SNM-42

CHAPTER 11

MANAGEMENT MEASURES

MANAGEMENT MEASURES
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11.0 Introduction

The site maintains several programs, systems and functions, which collectively are referred to as Management Measures. The purposes of Management Measures are to assure that all "Items Relied On For Safety" (IROFS) will be available and reliable, will remain available and reliable, and will be under surveillance for malfunction detection and appropriate corrective action. Documentation and management oversight are both essential functions of Management Measures. Management Measures serve to ensure that all IROFS are properly designed, constructed, inspected, calibrated, tested, implemented and maintained.

Management Measures are applied to all IROFS as necessary to assure reliability. Not all Management Measures necessarily apply to each IROFS. For example, administrative IROFS are heavily dependent upon specific procedures and training and generally dependent on audits, corrective actions, etc. to ensure availability and reliability. In contrast, engineered IROFS are less dependent upon procedures and training but may be highly dependent upon inspection and testing or maintenance. The site considers the need for all Management Measures for IROFS and invokes those that are necessary to ensure that IROFS reliability is consistent with the level assigned during the ISA. The key elements of Management Measures that are in place include:

a. Configuration Management
b. Maintenance
c. Training and Qualification
d. Procedures
e. Audits and Assessments
f. Corrective Action Program
g. Records Management
h. Other QA Elements – B&W NOG's Quality System

These eight key elements are amplified in the following sections of this chapter. All Management Measures are implemented through the site's quality system, which is described in, section 11.8.

11.1 Configuration Management

11.1.1 Configuration Management Policy

The site has completed the initial Integrated Safety Analysis and identified Items Relied on For Safety. The Configuration Management Process described in this Chapter shall apply to all processes that have accident scenarios requiring Items Relied on For Safety to assure an acceptable risk profile.

11.1.2 Design Requirements

The site has implemented procedures describing requirements for design of new facilities or new processes at existing facilities where Special Nuclear Material is

handled or where the safety of Special Nuclear Material may be affected. A graded level of design review is required depending on the risks of the proposed facility.

The design criteria in the Design Review procedures assure the requirements of 10CFR70.64 are met. Additionally, the procedures contain design criteria and guidelines that assure other safety regulatory requirements and industry guidance are adequately considered. The Design Review procedures require that the Baseline Design Criteria of 10 CFR 70.64 "Requirements for New Facilities or New Processes at Existing Facilities" be addressed in the design of any new facility or process at the site. In addition, the procedures include radiation protection, criticality safety, and industrial health and safety guidelines to be followed when designing a new facility or process at the site.

Design reviews are approved by a Design Review Board. Not all changes require a design review; however, all changes are reviewed and approved per section 11.1.3.

11.1.3 Change Control

Modifications or additions to the facilities, processes, and equipment, used for handling, processing, or storing licensed material, shall be evaluated and approved following an approved procedure before the change is made and the ISA Summary is modified. Examples of changes that require evaluation and approval include:

- A change that requires amending License SNM-42.
- A change that involves a new core design, fuel process, or storage area.
- A change that involves the relocation or decommissioning of a fuel processing area.
- A change that involves ground breaking for a new fuel processing or fuel storage area or the expansion of an existing fuel processing or fuel storage area.
- A change that involves radiological safety or nuclear material control systems that may reduce the level of safety previously approved for an operation.
- A change that indicates a potential increase in the monthly average of radioactive effluents.
- A change that requires the addition of a radioactive effluent release point.
- A change that adds, alters or removes an IROFS.
- Any change to a process or facility in such a way that it could impact the results of the ISA.

11.1.3.1 Evaluation of Changes

All changes shall be reviewed by area management and the following disciplines:

- Licensing
- Nuclear Criticality Safety

- Radiation Protection
- Industrial Health & Safety (Fire Protection and Chemical Safety)
- Environmental Protection Engineering
- Security
- Nuclear Materials Control

A determination may be made that a specific discipline may not be required to evaluate a change. The basis for this determination is contained in change management procedures and checklists. As an example, Nuclear Materials Control may not be required to evaluate a change that involves radioactive material but does not involve SNM. Individuals in Nuclear Criticality Safety, Radiation Protection, Industrial Health & Safety, and Environmental Protection who perform evaluations shall have the qualifications identified in Chapter 2 as applicable to their discipline.

The ISA Summary and supporting scenarios, along with it's referenced documentation for the process or area to be changed, shall be used as the starting point for evaluations. Chapter 3 describes a graded approach to performing the hazards analysis from a basic what-if/checklist method to a more formal HAZOPS method that is applied to all changes. The ISA Process described in Chapter 3 shall be used to identify accident scenarios and all IROFS and controls necessary for safe operation, shall specify the limits for controlled parameters, and shall assure that the following are addressed prior to implementation:

a. technical basis for the change,
b. impact of the change on safety and health or control of licensed material,
c. modification to existing operating procedures including any necessary training or retraining before operation,
d. expiration date for a temporary change, and
e. impact on the ISA and ISA Summary.

In addition, evaluation of changes shall be in accordance with any specific commitments and criteria set forth in Chapters 4 through 7 of the application for Radiation Protection, Nuclear Criticality, Chemical Safety and Fire Safety, respectively.

As part of the evaluation of the change, a determination shall be made whether or not NRC pre-approval is required for the proposed change based on the requirements of 10 CFR 70.72. Changes that will require NRC pre-approval are those meeting one or more of the following criteria:

a. Any change that creates new types of accident sequences with unmitigated consequences exceeding the performance requirements of 10 CFR 70.61. New types of accident sequences are those that

have not been previously described in the ISA Summary for the system being evaluated or for similar systems.

b. Any change using a new process, technology or control system for which the site has no prior experience.

c. Any change that removes an IROFS, without an equivalent replacement of the safety function. The safety function is defined as the function necessary to prevent the accident not necessarily the function necessary to maintain a particular parameter. The following criteria area used to determine if IROFS replacement is equivalent:

Through a documented re-evaluation, an IROFS is removed without replacement under one of the following conditions:

- Equipment or process was removed or modified so that the scenario(s) requiring the IROFS no longer exists.
- The scenario(s) requiring the IROFS were re-evaluated and the unmitigated consequences were determined to no longer require IROFS (i.e., consequences are below the 10CFR70.61 thresholds).
- Process parameters (e.g., quantities of hazardous chemicals, radiological source term, etc.) were changed such that the unmitigated consequences no longer require IROFS (i.e., consequences are below the 10CFR70.61 thresholds).
- The IROFS being removed provides an Overall Likelihood in excess of that required to meet the performance requirements of 10CFR70.61, and is being removed under the condition that the remaining IROFS continue to provide an acceptable Overall Likelihood.

  or

  Through a documented re-evaluation, an IROFS is removed and replaced under one of the following conditions:
- Replacement of an IROFS with another that maintains the preferred control type hierarchy (i.e., Passive Engineered over Active Engineered over Enhanced Administrative over Administrative) and for which the effectiveness of the replacement IROFS is at least the same as the effectiveness of the IROFS being replaced.
- Replacement of one IROFS with multiple IROFS for which the combined effectiveness of the replacement IROFS(s) is at least the same as the IROFS being replaced.
- Replacement of multiple IROFS with one IROFS that is higher on the preferred control type hierarchy and for which the effectiveness of the replacement IROFS is at least the same as the combined effectiveness of the IROFS being replaced.
- The IROFS being removed and replaced provides Overall Likelihood in excess of that required to meet the performance requirements of 10CFR70.61, and is being removed under the

condition that remaining IROFS continue to provide acceptable Overall Likelihood.

d. Those changes that alter any IROFS listed in the ISA Summary that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of 10 CFR 70.61.

Determination of equivalency according to criteria c.) shall consider the reliability and availability characteristics of the replacement IROFS (if applicable), including information regarding failure or degradation of IROFS, collected in accordance with Section 11.6.1.

11.1.3.2 Approval of Changes

Minor changes, as defined by internal procedures and checklists, are approved by all required evaluators, area management and the change originators. This approval is based upon a review of the results of each evaluation. Examples of minor changes include:

- Relocation of posted fuel processing equipment (e.g. machine shop mill) with no change to safety controls.
- Minor relocations of services such as drain lines.
- Changes to non-radiological equipment in controlled areas.
- Like kind replacements.
- Procedure, NCS Posting, and Fuel Inventory Computer Program revisions.
- Safety Analysis Report changes that do not result in modifications to facilities, equipment, or process parameters.
- Minor modifications to equipment that do not impact IROFS.
- Removal of equipment.

All other changes are reviewed and approved by the Change Review Board. This approval is based upon the evaluations and recommendations of the evaluators. Upon implementation of the approved change, the IROFS, limits and controls specified by the evaluations shall become requirements.

11.1.4 Document Control

The ISA Summary and supporting documents that are referenced in the ISA Summary are maintained up-to-date. Supporting documents include:

- Evaluations of Changes including the safety analysis and identification of accident scenarios and IROFS
- Reviews conducted by the CRB
- Approvals of changes
- Drawings representing the change

- Operating Procedures
- Releases and readiness reviews

The ISA Summary is updated and distributed after the change is released to operate. On an annual basis, per 10CFR70.72(d)(2) & (3), B&W NOG will submit to NRC a brief summary of all changes that do not require pre-approval and the revised ISA Summary.

11.1.5 Assessments

Audits and assessments are described in Chapter 11.5. The Configuration Management Process shall be included as an area of review during these audits and assessments.

11.1.6 Design Reconstitution

The baseline safety basis for the facility was re-verified during the ISA Process. This included facility walk-downs and verification of accuracy of documents referenced by the ISA Summary. The ISA Summary and its supporting documentation represent the existing safety basis and is consistent with the as built configuration for the facility.

11.2 Maintenance

To ensure that each IROFS (primarily engineered features versus administrative controls) remains functionally available and reliable, the site has a procedural program for maintenance as described in 11.2.1, 11.2.2, & 11.2.3. The primary function of the maintenance activities is to assure IROFS are and will perform their intended safety function when needed. In the event of a failure of an IROFS during a scheduled test or during service an investigation shall be conducted according to Chapter 11.6. The results of the investigation shall provide feedback and may warrant modification to the IROFS or the maintenance of the IROFS. Documentation of all maintenance activities shall be maintained.

11.2.1 Surveillance Monitoring and Functional Testing

For all IROFS that have engineered features identified in the ISA Summary, a monitoring or functional testing frequency has been established to assure the IROFS remain functionally available and reliable. This frequency is based on information such as vendor specification, published failure rates, operational experience, and engineering judgement. This surveillance monitoring or testing is described in written procedures or work orders which contain written procedures that have been reviewed and approved according to section 11.4.2. The procedures or work orders contain the following instructions:

- a procedure for executing maintenance that verifies the functionality of the safety control function

- the expected response of the test
- steps to be taken if the test fails including immediate notification of safety management and operations management
- documentation of the test

During surveillance or testing, the system can continue to operate only if the surveillance or test does not impair or degrade the ability of the IROFS to perform its safety function. Otherwise, the system must be shut down. Additional requirements regarding IROFS that protect against Criticality scenarios are described in the Appendix of Chapter 5. Feedback from surveillance is used to establish preventative maintenance frequencies.

11.2.2 Corrective Maintenance

Corrective maintenance is performed in response to in-service failures. This maintenance is conducted according to maintenance procedures. Operations personnel are involved in corrective maintenance notifications. At completion of any corrective maintenance, functional tests, as necessary, shall be conducted to assure the proper function of the IROFS. The functional tests determine that the IROFS is performing properly.

In the event of an in-service failure, the safety of the system is immediately evaluated to determine if the performance requirements of 10CFR70.61 continue to be met. If not, the system is shut down until the IROFS can be returned to service or compensatory measures can be formally implemented.

11.2.3 Preventive Maintenance

For IROFS identified in the ISA Summary, a preventive maintenance frequency has been established to assure IROFS are not used beyond their anticipated life. This maintenance is described in written procedures or work orders containing the following instruction:

- a procedure for executing maintenance
- post maintenance functional tests to assure the IROFS will perform as intended
- documentation of the maintenance

Certain IROFS, however, do not require recurring maintenance because they are not expected to change over time. These controls are typically passive engineered controls such as siphon breaks or dikes with limited height. The need for recurring preventive maintenance is established during the ISA or Change Management System implementation based upon a complete understanding of the process, accident scenarios, operating history, and aspects of the control being credited to assure IROFS are not used beyond their anticipated life.

11.3 Training and Qualification

Training programs shall be established that include; instruction in radiological safety for personnel with access to restricted areas; on-the-job safety instruction for special skills; instruction in nuclear criticality safety; instruction in fire protection, chemicals and hazardous materials; and safety retraining of previously trained employees. OSHA required training, such as, Hazard Communication or Fire Extinguisher is included as part of the annual General Employee Safety Training or through the training of specific groups of employees in such topics as powered industrial truck operation, confined spaces, or ignition sources. A detailed description of the frequency, subject content, training methodology and requirements for radiation protection and nuclear criticality safety training programs is included in Chapters 4 and 5 respectively, of SNM-42. Retraining programs shall include updates and changes in information and required skills as appropriate.

Many IROFS are administrative and rely on the actions of individuals to assure the safety function is properly executed. These IROFS are formally communicated to the operator through procedures or postings as described in Chapter 11.4. Each individual is trained in the proper execution of these functions to assure the IROFS is available when needed.

11.3.1 Effectiveness of Training

One or a combination of the following will verify the effectiveness of training (details are provided in chapters 4 and 5):

- Oral examinations
- Written examinations
- Supervisory observation of employee ability and performance through On-the-Job-Training
- Management observation of the supervisors ability and performance through On-the-Job-Training

11.3.2 Records

Records of training classes will be maintained to show as a minimum:

- Attendees
- Dates of training and retraining
- Outline or script of subject matter
- Test and re-test results

11.4 Procedures

Activities at the site involving licensed material shall be conducted in accordance with written and approved procedures. Personnel shall be trained to perform all operations in strict compliance with procedures, Radiation Work Permits, or postings and not to perform an operation, utilizing licensed material, that is not addressed in a written and approved procedure, RWP, or posting.

Procedures are the fundamental formal mechanism to implement IROFS that are administrative and rely on the actions of individuals. One or more of the procedural systems described below shall be used to implement all administrative IROFS.

11.4.1 Safety Procedures

Activities of the Nuclear Safety & Licensing Section are conducted in accordance with written procedures approved by the Nuclear Safety and Licensing Manager. These procedures may also be reviewed/approved by other section managers, as appropriate, if their safety or safeguards discipline is involved in or affected by the activity covered by the procedure. Procedures shall be reviewed, and revised if appropriate, every 5 years, by the originator. Emergency procedures will be reviewed, and revised if appropriate, every year, by the originator.

11.4.2 Operating Procedures

All procedures that implement IROFS are reviewed and approved by the appropriate safety disciplines. These reviews occur during routine procedure revision and during evaluation of facility changes to assure IROFS have been appropriately implemented.

In addition, operating procedures involving licensed material in radiological controlled areas (unencapsulated radioactive material areas) are generated by the operating departments and submitted to the Nuclear Safety & Licensing Section for review and approval by the appropriate disciplines.

Operating procedures involving licensed material in radiological uncontrolled areas (encapsulated radioactive material areas) are generated and approved by the operating departments. These procedures typically do not include information related to IROFS. IROFS for encapsulated fuel operations are normally included in postings described in Section 11.4.4 below.

Operating procedures are reviewed on a random sampling basis by the Nuclear Safety & Licensing Section and the Environmental & Industrial Safety Section during routine quarterly audits to assure the appropriate implementation of IROFS.

Operating procedures are supplemented by a nuclear criticality safety manual, radiation protection manual, postings, radiation work permits and radiation protection procedures. Procedures shall be reviewed, and revised if appropriate, every 5 years by the originator.

11.4.3 Safety Manuals

11.4.3.1 Nuclear Criticality Safety (NCS) Manual

The NCS Manual is a compilation of Nuclear Criticality Safety procedures that have generic applicability. These manuals are placed at stations located throughout the site.

11.4.3.2 Radiation Protection Manual

The Radiation Protection Manual is a compilation of Radiation Protection procedures that have generic applicability at the site. These manuals are placed at stations located throughout the site.

11.4.3.3 Industrial Health and Safety Manual

The Industrial Health and Safety Manual is a compilation of Industrial Health and Safety procedures that have generic applicability at the site. These manuals are placed at stations located throughout the facility.

11.4.4 Postings

11.4.4.1 Nuclear Criticality Safety Postings

NCS postings shall be developed and posted for operations in which SNM is stored or processed and shall provide the administrative limits to which operators must comply. A sampling of the postings are checked during the quarterly NCS audits.

11.4.4.2 Radiation Protection Postings

Radiation Protection postings shall comply with the minimum requirements specified in 10 CFR 20.1902 and shall be displayed in numbers and locations sufficient to alert personnel of special controls necessary for personnel protection.

11.4.5 Radiation Work Permits (RWP's)

RWP's shall be issued for non-routine activities involving licensed material that are not covered by a written and approved procedure, that requires access to high or very high radiation areas, or that have a high potential for exceeding exposure estimates. RWP's shall provide operators with requirements necessary to ensure radiation, criticality, and industrial (including chemical and fire) safety. RWP's are reviewed and approved by Radiation Protection, Nuclear Material Control, Nuclear Criticality Safety, Industrial Health and Safety, and Area Supervision. All individuals working under an RWP are trained in its requirements.

11.5 Audits and Assessments

Audits and inspections shall be performed to determine that site operations are conducted in compliance with regulatory requirements, license conditions, written procedures, and postings.

11.5.1 Internal Audits and Inspections

11.5.1.1 Nuclear Criticality Safety (NCS) Inspections

NCS inspection of selected site operations, involving SNM, shall be performed weekly by NCS Engineers to determine if activities are being conducted in accordance with nuclear Criticality Safety limits and IROFS. Additionally, Radiation Control Technicians shall perform daily inspections in unencapsulated fuel handling areas that are in operation. Inspections will be performed at least monthly on selected weekends or back shifts when operations are being performed.

11.5.1.2 NCS Audits

NCS audits of selected plant activities involving SNM shall be conducted quarterly. A Nuclear Criticality Safety Engineer shall conduct audits. The entire site, where SNM is processed or stored, shall be audited biannually (twice each year). The purposes of the audits are:

- To determine that site operations are conducted in compliance with the NCS aspects of regulatory requirements, license conditions, operating procedures, and posted limits.
- To determine the adequacy of administrative controls and postings and to verify the use of sound NCS practices.
- To examine equipment and operations to determine that past evaluations remain adequate.
- To examine trends in findings of NCS inspections and the adequacy of corrective actions.
- To assure the Safety Analysis Report is in line with current operations and that IROFS are being appropriately maintained

11.5.1.3 Radiation Protection Inspections

Radiation Protection inspections are performed each working day by the Radiation Control and Health Physics technicians in each on-site controlled area. The purpose of these inspections is to ensure those radiation protection procedures and postings are being followed.

11.5.1.4 Radiation Protection Audits

Radiation Protection audits shall be performed in all permanently established controlled areas by a Health Physicist, quarterly. The purposes of these audits are:

- To assess the adequacy of radiological safety procedures.
- To determine the applicability of current controls.
- To assess the progress made on actions to correct previous audit findings.
- To assure the Safety Analysis Report is in line with current operations and that IROFS are being appropriately maintained

11.5.1.5 Quality Assurance (QA) Audits

QA auditors shall audit Nuclear Criticality Safety and Radiation Protection quarterly. Licensing, including Management Measures, and Emergency Preparedness shall be audited biannually. Reviews of operating and process procedures and equipment are performed as part of these audits to determine that only currently applicable approved procedures and equipment are available to the users. These audits shall be conducted in accordance with a written procedure, to determine compliance with the requirements of SNM-42 and internal procedures.

11.5.1.6 Chemical and Fire Safety Audits

Industrial Health & Safety (IH&S) audits of selected plant activities involving chemicals and fire safety in relation to licensed activities shall be performed by an IH&S Specialist quarterly. The entire site where there are chemical or fire IROFS shall be audited at least annually. The purpose of these audits are:

- To assess the adequacy of chemical safety procedures.
- To assess the progress made on actions to correct previous audit findings.
- To assure the Safety Analysis Report reflects current operational IROFS and that IROFS are being appropriately maintained for fire and chemical safety through a sampling of IROFS.

11.5.2 External Audits and Inspections

11.5.2.1 External Audit of Nuclear Criticality Safety

An audit will be performed by an individual with experience in Nuclear Criticality Safety and not an employee of the site. This external audit shall be performed triennially and will include an assessment of the adequacy and effectiveness of the Nuclear Criticality Safety Program.

11.5.2.2 External Audit of Radiation Protection

An audit shall be performed by an individual with Radiation Protection experience and not an employee of the site. This external audit will be performed triennially and will include an assessment of the adequacy and effectiveness of the Radiation Protection Program.

11.5.3 Reports

11.5.3.1 NCS Audit & Inspection Reports

Summaries of findings and observations from NCS audits and inspections shall be forwarded to the General Manager; the Manager of Environment, Safety, Health & Safeguards; the Manager of Nuclear Safety & Licensing; the Manager of Licensing & Safety Analysis, and the department and section managers of the areas in which the findings or observations were identified. The section manager (or designee) of the area in which the findings or observations were identified shall respond to the findings or observations with immediate and long term corrective actions to prevent a recurrence. The corrective actions shall be entered into the Preventative/Corrective Action System. Corrective actions shall be tracked to completion in the Commitment Tracking System. NCS shall be responsible for determining the adequacy of the corrective action.

11.5.3.2 Radiation Protection Audit & Inspection Reports

Radiation Protection Audit and Inspection Reports, summarizing findings and observations, shall be forwarded to the General Manager; the Manager of Environment, Safety, Health & Safeguards; the Manager of Nuclear Safety & Licensing; the Manager of Licensing & Safety Analysis and the department manager and section manager of the area in which findings or observations were identified. The section manager (or designee) of the area in which the findings or observations were identified shall respond to the findings or observations with immediate and long term corrective actions to prevent a recurrence. The corrective actions shall be entered into the Preventative/Corrective Action System. Corrective actions shall be tracked to completion in the Commitment Tracking System. RP shall be responsible for determining the adequacy of the corrective actions.

11.5.3.3 QA Audit Reports

QA audit reports, including findings and observations shall be distributed to the General Manager; the Manager of Quality Control; the Manager of Environment, Safety, Health & Safeguards; the Manager of Engineering; the Manager of Security; the Manager of Nuclear Safety & Licensing; the Manager of Environmental Protection & Industrial Safety; the Manager of

Quality Engineering; the Manager of Licensing & Safety Analysis; and the manager of the area in which findings and observations were identified. The manager (or designee) of the area where the findings and observations were identified shall respond to the findings or observations with immediate and long term corrective actions to prevent recurrence. The corrective actions shall be entered into the Preventative/Corrective Action System. Corrective actions shall be tracked to completion in the Commitment Tracking System. QA and Safety Managers shall be responsible for determining the adequacy of corrective actions.

11.5.3.4 External NCS Audit Reports

External NCS audit reports shall be distributed to the General Manager; the Manager of Environment, Safety, Health & Safeguards; the Manager of Nuclear Safety & Licensing, and the Manager of Nuclear Criticality Safety. Development and implementation of program improvements shall be the responsibility of the Manager of Nuclear Criticality Safety. All corrective actions shall be tracked to completion in the Commitment Tracking System.

11.5.3.5 External Radiation Protection Audit Reports

External Radiation Protection audit reports shall be distributed to the General Manager; the Manager of Environment, Safety, Health & Safeguards, the Manager of Nuclear Safety & Licensing; and the Manager of Radiation Protection. Development and implementation of program improvements shall be the responsibility of the Manager of Radiation Protection. All corrective actions shall be tracked to completion in the Commitment Tracking System.

11.6 Corrective Action Program

11.6.1 Investigations and Root Cause Determination

Incident investigations are performed at the direction of management in order that an upset condition can be fully understood, root causes determined and corrective actions implemented to prevent recurrence. Investigations using the corrective action system shall be conducted for the following:

- Audit and assessment findings
- Unusual incidents
- Failed or degraded IROFS

For minor infractions, the manager of the affected area shall investigate, record, and report incidents having safety significance. Minor infractions include things like procedure or posting infractions where the cause can be readily determined without assembling a team. For more significant infractions or incidents,

procedures require investigation by a trained team using formal root cause analysis techniques. Managers within the Nuclear Safety & Licensing, and Environmental Protection & Industrial Safety Sections shall review the results of the investigation and advise the appropriate manager regarding actions to be taken as appropriate. As part of a formalized system, issues are reviewed to ensure that timely reports are made as required by NRC regulations contained in 10 CFR.

11.6.2 Corrective Actions

All corrective actions in response to an incident shall be tracked using the division-wide Preventative/Corrective Action and Commitment Tracking system. The manager of the affected area shall be responsible for assuring that actions are completed. The Radiation Protection Manager, Nuclear Criticality Safety Manager, Industrial Health & Safety Manager, Licensing and Safety Analysis Manager or QA Auditors, as appropriate, shall be responsible for verifying that corrective actions have been taken. The site Preventative/Corrective Action System includes information such as the corrective action, person responsible, and date due. Corrective action reports are periodically distributed to ensure timely completion of assigned corrective actions.

11.7 Records Management

This section describes general types of records and how they are managed. It does not list all types of records required by regulation. The fact that a record is not listed in no way excuses the regulatory requirement.

11.7.1 Responsibility for Records Management

The Nuclear Safety & Licensing Section shall maintain the records relative to radiological health and safety and training.

11.7.2 Records Retention Times

In addition to the record retention requirements set forth in Section 4.5, the following types of records shall be retained at the site until the NRC authorizes disposal:

Radiation Protection Procedures
Radioactive Waste Disposal Pursuant to 10CFR20
Nuclear Criticality Safety evaluations, reviews and approvals
Radiation Protection Safety evaluations, reviews and approvals
ISA Summary including the evaluators that provide the basis for the determination that changes do not require NRC approval

The following types of records shall be retained for a period of at least three years:

Change Review Board Actions

Safety Committee Minutes and Actions
Internal Audits and Inspections
Operating Procedure Approval
Reportable Incident Reports
Radioactivity Measuring Instrument Calibration

11.8 Other QA Elements of the Site's Quality System

The site quality system consists of the organizational structure, procedures, processes, and resources needed to implement quality management. This System is based on the ISO 9001 standard (ANSI/ISO/ASQC Q9001-1994) and incorporates all 20 elements of ISO 9001. Figure 1 describes how regulatory requirements are ultimately implemented by the Quality System. Specifically the Quality System Elements are:

1. Management responsibility,
2. Quality System Structure and Documentation (Quality Planning),
3. Contract Review,
4. Design Control,
5. Document Control,
6. Purchasing,
7. Control of Customer-Supplied Property,
8. Product Identification and Traceability,
9. Process Control,
10. Inspection and Testing,
11. Control of Measuring and Test Equipment,
12. Inspection and Test Status,
13. Control of Nonconforming Product,
14. Corrective and Preventive Action,
15. Handling, Storing, Packaging, Preservation and Delivery,
16. Control of Quality Records,
17. Internal Quality Audits,
18. Training,
19. Servicing, and
20. Statistical Technique

The Quality system is implemented by a set of procedures called Quality System Procedures and Quality Work Instructions (QWIs). These QWIs outline quality measures that are applicable to the entire facility, including implementing the requirements of SNM-42. As an example, the Corrective Action Program described in Section 11.6 is implemented through QWIs contained in Section 14 of the Quality System. Operating in parallel with the QWIs are the Safety Manuals described in Section 11.4.3. The QWIs and Safety Manuals contain general administrative requirements for implementation of an effective safety and quality program.

Ultimately, the Quality System includes the implementation of Operating Procedures and Postings as described in Section 11.4 and includes systems for documentation as described in Section 11.7.

Figure 1: Relationship of Regulatory Requirements & the Site Quality System