U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

11.0 MANAGEMENT MEASURES

11.1 PURPOSE OF REVIEW

Management measures are functions, performed by a licensee, generally on a continuing basis, that are applied to items relied on for safety (IROFS), to provide reasonable assurance that the items are available and able to perform their functions, when needed. The phrase "available and reliable," as used in the revised 10 CFR Part 70, means that, based on the analyzed, credible conditions in the ISA, IROFS will perform their intended safety function when needed to prevent accidents or mitigate the consequences of accidents. Management measures will be implemented to provide reasonable assurance of compliance with the performance requirements, considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the items and the measures. The following discussion addresses each of the management measures included in the 10 CFR Part 70 definition of management measures, i.e., configuration management (CM); maintenance; training and qualifications; procedures; audits and assessments; incident investigations; records management; and other QA elements. The degree to which measures are applied to the items may be a function of the item's importance in terms of meeting the performance requirements as evaluated in the ISA.

Applicant's descriptions of management measures should address how the measure is designed, organized, and conducted in sufficient detail that the reviewer can understand the capability of the measure to be implemented at the facility. If a "graded" application of a particular management measure is to be used for IROFS of differing importance to risk management, then the variations should be described.

In order to assist members of the public outside the NRC in understanding the level of detail considered adequate to provide sufficient information for staff review, staff has provided an example in an Appendix B to this SRP. The example explains what an applicant should consider in responding to each sentence of a paragraph from this SRP (Section 11.4.3.2 Maintenance, item 1, Surveillance/Monitoring).

The purpose of this review is to enable the staff to conclude, with reasonable assurance, that the management measures applied to IROFS, as documented in the ISA Summary, provide reasonable assurance that the items will be available and able to perform their functions, when needed, consistent with the performance requirements of 10 CFR 70.61. If a graded approach is used, the review should also determine whether the measures are applied to the IROFS commensurate with the IROFS' importance to safety.

11.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary:

Configuration Management: Primary ISA Reviewer, QA and Records Management Reviewers
Maintenance: Criticality, Chemical, Fire, Radiation Protection, and Environmental Reviewers
Training and Qualification: Training Specialist, QA Reviewer
Procedures: Radiation Protection, Criticality and Fire Protection Engineers, Fuel Cycle Facility Inspector
Audits and Assessments: QA Reviewer
Incident Investigations: Inspection Specialist
Records Management: QA Reviewer
QA: Quality Assurance Engineer

Supporting: Technical Discipline Engineers, Fuel Cycle Facility Inspectors, Resident Inspectors

11.3 AREAS OF REVIEW

11.3.1 Configuration Management (CM)

This review should provide reasonable assurance that the applicant has committed to develop and implement a CM function that is consistent with the requirements of 10 CFR 70.72(a). The review should determine, with reasonable assurance, that the applicant has described and committed to a CM function that assures consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. The review should also determine that the applicant's 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, as identified and described in the ISA. The review should assure that the CM function is adequately coordinated and integrated with the other management measures.

The NRC staff should review the applicant's descriptions and commitments for CM, including: descriptions of the organizational structure responsible for CM activities; descriptions of the process, procedures, and documentation required by the applicant for modifying the site; and descriptions of the various levels of CM to be applied to IROFS designated in the ISA Summary. The staff review should focus on the applicant's CM measures that provide reasonable assurance of the disciplined documentation of: engineering, installation, and operation of modifications; the training and qualification of affected staff; the revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; post-modification testing; and readiness review.

The NRC staff should review the following:

1. CM Policy

   The review should cover the applicant's description of overall CM functions, including at least the following topics: (a) the scope of the IROFS to be included in the CM function; (b) objectives of each CM activity; (c) a description of each CM activity; and (d) the organizational structure and staffing interfaces.

   The review should examine the applicant's establishment of a CM policy applicable to all operations, in accordance with 10 CFR 70.72.

2. Design Requirements

   The reviewer should examine the applicant's descriptions concerning how design requirements and associated design bases have been established and are maintained. The applicant's CM controls on the design requirements and the ISA Summary should be evaluated.

3. Document Control

   The reviewer should examine the applicant's description of its methods used to establish and control documents within the CM function.

4. Change Control

   The review should examine the applicant's commitments to provide reasonable assurance that the CM function maintains consistency among the design requirements, the physical configuration, and the facility documentation, in accordance with 10 CFR 70.72, "Facility changes and change process."

5. Assessments

   The review should examine the applicant's commitments to conduct initial and periodic assessments of the CM function, to determine the function's effectiveness, and to correct deficiencies, consistent with the acceptance criteria for "Audits and Assessments."

6. Design Reconstitution [Existing Facilities Only]

   The review should examine the applicant's discussion of design reconstitution of the current design basis that has been done for the purpose of the application, and how that reconstitution was translated into a fixed baseline design basis from which subsequent changes will be measured.

11.3.2 Maintenance

The NRC staff will evaluate the applicant's description of its maintenance function. The reviewer will examine the applicant's commitments to inspect, calibrate, test, and maintain IROFS to a level commensurate with the items' importance to risk reduction, to provide reasonable assurance of their ability to perform their safety functions when required. The applicant identifies these IROFS in the ISA summary. The staff will review the applicant's description of how each of the following functions is implemented within the site organization. Note that not every aspect of each of the four maintenance functions is necessarily required; the applicant is expected to identify the IROFS in the ISA Summary and would justify assigning differing degrees of maintenance to individual IROFS, based on the item's contribution to the reduction of risk.

1. Corrective maintenance

   a. A commitment to promptly perform corrective actions to remediate IROFS unacceptable performance deficiencies; and

b. A description of the approach and methods for planning and implementing repairs to IROFS with the objective of eliminating or minimizing the recurrence of unacceptable performance deficiencies.

2. Preventive maintenance (PM)

   a. A commitment to conduct preplanned and scheduled periodic refurbishing and/or overhauls of IROFS; and

   b. A description of PM activities including, for example, instrumentation calibration and testing, and the methods used to establish the frequency of PM activities.

3. Surveillance/monitoring

   a. A commitment to design and implement a program to survey and monitor the performance of IROFS; and

   b. A description of the components of the surveillance and monitoring program including methods used to establish the frequency of such inspections for IROFS having different degrees of safety importance.

4. Functional testing

   a. A commitment to perform the appropriate post-maintenance functional testing to provide reasonable assurance that the maintenance activity did not adversely affect the reliability of the IROFS; and

   b. A general description of functional testing, and the test results documentation.

11.3.3 Training and Qualifications

10 CFR Part 70 requires that personnel who perform activities relied on for safety be trained and tested, as necessary to provide reasonable assurance that they understand, recognize the importance of, and are qualified to perform these activities in a manner that adequately protects: (1) the health and safety of the public and workers; and (2) the environment. As appropriate for their authority and responsibilities these personnel should have the knowledge and skills necessary to design, operate, and maintain the facility in a safe manner. Therefore, the training, testing, and qualification of these personnel should be described in the application and should be reviewed by the staff. This should include the training, testing, and qualification of all personnel who perform activities relied on for safety. The review should examine the applicant's training and qualifications based on the adequacy to fulfill the objectives for the training identified by the licensee, especially when human factors are relied on for safety. The review of the training and qualification should address the following training areas:

1. Organization and management of the training function;
2. Analysis and identification of functional areas requiring training;
3. Position training requirements
4. Development of the basis for training, including objectives;
5. Organization of instruction, using lesson plans and other training guides;
6. Evaluation of trainee learning;

7. Conduct of on-the-job training;
8. Evaluation of training effectiveness;
9. Personnel qualification; and
10. Applicant's provisions for continuing assurance, including the needs for retraining or reevaluation of qualification.

11.3.4 Procedures

The review should examine the applicant's process for the preparation, use, and management control of written procedures. This should include the basic elements of identification; development; verification; review and comment resolution; approval; validation; issuance; change control; and periodic review. The applicant should prepare two general types of procedures for use at the facility:

1. Procedures used to directly control process operations, commonly called "operating procedures." These are procedures for workstation operators and should include directions for normal operations as well as off-normal events caused by human error or failure of an IROFS. Procedures of this type include required actions to provide reasonable assurance of nuclear criticality safety; chemical safety; fire protection; emergency planning; and environmental protection; and,

2. Procedures used for activities that support the process operations, which are commonly referred to as "management control procedures." These are procedures used to manage the conduct of activities such as CM; radiation safety; maintenance; QA; training and qualification; audits and assessments; incident investigations; record-keeping; and reporting.

The actual operating procedures are not part of the license and would not normally be reviewed for technical adequacy for low-risk processes, since this aspect is addressed by the inspection function. For new licenses or processes, especially those that involve high-risk operations, such as some highly enriched uranium liquid processes or some mixed-oxide processes, the licensing review may include a site visit, to make an adequate safety determination, at which time some procedures may be reviewed.

The NRC staff should review the commitments in the application to provide reasonable assurance that the applicant's program adequately addresses the following:

1. The method for identification of the procedures that are needed plant-wide. The ISA Summary identifies IROFS where human actions are important. Procedures should be provided for all necessary steps or operations that are conducted at the facility. Procedures should be provided for every element of management control that is discussed in the SRP sections;

2. Essential elements that are generic to all procedures including: criticality; chemical process and fire safety; warning notes; reminders or pertinent information regarding specific hazards or concerns which include station limits; Materials Safety Data Sheet availability; special precautions; radiation and explosive hazards; and special personal protective equipment;

3. The method for creating and controlling procedures within plant management control systems. This includes how procedures are managed within the plant CM function;

4. Method for verifying and validating procedures before use. During procedure development, workers and operators review procedures to provide assurance that they are usable and accurate.

5. The method and schedule for periodically reverifying and revalidating procedures; and

6. The method for ensuring that current procedures are available to personnel and that personnel are qualified to use the latest procedures.

11.3.5 Audits and Assessments

The applicant should describe a system of audits and assessments that consists of two distinct levels of activities: an audit activity structured to monitor compliance with regulatory requirements and license commitments, and an assessment activity oriented to determining the effectiveness of the activities in achieving applicant-specified objectives that provide reasonable assurance of the continued availability and reliability of IROFS. An applicant may describe a “corrective actions program” which includes the functions of both audits and assessment and incident investigations (see following section 11.3.6). This approach is acceptable and the reviewer should, in that case, review applicant’s description and commitments with regard to the acceptance criteria in this SRP chapter for both audits and assessments and incident investigations.

The reviewer should examine the applicant's presentation with respect to:

1. The commitments to audit and assessment activities;

2. The use of qualified and independent audit and assessment personnel;

1. The general structure of typical audits and assessments;

2. The facility procedures to be used to direct and control the audit and assessment activities;

3. The planned use of the results of the audit and assessment activities;

4. The documentation to record and distribute the findings and recommendations of these audits and assessments; and

5. The planning and implementation of corrective actions based on the findings and recommendations.

11.3.6 Incident Investigations

The NRC staff should review the applicant's policy, procedures, and management structure for investigating abnormal events and completing appropriate corrective actions. The review should include the provisions for establishing investigating teams, the methods for determining root causes, and procedures for tracking and completing corrective actions and for documenting the process for the purpose of applying the "lessons learned" to other operations. An applicant may describe a “corrective actions program” which includes the functions of both audits and assessment and incident investigations. This approach is acceptable and the

reviewer should, in that case, review applicant's description and commitments with regard to the acceptance criteria in this SRP chapter for both audits and assessments and incident investigations.

11.3.7 Records Management

The requirements for the management of records vary according to the nature of the facility and the hazards and risks posed by it. The staff should review areas related to the handling and storing of health and safety records and the records generated or needed in the design, construction, operation, and decommissioning phases of the facility. The staff should review the following:

1. The process whereby records - training records; dosimetry records; effluents records; records of classified information; records concerning facility IROFS; and records of their failure - are created; selected; verified; categorized; indexed; inventoried; protected; stored; maintained; distributed; deleted; or preserved. The review should provide reasonable assurance that the records management function is adequately coordinated and integrated with other management measures.

2. The handling and control of various kinds of records and the methods of recording media that comprise the records (including contaminated and classified records); and

3. The physical characteristics of the records storage area(s) with respect to the preservation and protection of the records for their designated lifetimes.

11.3.8 Other QA Elements

The application must address the 10 CFR Part 70 requirements with respect to management measures, to include other QA elements. 10 CFR 70.62(d) requires that each applicant or licensee shall establish management measures to provide continuing assurance of compliance with the performance requirements of 10 CFR 70.61.

The review should determine that a complete description of the applicant's application of QA elements to IROFS is included in the application. The review objective is to obtain reasonable assurance of the implementation of accepted QA principles in the design, construction, operation, maintenance, and modification phases of a facility's life. Fundamental to this effort is the applicant's application of QA elements to the identified IROFS resulting from the ISA and identified in the ISA summary. QA elements would also be applicable, as appropriate, to the hazards analysis process in the applicant's ISA.

The application defines the QA elements and the levels to be applied to IROFS identified by the ISA (SRP Section 3.0). Further, the relationship between QA and other management measures should be described. The applicant determines the relative risk, or relative safety importance, of the various IROFS, to determine the QA elements and their levels to be applied to individual IROFS.

The review should recognize that facility safety may not be the only area requiring QA elements at a fuel cycle facility. The applicant's customers and the NRC, under 10 CFR Part 50, may impose product-related QA criteria. The focus of the review of QA measures per this SRP is

limited to ensuring the safety of workers and the public, and protecting the environment (i.e., in relation to the performance requirements of 10 CFR 70.61). The review should provide reasonable assurance that the QA function is adequately coordinated and integrated with other management measures.

Since many QA elements may be described in other sections of the application, the reviewer should determine the applicant's commitment to overall QA, the selection of quality criteria and quality level, and the proposed method for implementation. The applicant may reference other areas of the application that present information relevant to QA. The reviewer should focus on the management measures applied to criticality, containment of licensed materials, personnel protection, and environmental safety. With the application of graded QA and quality levels commensurate with the risk involved should parallel the same risk levels established for maintenance and other management measures.

11.4 ACCEPTANCE CRITERIA

The reviewer should find the applicant's information acceptable if it provides reasonable assurance that the following acceptance criteria are satisfactorily addressed.

11.4.1 Regulatory Requirements

The requirements for fuel cycle facility management measures are specified in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," as revised.

10 CFR 70.4 states that management measures include CM; maintenance; training and qualifications; procedures; audits and assessments; incident investigations; records management; and other QA elements.

10 CFR 70.62(a)(3) states that failure records must be kept for all IROFS failures, describes required data to be reported, and sets time requirements for updating the records.

10 CFR 70.62(d) requires an applicant to establish management measures, for application to engineered and administrative controls and control systems that are identified as IROFS, pursuant to 10 CFR 70.61(e) so they are available and reliable to perform their functions when needed.

A regulation specifically applicable to personnel training and qualification is 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," specifically Section 19.12, "Instructions to Workers."

The regulatory requirement for procedures that protect health and minimize danger to life is specified in 10 CFR 70.22(a)(8).

Facility change processes are required to conform with 10 CFR 70.72.

Incident investigation and reporting are required by 10 CFR 70.74(a) and (b).

11.4.2 Regulatory Guidance

1. American Society of Mechanical Engineers standard, "Quality Assurance Requirements for Nuclear Facility Applications," ANSI/ASME NQA -1, 1994

2. American National Standards Institute standards for quality management, ANSI/ISO/ASQ 9000 series;

3. International Atomic Energy Agency Safety Guide, "Establishing and Implementing a Quality Assurance Program," Safety Guide 50-SG-Q1, 1995;

4. U.S. Department of Energy, Draft, "Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C, September 1997;

5. U.S. Nuclear Regulatory Commission, "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities", Federal Register 54 (No. 53), 11590–11598, March 21, 1989.

6. U.S. Nuclear Regulatory Commission, "Training Review Criteria and Procedures," NUREG-1220, Revision 1, January 1993.

11.4.3 Regulatory Acceptance Criteria

11.4.3.1 Configuration Management (CM)

1. CM Policy

   The applicant's description of overall CM functions describes at least the following topics: (a) the scope of the IROFS and management measures to be included in the CM function (coordinate with the Section 3, ISA, reviewer for the application), (b) the objectives of each CM activity, (c) a description of each CM activity, and (d) the organizational structure and staffing interfaces. The functional interfaces with maintenance and training and qualification are of particular importance and should be addressed individually. The IROFS under CM should include all those IROFS as defined by the ISA Summary.

   An important element of an applicant's overall CM policy is the establishment of a baseline CM policy applicable to all new facilities or new processes at existing facilities, in accordance with 10 CFR 70.64. That baseline initially includes all the CM functions described in this SRP Chapter. After an ISA is completed and IROFS are identified that may not be associated with high-risk accident sequences, as defined by the ISA Summary or the ISA, the applicant may choose to reduce or eliminate certain features of the CM function as applied to those lesser-risk design or operational features. In that case, the applicant then, in its description of CM policy, defines the specific attributes of a reduced level or levels of CM that would be applied to selected IROFS, and in the ISA identifies those items that will be assigned the lesser category of CM.

   The design process leading to drawings and other statements of requirements proceeds logically from the design basis. IROFS to be listed under CM are clearly defined in the ISA

Summary, along with the assignment of any grades or quality levels. The applicant should have indicated in the ISA Summary what level of CM attributes is applied to a particular item. However, in the ISA Summary, this indication may only consist of an index or category designation. The definition of the multiple CM levels, if used, should be in the CM description within the application.

2. Design Requirements

The applicant describes how design requirements and associated design bases are established and are maintained through control of the design process. Technical management review and approval functions are described.

3. Document Control

The applicant describes an acceptable method to establish and control documents within the CM function, including cataloging the document data base, the information content of the document data base, maintaining and distributing documents, document retention policies, and document retrieval policies. The applicant describes how CM will capture documents that are relevant and relied on for safety. This includes design requirements; the ISA; as-built drawings; specifications; all procedures that are IROFS; procedures involving training; QA; maintenance; audits and assessments; emergency operating procedures; emergency response plans; system modification documents; assessment reports; and others that the applicant may deem part of CM. The document database is used to control documents and track document change status.

4. Change Control

The applicant describes how the CM function will maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. The applicant commits to an acceptable process for identifying and authorizing proposed changes; for performing appropriate technical, management, and safety reviews of proposed changes in IROFS; for tracking and implementing changes; and for documenting changes (including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and QA). The applicant also describes an acceptable process, within the CM function, for providing reasonable assurance that the ISA is systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety-basis changes are properly modified, authoritatively approved, and made available to personnel. When a change is made in accordance with 10 CFR 70.72, the affected on-site documentation must be made within five working days [10 CFR 70.72(e) states “promptly”].

5. Assessments

The applicant confirms that initial and periodic assessments of the CM function are conducted to determine the program's effectiveness and to correct deficiencies. Both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function. All assessments and follow-ups are documented. These reports can provide a basis for future changes. The applicant indicates that such assessments are systematically planned and conducted in accordance

with an overall facility audit and assessment function (see sections in Chapter 11 for details on audits and assessments).

6. Design Reconstitution [Existing Facilities Only]

   The applicant describes whatever design reconstitution has been done for the purpose of the application. Because this information may duplicate the plant design bases information described elsewhere to support the ISA, this information may be included by reference to other parts of the application. The applicant has available current design bases, including design requirements, supporting analyses, and documentation supporting all IROFS. A verification process, including walk-downs, is complete and has verified that the configuration is consistent with as-built facility documentation.

11.4.3.2 Maintenance

The reviewers should find the applicant's submittal acceptable if the application includes the following:

1. Surveillance / monitoring

   For IROFS identified in the ISA summary, the applicant describes the surveillance function and its commitment to the organization and conduct of surveillance at a specified frequency. The surveillance activity should support the determination of performance trends for IROFS, thus providing data useful in determining PM frequencies. Applicant describes how results from incident investigations, review of the failure log required by 10 CFR 70.62(a)(3), and identified root causes, are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Records showing the current surveillance schedule, performance criteria, and test results for all IROFS are maintained by the applicant. For surveillance tests that can only be done while IROFS are out of service, proper compensatory measures are prescribed for the continued normal operation of a process.

2. Corrective maintenance

   Applicant provides the documented approach used to perform corrective actions or repairs on IROFS. The maintenance function provides a planned, systematic, integrated, and controlled approach for the repair and replacement activities associated with identified unacceptable performance deficiencies of IROFS. After conducting corrective maintenance and before returning an IROFS to operational status, if necessary, a functional test is conducted to provide reasonable assurance that the safety control performs as designed and provides the safety action expected.

3. PM

   Applicant provides a description of the PM function that demonstrates a commitment to conduct preplanned and scheduled periodic refurbishing, or partial or complete overhaul, for the purpose of ensuring that unanticipated loss of IROFS do not occur. This activity includes using the results of the surveillance component of maintenance and the failure log required by 70.62(a)(3). Instrumentation calibration and testing are

addressed by the applicant as part of this component. The applicant describes how the function will be designed to assure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of IROFS because of monitoring or PM. After conducting PM and before returning a safety control to operational status, if necessary, a functional test is conducted to ensure that an IROFS performs as designed and provides the safety action expected. The methodology or basis used to determine PM frequency is described. Applicant describes how results from incident investigations and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Feedback from PM, corrective maintenance, and incident investigations is used as appropriate to modify frequency or scope of the PM activity. A rationale for deviation from industry standards or from vendor recommendations for PM is provided. Records showing the PM schedule, and results, for all IROFS subject to this maintenance component, are maintained by the applicant.

4. Functional testing

Applicant includes a general description of the methods used and the commitment to perform functional testing, as needed, of IROFS, after PM or corrective maintenance. These tests should be conducted using applicant-approved procedures and should include compensatory measures while the test is being conducted. Applicant designs the functional test to include all operational aspects of the IROFS that are important to safety.

For illustrative purposes only, the following scenario is provided:

A level controller, identified as an IROFS, is used to actuate a three-way valve and divert flow to an alternate tank. The level monitor sending unit and the valve, power supplies, utility services, and any corresponding local or control room displays should be tested at the same time during the functional test. The objective should be to simulate actual upset conditions and demonstrate that the IROFS is available and reliable and will function in the field as intended.

As necessary, during start-up of new process equipment, functional tests are conducted, documented, and maintained, for NRC review. Records showing the functional test schedule, and results, for all IROFS subject to this maintenance component, are maintained by the applicant.

Administrative controls are often identified as IROFS. The applicant should provide a general discussion about how these IROFS are assured to be available and reliable to perform their intended safety function over extended periods of operation. Specific management measures and how they are applied should be described.

A general acceptance criterion applicable to all maintenance functions is an adequate description of work-control methods. Listed below are methods or practices that should be applied to the corrective, preventive and functional test maintenance elements, and for which the applicant should commit to prepare written procedures. These include, as applicable: a) authorized work instructions with detailed steps and a reminder of the importance of the IROFS identified in the ISA summary; b) parts lists; c) as-built or redlined drawings; d) a notification step to the operations function before conducting repairs and removing an IROFS from service;

e) radiation work permits; f) replacement with like-kind parts and the control of new or replacement parts to ensure compliance with 10 CFR Part 21; g) compensatory measures while performing work on IROFS; h) procedural control of removal of components from service for maintenance and for return to service; i) ensuring safe operations during the removal of IROFS from service; and j) notification to operations personnel that repairs have been completed. Written procedures for the performance of maintenance include steps a) through j). The details of maintenance procedure acceptance criteria are addressed in Section 11.4.3.2 of this SRP. All work requests and maintenance procedures include technical and safety discipline reviews and approval.

As applicable, contractors that work on or near IROFS identified in the ISA Summary should be required, by the applicant, to follow the same maintenance guidelines described for the corrective, preventive, functional, or surveillance/monitoring activities listed above for the maintenance function.

The four maintenance elements described above are covered by elements of the management measures discussed in SRP Section 11.0. The applicant should include a discussion of or provide references to how the maintenance function uses, interfaces with, or is linked to the various management measures. As an example, since maintenance workers are trained and qualified to perform their duties, a description of the link between maintenance and the training and qualification function should be described.

11.4.3.3 Training and Qualification

The applicant's submittal regarding personnel training and qualification should be acceptable if it satisfies the following criteria. In addition to the regulatory acceptance criteria given below, SRP section 4.4.5.3 provides specific criteria for training and qualification for radiation safety personnel. Similarly, some of the information specified below may be found in other sections of the SRP and incorporated by reference.

1. Organization and Management of Training - The organization and management of training are acceptable if the design, operation, and maintenance of the facility are organized, staffed, and managed to facilitate planning, directing, evaluating, and controlling a training process that fulfills the objectives for the training as identified by the licensee, especially where human factors are relied on for safety. Formal training should be provided for each position or activity for which the required performance is relied on for safety. Training may be either or both classroom or on-the-job training. The application should state what training will be conducted and which personnel will be provided with this training.

The following commitments should be in the application regarding organization and management of training:

1. Line management is responsible for the content and effective conduct of the training.
2. The job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training is clearly defined.
3. Performance-based training is used as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.
4. Procedures are documented and implemented to provide reasonable assurance that all phases of training are conducted reliably and consistently.

5. Training documents are linked to the CM system to provide reasonable assurance that design changes and modification are accounted for in the training.
6. Exemptions from training are granted to trainees and incumbents only when justified, documented, and approved by management.
7. Both programmatic and individual training records are maintained. These records, support management information needs and provide required data on each individual's training, job performance, and qualification.

2. Analysis and Identification of Activities Requiring Training - analysis and identification of activities requiring training is acceptable if the activities required for competent and safe job performance are identified, documented, and addressed by the training.

Design, construction, operations, training, and other subject matter experts, as appropriate, should conduct an analysis to identify activities requiring training. The activities treated in this manner should include - as a minimum - those for managing, supervising, performing, and verifying the activities relied on for safety specified in the ISA Summary as preventing or mitigating accident sequences. Each activity selected for training (initial or continuing) from the facility-specific activities should be matrixed to supporting procedures and training materials. The facility-specific activities selected for training and the comparison with training materials should be reviewed on an established schedule and updated as necessitated by changes in procedures, facility systems/equipment, or job scope.

3. Position Training Requirements - position training requirements are acceptable if minimum requirements for positions are specified for candidates whose activities are relied on for safety or who perform actions that prevent/mitigate accident sequences described in the ISA Summary. Trainees should meet entry-level criteria defined for the position, including minimum educational, technical, experience, and physical fitness (if necessary) requirements.

4. Development of the Basis for Training Including Objectives - The development of the basis for training including the objectives is acceptable if the basis identifies training content, defines satisfactory trainee performance and identifies objectives from the analysis of activiesand performance requirements. Objectives should state 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 on completion of the training activity.

5. Organization of Instruction Using Lesson Plans and Other Training Guides - Lesson plans and other training guides should provide guidance to assure the consistent conduct of training activities, and should be based on required learning objectives derived from specific job performance requirements. Plans/guides should be used for in-class training and on-the-job training and should include standards for evaluating acceptable trainee performance. Review and approval requirements should be established for all plans/guides and other training materials before their issue and use.

6. Evaluation of Trainee Accomplishment - The evaluation of trainee accomplishment is acceptable if trainees are evaluated periodically during training to determine their progress toward full capability to perform the job requirements and, at the completion of training, to determine their capability to perform the job requirements.

7. Conduct of On-the-Job Training - The conduct of on-the-job training is acceptable if on-the-job training used for activities required by the ISA are fully described. On-the-job training

should be conducted using well-organized and current training materials. On-the-job training should be conducted by designated personnel who are competent in the program standards and methods of conducting the training. Completion of on-the-job training should be by actual task performance. When the actual task cannot be performed and is therefore "walked-down," the conditions of task performance, references, tools, and equipment should reflect the actual task to the extent possible.

8. Evaluation of Training Effectiveness - An evaluation of training effectiveness and its relation to job performance is acceptable if it provides reasonable assurance that the training conveys all required skills and knowledge and is used to revise the training, where necessary, based on the performance of trained personnel in the job setting. A comprehensive evaluation of individual training should be conducted periodically by qualified individuals to identify strengths and weaknesses. Feedback from trainee performance during training and from former trainees and their supervisors should be used to evaluate and refine the training. Change actions (for example procedure changes, equipment changes, facility modifications) should be monitored and evaluated for their impact on the development or modification of initial and continuing training and should be incorporated in a timely manner. This should be accomplished with document control through the CM function. Improvements and changes to initial and continuing training should be initiated, evaluated, tracked, and incorporated to correct training deficiencies and performance problems.

9. Personnel Qualification - Commitments should be provided regarding personnel minimum qualifications for personnel required to meet NRC regulations Minimum qualifications should be commensurate with the assigned functional responsibility and authority of the respective personnel. Such commitments should be in the application regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel, and other staff required to meet NRC regulations:

1. Managers should have a minimum of a B.S./B.A. or equivalent. Each manager should have either management experience or technical experience in facilities similar to the facility identified in the application.
2. Supervisors should have at least the qualifications required of personnel being supervised, plus, either one additional year of experience supervising the technical area at a similar facility, or, completion of a supervisor training course.
3. Technical professional staff identified in the ISA Summary whose actions or judgments are critical to satisfy the performance requirements identified in 10 CFR Part 70 (i.e. related to an IROFS) should have a B.S. in the appropriate technical field and 3 years of experience. Other technical professional staff should have a B.S. in the appropriate technical field and one year of experience.
4. Construction personnel, plant operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations should have completed the applicant's training process or have equivalent experience or training.
5. Candidates for process operators should be required to meet minimum qualifications described in the application. Candidates for job functions other than process operators should also be required to meet minimum qualifications, but these minimum qualifications need not be described in the application.

10. Applicant's Provisions for Continuing Assurance - The applicant's provisions for continuing assurance of personnel training and qualification are acceptable if the submittal addresses periodic requalification of personnel, as necessary, by training and/or testing, to provide

reasonable assurance that they continue to understand, recognize the importance of, and are qualified to perform their activities that are relied on for safety.

11.4.3.4 Procedures Development and Implementation

The reviewer should determine that the applicant's process for developing and implementing procedures is acceptable if it satisfies the following:

1. Procedures are written or planned for the operation of IROFS and for all management measures supporting those controls.

2. Operating procedures contain the following elements: (a) purpose of the activity; (b) regulations, polices, and guidelines governing the procedure; (c) type of procedure; (d) steps for each operating process phase; (e) initial start-up; (f) normal operations; (g) temporary operations; (h) emergency shutdown; (I) emergency operations; (j) normal shutdown; (k) start-up following an emergency or extended downtime; (l) hazards and safety considerations; (m) operating limits; (n) precautions necessary to prevent exposure to hazardous chemicals (resulting from operations with SNM) or to licensed SNM; (o) measures to be taken if contact or exposure occurs; (p) IROFS associated with the process and their functions; and (q) the time frame for which the procedure is valid. It is particularly important that safety limits and IROFS (such as mass limits, moderator exclusion, independent sampling requirements, etc.) be clearly identified as such in the procedure for the operators.

3. Procedures reflect the important elements of the functions described in the applicable chapters of this SRP. Procedures exist to direct the following activities: a) design; b) CM; c) procurement; d) construction; e) radiation safety; f) maintenance; g) QA elements; h) training and qualification; i) audits and assessments; j) incident investigations; k) records management; l) criticality safety; m) fire safety; n) chemical process safety; and o) reporting requirements.

4. The applicant describes the method for identifying, developing, approving, implementing, and controlling operating procedures. Identifying needed procedures includes consideration of ISA results. The method includes, as a minimum, that: (a) operating limits and IROFS are specified in the procedure; (b) procedures include required actions for off-normal conditions of operation, as well as normal operations; (c) if needed, safety checkpoints are identified at appropriate steps in the procedure; (d) procedures are validated through field tests; (e) procedures are approved by management personnel responsible and accountable for the operation; (f) a mechanism is specified for revising and reissuing procedures in a controlled manner; (g) the QA elements and CM functions at the plant provide reasonable assurance that current procedures are available and used at all work locations; and (h) the plant training program trains the required persons in the use of the latest procedures available.

5. The applicant includes the following commitment regarding procedure adherence: “Activities involving licensed special nuclear material and/or IROFS will be conducted in accordance with approved procedures.”

6. The applicant describes the types of procedures used during facility operation. These will typically include management control, operating, maintenance, and emergency

procedures. The applicant provides information regarding the procedure categories used at the facility. The applicant develops procedures for site-wide safe work practices to provide for the control of processes and operations with licensed SNM and/or IROFS and/or hazardous chemicals produced from licensed materials. These safe work practices apply to workers, visitors, contractors, and vendors. An acceptable identification discussion clearly states areas for which a procedure is required. Procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA ISA Summary. The applicant provides a listing (in an appendix) of the types of activities that are covered by written procedures. The listing includes the topics of administrative procedures; system procedures that address start-up, operation, and shutdown; abnormal operation/alarm response; maintenance activities that address system repair, calibration, inspection, and testing; and emergency procedures. Appendix A to this chapter provides an acceptable listing of the items to be included under each topic.

7. Applicant reviews procedures after unusual incidents, such as an accident, unexpected transient, significant operator error, or equipment malfunction, or after any modification to a system, and revises procedures as needed.

8. Applicant ensures technical accuracy of procedures and that they can be performed as written. The discussion identifies who is responsible for verification. The verification process provides reasonable assurance that the technical information is included and correct, including formulas, set points, and acceptance criteria, and includes either a walk-down of the procedure in the field, or a table-top walk-through. The review process includes technical, cross-discipline reviews by affected organizations. This process includes both new procedures and procedure changes. The review provides reasonable assurance that the operating limits and IROFS identified in the ISA Summary are specified in the procedures and that QA requirements are identified and included in operating procedures. The applicant describes who can approve procedures and includes the approval level for each procedure type. At a minimum, responsible management, along with the safety disciplines, approves new procedures and changes to existing procedures.

9. Documents are distributed in accordance with applicable distribution lists. A process is used to limit the use of outdated procedures. Copies are available to appropriate personnel. Issuance and distribution of procedures are documented and refer to the Records Management function.

10. The applicant has formal requirements governing temporary changes. Temporary changes do not involve a change to the ISA. The review and approval process is documented. Temporary procedures may be issued only when permanent procedures do not exist to: a) direct operations during testing, maintenance, and modifications; b) provide guidance in unusual situations not within the scope of permanent procedures; and, c) provide assurance of orderly and uniform operations for short periods when the plant, a system, or component of a system 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. The discussion includes establishment of a timeframe for use of the temporary procedure and includes the same level of review and approval as that for permanent procedures.

11. Maintenance procedures involving IROFS commit to the topics listed below for corrective, preventive, functional testing after maintenance, and surveillance maintenance activities:

    a. Pre-maintenance activity requires reviews of the work to be performed, including procedure reviews for accuracy and completeness;

    b. Steps that require notification of all affected parties (operators and supervisors) before performing work and on completion of maintenance work. The discussion includes potential degradation of IROFS during the planned maintenance;

    c. Control of work by comprehensive procedures to be followed by maintenance technicians. Maintenance procedures are reviewed by the various safety disciplines including criticality, fire, radiation, industrial, and chemical process safety. The procedures describe, as a minimum the following:

        i. Qualifications of personnel authorized to perform the maintenance or surveillance;

        ii. Controls on and specification of any replacement components or materials to be used (this should be controlled by the CM function, to ensure like-kind replacement and adherence to 10 CFR Part 21;

        iii. Post-maintenance testing to verify operability of the equipment;

        iv. Tracking and records management of maintenance activities;

        v. Safe work practices (e.g., lockout/tagout; confined space entry; moderation control or exclusion area; radiation or hot work permits; and criticality, fire, chemical, and environmental issues).

12. Applicant conducts periodic reviews of procedures to assure their continued accuracy and usefulness and establishes the timeframe for reviews of the various types of procedures. At a minimum all operating procedures are reviewed every 5 years and emergency procedures are reviewed every year. The applicant describes the use and control of procedures. Provisions allow for operations to stop and place the process in a safe condition if a step of a procedure cannot be performed as written. Guidance identifies the manner in which procedures are to be implemented. Routine procedural actions that are frequently repeated might not require the procedure to be present. Procedures for complex jobs or dealing with numerous sequences where memory cannot be trusted may require valve alignment check sheets, approved operator aids, or in-hand procedures that are referenced directly, when the job is conducted.

11.4.3.5 Audits and Assessments

The NRC reviewers should find the applicant's submittal regarding audits and assessments provides reasonable assurance that the regulatory review criteria below are adequately addressed and satisfied.

1. The applicant should describe policy directives covering the audit and assessment function (i.e., at a minimum, the activities to be audited; audit frequency; guidance in conducting the

audit or assessment; assigned responsibilities for each phase of the work; and procedures for recording the results and recommending actions to be taken).

2. The applicant has committed to conduct internal audits and independent assessments of activities significant to plant safety and environmental protection;

3. Audits will be conducted to verify that operations are being conducted in accordance with regulatory requirements and commitments in the license application;

4. Independent assessments will be conducted by off-site groups or individuals not involved in the licensed activity, to verify that the health, safety, and environmental compliance functions are effectively achieving their designed purposes;

5. Audits and assessments will be conducted for the areas of radiation safety; nuclear criticality safety; chemical safety; fire safety; environmental protection; emergency management; QA; CM; maintenance; training and qualification; procedures; incident investigation; and records management; and

6. Qualified personnel without direct responsibility for the function and area being audited or assessed will be used. The staff positions and committees responsible for audits and assessments are specified. The levels of management to which results are reported, and the systems to provide corrective actions, are also described.

11.4.3.6 Incident Investigations

The applicant's description and commitments in the application will be acceptable if the reviewer finds reasonable assurance of the following:

1. The applicant will establish a process to investigate abnormal events that may occur during operation of the facility, to determine their specific or generic root cause(s) and generic implications, to recommend corrective actions, and to report to the NRC as required by 10 CFR 70.50 and 70.74. The investigation process should include a prompt risk-based evaluation and, depending on the complexity and severity of the event, an individual may be all that is required to conduct the evaluation. The investigator(s) will be independent from the line function(s) involved with the incident under investigation. Investigations will begin within 48 hours of the abnormal event, or sooner, depending on the safety significance of the event. The failure log required for IROFS should be reviewed as part of the investigation.

2. The applicant will monitor and document corrective actions, through completion; and

3. The applicant will maintain documentation so that "lessons learned" may be applied to future operations of the facility. Details of the event sequence will be compared with accident sequences already considered in the ISA, and the ISA Summary will be modified to include the evaluation of the risk associated with accidents of the type actually experienced.

The applicant has a formal policy or procedure in place for conducting an incident investigation, and the policy or procedures contain the following elements:

1. A documented plan for investigating an abnormal event. This plan is separate from any required Emergency Plan. The investigation of an abnormal event should begin as soon as

possible, commensurate with the safety of the investigative team, after the event has been brought under control;

2. A description of the functions, qualifications, and responsibilities of the management person who would lead the investigative team and those of the other team members; the scope of the team's authority and responsibilities; and assurance of cooperation of management;

3. Assurance of the team's authority to obtain all the information considered necessary, and independence from responsibility for or to the functional area involved in the incident under investigation;

4. Procedures requiring maintenance of all documentation relating to abnormal events for 2 years or for the life of the operation, whichever is longer;

5. Guidance for personnel conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the root cause(s) of the problem. The level of investigation should be based on a graded approach relative to the severity of the incident;

6. Requirements to make available, to the NRC, original investigation reports on request; and

7. A system for monitoring the completion of appropriate corrective actions.

The assessment of the adequacy of the applicant's commitments to establish and use a plan for the investigation of abnormal events will also be based on the following acceptance criteria:

1. The licensee has described the overall plan and method for investigating abnormal events;

2. The functions, responsibilities, and scope of authority of investigators and/or teams are documented in the plan;

3. Qualified internal or external investigators are appointed to serve on investigating teams when required. The teams will include at least one process expert and at least one team member will be trained in root-cause analysis;

4. The applicant commits to prompt investigation of any abnormal events, and precursors to abnormal events (such as undetected failure of IROFS);

5. The investigation process and investigating team are independent of the line management, and participants are assured of no retribution from participating in investigations;

6. A reasonable, systematic, structured approach is used to determine the root cause(s) of abnormal events;

7. Auditable records and documentation related to abnormal events, investigations, and root cause analysis are maintained. For each abnormal event, the incident report should include a description, contributing factors, root-cause analysis, and findings and recommendations. Relevant findings are reviewed with all affected personnel, and

8. Documented corrective actions are taken within a reasonable period to resolve findings from abnormal event investigations.

11.4.3.7 Records Management

The reviewer will find the applicant's records management system for records acceptable if it satisfies the following criteria:

1. Records are specified, prepared, verified, characterized, and maintained;

2. Records are legible, identifiable, and retrievable for their designated lifetimes;

3. Records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage;

4. Procedures are established and documented specifying the requirements and responsibilities for record selection; verification; protection; transmittal; distribution; retention; maintenance; and disposition; and

5. The organization and procedures are in place to promptly detect and correct any deficiencies in the records management system or its implementation.

   Examples of records that should be included in the system are listed in Appendix B to Chapter 11. Records are categorized by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records. The procedures should: 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, or theft or during an emergency; and e) specify procedures for ensuring that the records management system remains effective.

   For computer codes/computerized data used for activities relied on for safety, as specified in the ISA Summary, the applicant establishes procedure(s) for maintaining readability and usability of older codes/data as computing technology changes. This could include transcribing the older forms of information (e.g., punched cards or paper tapes) and codes for older computing equipment to contemporary computing media and equipment. 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 five working days [10 CFR 70.62(a)(3) states "promptly"].

11.4.3.8 Other QA Elements

To be acceptable, the applicant's QA elements should be structured to apply appropriate measures to IROFS, which may include site design features. QA elements may be applied in proportion to the importance of the item to the achievement of safety (graded approach). Applicants'/licensees' QA elements are expected to differ based on the purpose and complexity of the facility and processes to be controlled.

The ISA summary should identify the IROFS, the degree of their importance to safety, and their related activities that are required for safety. The applicant's selection of QA elements to be applied to an IROFS, and the applicant's grading and level of the QA elements may be proportional to the importance to safety of the IROFS. An applicant may choose to apply all QA elements and the highest level to all IROFS, or may grade the application in proportion to the importance of the item to the achievement of safety.

All IROFS should have all appropriate QA elements applied. If the applicant grades the application of QA elements, the relative risk importance ranking of IROFS, as established within the maintenance function, should parallel those used in for QA elements.

A checklist for evaluating the application of QA elements is given below. If the application of QA is graded, the attributes described for each element listed below are applied for accident sequences based on the highest level of risk. The application of QA elements may be reduced by modifying or eliminating either the number of elements or the attributes within each element, based on evaluations performed and documented in the ISA. Attributes of QA elements are as follows:

1. The applicant describes the: a) organizational structure; b) functional responsibilities; and c) charts of the lines, interrelationships, and areas of responsibility and authority for all organizations performing activities relied on for safety, including the organization of the applicant and, as applicable, its principal contractors (architect/engineer, constructor, construction manager, and operator). Persons or organizations responsible for ensuring that appropriate QA has been established and for verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities;

2. The applicant may describe its application of QA elements in the form of a QA program, in which the applicant commits to meet the applicable requirements of applicable industry standards. The commitment may describe the applicant's graded approach to QA, describing measures implemented consistent with an item's importance to safety, or the commitment may describe a QA program applied to all IROFS. The application of QA elements should be well-documented, planned, implemented, and maintained to provide reasonable assurance that, together with the other management measures, IROFS will be available and reliable when needed. It should be functional before performing the ISA required by 10 CFR Part 70. See references in Section 11.7 (e.g., ANSI/ASME NQA-1).

3. A design control function is established that includes design inputs, process, analyses, verification, interfaces, changes, and design documentation and records (see Sections 11.3.1, 11.4.3.1, 11.5.2.1, and 11.6.1 for details on CM);

4. Applicable design bases and other requirements necessary to provide reasonable assurance of quality are included or referenced in documents for procurement of items or service for IROFS. To the extent necessary, suppliers are required to have QA consistent with the quality level of the item or service to be procured;

5. Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate for the circumstances (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures);

6. The preparation, issuance, and changes of documents that specify quality requirements or prescribe activities affecting quality are controlled to provide reasonable assurance that the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by authorized personnel (see Sections 11.3.1, 11.4.3.1, 11.5.2.1, and 11.6.1 for details on CM and sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures);

7. Purchased items and services for IROFS are controlled to provide reasonable assurance of conformance with specified requirements;

8. Provisions are made to identify and control IROFS and to provide reasonable assurance that incorrect or defective items are not use;.

9. Measures are established to maintain the acceptability of special processes used in the course of construction, maintenance, modifications, and testing activities, such as welding, heat treating, nondestructive testing, and chemical cleaning and to assure that they are performed by qualified personnel using qualified procedures and equipment;

10. Inspection required to verify conformance of IROFS with requirements is planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). Personnel qualification programs are established for inspection test personnel (see Sections 11.3.3, 11.4.3.3, 11.5.2.3, and 11.6.3 for details on training and qualifications);

11. Tests are conducted to verify that IROFS conform to specified requirements and will perform satisfactorily in service. Test requirements are specified in written procedures with provisions included for documenting and evaluating test results (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). Personnel qualification programs are established for test personnel (see Sections 11.3.3, 11.4.3.3, 11.5.3, and 11.6.3 for details on training and qualifications);

12. Provisions are made to provide reasonable assurance that tools, gauges, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals, to maintain performance within required limits;

13. Provisions are made to control the handling, storage, shipping, cleaning, and preservation of IROFS, in accordance with work and inspection instructions, to prevent damage, loss, and deterioration caused by environmental conditions such as temperature or humidity;

14. Provisions are made to control the inspection, test, and operating status of IROFS to prevent inadvertent use of nonconforming items or bypassing of inspections and tests;

15. Provisions are made to control the identification, segregation, disposition, and prevention of installation or use of nonconforming IROFS;

16. Provisions are made to provide reasonable assurance that conditions adverse to safety are promptly identified and corrected and that measures are taken to preclude repetition. These actions should be documented and reported to appropriate levels of management (see Sections 11.3.6, 11.4.3.6, 11.5.2.6, and 11.6.6 for details on incident investigations, and Sections 11.3.5, 11.4.3.5, 11.5.2.5, and 11.6.5 for details on audits and assessments);

17. Provisions are made for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality for IROFS (see Sections 11.3.7, 11.4.3.7, 11.5.2.7, and 11.6.7 for details on records management);

18. Provisions are made for planning and scheduling assessments and audits to verify compliance with and to determine the effectiveness of QA; responsibilities and procedures are identified for assessing, auditing, documenting, and reviewing results and for designating management levels to review assessment and audit results; and provisions are made for incorporating the status of findings and recommendations in management reports (see Sections 11.3.5, 11.4.3.5, 11.5.2.5, and 11.6.5 for details on audits and assessments);

19. The applicant's provisions for continuing QA address reviews and updates of QA documents based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA program changes.

11.5 REVIEW PROCEDURES

11.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 11.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation review.

11.5.2 Safety Evaluation

After the primary reviewer determines that the application is acceptable for review in accordance with Section 11.5.1, above, the primary and secondary reviewers should perform a safety evaluation review against the acceptance criteria described in Section 11.4. Review procedures for each criterion are discussed in the sections below. If deficiencies are identified, the applicant should be requested to submit additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP. The reviews for all management measures should be coordinated with the primary reviewer of the ISA Summary.

11.5.2.1 CM

1. CM Policy Management

The primary reviewer should consider whether the CM plan acceptably states management commitments, gives the policy directive, and defines key responsibilities, terminology, and equipment scope. The secondary reviewers should examine the ISA Summary and the ISA, as needed, to assure that identified IROFS will be subject to the CM function. Appropriate interfaces both within the CM function and with external organizations and functions should be examined. In particular, the functional interfaces with QA, maintenance, and training (including qualification) should be examined. The reviewers should look for the applicant's identification of required databases and the rules for their maintenance. The reviewers should examine implementing procedures for the CM function.

2. Design Requirements

The primary reviewer should confirm that the design process leading to drawings and other statements of requirements proceeds logically from the design basis. The design basis is a set of facts, about the systems covered by CM, that has been reviewed and approved by appropriate authority within the organization. The reviewers should verify that specific

personnel are assigned the responsibility for maintaining the design bases and requirements. The reviewers should verify that the IROFS to be listed under CM will be clearly defined in the requirements documents, along with the assignment of any grades or quality levels. This part of the review should be coordinated with the ISA primary reviewer. The ISA Summary should specify all IROFS, and the applicant should have indicated in the ISA Summary, what level of CM attributes is applied to a particular item. However, in the ISA Summary this indication may consist of only an index or category designation. The definition of the individual content of multiple CM levels, if used, should be in the CM Chapter of the application. The primary reviewer for the CM Chapter is responsible to determine if the reduced levels the applicant would apply to safety items for lesser risk accident sequences are adequate.

3. Document Control

The primary reviewer should evaluate the applicant's material showing that the CM system will capture documents that are relevant and important to safety. The documents should include design requirements; the ISA; the ISA Summary; as-built drawings; specifications; all safety-important operating procedures; procedures involving training, maintenance, audits and assessments; emergency operating procedures; emergency response plans; system modification documents; assessment reports; and others, as necessary, that the applicant may deem part of the CM function. The primary reviewer should determine whether a controlled document database is used to control documents and track document change status. Rules of storage for originals or master copies of documents within the CM function follow the guidance of “Records Management.”

4. Change Control

The primary reviewer should be able to find that the description of change control within the CM function commits to acceptable methods in place for: (a) the identification of changes in configurations that are IROFS; (b) technical and management review of changes; and (c) tracking and implementing changes, including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and other QA elements.

5. Assessments

The primary reviewer should be able to find that both document assessments and physical assessments (system walkdowns) will be conducted periodically, to check the adequacy of the CM function. The primary reviewer should be able to find that all assessments and follow-ups will be documented. These reports can provide a supporting basis for future changes.

6. Design Reconstitution (Existing Facilities Only)

Design reconstitution may be necessary for existing facilities if current design information is not adequate. The primary reviewer examines the applicant's description of work to establish, organize, and document design requirements and design bases for items for which design information was not available before the application was submitted. Of particular importance are the methods used to evaluate, verify, and validate reconstituted design data for IROFS. For existing facilities, the design requirements and physical configuration may have greatly changed according to the demands of a changed mission. If

documentation has not kept pace, it will be necessary for the applicant to walk down systems, update drawings and specifications, perform new calculations and analyses, and otherwise rebuild the design bases. The reviewer will seek evidence that the need for design bases reconstitution was investigated, that reconstitution was accomplished as necessary, and that new or revised documentation was properly incorporated into the CM function. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the CM input for the Safety Evaluation Report (SER) as described in SRP Section 11.6, using the regulatory acceptance criteria from SRP Section 11.4.3.1.

11.5.2.2 Maintenance

The reviewer will evaluate the applicant's description of how the maintenance function will coordinate with and use the other management measures listed in this chapter. The primary reviewer should consult with the supporting reviewers to identify any common weaknesses in the applicant's approach and consider these during the review.

An acceptable maintenance function includes descriptions and applicant's commitments regarding corrective maintenance, preventive maintenance, surveillance/monitoring, and functional testing.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the maintenance input for the SER as described in SRP Section 11.6 using the regulatory acceptance criteria from SRP Section 11.4.3.2.

11.5.2.3 Training and Qualification

The primary reviewer performs a safety evaluation against the acceptance criteria described in Section 11.4, recognizing that thetraining objectives and methods and the required personnel qualification may be graded to correspond to the hazard potential of the facility, and the IROFS, and to the complexity of the training needed. The review should evaluate the adequacy of training and qualification on the basis of how well it fulfills the objectives for the training as identified by the applicant, especially when human factors are relied on for safety. The review should determine whether the applicant has adequately planned for the training and personnel qualification to be accomplished and whether necessary policies, procedures, and instructions will be in place and appropriate training and qualification will be accomplished before personnel begin activities relied on for safety. The reviewers should focus on the training and qualification of personnel who will perform activities relied on for safety.

The secondary reviewer should confirm that the applicant's personnel training and qualification commitments are consistent with other sections of the submittal.

The supporting reviewer should become familiar with the applicant's personnel training and qualification commitments and determine whether ongoing activities are in agreement with them.

The review should result in a determination that there is reasonable assurance that the applicant's personnel training and qualification will result in only properly trained and qualified personnel performing activities relied on for safety.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the personnel training and qualification input for the SER as described in Section 11.6, using the acceptance criteria from Section 11.4.3.3.

11.5.2.4 Procedures

On acceptance of the application for review, the secondary reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria listed in Section 11.4. The secondary reviewer will document in an SER that the applicant has committed to the following:

1. IROFS identified in the ISA Summary are highlighted in safety procedures (including procedures that constitute administrative controls for safety). There may be several levels of requirements within procedures for diagnosing and correcting process upsets, dealing with abnormal situations, or other matters. There is a clear hierarchy of requirements within procedures. Cautions and notes appearing in procedures precede the steps to which they apply. Rules for entering and leaving a procedure are clear.

2. Procedures important to safety are independently verified and validated before use, and this is documented in a policy on procedures.

3. Policy and administrative procedures, non-crucial operating procedures, and other non-operational procedures that do not impact IROFS or other environmental, safety, and health concerns need not be controlled with the stringency applied to operating procedures or management control procedures associated with IROFS specified by the ISA Summary. The applicability of less stringent procedure control should be specified to avoid misunderstandings in implementation.

4. Changes to operating, management measure, or maintenance procedures are reviewed and approved by an independent multi-disciplinary safety review team and controlled by the CM function.

5. The applicant includes a statement to follow approved procedures while processing licensed SNM.
6. Procedures exist for the notification of operations personnel before and after maintenance is performed on IROFS and activities are controlled by procedures.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the procedures input for the SER, as described in Section 11.6, using the acceptance criteria from Section 11.4.3.4.

11.5.2.5 Audits and Assessments

After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the secondary reviewer will perform a safety evaluation against the acceptance criteria described in Section 11.4. The review should determine whether the applicant has adequately planned for audits and assessments to be accomplished and

whether necessary policies, personnel, procedures, and instructions will be in place to begin audits and assessments early, that is, during the design of IROFS.

If the applicant references other sections of the application when describing its audits and assessments, the primary reviewer should review these other sections of the application to determine the applicant's commitment to overall audits and assessments and the proposed method for implementation. The reviewers should focus on audits and assessments of IROFS.

The secondary reviewer should confirm that the applicant's audit and assessment commitments are consistent with other sections of the submittal. The secondary reviewer is also responsible for integrating the audit and assessment input into the SER.

The supporting reviewer should become familiar with the applicant's audit and assessment commitments and determine whether ongoing audits and assessments of the applicant and the applicant's principal contractors are in agreement with them.

The review should result in a determination that there is reasonable assurance that the audits and assessments of the applicant and the applicant's principal contractors will provide additional assurance that IROFS will perform satisfactorily in service and that activities relied on for safety will be performed satisfactorily.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the audits and assessments input for the SER, as described in Section 11.6, using the acceptance criteria from Section 11.4.3.5.

11.5.2.6 Incident Investigations

The primary reviewer will verify that the applicant has described a comprehensive incident investigation function based on the areas of review in Section 11.3 and the acceptance criteria presented in Section 11.4 of this SRP.

During the review, the primary reviewer will consult with the NRC inspection staff and review any historical information regarding the adequacy of the applicant's incident investigation process. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 3.7.4 of this SRP.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the incident investigation input for the SER as described in Section 11.6, using the acceptance criteria from Section 11.4.3.6.

11.5.2.7 Records Management

The reviewer will review the applicant's records management system to determine the adequacy of the policies, procedures, and practices. The reviewer should coordinate this review with the person reviewing the CM function.

For fuel cycle facilities that are parts of larger organizations, certain documents may be retained or stored at a site other than the plant site. For example, master drawings for structures might be kept in the engineering department of the headquarters of the parent

company. The reviewer may choose to review the physical characteristics of these offsite record storage areas, as well, particularly for records for IROFS or high-risk accident sequences.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the records management input for the SER, as described in Section 11.6, using the acceptance criteria from Section 11.4.3.7.

11.5.2.8 Other QA Elements

After the primary reviewer has determined that the application is acceptable for review in accordance with Section 11.5.1, above, the primary reviewer should confirm that the applicant's (and the applicant's principal contractors') QA element commitments are consistent with other sections of the submittal. The secondary reviewer should review the QA elements information with respect to the acceptance criteria in Section 11.4. The secondary staff reviewer should determine whether the applicant has adequately planned the work to be accomplished and whether necessary policies, procedures, and instructions either are in place or will be in place before work starts. The review is based on an assessment of the material presented. It should provide reasonable assurance that the applicant's QA elements, maintenance, and CM are coordinated and that the QA elements are an integral part of everyday work activities. The review should provide reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of QA elements and will make needed adjustments on a timely basis. The staff is to look for and measure the effectiveness of the QA elements design, not just the existence of appropriate elements.

The secondary reviewer should also determine that the applicant has specified the QA elements criteria and the basis on which the criteria were selected and how they are apportioned within the sections of the application as well as the proposed method for implementation. If the applicant references other sections of the application when describing its QA elements, the reviewer should review these other sections of the application to determine the applicant's commitment to the QA elements and the proposed method for implementation.

The supporting reviewers should become familiar with the applicant's (and principal contractors') QA elements commitments and determine whether ongoing activities are in agreement with them.

Staff Reviewers of SRP Chapters 3 through 15 should determine whether IROFS within their areas of review are specified to be within the appropriate QA elements and level.

The review should result in a determination that there is reasonable assurance that the applicant's (and the applicant's principal contractors') QA elements will provide reasonable assurance that IROFS will perform their safety functions in a satisfactory manner.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the QA input for the SER, as described in SRP Section 11.6, using the acceptance criteria from SRP Section 11.4.3.8.

11.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 11.4.1 and that the regulatory acceptance criteria in Section 11.4.3 have been appropriately considered in satisfying the requirements. On the basis of this information, the staff should conclude that this evaluation is complete. The reviewers should write material suitable for inclusion in the SER prepared for the entire application. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

In cases where the SER is drafted in advance of resolving all open issues, the reviewer should document the review as described below and include a list of open issues that require resolution before the staff can reach a reasonable-assurance-of-safety conclusion. For partial reviews, revisions, and process changes, the reviewer should use applicable sections of the acceptance criteria and the SER should be written to reflect what portions were not reviewed and the safety significance, if any.

The staff can document the evaluation as follows:

11.6.1 CM

The staff has reviewed the CM function for (name of facility) according to Section 11 of the SRP. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.]

The applicant has suitably and acceptably described its commitment to a proposed CM system, including the method for managing changes in procedures, facilities, activities, and equipment for IROFS. Management-level policies and procedures, including an analysis and independent safety review of any proposed activity involving IROFS, are described that will provide reasonable assurance that the relationship between design requirements, physical configuration, and facility documentation is maintained as part of a new activity or change in an existing activity involving licensed material. The management measures will include (or do include) the following elements of CM:

1. CM Management

   The organizational structure, procedures, and responsibilities necessary to implement CM are in place or committed to.

2. Design Requirements

   The design requirements and bases are documented and supported by analyses, and the documentation is maintained current.

3. Document Control

   Documents, including drawings, are appropriately stored and accessible. Drawings and related documents captured by the system are those necessary and sufficient to adequately describe IROFS.

4. Change Control

Responsibilities and procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. Methods are in place for suitable analysis, review, approval, and implementation of identified changes to IROFS. This includes appropriate CM controls to assure configuration verification, functional tests, and accurate documentation for equipment or procedures that have been modified.

5. Assessments

The applicant has committed to an adequate function that includes both initial and periodic assessments as described in the acceptance criteria in this SRP. The assessments are expected to verify and assure the adequacy of the CM function.

6. Design Reconstitution [Existing Facilities Only]

The applicant has adequately described that design reconstitution that has been done. Current design bases are available and verified for all IROFS, such that the configuration is consistent with as-built facility documentation.

11.6.2 Maintenance

The applicant has committed to maintenance of IROFS. The applicant's maintenance commitments contain the basic elements to maintain availability and reliability: corrective maintenance, preventive maintenance, functional testing, equipment calibration, and work control for maintenance of IROFS. The applicant's maintenance function is proactive, using maintenance records, PM records, and surveillance tests to analyze equipment performance and to seek the root causes of repetitive failures.

The surveillance/monitoring, PM and functional testing activities described in the license application provide reasonable assurance that IROFS, identified in the ISA Summary, will be available and reliable to prevent or mitigate accident consequences.

The maintenance function: (1) is based on approved procedures; (2) employs work-control methods that properly consider personnel safety, awareness of facility operating groups, QA, and the rules of CM; (3) uses the ISA Summary to identify IROFS that require maintenance and at what level; (4) justifies the PM intervals in the terms of equipment reliability goals; (5) provides for training that emphasizes the importance of ISA or ISA Summary identified IROFS, regulations, codes, and personal safety; and (6) creates documentation that includes records of all surveillance, inspections, equipment failures, repairs, and replacements of IROFS.

The staff concludes that the applicant's maintenance functions meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the worker and the public are provided for.

11.6.3 Training and Qualification

Based on its review of the license application [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] the NRC staff has concluded that the applicant has adequately described and assessed its personnel training

and qualification in a manner that (1) satisfies regulatory requirements; (2) is consistent with the guidance in this SRP; and (3) is acceptable.

There is reasonable assurance that implementation of the described training and qualification will result in personnel who are qualified and competent to design, construct, start-up, operate, maintain, modify, and decommission the facility safely. The staff concludes that the applicant's plan for personnel training and qualification meet the requirements of 10 CFR Part 70.

11.6.4 Procedures

The application has described a suitably detailed process for the development, approval, and implementation of procedures. IROFS have been addressed, as well as items important to the health of plant workers and the public and to the protection of the environment. The staff concludes that the applicant's plan for procedures meets the requirements of 10 CFR Part 70.

11.6.5 Audits and Assessments

Based on its review of the license application [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] the NRC staff has concluded that the applicant has adequately described its audits and assessments. The staff has reviewed the applicant's plan for audits and assessments and finds them acceptable.

The staff concludes that the applicant's plan for audits and assessments meets the requirements of 10 CFR Part 70 and provides reasonable assurance of protection of: (1) the health and safety of the public and workers, and (2) the environment.

11.6.6 Incident Investigations

The applicant has committed to and established an organization responsible for: (1) performing incident investigations of abnormal events that may occur during operation of the facility; (2) determining the root cause(s) of the event; and (3) recommending corrective actions for ensuring a safe facility and safe facility operations, in accordance with the acceptance criteria of Subsection 11.4 of the SRP.

The applicant has committed to monitoring and documenting of corrective actions, through completion.

The applicant has committed to the maintenance of documentation so that "lessons learned" may be applied to future operations of the facility.

Accordingly, the staff concludes that the applicant's description of the incident investigation process complies with applicable NRC regulations and is adequate.

11.6.7 Records Management

The staff has reviewed the applicant's records management system against the SRP's acceptance criteria and concluded that the system: (1) will be effective in collecting, verifying, protecting, and storing information about the facility and its design, operations and

maintenance will be able to retrieve the information in readable form for the designated lifetimes of the records; (2) will provide a records storage area(s) with the capability to protect and preserve health and safety records that are stored there during the mandated periods, including protection of the stored records against loss, theft, tampering, or damage during and after emergencies; and (3) will provide reasonable assurance that any deficiencies in the records management system or its implementation will be detected and corrected in a timely manner.

11.6.8 Other QA Elements

Based on its review of the license application [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable. The review record should demonstrate the adequacy of the applicant's application of other QA elements, as applied to IROFS, for design, construction, and operations] the NRC staff has concluded that the applicant has adequately described the application of other QA elements (and the applicable QA elements of its principal contractors). The staff concludes further that:

1. The applicant has established and documented a commitment for an organization responsible for developing, implementing, and assessing the management measures for providing reasonable assurance of safe facility operations in accordance with the criteria in Section 11.4 of this SRP;

2. The applicant has established and documented a commitment for QA elements, and the administrative measures for staffing, performance, assessing findings, and implementing corrective actions are in place;

3. The applicant has developed a process for preparation and control of written administrative plant procedures, including procedures for evaluating changes to procedures, items, and tests. A process for review, approval, and documentation of procedures will be implemented and maintained;

4. The applicant has established and documented surveillances, tests, and inspections to provide reasonable assurance of satisfactory in-service performance of IROFS. Specified standards or criteria and testing steps have been provided;

5. Periodic independent audits are conducted to determine the effectiveness of the management measures. Management measures will provide for documentation of audit findings and implementation of corrective actions;

6. Training requirements have been established and documented to provide employees with the skills to perform their jobs safely. Management measures have been provided for evaluation of the effectiveness of training against predetermined objectives and criteria;

7. The organizations and persons performing QA element functions have the required independence and authority to effectively carry out their QA element functions without undue influence from those directly responsible for process operations;

8. QA elements cover the IROFS, as identified in the ISA summary, and measures are established to prevent hazards from becoming pathways to higher risks and accidents.

Accordingly, the staff concludes that the applicant's application of other QA elements (and the applicable QA elements of its principal contractors) meets the requirements of 10 CFR Part 70 and provide reasonable assurance of protection of public health and safety and of the environment.

11.7 REFERENCES

1. American National Standards Institute/American Society of Mechanical Engineers Standard, "Quality Assurance Requirements for Nuclear Facility Applications," ANSI/ASME NQA-1-1994.

2. International Atomic Energy Agency, "Establishing and implementing a Quality Assurance Program," Safety Guide 50-SG-Q1, 1995.

3. International Standards Organization, ISO 9000 series of quality management standards.

4. U.S. Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Government Printing Office, Washington, DC.

5. U.S. Code of Federal Regulations, Title 10, Part 21, "Reporting of Defects and Noncompliance," U.S. Government Printing Office, Washington D.C., as revised.

6. U.S. Code of Federal Regulations, Title 29, Chapter XVII, Section 1910.119, "Process Safety Management of Highly Hazardous Chemicals," U.S. Government Printing Office, Washington D.C., as revised.

7. U.S. Code of Federal Regulations, Title 40, Part 68, "Risk Management Program for Chemical Accidental Release Prevention," U.S. Government Printing Office, Washington D.C., as revised.

8. U.S. Department of Energy,"DOE Standard: Guide for Operational CM Function," Parts I and II, DOE-STD-1073-93

9. U.S. Department of Energy, Draft, "Implementation Guide for Use with 10 CFR Part 830.120 and DOE Order 5700.6C," September 1997.

10. U.S. Nuclear Regulatory Commission, "A Systematic Approach to Repetitive Failures," NUREG/CR-5665, February 1991.

11. U.S. Nuclear Regulatory Commission, "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities," Federal Register 54 (No. 53), 11590–11598, March 21, 1989.

12. U.S. Nuclear Regulatory Commission, "Guide to NRC Reporting and Recordkeeping Requirements," NUREG-1460, Rev. 1, July 1994.

13. U.S. Nuclear Regulatory Commission, "Maintenance and Inspection," Inspection Procedure 88062, January 16, 1996.

14. U.S. Nuclear Regulatory Commission, "Maintenance and Surveillance Testing," Inspection Procedure 88025, May 23, 1984.

15. U.S. Nuclear Regulatory Commission, “Proposed Method for Regulating Major Materials Licensees,” Section 3.2.6, ‘Configuration Management,’ NUREG-1324, 1992.

16. U.S. Nuclear Regulatory Commission, “Proposed Revision to Code of Federal Regulations, Title 10, Part 70, ‘Domestic Licensing of Special Nuclear Material,’ as revised.

17. U.S. Nuclear Regulatory Commission, “Root Causes of Component Failures Program: Methods and Applications,” NUREG/CR-4616, December 1986.

18. U.S. Nuclear Regulatory Commission, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” Information Notice 96-28, May 1966.

19. U.S. Nuclear Regulatory Commission, ”Training Review Criteria and Procedures,” NUREG 1220, Rev. 1, January 1993.