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NUREG-1520 STANDARD REVIEW PLAN – CHAPTER 11

REVISIONS PROPOSED BY THE NUCLEAR ENERGY INSTITUTE – 30 August 2000

11.0 MANAGEMENT MEASURES

11.1 PURPOSE OF REVIEW

Management measures are functions, performed by a licensee, generally on a continuing basis, that support items relied on for safety (IROFS), to provide reasonable assurance that the items are available and reliable to perform their functions, when needed. The phrase "available and reliable," as used in the revised Part 70, means that, based on the analyzed, credible conditions in the ISA, IROFS will perform their intended safety functions when needed to prevent accidents or mitigate the consequences of accidents. Management measures will be developed 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 supporting management measures. The following discussion addresses each of the management measures included in the 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.

Management measures supporting an IROFS may be graded commensurate with the importance of the IROFS to facility safety. The license applicant should describe methods used to decide which management measures should be applied to an IROFS and how each management measure is to be graded (e.g. in terms of robustness and comprehensiveness).

The applicant should describe the purpose, principal elements, organization and safety grading (if any) and application of management measures to IROFS. The descriptions should be in sufficient detail to enable the reviewer to understand how the management measures will support achievement of the performance requirements of 10 CFR 70.61. Appendix C provides an example of how a license applicant's might describe the Maintenance Management Measure and illustrates what level of detailed information would be expected by a reviewer.

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 confirm that the applicant has committed to develop and implement a CM System that is consistent with the requirements of 10 CFR 70.72(a). The CM System must assure consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. The NRC staff should review the applicant's descriptions of, and commitments to, 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 facility; 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; training and qualification of affected staff; revision and distribution of operating, and maintenance procedures and drawings; post-modification (or functional) testing; and readiness review.

The NRC staff should review the following:

1. CM System

The review should cover the applicant's description of overall CM functions, including descriptions and objectives of each CM activity and the organizational structure.

The review should examine the applicant's establishment of a CM system applicable to all operations.

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 system.

4. Change Control

The review should examine the applicant's commitments to provide reasonable assurance that the CM system maintains consistency among the design requirements, the physical

configuration, and the facility documentation.

5. Assessments

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

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' safety significance. The staff will review the applicant's description of how each of the following four elements of a maintenance program are implemented. Note that not every aspect of each maintenance function is necessarily required; the applicant should specify which maintenance elements will be applied to an IROFS.

1. Corrective maintenance

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

2. Preventive maintenance (PM)

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

3. Surveillance/monitoring

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

4. Functional testing

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

11.3.3 Training and Qualifications

Part 70 requires that personnel who perform activities relied on for safety be trained, 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. The review of the

training and qualification should address the following training areas:

1. Organization and management of training
2. Analysis and identification of functional areas requiring training;
3. Position training requirements
4. Development of the basis for training, including objectives;
5. Conduct of on-the-job training;
6. Evaluation and continuing assurance of training effectiveness;
7. Personnel qualification

11.3.4 Procedures

The review should examine the applicant's process for the preparation, use, and control of written procedures. 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; radiation protection; and,

2. Procedures used for activities that support the process operations. These are procedures used to define 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 procedures are not part of the license and would not normally be reviewed for technical adequacy, since this aspect is addressed by the inspection function. The NRC staff should review the commitments in the application to provide reasonable assurance that the applicant's program adequately addresses the following:

1. Procedures should be provided for all necessary steps or operations that are conducted at the facility with licensed material and with IROFS.;

2. The method for creating and controlling procedures within plant management control systems.

3. Method for verifying and validating procedures before use.

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

5. The method for ensuring that current procedures are available to personnel.

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 action 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 the 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 audit and assessment personnel;

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

4. 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 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 for documenting the process for the purpose of applying the "lessons learned" to other operations. An applicant may describe a "corrective action 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 the 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 managed. 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 reviewer should evaluate how the applicant proposes to apply QA to IROFS and their supporting management measures. 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 to the IROFS identified in the ISA Summary. QA would also be applicable, as appropriate, to the hazards analysis process in the applicant's ISA.

The application defines QA including any grading of the levels to be applied to IROFS identified in the ISA Summary. QA grading will be determined by the relative risk, or relative safety importance, of an IROFS.

The focus of the review of QA measures is limited to ensuring the safety of workers and the public, and protecting the environment. The review should provide reasonable assurance that the application of QA is appropriately coordinated and integrated with other management measures.

Since QA 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, and specifically management measures applied to criticality, containment of licensed materials, personnel protection, and environmental safety. Application of graded QA and quality levels commensurate with risk 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 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 and management measure 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 to 10 CFR 70.72.

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

11.4.2 Regulatory Guidance

1. 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.

2. 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 System

   The applicant's description of the CM System confirms its application to all IROFS and describes at least the following topics: (a) assignment of CM grades (or quality levels) to IROFS and how such grades were established, (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.

   An important element of an applicant’s overall CM System is the establishment of a baseline applicable to all new facilities or new processes at existing facilities, in accordance with 10 CFR 70.64. That baseline may initially include 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-consequence events, as defined by the ISA Summary, the applicant may choose to reduce or eliminate certain features of the CM System as applied to those lesser-consequence 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 Summary 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.

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. This attribute may be described as part of CM or as part of QA.

3. Document Control

The applicant describes an acceptable method to establish and control documents within the CM System. The applicant describes how CM will capture documents that are important to safety. The document database is used to control documents and track document change status.

4. Change Control

The applicant describes how the CM System 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. The applicant also describes an acceptable process, within the CM System, for providing reasonable assurance that the ISA and ISA Summary are 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 thirty days.

5. Assessments

The applicant confirms that periodic assessments of the CM System will be conducted to determine the system's effectiveness and to correct deficiencies. Both document assessments and physical assessments (system walkdowns) will be conducted periodically. 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 program (see sections 11.3.5. and 11.4.3.5 for details on audits and assessments).

11.4.3.2 Maintenance

The reviewers should find the applicant's submittal acceptable if the application addresees the following four components of a maintenance program:

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 records of failure of IROFS and management measures 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 listed in the ISA Summary are maintained by the applicant. For surveillance tests that can only be done while IROFS listed in the ISA Summary 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.

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(es) of IROFS do not occur. This activity includes using the results of the surveillance component of maintenance and the records of failure of IROFS and management measures 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. 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(s) from recurring. Feedback from PM, corrective maintenance, and incident investigations is used, as appropriate, to modify the frequency or scope of the PM activity. 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, unless the process or operation is shut down while the test is being performed. 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 in the ISA Summary, 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 (or system of 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 dates of functional tests, 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 describe how the training and qualification management measure will be used to provide reasonable assurance that plant personnel will be trained to perform activities relied on for safety when required.

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 IROFS from service for maintenance and for return to service; and i) notification to operations personnel that repairs have been completed. Written procedures for the performance of maintenance include, as applicable, steps a) through i). The details of maintenance procedure acceptance criteria are addressed in Section 11.4.3.2 of this SRP.

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 test, or surveillance/monitoring activities listed above for the maintenance function.

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 programs should be described.

The reviewer should find the applicant's submittal acceptable if, in addition to the four maintenance elements described above, the application includes the following:

1. Inspections and tests are conducted to verify that IROFS conform to specified requirements and will perform satisfactorily in service. Inspection and test requirements are specified in written procedures with provisions included for documenting and evaluating test results. This attribute may be described as part of maintenance or as part of QA.

2. Provisions are made to provide reasonable assurance that tools, gauges, instruments, and other measuring devices are properly identified, controlled, and calibrated at specified intervals, to maintain performance within required limits. This attribute may be described as part of maintenance or as part of QA.

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 may be incorporated by reference.

1. Organization and Management of Training - The organization and management of training are acceptable if the program fulfills the objectives identified by the licensee, especially where human actions 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 the plant positions for which training will be provided.

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

1. Responsibility for the content and effective conduct of the training and management of the training program is clearly defined.
2. Training is used as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.
3. Procedures are documented and implemented to provide reasonable assurance that all phases of training are conducted reliably and consistently.
4. Training documents are linked to the CM system to provide reasonable assurance that design changes and modifications are accounted for in the training.
5. Exemptions from training are granted to trainees and incumbents only when justified, documented, and approved by management.
6. 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 for Which Training is Required - analysis and identification of activities for which training is required 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 performing, and verifying the activities relied on for safety specified in the ISA Summary.

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. 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 standards or achievement levels and identifies objectives from the analysis of activities and performance requirements.

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 proficiency is acceptable if trainees are evaluated at the completion of training, to determine their capability to perform the job requirements.

7. Conduct of On-the-Job Training - On-the-job training is acceptable when used for activities relied on for safety required by the ISA Summary are fully described. On-the-job training should be conducted using well-organized and current training materials and 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.

7. 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.

8. 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 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 are relied on for safety 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.
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 job performance and proficiency, 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. 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, 11.5.2.4, and 11.6.4 for details on procedures). This attribute may be described as part of the procedures or as part of QA.

2. A system of operating, safety and administrative procedures addresses 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.

3. Procedures exist to direct the following activities: a) design; b) CM; c) procurement; d) construction; e) radiation safety; f) maintenance; g) QA ; 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 developing, approving, implementing, and controlling operating procedures.

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 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. The license applicant should list 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, 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 applied to IROFS and/or licensed material and that they can be performed as written. The discussion identifies who is responsible for verification.

9. Documents containing procedures are distributed in accordance with applicable distribution lists. A process is used to limit the use of outdated procedures.

10. The applicant has formal requirements governing the review, approval and use of temporary changes to procedures. Temporary procedure changes do not involve a change to the ISA or ISA Summary. 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 reasonable 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;

    c. Control of work by comprehensive procedures to be followed by maintenance

technicians. Maintenance procedures are reviewed by the appropriate safety disciplines, as required.

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 two years. 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 acceptable if it satisfies the following:

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; 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 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 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 or processes to address findings, recommendations and to provide corrective actions, are also described.

7. 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. This attribute may be explained as part of audits and assessments or as part of QA.

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. Investigations will begin within 72 hours of the abnormal event, or sooner, depending on the safety significance of the event. Failures of IROFS and management measures, if relevant, 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 and ISA Summary will be modified accordingly.

The applicant has a formal policy or procedure in place for conducting an incident investigation that contains 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 of qualified internal and external investigators (including experts in root cause analysis) 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;

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. 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 applicant commits to prompt investigation of any abnormal events;

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

3. 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;

4. 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 acceptable if it satisfies the following criteria:

1. Records are prepared, approved, 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 a record management system. This attribute may be described as part of records management or as part of QA; and

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

   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. 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 thirty working days [10 CFR 70.62(a)(3) states "promptly"].

11.4.3.8 QA

To be acceptable, the applicant's QA should be structured to support IROFS, which may include site design features. QA may be graded in accordance with the importance of the IROFS to the achievement of safety.

All IROFS should have all appropriate QA elements applied.

A checklist for evaluating the application of QA is given below. The application of QA 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 are as follows are provided below:

1. The applicant describes the: a) organizational structure; b) functional responsibilities; and c) responsibility and authority for all organizations performing activities relied on for safety, including the organization of its principal contractors (architect/engineer, constructor, construction manager, and operator), as applicable. 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. This attribute may be described as part of QA or as part of Chapter 2, Organization and Administration;

2. The applicant may describe its application of QA 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;

3. 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;

4. Purchased items and services for IROFS are controlled to provide reasonable assurance of conformance with specified requirements. This attribute may be described as part of QA or as part of the management measure on procedures;

5. Provisions are made to identify and control IROFS and to provide reasonable assurance that incorrect or defective items are not used. This attribute may be described as part of QA or as part of the management measure on procedures;

6. Measures are established to maintain the acceptability of special processes used in the course of construction, maintenance, modifications, and testing of IROFS, 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;

7. 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. This attribute may be

described as part of QA or as part of the management measure on maintenance;

8. Provisions are made to control the handling, storage, shipping, cleaning, and preservation of IROFS, to prevent damage, loss, and deterioration caused by environmental conditions such as temperature or humidity;

9. 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. This attribute may be described as part of QA or as part of the management measure on maintenance;

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

11. 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 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). This attribute may be described as part of QA or as part of the management measure on audits and assessments;

12. 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. This attribute may be described as part of QA or as part of the management measure on audits and assessments and/or CM.

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.

In discussing individual management measures the applicant may reference information presented in other parts of the license. In such cases the primary reviewer should review the referenced sections to confirm the applicant's commitments to the measure and proposed methods of implementation are acceptable.

The reviewer may need to visit the facility to review information in the facility ISA, or, in the case of an existing licensee, to inspect the facility or to discuss licensee performance with resident or region inspection staff.

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 (SER) 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 System Management

   The primary reviewer should consider whether the CM System acceptably states management commitments, gives the policy directive, and defines key responsibilities, and equipment scope. The secondary reviewers should examine the ISA Summary to assure that the applicant has committed to apply CM to IROFS identified in the ISA Summary.

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 primary reviewer for CM is responsible for determining that appropriate levels of CM are applied to IROFS of differing safety significance.

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 primary reviewer should determine whether a controlled document database is used to control documents and track document change status.

4. Change Control

   The primary reviewer should confirm that the CM System commits to acceptable methods for: (a) the identification of changes in configurations that are IROFS listed in the ISA Summary; (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 confirm that both document assessments and physical assessments (system walkdowns) will be conducted periodically, to check the adequacy of the CM System.

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

11.5.2.2 Maintenance

The primary reviewer will evaluate the applicant's description of how the maintenance function will coordinate with 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.

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 evaluates the adequacy of the applicant's training and qualification program to ensure that personnel whose activities are relied on for safety will be knowledgeable in how to perform such activities when required.

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

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

The secondary reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria for procedures listed in Section 11.4.

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.

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

The review should determine whether the applicant has adequately planned for audits and assessments in accordance with the acceptance criteria in §11.4.

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.

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. The reviewer may choose to review the physical characteristics of offsite record storage areas.

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

The primary reviewer should confirm that the applicant's (and the applicant's principal contractors') QA commitments are consistent with other sections of the submittal and with the acceptance criteria in Section 11.4.

The secondary reviewer should also determine that the applicant has specified QA criteria, 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.

Staff Reviewers of SRP Chapters 3 through 11 should determine whether IROFS within their areas of review are assigned appropriate QA and appropriate grading.

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 System 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 are described that will provide reasonable assurance that the relationship 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. <u>CM Management</u>

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

2. <u>Design Requirements</u>

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 periodic audits and assessments. The assessments are expected to verify and assure the adequacy of the CM function.

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. 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 appropriate procedures 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 maintenance personnel that emphasizes the importance of identified IROFS, 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 provide reasonable assurance that engineered safety controls will be available and reliable when required.

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; and (2) 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 start-up, operate, maintain, and modify the facility safely and to perform activities relied on for safety. The staff concludes that the applicant's plan for personnel training and qualification meet the requirements of Part 70.

11.6.4 Procedures

The application has described a suitably detailed process for the development, approval, and implementation of procedures. IROFS listed in the ISA Summary 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 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 program.

The staff concludes that the applicant's plan for audits and assessments meets the requirements of 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(s); 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 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 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 QA when coupled with the management measures and licensee commitments, as applied to IROFS, for design, construction, and operations] the NRC staff has concluded that the applicant has adequately described the application of QA (and the applicable QA 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 QA commitment, 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, revision and control of written administrative plant procedures. 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. Measures have been provided for evaluation of the effectiveness of training against predetermined objectives and criteria;

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

8. Management measures 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 management measures and QA program commitments meet the requirements of Part 70 and provide reasonable assurance of protection of public health and safety and of the environment.

11.7 REFERENCES

1 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," U.S. Government Printing Office, Washington, DC.

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

3. 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.

4. 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.

5. 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.

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

7. 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.
8. U.S. Nuclear Regulatory Commission, "Guide to NRC Reporting and Recordkeeping Requirements," NUREG-1460, Rev. 1, July 1994.

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

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

11. U.S. Nuclear Regulatory Commission, "Proposed Method for Regulating Major Materials Licensees," Section 3.2.6, 'Configuration Management,' NUREG-1324, 1992.

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

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

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

APPENDIX A

CHECKLIST FOR PROCEDURES

All activities listed below are covered by written procedures. The list is not intended to be all-inclusive nor is it intended to imply that procedures be developed with the same titles as those on the list. This listing is divided into four categories and provides guidance on topics to be covered.

1. Management Control Procedures:

   Training
   Audits and Assessments
   Incident Investigation
   Records Management
   Configuration Management
   Quality Assurance
   Procedure management
   Nuclear criticality safety
   Fire protection
   Radiation protection
   Radioactive waste management
   Maintenance
   Environmental protection
   Chemical process safety
   Operations

2. Operating Procedures:

   a. System Procedures That Address Startup, Operation, Shutdown, Control of Process Operations, and Recovery after a Process Upset

      Process Operations
      Ventilation Systems
      Criticality alarms Systems
      Decontamination operations
      Plant Utility Systems (air, other gases, cooling water, fire water, steam)
      Temporary changes in operating procedures

   b. Abnormal Operation/Alarm Response

      Loss of cooling water
      Loss of instrument air
      Loss of electrical power
      Loss of criticality alarm system
      Fires
      Chemical process releases

3. Maintenance Activities That Address System Repair, Calibration, Surveillance, and Functional Testing

   Repairs/replacement, calibration and testing of items relied on for safety (IROFS)
   Repairs/replacement and testing of criticality alarm units
   Repair/replacement and testing of ventilation and containment systems
   Surveillance/monitoring

4. Emergency Procedures:

   Response to a criticality
   Hazardous process chemical releases (including uranium hexafluoride)

APPENDIX B

RECORDS

The requirements for records management vary according to the nature of the facility and the hazards and risks posed by it. Examples of the records required by 10 CFR Parts 19, 20, 21, 25, and 70 are presented below. These listings are organized under the chapter headings of the Standard Review Plan (SRP). Although they indicate the kinds of records to be found in these chapters of the SRP, the listing is not intended to be exhaustive or prescriptive in format. For example, in particular instances, different or additional records might fall within these groupings. Further, the applicant may choose to organize the records in ways other than shown here.

Examples of Records

SRP Chapter

1.0 General Information

Construction records

Facility and equipment descriptions and drawings

Design criteria, requirements, and bases for items relied on for safety (IROFS) as specified by the facility CM function.

Records of facility changes and associated integrated safety analyses, as specified by the facility CM function.

Safety analyses, reports, and assessments

Records of site characterization measurements and data

Records pertaining to onsite disposal of radioactive or mixed wastes in surface landfills

Procurement records, including specifications for IROFS

2.0 Organization and Administration

Administrative procedures with safety implications

Change control records for material control and accounting program

Position descriptions, and personnel qualification records

Safety and health compliance records, medical records, personnel exposure records, etc.

QA records

Safety inspections, audits, assessments, and investigations

3.0 Integrated Safety Analysis

4.0 Radiation Safety

Bioassay data

Exposure records

Radiation protection records

Radiation training records

5.0 Nuclear Criticality Safety

Nuclear criticality safety procedures

Nuclear criticality safety analyses

Inspections, audits, investigations, and assessments

Incidents, unusual occurrences, or accidents

6.0 Chemical Safety

Procedures and plans

Inspections, audits, investigations, and assessments

Diagrams, charts, and drawings

Incidents, unusual occurrences, or accidents

Reports and analyses

Training

7.0 Fire Safety

Fire Hazard Analyses

Fire prevention measures, including hot-work permits and fire-watch records

Inspection, maintenance, and testing of fire protection equipment

Training and retraining of response teams

Pre-fire emergency plans

8.0 Emergency Management

Emergency plan(s) and procedures

Comments on emergency plan from outside emergency response organizations

Emergency drill records

Memoranda of understanding with outside emergency response organizations

Records of actual events

Training and retraining of personnel involved in emergency preparedness functions

Inspection and maintenance of emergency response equipment and supplies

9.0 Environmental Protection

Environmental release and monitoring records

Environmental Report and supplements to the Environmental Report, as applicable

10. 0 Decommissioning

Decommissioning records

Financial assurance documents

Decommissioning cost estimates

Site characterization data

Final survey data

Decommissioning procedures

11.0 Management Measures

11.1 Configuration Management

- Safety analyses, reports, and assessments that support the physical configuration of process designs, and changes thereto .
- Validation records for computer software used for safety analysis or material control and accounting
- Integrated Safety Analysis (ISA) documents
- Operating procedures

11.2 Maintenance

- PM records
- Maintenance, calibration and testing data for IROFS
- Corrective maintenance records

11.3 Training and Qualification

- Personnel training and qualification records
- Procedures

11.4 Procedures

- Standard operating procedures
- Maintenance test procedures

11.5 Audits and Assessments

- Audits and assessments of safety and environmental activities

11.6 Incident Investigations

- Investigation reports
- Incident investigation policy

11.7 Records Management

- Policy
- Material storage records
- Records of receipt, transfer and disposal of radioactive material

11. 8 Other Quality Assurance Elements

- Inspection records
- Test records
- Corrective action records

APPENDIX C

Additional Description of Information and
Level of Detail Needed in the License Application

This Appendix provides a sample submission that a license applicant might use to describe how the Maintenance Management Measure will be applied to IROFS. The example contains more detail than may be required and uses terminology for personnel positions and organizations that may not be appropriate for all licensees.

MAINTENANCE MANAGEMENT MEASURE

Description and Elements: The maintenance program is designed to ensure that IROFS are kept in a condition of readiness such that they will be able to perform their desired functions when called upon to do so. The maintenance program will embrace four elements: (i) preventive maintenance, (ii) surveillance monitoring, (iii) repair or replacement (corrective maintenance), and (iv) functional testing of IROFS.

Policy Overview: The maintenance program will support IROFS listed in ISA Summary and facility processes that involve handling or processing of licensed material. Grading of the maintenance program will be in accordance with the risk the IROFS or safety system is to protect against. Grading will be reflected, for example, in the frequency of surveillance of the IROFS, the thoroughness of the preventive maintenance, quality assurance applied to replacement IROFS components or the frequency of the functional testing of the IROFS. Preventive maintenance (PM) will be applied through use of maintenance planning and control computer programs to establish the frequency of PM activities, to initiate work orders for programmed maintenance and to record details of the execution of the work orders. PM will apply to engineered controls and other equipment such as plant air compressors and emergency generators, fire detection and fire control, natural gas valves, nuclear criticality detection, pressure relief valves and steam boilers. The frequency of PM and instrumentation calibration will be based upon manufacturers' recommendations, prior operating experience and safety importance of the IROFS or equipment. PM will include specified calibration and re-calibration or relevant systems that will be initiated and controlled by the maintenance planning and control computer programs. Surveillance/monitoring will be conducted by electronic monitoring of IROFS and operator inspections of their availability and operability. In the event an IROFS or safety system must be removed from service for inspection, compensatory measures including, for example, replacement with an equivalent IROFS, will be implemented. The frequency of surveillance and the use of redundant, back-up electronic monitoring systems will be graded based upon manufacturers' maintenance recommendations, the documented performance trends and the safety importance of the IROFS. Corrective maintenance will be promptly initiated upon discovery of any IROFS unacceptable performance deficiency and will address any recommendations originating from any Corrective Action Program analysis. Each report of an unacceptable performance deficiency will be recorded and if a recurring problem is apparent, it will be referred to the CAP. Functional Testing will be conducted on a periodic basis on IROFS and other facility safety systems including, for example, plant-wide Fire Alarm System and Criticality Alarm System, plant-wide Hazard Warning System, specified safety-related interlocks on process equipment and

hydrogen and natural gas line leak tests. When an IROFS component is repaired or replaced, the component will be field-tested to assure that it is likely to perform its desired function when called upon to do so. If the performance of a repaired or replaced IROFS component could be different from that of the original component, the IROFS will be field-tested to assure that it is likely to perform its desired function when called upon to do so. All maintenance activities will be conducted using written maintenance work orders authorized by the Manager of Maintenance Engineering that outline the safety system or IROFS to be worked on, identify potentially impacted IROFS and any required compensatory measures to be implemented, test procedures and acceptable ranges of test parameter results, documentation requirements for test results and other relevant information.

***Organizational Structure*:** The maintenance program will be overseen by the Manager of Maintenance Engineering, who will report directly to the Vice President of Manufacturing. The Manager will be responsible for all craft work associated with engineering, maintenance, modification and repair of plant equipment, IROFS and facilities and will oversee the conduct of PM. Calibration and inspection programs for all safety-related equipment and systems and for conducting tests of safety and emergency-related equipment will be the responsibility of this Manager..

Records: Written records shall be maintained of all maintenance activities including test results, PM maintenance schedules, performance criteria, functional test results, trends in IROFS performance, and corrective action investigations and implemented changes.

Maintenance Program Efficacy: A formal review of the efficacy of the Maintenance Program will be conducted under the auspices of the Manager of Maintenance Engineering and the Manager of Regulatory Compliance every two years. Deficiencies in any element of the Maintenance Program resulting from this review and identified in the annual Licensee Performance Reviews will be investigated and changes to the Maintenance Program developed for approval by the Manager of Process Engineering . Modifications to the CM system policy and procedures will be promptly implemented.

Coordination with Other Management Measures: The Maintenance Program will be complemented through application of complementary Management Measures including, for example, Training (of maintenance personnel), Incident Investigations (for investigation of abnormal and unusual plant events), Records Management (for retention of documentation of facility changes and safety bases), and Audits and Assessments (to evaluate the efficacy of the CM System).]