testing

Framatome will provide appropriate functional testing to assure that IROFS are available and able to perform their functions when needed. Functional testing may be provided in conjunction with corrective maintenance, preventive maintenance, or equipment installation/modification.

Corrective maintenance (see Section 11.2.1) will be conducted via a formally established and controlled procedure which shall include an evaluation step for post-maintenance functional testing.

Functional testing activities conducted under the preventive maintenance program (see Section 11.2.2) shall be specified within the applicable PM or IRM instructions.

Functional testing requirements associated with newly installed or modified safety-related equipment shall be specified and controlled via Framatome's established configuration control program (see Section 11.1.2).

11.2.4 Surveillance/Monitoring

Framatome will utilize established surveillance activities to monitor the current and long-term performance of IROFS. These activities include preventive maintenance and calibration (11.2.2), functional testing (11.2.3), and follow-up to corrective maintenance (11.2.1). IROFS

found to be out-of-tolerance or unable to perform their intended function are reported in a timely manner to the safety function.

Failed IROFS are entered into Framatome's corrective action program (CAP). The CAP will provide management of the process for evaluation of the IROFS failure, cause identification, and identification/assignment of corrective actions.

Records of IROFS surveillance, performance, failures, and corrective actions will be maintained within the maintenance and corrective action programs, as applicable.

11.3 *Training and Qualification*

Workers shall be provided training to allow them to conduct their assigned activities with licensed materials in a manner that is protective of their personal health and safety and the health and safety of their co-workers. Furthermore, these activities must be conducted in a manner that does not endanger the public or the surrounding environment. This training typically falls into one of two categories, namely:

- general health and safety training not specific to particular workstations and work activities; and
- training to assure proper performance for particular positions and work activities that are relied on for safety, in particular those affecting measures designated as IROFS in the ISA summary.

11.3.1 General Health and Safety Training

General health and safety training shall be provided in radiation protection, criticality safety, emergency procedures, fire safety, and chemical safety as it relates to the safety of licensed materials. The degree of training shall be commensurate with the workers' duties and their potential interactions with licensed materials. The minimum safety-related training requirements shall be established by the EHS&L component.

Training for radiation workers shall comply with the regulatory requirements of 10 CFR Parts 19 and 20. Specifics of the radiation protection training program are provided in Chapter 4, Radiation Protection.

Initial Training

Employees shall be provided with initial general health and safety training to allow them to safely access areas containing licensed materials and, if applicable, start on-the-job training. Prior to assignment to independent operation and as appropriate to their positions, employees are required to have been instructed in radiation protection, criticality safety, fire protection, emergency requirements, and chemical safety as it relates to the safety of licensed materials. This training shall be documented and records appropriately maintained.

Recurrent Training

Each employee routinely working with licensed materials shall receive periodic refresher training (including an examination) as part of the facility's continuing program in safety awareness. When changes are made relative to safety or emergency response requirements, provisions shall be made to assure that affected employees are appropriately informed and instructed on the change. Recurrent and update training shall be documented and records appropriately maintained.

11.3.2 Training and Qualification for Positions/Activities Impacting IROFS

Employees assigned to positions/activities involving licensed materials shall be appropriately qualified and trained so as to conduct their job duties in a way that does not adversely impact safety, and in particular the availability and reliability of measures designated as IROFS in the ISA Summary. Qualification for selected positions is achieved and maintained through a combination of education/experience requirements, general employee training, initial qualification, continuing training, and requalification. The training and qualification process may include classroom and/or on-the-job activities and shall be documented.

Organization and Management of Training

The assurance of appropriately trained and qualified workers is the responsibility of the Richland Site Manager and pertinent line management. Support to line management for the development, implementation, and administration of plant training and qualification programs is provided by the Training function (see Chapter 2, Organization and Administration).

Overall implementation of the training and qualification program for employees conducting activities or impacting measures relied on for safety shall be governed by a formal procedure(s).

Training records shall be created and maintained so as to allow the verification of the training and qualification status of individuals potentially impacting the safety of licensed material operations.

Activities Requiring Training

Positions impacting the availability/reliability of IROFS shall be assessed to determine training and qualification requirements. The assessment is based on a graded approach that considers hazards and rules associated with the positions and utilizes input of pertinent subject matter experts (SMEs) as appropriate.

Training and qualification requirements for job functions shall be maintained to ensure consistency with current systems, procedures, and policies.

Position Training Requirements

Position training requirements are established for positions whose incumbents conduct activities relied on for safety or who perform actions that prevent or mitigate accident sequences described in the ISA Summary. These requirements include, as applicable, procedure reviews, classroom instruction, and on-the-job training (OJT).

Bases for Training

The objective of training shall be to ensure safe and efficient operation of the facility and compliance with applicable established regulations and requirements. Learning objectives shall be 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

Training materials shall be appropriately formalized to assure the consistent conduct of training and should be based on learning objectives derived from training needs assessments of the safety/IROFS-related activities. Materials may take the form of instructor guides, lesson plans, or similar training tools and shall be subject to established review and approval criteria.

Computer-based training may also be utilized and shall be subject to a review and approval cycle consistent with that provided to other training materials.

Evaluation of Trainee Accomplishment

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

On-The-Job Training (OJT)

OJT requirements for activities relied on for safety and listed in the ISA Summary, if applicable, shall be 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 shall be documented.

Continued Assurance of Training/Qualification

Positions/activities impacting IROFS shall be evaluated for needed recurrent training/ qualification activities. Any such periodic retraining/requalification shall be provided as part of the formal training/qualification program and shall be documented.

Training Program Review

The effectiveness of the training and qualification program for positions impacting IROFS shall be assessed on a periodic basis (see 11.5.2, Assessments).

11.4 *Procedures Development and Implementation*

Framatome conducts its licensed activities in accordance with a system of written operating procedures. Activities involving licensed SNM and/or IROFS will be conducted in accordance with approved procedures.

Procedures may take various forms [standard operating procedures (SOPs), standard work instructions (SWIs), management control procedures (MCPs), maintenance instructions (PMs, IRMs)] and are subject to formal review and approval protocols. Safety-related procedures, and specifically those involving IROFS, are subject to formal review and approval by the EHS&L function, including when those procedures are revised.

The site process for the development and implementation of safety-related procedures shall be controlled via formal administrative/management control procedures. Those procedures shall address how procedures are developed, reviewed, approved, distributed, revised, and deleted. The system shall assure that the most current revisions of procedures are readily available to workers within their work areas.

The process for creating new and revising existing safety-related procedures, specifically those procedures involving IROFS-related activities, shall include a mechanism for triggering necessary training and/or qualification updates.

Revisions to procedures covering licensed material operations shall be evaluated in accordance with 10 CFR 70.72 as to their potential impacts to IROFS and the site integrated safety analysis, including the need for NRC pre-approval of the change.

Temporary changes to procedures, if allowed, shall be governed by a formal process, specifying the conditions under which temporary changes may be implemented and the associated review and approval requirements.

Procedures governing activities relied on for safety shall be subject to a formal program of periodic review with defined review frequencies. The review frequency may be graded based on importance to safety.

The issue investigation/corrective action program (see Section 11.6) shall include provisions to assess the role of procedures in adverse conditions/events evaluated within the program. Correction of procedural deficiencies shall be tracked to completion within the system

11.5 *Audits and Assessments*

Framatome will implement and maintain a program of audits and assessments of activities significant to facility safety and environmental protection.

Overall responsibility for the audit and assessment program rests with the manager of the Environmental, Health, Safety and Licensing function, who reports to the Richland Site Manager independently of the operations function (see Chapter 2, Organization and Administration). That overall responsibility includes:

- determining the appropriate utilization of internal and/or external personnel for particular audit/assessment activities;
- assuring that audit/assessment personnel have expertise and backgrounds sufficient to successfully conduct their assigned audit/assessment activities, and in the case of assessments, are sufficiently independent of the area being assessed.
- assuring the utilization of an effective corrective action system to address the findings of audits and assessments.

11.5.1 Audits

Audits are compliance-based evaluation activities with an objective of verifying the compliance of operations with regulatory requirements and license commitments. The audit program will apply as a minimum to radiation protection, nuclear criticality safety, fire protection, environmental protection, hazardous chemical safety, emergency management, quality assurance, configuration management, maintenance, training and qualification, procedures, incident investigations, and records management as these subjects relate to maintaining the safety of licensed material operations.

Audits of activities significant to facility safety and environmental protection shall be conducted by qualified individuals appropriately independent of the activities being audited. When full independence is not practicable, the auditor will be designated such that he was not directly involved in the performance of the activities being audited.

Audits shall be conducted in accordance with written guidance (e.g., audit plans or checklists) and results shall be documented.

Audit reports shall be directed to appropriate EHS&L management and to affected operational management. Records of audits shall be maintained in accordance with the Records Management section of this chapter.

Audit findings indicating non-compliance with regulatory and/or license requirements shall be entered into the corrective action program for appropriate documentation, evaluation, and corrective action. The Framatome corrective action program is described under Incident Investigation and Corrective Action (Section 11.6).

Audits shall be conducted in accordance with Table 11-1, Schedule of Audits.

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 designed purposes, particularly in providing reasonable assurance of the continued availability and reliability of IROFS.

Assessments will utilize personnel who are independent of the area being reviewed, however some utilization of individuals from the function being assessed may be required to ensure adequate knowledge of the area under review.

Assessments shall be conducted in accordance with written guidance (e.g., assessment objectives or plans) and results shall be documented.

Assessment reports shall be directed to appropriate EHS&L management and to affected operational management. Records of assessments shall be maintained in accordance with the Records Management section of this chapter.

Assessment findings indicative of program deficiencies and/or vulnerabilities shall be entered into the corrective action program for appropriate documentation, evaluation, and corrective action. (Certain sensitive issues, e.g., security or safeguards-related issues, may be dispositioned outside the general corrective action program.) Recommendations for program improvements/enhancements may be entered into the corrective action program at the discretion of the manager of the EHS&L function.

The assessment program will be applied at a minimum to the areas of radiation protection, nuclear criticality safety, chemical safety, fire safety, environmental protection, emergency preparedness, configuration management, and training and qualification. Assessments in these areas shall be scheduled such that each area is assessed on at least a triennial basis. The need for assessments of the subject areas of quality assurance, maintenance, procedures, incident investigation, and records management will be determined at the discretion of the manager of the EHS&L function after considering plant activities and the results of periodic audits of these subject areas. Actions to require interim assessments, to require more frequent assessments of any area, or to add other functional safety areas to the assessment program shall also be at the discretion of the manager of the EHS&L function.

Table 11-1 Schedule of Audits

Audit	Frequency	Comments
Radiation Protection	Monthly	Audit of compliance with plant radiation protection requirements and exposure controls
Nuclear Criticality Safety	Monthly	Audit of various plant systems/facilities where fissile materials are processed or stored for compliance with criticality safety requirements. Monthly audits conducted such that each area of plant is audited at least biennially.
Fire Protection	Monthly	Audit of selected areas of plant for housekeeping and industrial safety conditions pertinent to fire protection. In addition, monthly inspection of plant fire extinguishers, conducted in conjunction with or independently of the area audits.
Environmental Protection (Radiological)	Quarterly	Audit of compliance with environmental protection requirements and exposure controls relative to licensed materials.
Hazardous Chemical Safety	Biannually	Audits for compliance within areas of plant where hazardous chemicals which could affect licensed materials are stored, processed, or otherwise handled.
Emergency Management	Annual	Audit of compliance with requirements affecting emergency preparedness and emergency response.
Quality Assurance	Annual	Audit of compliance with quality program requirements applicable to IROFS.
Configuration Management	Annual	Audit of compliance with key elements of plant configuration management program for facilities and equipment, including items relied on for safety (IROFS).
Maintenance	Annual	Audit of compliance with maintenance requirements for activities affecting the safe handling of licensed materials, including corrective maintenance, preventive maintenance, and functional testing.
Training and Qualification	Annual	Audit of compliance status with training and qualification requirements for positions/ activities involving licensed materials.
Procedures	Annual	Audit of compliance with requirements for the generation, approval, and utilization of procedures governing licensed material activities.

Audit	Frequency	Comments
Incident Investigation	Annual	Audit of compliance with plant programs for the identification, evaluation, and correction of safety-adverse incidents or conditions.
Records Management	Annual	Audit of compliance with management requirements for health and safety-related records.

11.6 *Incident Investigation and Corrective Action*

Framatome will implement and maintain an integrated incident investigation/corrective action program to assure that safety-adverse incidents or conditions are appropriately identified, evaluated, and reported, and that suitable corrective actions are identified and applied. This integrated program will include incidents and adverse conditions involving the control and processing of licensed materials, including those with actual or potential adverse impacts to items relied on for safety (IROFS). The incident investigation and corrective action programs will be implemented via formally approved procedures.

11.6.1 Corrective Action Program

The Richland corrective action program (CAP) as applied to the safety of operations using or affecting licensed materials, including the effectiveness and reliability of IROFS, will contain the following features:

- a formal condition reporting mechanism readily available to all individuals involved in licensed material operations;
- provision for EHS&L function involvement in the safety significance screening of reported events/conditions;
- formal assignment of issue owner/issue investigator responsibilities;
- assignment of required level of incident investigation/cause analysis based on safety significance;
- formal assignment and tracking to completion of corrective actions;
- evaluation of regulatory, including NRC, reportability; and
- creation of permanent documentation of the issue identification, evaluation, and corrective action activities.

11.6.2 Issue Investigation and Causal Analysis

Level of issue investigation/causal analysis is driven by safety significance of the incident or condition, as determined under the corrective action program. Management discretion may be used to elevate the level of a particular issue. Response to low safety significance events may be limited to application of corrective actions as deemed necessary, without formal cause analysis and application of preventive actions. More significant safety-related incidents or conditions require formal investigation and cause analysis as dictated by an approved issue investigation/causal analysis procedure. This procedure defines:

- responsibilities to issue owners and investigators;

- general methods for conduct of investigations;
- requirements relative to identification of cause and generic implications;
- requirements for report preparation and approval, and for records maintenance;
- requirements for identification of corrective and preventive actions, as appropriate.

Issue investigations, causal analyses, and identified corrective/preventive actions require review/approval by the EHS&L function. Identified actions are assigned to action owners and tracked through to completion via the formal CAP.

11.7 *Records Management*

Framatome will establish pertinent controls to assure that records documenting its health, safety and environmental activities and the safety bases/controls of its facilities and processes are appropriately created, distributed, stored, protected, and, if necessary, restored.

Records will be identified and stored such that current records are readily accessible for use and historic records can be retrieved within a reasonable timeframe. Records that have been reconstructed due to inadvertent loss or destruction of the original record shall be identified as such.

Records documenting plant alterations or additions, abnormal occurrences involving licensed materials, events associated with radioactive releases, criticality safety analyses, audits, assessments, safety-related instrument calibrations and preventive maintenance, ALARA program results, worker training and retraining, personnel exposures, routine radiation surveys, environmental surveys, decommissioning plans and activities, emergency preparedness events/drills, and IROFS and/or management measures degradations or failures resulting in non-compliance with the performance requirements of 10 CFR 70.61 shall be maintained on file for a minimum of two years or as otherwise required by federal regulation or other license condition.

11.8 *Quality Assurance for IROFS*

Quality assurance (QA) elements are applied to IROFS as management measures to assure that there is reasonable assurance that IROFS are available and able to perform their functions when needed. The QA elements are applied to IROFS based on IROFS type as identified in Table 11-2. Commitments relative to the implementation of these QA elements are described elsewhere in this chapter.

Additional quality measures, listed below, may be applied to the site's safety programs or to individual IROFS, as needed, on an individual needs basis.

1. **Organization and Management Responsibility**. Chapter 2 of this license application provides the commitments associated with organizational structure, authority, and accountabilities to assure that they are able to carry out their responsibilities relative to the safety of licensed materials.

2. **QA Program**. Framatome maintains a QA program that meets the requirements of 10CFR50 Appendix B. Aspects of this program may be used for 10CFR70-related activities when deemed appropriate by Framatome.

3. **Design Control**. The design control function is an element of the configuration management program described in Section 11.1 of this chapter. This is detailed in Framatome's Engineering Change procedure which is available at the Framatome Richland site for review.

4. **Procurement Document Control**. The purchasing program has provisions for purchase specifications that define the necessary requirements. These specifications receive the appropriate reviews and approvals. This program provides reasonable assurance of conformance with specified requirements. This is integrated into the Work Order and engineering change procedures to assure appropriate features meet the needs of the IROFS to perform reliably. These procedures are available at the Framatome facility for review.

5. **Instructions, Procedures, and Drawings**. Section 11.4 of this application makes the commitment that all licensed activities will be performed "in accordance with a system of written operating procedures, which may take various forms, e.g. standard operating procedures, standard work instructions, maintenance instructions, etc.

   The procedure development process is described in Section 11.4 of this application. These operating procedures are reviewed and approved by the management of the functional component and by the safety organization as appropriate. Drawings are controlled as part of the CM program as described in Section 11.1.

6. **Document Control**. The document control program is described in Section 11.4 of this application and assures that all new or modified documents receive appropriate review and approval. The procedures and standards associated with Document Control are reviewed and approved by the management of the functional component. This process applies to all licensed activities including the ISA program.

7. **Control of Purchased Material**. The purchasing program has provisions for purchase specifications that define the necessary requirements for controlling purchased material. This program provides reasonable assurance of conformance with specified requirements. This program allows for appropriate receipt inspection, storage, and shelf life requirements for materials.

8. **Identification and Control of Materials and Parts**. The lock and tag procedures associated with the configuration management and safety management programs have provisions for tagging non-conforming IROFS such that they will not be used until such time as they repaired and able to perform the required function.

9. **Control of Special Processes**. Section 11.4 of this application makes the commitment that all licensed activities will be performed "in accordance with a system of written operating procedures." This commitment also applies to special processes. The development of the procedures associated with special processes is described in Section 11.4 of this application. Management is responsible to assure that personnel who perform such activities are suitably qualified. The Work Order and engineering change procedures detail the assessment and application of appropriate codes and standards including special processes such as welding. These in turn require qualified personnel, qualified procedures, and qualified materials.

10. **Inspection**. Acceptance testing is a part of the configuration management program which ensures that IROFS meet requirements prior to initial use. The Preventative Maintenance and Instrument Repetitive Maintenance programs as described in Sections 11.2.2 and 11.2.3 of this application provide assurance that IROFS and other safety-related equipment continue to meet requirements by assuring these inspection activities are scheduled and implemented.

11. **Test Control**. Acceptance testing is a part of the configuration management program which ensures that IROFS meet requirements prior to initial use. The Preventative Maintenance and Instrument Repetitive Maintenance programs as described in Sections 11.2.2 and 11.2.3 of this application provide assurance that IROFS and other safety-related equipment continue to meet requirements by assuring these testing activities are scheduled and implemented. .

12. **Calibration of Equipment**. Equipment calibration is a part of the maintenance program as described in Sections11.2.2 and 11.2.3 of this application. This portion of the program applies equally to newly installed components that require calibration and those that have been installed and require periodic recalibration.

13. **Handling Storage and Shipping**. The spare parts program has provisions to ensure that safety important items can be stored in such a manner as to prevent damage, loss, and deterioration caused by environmental conditions. Testing for potential damage during shipping, handling or storage is completed as part of the post-installation pre-operational testing as described in Item 14 below.

14. **Inspection, Testing and Operating Status**. Acceptance testing is a part of the configuration management program which ensures that IROFS meet requirements prior to initial use. The Preventative Maintenance and Instrument Repetitive Maintenance programs as described in Sections 11.2.2 and 11.2.3 of this application provide assurance that IROFS and other safety-related equipment continue to meet requirements by assuring these activities are scheduled and implemented. The lock and tag procedures associated with the configuration management and safety programs have provisions for tagging non-conforming IROFS and other safety-related equipment identified during testing such that they will not be used until such time as they are repaired and able to perform the required function.

15. **Nonconforming Material**. The lock and tag procedures associated with the configuration management and safety programs have provisions for tagging non-conforming IROFS such that they will not be used until such time as they repaired and able to perform the required function. The Fuel America Corrective action program described in sections 11.6.1 of this application provides the needed assurances that all conditions adverse to safety are promptly identified and that appropriate corrective actions to prevent recurrence are established and implemented.

16. **Corrective Actions**. The Fuel America Corrective Action Program records are permanent company records. These records and those associated with the PM/IRM program are adequate to track the performance reliability of IROFS and ensure a feed-back mechanism to the ISA process should any adjustment need to be made.

17. **QA Records**. QA records, including those associated with the corrective action program, are permanent company records.

18. **Audits and assessments**. Both the QA and EHS&L organizations plan, schedule, and execute assessments and audits to determine the effectiveness of organizations and programs and to inform management of any items needing attention. These commitments are described in Sections 11.5.1 and 11.5.2 of this application. Corrective actions and recommendations derived from audits and assessments are evaluated and tracked to completion via the Fuel America Corrective Action Program described in Section 11.6 of this application.

Table 11-2 Management Measures for IROFS

Management Measure	Passive Engineered Control (PEC)	Active Engineered Control (AEC)	Administrative Control	Enhanced Administrative Control
Configuration Management (design & change control for hardware & software)	X	X		X**
Document Control (includes records management and procedures)	X	X	X	X
Corrective Maintenance	X	X		X**
Preventive Maintenance (PM/IRM and Surveillance Monitoring)	X*	X		X**
Functional Testing (initial, periodic*, following maintenance)	X	X		X**
Personnel Training (initial, periodic, following changes) & Evaluation (testing, observation)			X	X
Problem Identification & Corrective Action Follow-up	X	X	X	X

***** Periodic surveillance is not required for all PECs.

** These management measures only apply to enhanced administrative controls that have an active engineered component such as an alarm.

The management organization responsible for the application of QA elements to IROFS is as described in Chapter 2, Organization and Administration.

Additional QA elements/management measures may be applied to IROFS based on the specific operational/maintenance characteristics of the individual IROFS. If so, the measures shall be applied in accordance with written instructions and the results documented and appropriately retained.