***** Note: This is a proposed revision to Chapter 11 of NUREG1520 *****

11. MANAGEMENT MEASURES

11.1 Purpose of Review

The purpose of the review of management measures is to determine whether there is reasonable assurance that items relied on for safety (IROFS) will be available and reliable to perform their intended safety functions when needed. Management measures are activities performed by a licensee, generally on a continuing basis, that are applied to IROFS to provide reasonable assurance that the IROFS will perform their intended safety function when needed to prevent accidents or mitigate the consequences of accidents to an acceptable level. The purpose of management measures is to provide reasonable assurance of compliance with Title 10, Section 70.61, "Performance Measures," of the *Code of Federal Regulations* (10 CFR 70.61) Reasonable assurance is established by considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the IROFS and the measures. As defined in 10 CFR 70.4, "Definitions," management measures include configuration management (CM), maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance (QA) elements.

11.2 Responsibility for Review

Primary: Quality Assurance Reviewer

Supporting: Primary Reviewers of Chapters 3 through 10 of this Standard Review Plan (SRP)
Fuel Cycle Facility Inspector

11.3 Areas of Review

According to 10 CFR 70.62(d), each applicant must establish management measures to ensure that IROFS, as documented in the integrated safety analysis (ISA) summary, provide reasonable assurance that they will be available and able to perform their intended functions, when needed, to comply with the performance requirements of 10 CFR 70.61. The degree to which measures are applied may be a function of the item's importance in meeting the performance requirements. If a "graded" application of a particular management measure is used for IROFS of differing importance, the applicant should describe the variations and the reviewer should determine whether the measures are commensurate with the importance to safety of the IROFS.

The specific areas of review are as follows:

- CM—The U.S. Nuclear Regulatory Commission (NRC) staff's review will determine whether the applicant has proposed a CM program that ensures consistency in the facility design and operational requirements, the physical configuration, and the facility documentation. The review should determine that the applicant's CM program captures formal documentation governing the design and continued modification of the site, structures, processes, systems, components, computer programs, personnel activities,

and supporting management measures. The review should also ensure that the CM program is adequately coordinated and integrated with 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's review should focus on the applicant's CM measures that provide reasonable assurance of the documentation of engineering, procurement, installation, and modifications; the training and qualification of affected staff; the revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; and the postmodification testing. The review of the overall approach to implementing CM should include the evaluation of the CM program, design requirements, document control, change control, assessments, and design reconstitution for existing facilities.

- Maintenance—The NRC staff's review should evaluate the applicant's description of its maintenance program. The staff will examine the applicant's commitments to inspect, calibrate, test, and maintain IROFS to a level commensurate with the items' importance to safety. The staff will review the applicant's description of how the site organization implements (1) corrective maintenance, (2) preventive maintenance, (3) surveillance and monitoring, and (4) functional testing. Not every aspect of each of the four maintenance functions is necessarily required. The applicant should justify the assignment of differing degrees of maintenance to individual IROFS based on the item's contribution to risk reduction.

- Training and Qualifications—The regulation in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," requires that all personnel who perform activities relied on for safety be trained and tested so as to provide reasonable assurance that they understand, recognize the importance of, and are qualified to perform these activities in a manner that adequately protects public health and safety and 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 safely. Therefore, the application should describe the training, testing, and qualification of these personnel, and the NRC staff should review this description. The review should examine the applicant's experience and capabilities to provide this training for its personnel who will perform activities relied on for safety. The review of the training and qualification should address the following areas:

  – organization and management of the training function

  – analysis and identification of functional areas requiring training

  – position training requirements

  – development of the basis for training, including objectives

- organization of instruction, using lesson plans and other training guides
- evaluation of trainee learning
- conduct of on-the-job training
- evaluation of training effectiveness
- personnel qualification
- applicant's provisions for continuing assurance, including the needs for retraining or reevaluation of qualification

- Procedures—The NRC staff's review should examine the applicant's process for the preparation, use, and management control of written procedures. This process should include the basic elements of identification, development, verification, review and comment resolution, approval, validation, issuance, change control, and periodic review.

- The actual operating procedures are not part of the license and would not normally be reviewed for technical adequacy since the inspection function addresses this aspect. The NRC staff should review the license application to ensure that the applicant's process for establishing procedures adequately addresses the following areas:
  - method for identifying procedures that are needed plantwide
  - essential elements that are generic to all procedures
  - method for creating and controlling procedures within plant management control systems
  - method for verifying and validating procedures before use
  - method for periodically reverifying and revalidating procedures
  - method for ensuring that current procedures are available to personnel and those personnel are qualified to use the latest procedure

- Audits and Assessments—The NRC staff should review the applicant's program of audits and assessments. The program should consist of two distinct levels of activities: (1) an audit activity structured to monitor compliance with regulatory requirements and license commitments and (2) 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 action program, which includes the functions of incident investigations as well as audits and assessment. This approach is acceptable and the reviewer should, in that case, review the applicant's description and commitments with regard to the acceptance criteria in this SRP chapter for incident investigations as well

as audits and assessments. The review of the audits and assessments should address the following areas:

  – the commitments to audit and assessment activities

  – the use of qualified and independent audit and assessment personnel

  – the general structure of typical audits and assessments

  – the facility procedures to be used to direct and control the audit and assessment activities

  – the planned use of the results of the audit and assessment activities

  – the documentation to record and distribute the findings and recommendations of these audits and assessments

  – the planning and implementation of corrective actions based on the findings and recommendations

- Incident Investigations—The NRC staff should review the applicant's program, 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 the procedures for tracking and completing corrective actions and for documenting the process for the purpose of applying the "lessons learned" to other operations. The applicant may describe a corrective action program, which includes the functions of audits and assessment as well as incident investigations. This approach is acceptable and the reviewer should, in that case, review the applicant's description and commitments with regard to the acceptance criteria in this SRP chapter for audits and assessments as well as incident investigations.

- Records Management—The requirements for the management of records vary according to the nature of the facility and the hazards and risks it poses. 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:

  – The process whereby records (i.e., training records, dosimetry records, effluents records, records of classified information, records concerning facility IROFS and their failures) 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.

  – The handling and control of various kinds of records (including contaminated and classified records) and the media in which the records are captured.

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

- Other QA Elements—The application must address other QA elements that will be applied to IROFS and other management measures. The NRC staff should evaluate whether the application of other QA elements is adequately described. The staff's review objective is to obtain reasonable assurance of the implementation of accepted QA principles in the design, procurement, construction, operation, maintenance, inspection, testing, and modification phases of a facility's life cycle. The NRC staff should examine the applicant's commitment to overall QA, the selection of quality criteria and quality level, and the proposed method for implementation. 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.

  The reviewer should recognize that facility safety may not be the only area at a fuel cycle facility requiring QA elements. The applicant's customers and the NRC, under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," may impose product-related QA criteria. In this SRP, the focus of the review of QA measures 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).

Review Interfaces

Other sections of the license application may include information on configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, record management, or other QA elements applied to management measures. The NRC staff should focus its review activities on management measures associated with IROFS of high risk importance. The reviewer of this SRP chapter should coordinate with the reviewers of SRP Chapters 3 through 10 to inform the selection of management measures for more detailed review.

11.4 Acceptance Criteria

11.4.1 Regulatory Requirements

Acceptance criteria are based on meeting the relevant requirements of the regulations described in this section.

The regulatory basis for the review is 10 CFR 70.22, "Contents of Applications," and 10 CFR 70.65, "Additional Content of Applications." In addition, the management measures review should provide reasonable assurance of compliance with the following regulations:

- 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 70.22(a)(8) requires that each application for a license shall contain proposed procedures to protect health and minimize danger to life or property.

- 10 CFR 70.62(a)(3) states that 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 engineered and administrative controls and control systems that are identified as IROFS, pursuant to 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

- 10 CFR 70.64(a)(1) states that new facilities or new processes at existing facilities shall develop and implement designs in accordance with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their safety function when needed.

- 10 CFR 70.64(a)(1) states that appropriate records of IROFS must be maintained by or under the control of the licensee throughout the life of the facility.

- 10 CFR 70.64(a)(8) states that the design of IROFS must provide for inspection, testing and maintenance adequate to ensure their availability and reliability to perform their function when needed.

Facility change and change processes are required to conform to 10 CFR 70.72, “Facility Changes and Change Process.”

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

11.4.2 Regulatory Guidance

Regulatory guidance appears in the American Society of Mechanical Engineers standard, "Quality Assurance Requirements for Nuclear Facility Applications" (ANSI/ASME NQA-1-1983), as endorsed by Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3. This guidance applies only to applications for plutonium processing and fuel fabrication facilities.

11.4.3 Regulatory Acceptance Criteria

The reviewer should find the applicant's management measures acceptable if the applicant has met the acceptance criteria described in the following sections or has identified and justified an alternative approach.

11.4.3.1 Configuration Management

The regulation in 10 CFR 70.4 defines CM as a management measure that provides oversight and control of design information, safety information, and records of modifications that might impact the ability of IROFS to perform their functions when needed. The applicant's description of CM is acceptable if it meets the following conditions:

(1) The application describes the CM program; design requirements, document control, change control, assessments, and design reconstitution (for existing facilities only).

(2) The application describes the CM program and defines the specific attributes of the levels of CM that will be applied to select IROFS.

(3) The ISA summary clearly defines the IROFS to be listed under CM along with the assignment of any grades or quality levels. The applicant should indicate in the ISA summary the level of CM attributes that is applied to a particular IROFS. However, in the ISA summary, this indication may consist of only an index or category designation.

(4) The application describes a design process leading to drawings and other statements of requirements that proceeds logically from the design basis.

(5) The application describes how design requirements and associated design bases are established and are maintained through control of the design process. It also describes technical management review and approval functions.

(6) The application describes an acceptable method to create and control documents that are relied on for safety. These documents include design requirements, 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 deems part of CM.

(7) The application describes how the CM function will maintain strict consistency among the design requirements, the physical configuration, and the facility documentation.

(8) The application contains a commitment to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.

(9) The application describes an acceptable process 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.

(10) The application describes the documentation process following changes made in accordance with 10 CFR 70.72. Changes to the affected onsite documentation should be made promptly to avoid inadvertent access by facility personnel to outdated design and other specifications for IROFS.

(11) The application confirms that initial and periodic assessments of the CM function are conducted to determine the program's effectiveness and to correct deficiencies. The application indicates that such assessments are systematically planned and conducted in accordance with an overall facility audit and assessment function.

(12) For existing facilities, the application may describe whatever design reconstitution has been done for the purpose of the application. The applicant has available the current design bases, including design requirements, supporting analyses, and documentation supporting all IROFS.

(13) For new facilities or new processes at existing facilities, the application describes facility and system design and facility layout based on defense-in-depth practices in accordance with 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities." Defense-in-depth practices should be applied early through the completion of design by providing successive levels of protection such that health and safety will not wholly depend on any single element of the design, construction, maintenance, or operation of the facility.

11.4.3.2 Maintenance

As required by 10 CFR 70.62(d), engineered and administrative controls that are identified as IROFS must be designed, implemented, and maintained to ensure that they are available and reliable when needed.

The regulation in 10 CFR 70.64(a)(8) requires that IROFS for new facilities or new processes at existing facilities receive adequate inspection, testing, and maintenance to ensure their availability and reliability when needed.

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

(1) descriptions of corrective maintenance, preventive maintenance, surveillance and monitoring, and functional testing

(2) description of how the maintenance function will be designed to ensure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of IROFS because of monitoring or preventive maintenance (PM)

(3) discussion of how the maintenance function uses, interfaces with, or is linked to the various management measures

(4) justifications for assignment of differing degrees of maintenance to individual IROFS, based on the item's contribution to the reduction of risk

(5) for IROFS identified in the ISA summary, a description of the surveillance function and its conduct at a specified frequency

(6) description of how the surveillance activity supports the determination of performance trends for IROFS, thus providing data useful in determining PM frequencies

(7) description of the applicant's retention of records of the current surveillance schedule, performance criteria, and test results for all IROFS

(8) for surveillance tests that can be done only while IROFS are out of service, a description of the proper compensatory measures that will be prescribed for the continued normal operation of a process

(9) description of how the results of incident investigations, the review of failure records 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

(10) documentation of the approach to performing corrective actions or repairs on IROFS

(11) description of how 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

(12) description of the PM function that demonstrates a commitment to conducting preplanned and scheduled periodic refurbishing, or partial or complete overhaul, of IROFS to minimize occurrences of their unanticipated losses

(13) description of the applicant's retention of records showing the PM schedule and results for all IROFS subject to this maintenance component

(14) general description of the methods used and the commitment to perform functional testing, as needed, of IROFS after PM or corrective maintenance

(15) as necessary, a commitment to conduct functional tests designed to include all operational aspects of the IROFS that are important to safety during startup of new processes

(16) description of how the applicant will maintain records showing the functional test schedule and results for all IROFS subject to this maintenance component

(17) general discussion of how administrative controls identified as IROFS are verified to be available and reliable to perform their intended safety function over extended periods of operation

11.4.3.3 Training and Qualifications

The application should be acceptable regarding personnel training and qualification if it satisfies the criteria described below. In addition to the regulatory acceptance criteria, the SRP provides additional specific criteria for training and qualification for radiation safety personnel in Section 4.4.5, for criticality safety in Section 5.4.3.2, and for emergency planning in Section 8.4.3.1.11. Similarly, some of the information specified below may appear in other sections of the application and may be incorporated by reference.

(1) The application should include the following commitments regarding organization and management of training:

a. Line management is responsible for the content and effective conduct of the training.

b. The job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training are clearly defined.

c. Performance-based training is used as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.

d. Procedures are documented and implemented to provide reasonable assurance that all phases of training are conducted reliably and consistently.

e. Training documents are linked to the CM system to provide reasonable assurance that the training reflects design changes and modifications.

f. Exemptions from training are granted to trainees and incumbents only when justified, documented, and approved by management.

g. Both programmatic and individual training records are maintained. These records support management information needs and provide required data on each individual's training and qualification.

(2) Formal training should be provided for each position or activity that is relied on for safety. Training may be classroom or on-the-job training or both. The application should state what training will be conducted and which personnel will be required to complete it.

a. Each activity selected for training (initial or continuing) from the facility-specific activities should be correlated with supporting procedures and training materials.

b. 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 and equipment, or job scope. 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.

(3) The application should contain commitments regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, facility

operators, technicians, maintenance personnel, and other staff who perform regulated activities.

(4) The application should contain commitments regarding minimum qualifications for personnel. Minimum qualifications should be commensurate with the assigned functional responsibility and authority of the respective personnel.

a. Managers should have a B.S., B.A., or equivalent degree. Each manager should have either management or technical experience in a facility similar to the facility identified in the application.

b. Supervisors should have at least the qualifications required of personnel being supervised.

c. Technical professional staff whose actions or judgments are critical to satisfying the performance requirements identified in 10 CFR Part 70 should have a B.S., B.A., or equivalent degree in the appropriate technical field.

d. Construction personnel, facility 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.

e. Candidates for process operators should be required to meet the minimum qualifications described in the application. Candidates for job functions other than process operators should be required to meet minimum qualifications, but the application need not describe these minimum qualifications.

(5) Training objectives should state the knowledge, skills, and abilities that the trainee should acquire; the conditions under which required actions will take place; and the standards of performance the trainee should achieve on completion of the training activity.

(6) Lesson plans and other training guides should provide guidance to ensure the consistent conduct of training activities and should be based on required learning objectives derived from specific job performance requirements.

(7) Lesson plans or guides should be used for all training and should include standards for evaluating acceptable trainee performance. 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.

(8) Review and approval requirements should be established for all lesson plans or guides and other training materials before their issue and use.

(9) The application describes any on-the-job training used for activities relied on for safety.

(10) On-the-job training should be conducted using well-organized and current training materials. Designated personnel who are competent in the program standards and training methods should conduct the training.

(11) 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.

(12) Provisions for continuing assurance of personnel training and qualification are acceptable if the application addresses periodic requalification of personnel by training and/or testing, as necessary, to provide reasonable assurance that they continue to understand, recognize the importance of, and be qualified to perform activities that are relied on for safety.

(13) 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. Qualified individuals should periodically conduct a comprehensive evaluation of individual training 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.

b. Improvements and changes to initial and continuing training should be initiated, evaluated, tracked, and incorporated to correct training deficiencies and performance problems.

11.4.3.4 Procedures Development and Implementation

The regulation in 10 CFR 70.22(a)(8) requires that the application contain procedures to protect public health and safety. The application is acceptable in this regard if it describes the applicant's process for developing and implementing procedures and satisfies the following:

(1) The applicant provides information regarding the procedure categories used at the facility. The categories typically include management control, operating, maintenance, and emergency procedures.

(2) Procedures are written or planned for the operation of IROFS and for all management measures supporting those IROFS.

(3) The applicant should include the following commitment regarding procedure adherence: "Activities involving licensed SNM and/or IROFS will be conducted in accordance with approved procedures."

(4) The applicant develops procedures for sitewide safe work practices to control processes and operations with licensed special nuclear material (SNM) and/or IROFS and/or hazardous chemicals incident to the processing of licensed material.

(5) Procedures exist or are planned 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.

(6) Procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA summary. The applicant provides a listing of the types of activities that are covered, or are planned to be covered, by written procedures. The listing includes the topics of administrative procedures; system procedures that address startup, operation, and shutdown; abnormal operation or alarm response; maintenance activities that address system repair, calibration, inspection, and testing; and emergency procedures. Appendix A to this SRP chapter provides an acceptable listing of the items to be included under each topic.

(7) The applicant describes the method for identifying, developing, approving, implementing, and controlling operating procedures.

a. The applicant considers the ISA in identifying needed procedures.

b. The procedure specifies operating limits and IROFS.

c. Procedures include required actions for off-normal conditions of operation, as well as normal operations.

d. If needed, safety checkpoints are identified at appropriate steps in the procedure.

e. Procedures are validated through field tests.

f. The management personnel who are responsible and accountable for the operation approve the procedures.

g. A mechanism is specified for revising and reissuing procedures in a controlled manner.

h. QA elements and CM functions at the facility provide reasonable assurance that current procedures are available and used at all work locations.

i. The training program instructs the required personnel in the use of the latest procedures.

(8) Procedures should incorporate the following elements:

a. title and identifying information, such as number, revision, and date
b. statement of applicability and purpose
c. prerequisites
d. precautions (including warnings, cautions, and notes)
e. important human actions
f. limitations and actions
g. acceptance criteria
h. checkoff lists
i. reference material

(9) Maintenance procedures involving IROFS commit to the topics listed below for corrective and preventive maintenance and functional testing after maintenance and surveillance activities:

a. Pre-maintenance activities involve reviews of the work to be performed, including procedure reviews for accuracy and completeness.

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

c. Control of work is ensured by comprehensive procedures to be followed by maintenance technicians. The various safety disciplines, including criticality, fire, radiation, industrial, and chemical process safety, review maintenance procedures. The procedures describe 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 (should be controlled by the CM function to ensure like-kind replacement and adherence to 10 CFR Part 21, "Reporting of Defects and Noncompliance")

   iii. post-maintenance testing to verify operability of the equipment

   iv. tracking and records management of maintenance activities

   v. safe work practices (e.g., moderation control or exclusion area; radiation or hot work permits; and criticality, fire, chemical, and environmental issues)

(10) The applicant has formal requirements governing the use of temporary procedures. 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 facility, system, or component is performing in a manner not covered by permanent procedures. The discussion establishes a timeframe for use of the temporary procedure and sets the same level of review and approval as for permanent procedures.

(11) The applicant verifies that the procedures are technically accurate and can be performed as written. The applicant periodically reviews the procedures to ensure their continued accuracy and usefulness and establishes the timeframe for reviews of the various types of procedures.

(12) 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.

(13) The 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.

(14) Program and administrative procedures and other nonoperational 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.

11.4.3.5 Audits and Assessments

The NRC reviewers should find the application acceptable in terms of audits and assessments if it provides reasonable assurance that the following are adequately addressed and satisfied:

(1) The application describes program directives covering the audit and assessment function (i.e., 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 application contains a commitment to conduct internal audits and independent assessments of activities significant to facility safety and environmental protection.

(3) The application states that audits will be conducted to verify that operations are being conducted in accordance with regulatory requirements and license commitments.

(4) The application states that independent assessments will be conducted by offsite 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) The application states that 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.

(6) The application states that qualified personnel without direct responsibility for the function and area being audited or assessed will perform the audits and assessments. The application specifies the staff positions and committees responsible for audits and assessments and describes the levels of management to which results are reported. The systems to provide corrective actions are also described.

11.4.3.6 Incident Investigations

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

(1) The applicant will establish a formal procedure to investigate abnormal events that may occur during operation of the facility to determine their specific or generic root cause(s), generic implications, and risk significance, to recommend corrective actions, and to report to the NRC as required by 10 CFR 70.50, "Reporting Requirements," and 10 CFR 70.74, "Additional Reporting Requirements." Appendix B to this SRP chapter presents guidance regarding the contents of an incident investigation program or procedure.

(2) The applicant will monitor and document corrective actions through completion and ensure that corrective actions are taken within a reasonable period to resolve findings from abnormal event investigations.

(3) The applicant will maintain documentation related to abnormal events for the life of the operation 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 evaluation of the risk associated with accidents of the type actually experienced.

11.4.3.7 Records Management

The reviewer will find the applicant's records management system acceptable if the application describes the following criteria:

(1) Records are prepared, verified, characterized, and maintained.

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

(3) 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.

(4) Records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration while in storage.

(5) Procedures are established and documented specifying the requirements and responsibilities for record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition.

(6) 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, and theft or during an emergency, and (e) specify procedures for ensuring that the records management system remains effective.

(7) Procedures are in place to promptly detect and correct any deficiencies in the records management system or its implementation.

(8) Records of IROFS failures must be kept and updated in accordance with 10 CFR 70.62(a)(3). Record revisions necessitated by postfailure investigation conclusions must be made promptly after completion of the investigation

(9) For computer codes and 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 and data as computing technology changes. The procedures could include transfer of the older forms of information and codes for older computing equipment to contemporary computing media and equipment.

Appendix C to this SRP chapter lists the types of records that should be included in the system.

11.4.3.8 Other Quality Assurance Elements

To be acceptable, the applicant's QA elements should be structured to apply appropriate measures to IROFS. Applicants' and licensees' QA elements are expected to differ based on the purpose and complexity of the facility and processes.

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

Other QA may include some or all of the elements listed below:

(1) Organization—The applicant describes the organizational structure, functional responsibilities, lines of authority, and lines of communication for control of activities affecting quality. The organization responsible for ensuring that appropriate QA has been established should have sufficient authority, access to work areas, and organizational independence to perform its responsibilities.

(2) QA Program—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 standards. The commitment may describe the applicant's graded approach to QA, in which measures are implemented commensurate 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.

(3) Design Control—The applicant's design controls should be defined, controlled, and verified. Design inputs should be specified and correctly translated to design documents. Controlled measures, commensurate with those applied to the original design, should govern the adequacy of design and design changes.

(4) Procurement Document Control—The design bases information and other documentation necessary to ensure adequate quality are included or referenced in documents for procurement of items and services. To the extent necessary, suppliers are required to have a QA program commensurate with the quality level of the item or service to be procured.

(5) Instructions Procedures and Drawing Control—Activities affecting the quality of IROFS are prescribed by and performed in accordance with documented instructions, procedures, or drawings appropriate for the circumstances and reference appropriate quantitative or qualitative acceptance criteria.

(6) Document Control—The applicant's document control system describes the preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality. The document control system is controlled in a manner that ensures that authorized personnel review documents and changes thereto for adequacy and approve them for release.

(7) Control of Purchased Items—The applicant describes controls for the procurement of items and services. Descriptive controls of purchased items and services include, as appropriate, source evaluation and selection, source inspection, audit, the examination of items or services upon delivery or completion, mechanisms for control of changes in items or services, commercial-grade item requirements, and control of supplier nonconformance.

(8) Identification and Control of Items—The applicant establishes controls to ensure that only the correct items are used or installed. The applicant describes provisions to identify and maintain traceability of items.

(9) Control of Processes—The applicant establishes controls of processes affecting the safety of IROFS or related services. Qualified personnel using qualified procedures in accordance with specified requirements perform special processes that control activities, such as welding, heat treating, and nondestructive examination.

(10) Inspection—When inspections are used to verify conformance of an IROFS item or activity, the inspection should be planned and executed. The characteristics to be inspected and inspection methods should be specified. The results of inspections should be documented. Qualified personnel other than those who performed or directly supervised the work being inspected should perform the inspections.

(11) Test Control—Tests performed to verify conformance of an IROFS or computer program should be conducted to specified requirements and demonstrate availability and reliability of performance. The characteristics to be tested and test methods should be specified. Test results should be documented and evaluated against the test requirements and acceptance criteria.

(12) Control of Measuring and Test Equipment—The applicant should establish controls for tools, gauges, instruments, and other measuring and test equipment used for IROFS and activities affecting IROFS. Controls of measuring and test equipment should consider methods and frequency of calibration and should be adjusted to maintain accuracy within specified limits.

(13) Handling, Storage, and Shipping—The applicant should consider methods to ensure that handling, storage, cleaning, packaging, shipping, and preservation of IROFS are controlled to prevent damage or loss and to minimize deterioration.

(14) Inspection, Test, and Operating Status—The applicant should identify the status of inspection and test activities for IROFS, either in the item or in documents traceable to IROFS. The applicant should specify the use of status-indicating devices such as tags, markings, shop travelers, stamps, and inspection records. The applicant should establish provisions to ensure that required inspections and tests are performed and ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

(15) Control of Nonconforming Items—The applicant should describe provisions that specify when IROFS do not conform to specified requirements. The applicant should control items that do not conform to prevent inadvertent installation or use of nonconforming material, parts, equipment, or services. The applicant should specify provisions for

identification, documentation, evaluation, segregation, and disposition of nonconforming IROFS and for appropriate notification to affected organizations.

(16) Corrective Action—The applicant should specify provisions for promptly identifying conditions adverse to quality and correcting them as soon as practicable.

(17) QA Records—QA records and records management systems may be used in lieu of or in conjunction with each other. In either case, the applicant should describe the methods used to document, prepare, maintain, and manage records. The applicant should describe the methods used to protect records against damage, deterioration, or loss. In addition, the applicant should establish and document the requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition.

(18) Audits—The applicant should plan and schedule audits and assessments to verify compliance with, and to determine the effectiveness of, quality assurance. The responsibilities and procedures for assessing, auditing, documenting, and reviewing results should be identified.

11.5 Review Procedures

For each area of review specified in Section 11.3, the review procedure is identified below. These review procedures are based on the identified SRP acceptance criteria. For deviations from these specific acceptance criteria, the staff should review the applicant's evaluation of how the proposed alternatives to the SRP criteria provide an acceptable method of complying with the relevant NRC requirements identified in Section 11.4.

During the review of the license application and ISA summary for a planned facility, the reviewer should identify and note any items or issues that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the engineered controls are implemented through procedures and operator training.

If, during the review, the primary reviewer determines a need for additional information, the primary reviewer coordinates a request for additional information with the licensing project manager. The reviewer should ascertain that the management measures approach is consistent throughout the application.

For an existing facility, the reviewer may consult NRC inspectors to identify and resolve any issues related to the licensing review. For a planned facility, the reviewer may wish to consult with the facility design team to gain a better understanding of the process, its potential hazards, and safety approaches. The reviewer should coordinate these interactions through the licensing project manager.

The primary reviewer will prepare safety evaluation report (SER) input for the licensing project manager in support of the licensing action.

11.5.1 Configuration Management

The reviewer should evaluate the six areas of CM described in the next sections.

11.5.1.1 Configuration Management Program

(1) The reviewer should consider whether the CM plan acceptably states management commitments, gives the program directive, and defines key responsibilities, terminology, and equipment scope.

(2) The reviewer should determine whether the applicant's description of overall CM functions covers the following topics: (a) the scope of the IROFS and management measures to be included (coordinate with the reviewer of Chapter 3 of this SRP), (b) the description and objectives of each CM activity, and (c) the organizational structure and staffing interfaces.

(3) The reviewer should determine that IROFS identified in the ISA summary are subject to the CM function.

(4) The reviewer should check for appropriate interfaces both within the CM function and with external organizations and functions. In particular, the review should examine functional interfaces with QA, maintenance, and training (including qualification).

(5) The reviewer should look for the applicant's identification of necessary databases and the rules for their maintenance.

11.5.1.2 Design Requirements

(1) The 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.

(3) The reviewer should verify that specific personnel are assigned the responsibility for maintaining the design bases and requirements.

(4) The reviewer should verify that IROFS to be listed under CM will be clearly defined in the requirements documents, along with the assignment of any grades or quality levels. The reviewer should coordinate this part of the review with the ISA primary reviewer.

Note: The reviewer, in conjunction with the appropriate technical reviewers, is responsible for determining if the reduced levels the applicant would apply to IROFS for accident sequences with lesser consequences are adequate.

11.5.1.3 Document Control

(1) The reviewer should evaluate the application to determine whether the CM system captures documents that are relevant and important to safety. These documents should include the design requirements, the ISA, the ISA summary, as-built drawings, specifications, all operating procedures important to safety, procedures involving training, maintenance, audits and assessments, emergency operating procedures,

emergency response plans, system modification documents, assessment reports, and other documents that the applicant deems pertinent to the CM function.

(2) The reviewer should examine information describing a controlled document database used to control documents and track document change status.

(3) Rules of storage for originals or master copies of documents within the scope of the CM function follow the guidance of Records Management.

11.5.1.4 Change Control

The reviewer should verify that the description of change control within the CM function commits to acceptable methods for (1) the identification of changes in configurations that are IROFS, (2) technical and management review of changes, and (3) 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.

11.5.1.5 Assessments

The reviewer should verify that both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function and that all assessments and follow-ups will be documented.

11.5.1.6 Design Reconstitution (Existing Facilities Only)

Design reconstitution may be necessary for existing facilities if current design information is not adequate.

(1) The reviewer should examine 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. This includes the methods used to evaluate, verify, and validate reconstituted design data for IROFS.

(2) 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.

11.5.2 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 supporting reviewers to identify common weaknesses in the applicant's approach and consider these in the review.

11.5.3 Training and Qualification

Recognizing that the training objectives and methods and the required personnel qualification may be graded to correspond to the hazard potential of the facility, the reviewer performs a safety evaluation against the acceptance criteria described in Section 11.4.

(1) The review should evaluate the adequacy of training and qualification on the basis of how well it fulfills the applicant's training objectives, especially when human factors are relied on for safety.

(2) 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.

(3) The reviewers should focus on the training and qualifications of personnel who will perform activities relied on for safety.

(4) The supporting reviewers should become familiar with the applicant's personnel training and qualification commitments and determine whether ongoing activities correspond to them.

(5) 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.

11.5.4 Procedures

The reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria listed in Section 11.4. The reviewer will document in an SER that the applicant has committed to the following:

(1) The applicant includes a statement to follow approved procedures while processing licensed SNM.

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

(7) Procedures exist for the notification of operations personnel before and after maintenance is performed on IROFS, and activities are controlled by procedures.

(8) An independent, multidisciplinary safety review team reviews and approves changes to operating, management measure, or maintenance procedures controlled by the CM function.

11.5.5 Audits and Assessments

The reviewer will determine whether the applicant has adequately planned for audits and assessments to be accomplished and whether necessary programs, personnel, and procedures will be established.

If the applicant refers to other sections of the application when describing its audits and assessments, the reviewer should examine these other sections of the application to determine the applicant's overall commitment to audits and assessments and the proposed method for implementation. The reviewer should confirm that the applicant's audit and assessment commitments are consistent with other sections of the submittal.

11.5.6 Incident Investigations

The 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 in Section 11.4 of this SRP. For existing facilities, the reviewer should consult with the NRC inspection staff and review any historical information regarding the adequacy of the applicant's incident investigation process.

11.5.7 Records Management

The review should determine whether the applicant has adequately implemented a records management system. For fuel cycle facilities that are parts of larger organizations, certain documents may be retained or stored at a site other than the facility 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, particularly the storage areas for records related to IROFS for high-consequence accident sequences.

11.5.8 Other Quality Assurance Elements

The reviewer should evaluate the applicant's submittal with regard to QA elements against the acceptance criteria in Section 11.4. Supporting reviewers should determine whether IROFS within their areas of review are specified to be within the appropriate QA elements and level. The reviewer should measure the effectiveness of the QA elements design, rather than just verifying the existence of appropriate QA elements.

The reviewer will document in the SER the results of the following:

(1) The reviewer should determine whether there is 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.

(2) The reviewer should determine whether there is reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of QA elements and will make needed adjustments promptly.

(3) The reviewer should determine that the applicant has specified the QA elements criteria, the basis for choosing the criteria, and the proposed method for implementation.

(4) If the applicant refers to other sections of the application when describing its QA elements, the reviewer should examine these other sections of the application to determine the applicant's commitment to the QA elements and the proposed method for implementation.

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 applicant has appropriately considered the regulatory acceptance criteria in Section 11.4.3 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 conclusion about reasonable assurance of safety. For partial reviews, license revisions, and process changes, the reviewer should use applicable sections of the acceptance criteria and write the SER to reflect only the portions of the submittal that were reviewed.

The following sections present examples of staff documentation for the SER.

11.6.1 Configuration Management

The staff has reviewed the CM function for [name of facility] according to Chapter 11 of the SRP (NUREG-1520). [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 and will provide reasonable assurance that consistency among 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 ensure 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 NUREG-1520. The assessments are expected to verify and ensure the adequacy of the CM function.

6. Design Reconstitution (Existing Facilities Only)

The applicant has adequately described the design reconstitution performed. Current design bases are available and verified for all IROFS, such that the configuration is consistent with the 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, PM, 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 and monitoring, PM, and functional testing activities described in the license application provide reasonable assurance that the 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 determine the level of maintenance needed, (4) justifies the PM intervals in terms of the equipment reliability goals, (5) provides for training that emphasizes the importance of IROFS identified in the ISA summary, regulations, codes, and personnel 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 of public health and safety and the protection of the environment.

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 satisfies the regulatory requirements and is consistent with the guidance in this SRP.

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 meets 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 facility 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 it 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 the health and safety of the public, workers, and 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) and generic implications of the event, and (3) recommending corrective actions for ensuring a safe facility and safe facility operations, in accordance with the acceptance criteria of Section 11.4 of the SRP.

The applicant has committed to monitoring and documenting corrective actions through to 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 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 and 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 promptly.

11.6.8 Other Quality Assurance 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 should demonstrate the adequacy of the applicant's use 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 also concludes the following:

1. The applicant has established and documented a commitment to 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 NUREG-1520.

2. The applicant has established and documented a commitment to QA elements, and the administrative measures for staffing, performance, assessing findings, and implementing corrective action 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, IROFS, 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.

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 the 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 use of other QA elements meets the requirements of 10 CFR Part 70 and provides reasonable assurance of protection of public health and safety and of the environment.

11.7 References

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

U.S. Code of Federal Regulations, Title 10, Part 50, "Domestic Licensing of Production and Utilization Facilities."

U.S. Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Code of Federal Regulations, Title 10, Part 21, "Reporting of Defects and Noncompliance," as revised.

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.

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

U.S. Nuclear Regulatory Commission, "Human Factors Engineering Program Review Model," NUREG-0711, Rev. 2, February 2004.