11. MANAGEMENT MEASURES

11.1 ~~PURPOSE OF REVIEW~~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 ~~functions,~~activities performed by a licensee, generally on a continuing basis, that are applied to ~~items relied on for safety (~~IROFS~~)~~ to provide reasonable assurance that the IROFS ~~are available and able to perform their functions when needed. The phrase "available and reliable," as used in 10 CFR Part 70, means that, based on the analyzed, credible conditions in the ISA, IROFS~~ will perform their intended safety function when needed to prevent accidents or mitigate the consequences of accidents to an acceptable level. ~~Management measures will be implemented~~ The purpose of management measures is to provide reasonable assurance of compliance with ~~the performance requirements,~~ 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. ~~The following discussion addresses each of the management measures included in the 10 CFR Part 70 definition of~~As defined in 10 CFR 70.4, "Definitions," management measures~~, i.e.,~~ include configuration management (CM), maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance (QA) elements. ~~The degree to which measures are applied to the IROFS may be a function of the item's importance in terms of meeting the performance requirements as evaluated in the ISA.~~

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

~~Examples of the kind of information that the reviewer(s) require to assess the adequacy of a management measure is provided in Appendix B to this SRP chapter. The purpose of this review is to enable the staff to conclude, with reasonable assurance, that the management measures applied to IROFS, as documented in the ISA Summary, provide reasonable assurance that the IROFS will be available and able to perform their functions, when needed, consistent with the performance requirements of 10 CFR 70.61. If a graded approach is used, the review should also determine whether the measures are applied to the IROFS commensurate with the IROFS' importance to safety.~~

*** Note: This is a proposed revision to Chapter 11 for NUREG-1520 ***

11.2 ~~RESPONSIBILITY FOR REVIEW~~Responsibility for Review

~~Primary: Licensing Project Manager~~

~~Secondary:~~

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~~Configuration Management: Primary ISA Summary 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~~ Reviewer

~~Supporting:~~ ~~Technical Discipline Engineers,~~ Supporting: Primary Reviewers of Chapters 3 through 10 of this Standard Review Plan (SRP)
Fuel Cycle Facility Inspector~~s, Resident Inspectors~~

~~**11.3 AREAS OF REVIEW**~~

~~**11.3.1 Configuration Management (CM)**~~

~~This review should provide reasonable assurance that the applicant has committed to develop and implement a CM function that is consistent with the requirements of 10 CFR 70.72(a). The review should determine, with reasonable assurance, that the applicant has described and committed to a CM function that assures consistency among~~

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 ~~s~~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 ~~also~~ determine that the applicant's CM ~~function~~ program captures formal documentation governing the design and continued modification of the site, structures, processes, systems, ~~equipment,~~ components,

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computer programs, personnel activities, and supporting management measures~~, as identified and described in the ISA Summary~~. The review should ~~assure~~also ensure that the CM ~~function~~program is adequately coordinated and integrated with ~~the~~ other management measures.

The NRC staff should review the ~~applicant's~~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.~~summary. The ~~staff~~ staff's review should focus on the applicant's CM measures that provide reasonable assurance of the ~~disciplined~~ documentation of engineering, procurement, installation, and ~~operation of~~ modifications; the training and qualification of affected staff; the revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; and the post-modification testing~~; and readiness review~~. 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 should~~staff's review ~~the following:~~

~~1. CM Policy~~

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

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

~~2. Design Requirements~~

~~The reviewer should examine the applicant's descriptions of how design requirements and associated design bases have been established and are maintained. The reviewer~~ should evaluate the applicant's ~~CM controls on the design requirements and for the ISA Summary.~~

~~3. Document Control~~

~~The reviewer should examine the applicant's description of its methods for controlling documents within the CM function.~~

~~4. Change Control~~

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

configuration, and the facility documentation, in accordance with 10 CFR 70.72, "Facility changes and change process."

5. Assessments

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

6. Design Reconstitution (Existing Facilities Only)

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

11.3.2 Maintenance

- The NRC staff will evaluate the applicant's description of its maintenance function.program. The reviewerstaff will examine the applicant's commitments to inspect, calibrate, test, and maintain IROFS to a level commensurate with the items' importance to safety to provide reasonable assurance of their ability to perform their safety functions when required. The applicant identifies these IROFS in the ISA Summary. The staff will review the applicant's description of how each of the following functions is implemented within the site organization. Note that not 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 the risk reduction of risk.

1. Corrective maintenance

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

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

2. Preventive maintenance (PM)

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

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

~~3. Surveillance/monitoring~~

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

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

~~4. Functional testing~~

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

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

~~11.3.3~~ Training and Qualifications

- ~~10 CFR Part 70—~~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 ~~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~~ public 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.~~safely. Therefore, the application should describe the training, testing, and qualification of these personnel ~~who perform activities relied on for safety should be described in the application and should be reviewed by the staff.~~, and the NRC staff should review this description. The review should examine the applicant's experience and capabilities to provide this ~~required~~ training for its personnel who will perform activities relied on for safety. The review of the training and qualification should address the following ~~training~~ areas:

  – ~~1. Organization~~organization and management of the training function
  ~~2. Analysis~~
  – analysis and identification of functional areas requiring training
  ~~3. Position~~
  – position training requirements
  ~~4. Development~~
  – development of the basis for training, including objectives
  – ~~5. Organization~~organization of instruction, using lesson plans and other training guides
  ~~6. Evaluation~~

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– evaluation of trainee learning
~~7. Conduct~~
– conduct of on-the-job training
~~8. Evaluation~~
– evaluation of training effectiveness
~~9. Personnel~~
– personnel qualification
~~10. Applicant's~~
– applicant's provisions for continuing assurance, including the needs for retraining or reevaluation of qualification

~~11.3.4~~ Procedures

- ~~The~~ 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 applicant should prepare two general types of procedures for use at the facility:~~

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

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

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

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

– ~~1. The~~ method for identifying procedures that are needed plant~~-~~wide~~. The ISA Summary identifies IROFS where human actions are important. Procedures~~

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should be provided for all necessary steps or operations that are performed at the facility. Procedures should be provided for every element of management control that is discussed in the SRP sections.

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

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

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

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

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

11.3.5

Audits and Assessments

- The applicantNRC staff should describe a systemreview the applicant's program of audits and assessments thatconsists. 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 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 (see 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 incident investigations as well as audits and assessments. The review of the audits and assessments should address the following areas:

and assessment.

*** Note: This is a proposed revision to Chapter 11 of NUREG-1520 ***

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

– The commitments to audit and assessment activities

– The the use of qualified and independent audit and assessment personnel

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- ~~1. The~~ the general structure of typical audits and assessments
- ~~2. The~~the facility procedures to be used to direct and control the audit and ~~assessment~~ assessment activities
- ~~3. The~~ the planned use of the results of the audit and assessment activities
- ~~4. The~~ the documentation to record and distribute the findings and recommendations of these audits and assessments
- ~~5. The~~ 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~~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. ~~An~~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.

~~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 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 ~~records of~~ their ~~failure~~ 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~~ management measures.

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

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

11.3.8 Other QA Elements

The application must address other QA elements that will be applied to IROFS and other management measures. The review NRC staff should determine that a complete description of evaluate whether the applicant's application of other QA elements to IROFS is included in the application. adequately described. The 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 facility's life.

Fundamental to this effort is the applicant's application of QA elements to the identified IROFS resulting from the ISA and identified in the ISA Summary. QA elements would also be applicable, as appropriate, to the hazards analysis process in the applicant's ISA.

The application defines the QA elements and the levels to be applied to IROFS identified in the ISA Summary (SRP Chapter 3). Further, the manner in which the QA function is coordinated and integrated with other management measures should be described. If the applicant applied a graded safety program to the IROFS, the application should explain how the QA elements were also applied in a graded manner to the IROFS.

The reviewer(s) 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, may impose product related QA criteria. The focus of the review of QA measures per this SRP is limited to ensuring the safety of workers and the public and protecting the environment (i.e., in relation to the performance requirements of 10 CFR 70.61).

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

11.4 ACCEPTANCE CRITERIA The reviewer should 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

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and the public and protecting the environment (i.e., in relation to the performance requirements of 10 CFR 70.61).

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

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

~~The requirements for fuel cycle facility management measures are specified in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," as revised~~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 ~~application to~~ engineered and administrative controls and control systems that are identified as IROFS, pursuant to ~~10 CFR~~ 10 CFR 70.61(e), so that 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," Section 19.12, "Instructions to Workers."~~10 CFR 70.64(a)(1) states that new facilities or new processes at existing facilities shall develop and implement designs in accordance

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with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their safety function when needed.

- ~~The regulatory requirement for procedures that protect health and minimize danger to life is specified in 10 CFR 70.22(a)(8).~~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 ~~with 10 CFR 70.~~to 10 CFR 70.72~~.~~, "Facility Changes and Change Process."

Incident investigation and reporting are required by ~~10 CFR~~ 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~~,~~ ~~1994.~~

~~• American National Standards Institute Standards for Quality Management, ANSI/ISO/ASQ 9000 series.~~

~~•~~ International Atomic Energy Agency~~ Safety~~ 1983), as endorsed by Regulatory Guide~~,~~ ~~"Establishing and Implementing a~~ 1.28, "Quality Assurance Program~~," Safety Guide 50-SG-Q1, 1995.~~

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

~~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.~~(Design and Construction)," Revision 3. This guidance applies only to applications for plutonium processing and fuel fabrication facilities.

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

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11.4.3 Regulatory Acceptance Criteria

~~**11.4.3.1 Configuration Management (CM)**~~

~~1. CM Policy~~

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

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

~~The design process leading to drawings and other statements of requirements proceeds logically from the design basis.~~ (3) The ISA summary clearly defines the IROFS to be listed under CM ~~are clearly defined in the ISA Summary,~~ along with the assignment of any grades or quality levels. The applicant should ~~have indicated~~indicate in the ISA ~~Summary what~~ summary the level of CM attributes that is applied to a particular IROFS. However, in the ISA ~~Summary~~summary, this indication may ~~only~~ consist of only an index or category designation. ~~The definitions of the multiple CM levels, if used, should be in the CM description in the application.~~

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~~2. Design Requirements~~

~~The applicant~~

(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. ~~Technicalit~~ also describes technical management review and approval functions ~~are described~~.

~~3. Document Control~~

~~The applicant~~(6) The application describes an acceptable method to create and control documents ~~within the CM function, including cataloging the document database, the information content of the document database, maintaining and distributing documents, document retention policies, and document retrieval policies. The applicant describes how CM will capture documents~~ that are ~~relevant and~~ relied on for safety. ~~The description includes~~These documents include design requirements, ~~the~~ ISA, as-built drawings, specifications, all procedures that are IROFS, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others that the applicant ~~may deem~~deems part of CM. ~~The document database is used to control documents and track document change status.~~

~~4. Change Control~~

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

(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 ~~identifying and authorizing proposed changes; for performing appropriate technical, management, and safety reviews of proposed changes in IROFS; for tracking and implementing changes; and for documenting changes (including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and QA). The applicant also describes an acceptable process, within the CM function, for~~ providing reasonable assurance that the ISA is systematically reviewed and modified to reflect design or operational changes from an established safety basis~~,~~ and that all documents outside the ISA that are affected by safety basis changes are properly modified, authoritatively approved, and made available to personnel. ~~When a change is~~

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

~~5. Assessments~~

~~The applicant~~(11) The application confirms that initial and periodic assessments of the CM function are conducted to determine the ~~program's~~program's effectiveness and to correct deficiencies. ~~Both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function. All assessments and followups are documented. These reports can provide a basis for future changes.~~ The ~~applicant~~ application indicates that such assessments are systematically planned and conducted in accordance with an overall facility audit and assessment function ~~(see the sections in Chapter 11 for details on audits and assessments)~~.

~~6. Design Reconstitution (Existing Facilities Only)~~

~~The applicant describes~~(12) For existing facilities, the application may describe whatever design reconstitution has been done for the purpose of the application. ~~Because this information may duplicate the facility design bases information described elsewhere to support the ISA, this information may be included by reference to other parts of the application.~~ The applicant has available the current design bases, including design requirements, supporting analyses, and documentation supporting all IROFS. ~~A verification process, including walkdowns, is complete and has verified that the configuration is consistent with as-built facility documentation.~~

(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.

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

(1~~. Surveillance/monitoring~~

~~For IROFS identified in the ISA Summary, the applicant describes the surveillance function and its commitment to the organization and conduct~~) descriptions 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. The applicant describes how the results from incident investigations, the review of the 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. Records showing the current surveillance schedule, performance criteria, and test results for all IROFS are maintained by the applicant. For surveillance tests that can only be done while IROFS are out of service, proper compensatory measures are prescribed for the continued normal operation of a process.~~

~~2. Corrective~~ corrective maintenance

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

~~3. PM~~

~~The applicant provides a~~ (2) description of how the ~~PM function that demonstrates a commitment to conduct preplanned and scheduled periodic refurbishing, or partial or complete overhaul, for the purpose of ensuring that unanticipated loss of IROFS do not occur. This activity includes using the results of the surveillance component of~~ maintenance ~~and the failure records 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~~ensure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of IROFS because of monitoring or ~~PM. After conducting PM and before returning a safety control to operational status, *if necessary*, a functional test is conducted to ensure that an IROFS performs as designed and provides the safety action expected. The methodology or basis used to determine PM frequency is described. The applicant describes how results from incident investigations and identified root causes are used to modify the affected~~preventive maintenance ~~function and eliminate or minimize the root cause from recurring. Feedback from~~ (PM~~, corrective maintenance, and incident investigations is used, as appropriate, to modify the frequency or scope of the PM activity. A rationale for deviations from industry standards~~

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~~or from vendor recommendations for PM is provided. Records showing the PM schedule, and results, for all IROFS subject to this maintenance component are maintained by the applicant.~~)

~~4. Functional testing~~(3) discussion of how the maintenance function uses, interfaces with, or is linked to the various management measures

~~The application includes a~~ (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~~. These~~

(15) as necessary, a commitment to conduct functional tests ~~should be conducted using applicant-approved procedures and should include compensatory measures while the test is being conducted. The applicant designs the functional test~~ designed to include all operational aspects of the IROFS that are important to safety~~.~~

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

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~~For illustrative purposes only, the following scenario is provided:~~

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

~~As necessary,~~ during startup of new ~~process equipment, functional tests are conducted and documented and the documents are maintained for NRC review. Records~~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 ~~are maintained by the applicant.~~

~~Administrative controls are often identified as IROFS. The applicant should provide a~~ (17) general discussion ~~about~~of how ~~these~~administrative controls identified as IROFS are ~~assured~~verified to be available and reliable to perform their intended safety function over extended periods of operation

~~. Specific management measures and how they are applied should be described.~~

~~A general acceptance criterion applicable to all maintenance functions is an adequate description of work control methods. Listed below are methods or practices that should be applied to the corrective, preventive, and functional test maintenance elements, and for which the applicant should commit to prepare written procedures. These include, as applicable: (a) authorized work instructions with detailed steps and a reminder of the importance of the IROFS identified in the ISA Summary, (b) parts lists, (c) as-built or redlined drawings, (d) a notification step to the operations function before conducting repairs and removing an IROFS from service, (e) radiation work permits, (f) replacement with like-kind parts and the control of new or replacement parts to ensure compliance with 10 CFR Part 21, (g) compensatory measures while performing work on IROFS, (h) procedural control of removal of components from service for maintenance and for return to service, (i) ensuring safe operations during the removal of IROFS from service, and (j) notification to operations personnel that repairs have been completed. Written procedures for the performance of maintenance include steps a through j. The details of maintenance procedure acceptance criteria are addressed in Section 11.4.3.2 of this SRP. All work requests and maintenance procedures include technical and safety discipline reviews and approval.~~

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

~~The four maintenance elements described above are covered by elements of the management measures discussed in Chapter 11 of this SRP. The applicant should include a discussion of how, or provide references to, the maintenance function uses, interfaces with, or is linked to the~~

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~~various management measures. As an example, since maintenance workers are trained and qualified to perform their duties, the link between maintenance and the training and qualification function should be described.~~

11.4.3.3 Training and Qualifications

~~The applicant's submittal~~ The application should be acceptable regarding personnel training and qualification ~~should be acceptable~~ if it satisfies the ~~following~~ criteria described below. In addition to the regulatory acceptance criteria ~~given below, SRP Section 4.4.5.3 provides~~, 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 ~~be found~~appear in other sections of the ~~SRP~~ application and may be incorporated by reference.

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

~~The~~ include the following commitments ~~should be in the application~~ 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 ~~are accounted for in the training~~.

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~~individual's training~~, job performance,~~ and qualification.

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

Design, construction, operations, training, and other subject matter experts, as appropriate, should conduct an analysis to identify activities requiring training. The activities treated in this manner should include - as a minimum - those for managing, supervising, performing, and verifying the activities should be provided for each position or activity that is relied on for safety specified in the ISA Summary as preventing or mitigating accident sequences. . 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 matrixed to 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.

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

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

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 or 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 or guides and other training materials before their issue and use.

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

~~7. Conduct of On-the-Job Training - The conduct of on-the-job training is acceptable if on-the-job training used for activities relied on for safety and listed in the ISA Summary is fully described. On-the-job training should be conducted using well-organized and current training materials. On-the-job training should be conducted by designated personnel who are competent in the program standards and methods of conducting the training. Completion of on-the-job training should be by actual task performance. When the actual task cannot be performed and is, therefore, "walkeddown," the conditions of task performance, references, tools, and equipment should reflect the actual task to the extent possible.~~

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

~~9. Personnel Qualification - Commitments should be provided regarding 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.~~ (3) The application should contain ~~such~~ commitments regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, facility operators, technicians, maintenance personnel, and other staff ~~required to meet NRC regulations:~~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 ~~minimum of a~~ B.S~~.~~., B.A., or ~~B.A. or the~~ equivalent degree. Each manager should have either management ~~experience~~ or technical experience in ~~facilities~~ a facility similar to the facility identified in the application.

b. Supervisors should have at least the qualifications required of personnel being supervised~~, plus, either 1 additional year of experience supervising the technical area at a similar facility or completion of a supervisor training course~~.

c. Technical professional staff ~~identified in the ISA Summary~~ whose actions or judgments are critical to ~~satisfy~~satisfying the performance requirements identified in ~~10 CFR Part~~ 10 CFR Part 70 ~~(i.e., related to an IROFS)~~ should have a B.S~~.~~.,

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B.A., or equivalent degree in the appropriate technical field ~~and 3 years of experience. Other technical professional staff should have a B.S. in the appropriate technical field and 1 year of experience~~.

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 ~~also~~ be required to meet minimum qualifications, but the application need not describe these minimum qualifications ~~need not be described in the application.~~ .

(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~~. Applicant's~~ 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 - The applicant's provisions for~~ continuing assurance of personnel training and qualification are acceptable if the ~~submittal~~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 ~~their~~ 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 reviewer should determine that the applicant's~~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 ~~is acceptable if it~~ 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.

~~2. Operating procedures contain the following elements: (a) purpose of the activity, (b) regulations, polices, and guidelines governing the procedure, (c) type of procedure, (d) steps for each operating process phase, (e) initial startup, (f) normal operations, (g) temporary operations, (h) emergency shutdown, (I) emergency operations, (j) normal shutdown, (k) startup 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 timeframe for which the procedure is valid. It is particularly important that safety limits and IROFS (such as mass limits, moderator exclusion, and independent sampling requirements) be clearly identified as such in the procedure for the operators.~~

~~(3. Procedures reflect the important elements of the functions described in the applicable chapters of this SRP. Procedures exist to direct the following activities: (a) design, (b) CM, (c) procurement, (d) construction, (e) radiation safety, (f) maintenance, (g) QA elements, (h) training and qualification, (i) audits and assessments, (j) incident investigations,~~

~~*** Note: This is a proposed revision to Chapter 11 of NUREG-1520 ***~~

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~~(k) records management, (l) criticality safety, (m) fire safety, (n) chemical process safety, and (o) reporting requirements.~~

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

~~5. The applicant includes~~ the following commitment regarding procedure adherence: "Activities involving licensed SNM and/or IROFS will be conducted in accordance with approved procedures."

~~6.~~(4) The applicant ~~describes the types of procedures used during facility operation. These will typically include management control, operating, maintenance, and emergency procedures. The applicant provides information regarding the procedure categories used at the facility. The applicant~~ develops procedures for site-wide safe work practices to control processes and operations with licensed special nuclear material (SNM) and/or IROFS and/or hazardous chemicals incident to the processing of licensed material. ~~These safe work practices apply to workers, visitors, contractors, and vendors. An acceptable identification discussion clearly states areas for which a procedure is required.~~

(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.~~summary. The applicant provides a listing ~~(in an appendix)~~ 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~~ Appendix A to this SRP chapter provides an acceptable listing of the items to be included under each topic.

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

a. ~~8.~~ The applicant ~~verifies~~considers the ~~technical accuracy of~~ISA in identifying needed procedures ~~and that they can be performed as written.~~.

b. The ~~discussion identifies who is responsible for verification. The verification process provides reasonable assurance that the technical information, including formulas, set points, and acceptance criteria, is all there and is correct, and includes either a walkdown of the~~ procedure ~~in the field, or a tabletop walkthrough. The review process includes technical, cross-disciplinary reviews by affected organizations. This process includes both new procedures and procedure changes. The review provides reasonable assurance that the~~ specifies operating limits and IROFS ~~identified in the ISA Summary are specified in the procedures and that QA requirements are identified and included in operating procedures. The applicant specifies who can approve procedures and the approval level for each procedure type. At a minimum, responsible management and the safety disciplines approve new procedures and changes to existing procedures.~~.

c. ~~9. Documents are distributed in accordance with applicable distribution lists. A process is used to limit the use of outdated procedures. Copies are available to appropriate personnel. Issuance and distribution of procedures are documented and refer to the records management function~~Procedures include required actions for off-normal conditions of operation, as well as normal operations.

~~10. The applicant has formal requirements governing temporary changes. Temporary changes do not involve a change to the ISA. The review and approval process is documented. Temporary procedures may be issued only when permanent procedures do not exist to~~

~~(a) direct operations during testing, maintenance, and modifications, (b) provide guidance in unusual situations not within the scope of permanent procedures; and, (c) provide assurance of orderly and uniform operations for short periods when the plant, a system, or a 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 establishes a time frame for use of the temporary procedure and sets the same level of review and approval as for permanent procedures.~~

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.

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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 ~~maintenance~~ activities:

a. Pre-~~-~~maintenance activities ~~require~~involve 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~~ 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. ~~Maintenance procedures are reviewed by the~~ The various safety disciplines, including criticality, fire, radiation, industrial, and chemical process safety, review maintenance procedures. The procedures describe~~, as a minimum,~~ the following:

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

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

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

iv. ~~Tracking~~tracking and records management of maintenance activities

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

(10) The applicant ~~conducts periodic reviews~~ has formal requirements governing the use of temporary procedures. Temporary procedures may be issued only when permanent procedures do not exist to ~~assure~~(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 time~~-~~frame for reviews of the various types of procedures. ~~At a minimum all operating procedures are reviewed every 5 years and emergency procedures are reviewed every year.~~

(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. ~~Guidance identifies the manner in which procedures are to be implemented. Routine procedural actions that are frequently repeated may 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.~~

(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

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The NRC reviewers should find the ~~applicant's submittal~~application acceptable in terms of audits and assessments if it provides reasonable assurance that the following ~~regulatory review criteria for audits and assessments~~ are adequately addressed and satisfied~~.~~:

(1~~.~~) The ~~applicant~~application describes ~~policy~~program directives covering the audit and assessment function (i.e.,~~ at a minimum,~~ the activities to be audited, audit frequency, guidance in conducting the audit or assessment, assigned responsibilities for each phase of the work, and procedures for recording the results and recommending actions to be taken).

(2~~.~~) The ~~applicant has committed~~application contains a commitment to conduct internal audits and independent assessments of activities significant to facility safety and environmental protection.

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

(4~~. Independent~~) 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) ~~5. Audits~~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~~. Qualified~~) The application states that qualified personnel without direct responsibility for the function and area being audited or assessed will ~~be used.~~perform the audits and assessments. The application specifies the staff positions and committees responsible for audits and assessments ~~are specified. The~~ and describes the levels of management to which results are reported~~, and the~~ . 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 ~~process~~ formal procedure to investigate abnormal events that may occur during operation of the facility~~,~~ to determine their specific or generic root cause(s~~) and~~), generic implications, and risk significance, to recommend corrective actions, and to report to the NRC as required by ~~10~~ 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, one individual may suffice to conduct the evaluation. The investigator(s) will be independent from the line function(s) involved with the incident under investigation. Investigations will begin within 48 hours of the~~

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~~abnormal event, or sooner, depending on the safety significance of the event. The record of IROFS failures required by 10 CFR 70.62(a)(3)for IROFS should be reviewed as part of the investigation~~, "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~~summary will be modified to include evaluation of the risk associated with accidents of the type actually experienced.

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

~~1. A documented plan for investigating an abnormal event. This plan is separate from any required Emergency Plan. The investigation of an abnormal event should begin as soon as possible, commensurate with the safety of the investigative team, after the event has been brought under control.~~

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

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

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

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

~~6. Requirements to make available original investigation reports to the NRC on request.~~

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

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

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

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

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

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

~~5. The investigation process and investigating team are independent of the line management, and participants are assured of no retaliation for participating in investigations.~~

~~6. A reasonable, systematic, structured approach is used to determine the specific or generic root cause(s) and generic implications of abnormal events.~~

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

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

11.4.3.7 Records Management

The reviewer will find the applicant's records management system ~~for records~~ acceptable if ~~it satisfies the~~ 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 protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage~~) 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.

~~5.~~(6) The ~~organization and procedures are in place to promptly detect and correct any deficiencies in the records management system or its implementation~~

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The types of records that should be included in the system are listed in Appendix B to this SRP chapter. Records are categorized by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records. The procedures should (a) assign responsibilities for records management, (b)) specify the authority needed for records retention or disposal, (c)) specify which records must have controlled access and provide the controls needed, (d)) provide for the protection of records from loss, damage, tampering, and theft or during an emergency, and (e)) specify procedures for ensuring that the records management system remains remains effective.

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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 (e.g., punched cards or paper tapes) and codes for older computing equipment to contemporary computing media and equipment. (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 10 CFR 70.62(a)(3). Record revisions necessitated by post-failure investigation conclusions shouldmust be made within 5 working days of the promptly after completion of the investigation (10 CFR 70.62(a)(3) states "promptly").

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(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 QAQuality Assurance Elements

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

The ISA Summary 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 and at the highest level to all IROFS or may grade the application in proportion to the item's importance of the item to the achievement of safety.

All IROFS should have all appropriate QA elements applied. If the
Other QA may include some or all of the elements listed below:

Organization—The applicant ~~grades the application of QA elements, the relative risk importance rankings of IROFS, as established within the maintenance function, should parallel the rankings used in for QA elements.~~

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

(1) ~~The applicant~~ describes the ~~(a)~~ organizational structure, ~~(b)~~ functional responsibilities, ~~and (c) charts of the~~ lines~~, interrelationships, and areas~~ of ~~responsibility and~~ authority ~~for all organizations performing activities relied on for safety, including the~~, and lines of communication for control of activities affecting quality. The organization ~~of the applicant and, as applicable, its principal contractors (architect/engineer, constructor, construction manager, and operator). Persons or organizations~~ responsible for ensuring that appropriate QA has been established ~~and for verifying that activities affecting quality have been correctly performed~~should have sufficient authority, access to work areas, and organizational independence to ~~carry out their~~ 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 ~~industry~~ standards. The commitment may describe the applicant's graded approach to QA, in which measures are implemented ~~consistent~~ 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. ~~The QA program should be functional before performing the ISA required by 10 CFR Part 70. See references in Section 11.7 (e.g., ANSI/ASME NQA-1).~~

(3) ~~A design control function is established that includes design inputs, process, analyses, verification, interfaces, changes, and design~~ 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.

~~1.~~ Procurement Document Control—The design bases information and other documentation ~~and records (see Sections 11.3.1, 11.4.3.1, 11.5.2.1, and 11.6.1 for details on CM).~~

(4) ~~Applicable design bases and other requirements~~ necessary to ~~provide reasonable assurance of~~ ensure adequate quality are included or referenced in documents for procurement of items ~~or~~ and services ~~relied on for safety~~. To the extent necessary,

~~*** Note: This is a proposed revision to Chapter 11 of NUREG-1520 ***~~

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suppliers are required to have ~~QA consistent~~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 ~~of a type~~ appropriate for the circumstances ~~(see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures)~~and reference appropriate quantitative or qualitative acceptance criteria.

(6) Document Control—The applicant's document control system describes the preparation, ~~issuance~~issue, and ~~modification~~change of documents that specify quality requirements or prescribe activities affecting quality ~~are~~. The document control system is controlled ~~to provide reasonable assurance~~in a manner that ~~the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by~~ensures that authorized personnel ~~(see Sections 11.3.1, 11.4.3.1, 11.5.2.1, and 11.6.1 for details on CM and Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures).~~review documents and changes thereto for adequacy and approve them for release.

(7) ~~Purchased IROFS and services relied on for safety are controlled to provide reasonable assurance of conformance with specified requirements~~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) ~~Provisions are made to identify and control IROFS and to provide reasonable assurance that incorrect or defective items are not use~~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.

~~2. Measures are established to maintain the acceptability of special processes used in the course of construction, maintenance, modifications, and testing activities (e.g., welding, heat treating, nondestructive testing, and chemical cleaning) and to assure that they are performed by qualified personnel using qualified procedures and equipment.~~

~~3. Inspections required to verify conformance of IROFS with requirements are planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). Personnel qualification programs are established for inspection test personnel (see Sections 11.3.3, 11.4.3.3, 11.5.2.3, and 11.6.3 for details on training and qualifications).~~

~~4. Tests are conducted to verify that IROFS conform to specified requirements and will perform satisfactorily in service. Test requirements are specified in written procedures with provisions included for documenting and evaluating test results (see Sections~~

~~11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). Personnel qualification programs are established for test personnel (see Sections 11.3.3, 11.4.3.3, 11.5.3, and 11.6.3 for details on training and qualifications).~~

~~5. 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.~~

~~6. Provisions are made to control the handling, storage, shipping, cleaning, and preservation of IROFS, in accordance with work and inspection instructions, to prevent damage, loss, and deterioration caused by environmental conditions such as temperature or humidity.~~

(9) ~~Provisions are made to control the inspection, test, and operating status of IROFS to prevent inadvertent use of nonconforming items or bypassing~~ 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.

~~7.~~ 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 ~~and tests.~~

~~8. Provisions are made to control the identification, segregation, disposition, and prevention of installation or use of nonconforming IROFS.~~

(10) ~~Provisions are made to provide reasonable assurance that conditions adverse to safety are promptly identified and corrected and that measures are taken to preclude repetition. These actions~~ should be documented ~~and reported to appropriate levels of management (see Sections 11.3.6, 11.4.3.6, 11.5.2.6, and 11.6.6 for details on incident investigations, and Sections 11.3.5, 11.4.3.5, 11.5.2.5, and 11.6.5 for details on audits and assessments)~~. Qualified personnel other than those who performed or directly supervised the work being inspected should perform the inspections.

(11) ~~Provisions are made for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality for IROFS (see Sections 11.3.7, 11.4.3.7, 11.5.2.7, and 11.6.7 for details on records management)~~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) ~~Provisions are made for planning and scheduling assessments and audits~~Control of Measuring and Test Equipment—The applicant should establish controls for tools,

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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, ~~QA;~~quality assurance. The responsibilities and procedures ~~are identified~~ for assessing, auditing, documenting, and reviewing results ~~and for designating management levels to review assessment and audit results; and provisions are made for incorporating the status of findings and recommendations in management reports (see Sections 11.3.5, 11.4.3.5, 11.5.2.5, and 11.6.5 for details on audits and assessments).~~should be identified.

~~9. 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.~~

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~~11.5 REVIEW PROCEDURES~~11.5 Review Procedures

~~11.5.1 Acceptance Review~~

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

~~11.5.2 Safety Evaluation~~

~~After the primary reviewer determines that the application is acceptable for~~ For each area of review specified in Section 11.3, the review procedure is identified below. These review ~~in accordance with Section 11.5.1, above, the primary and secondary reviewers should perform a safety evaluation review against the acceptance criteria described in Section 11.4. Review~~ procedures ~~for each criterion~~ are ~~discussed in the sections below. If deficiencies are identified,~~ based on the ~~applicant should be requested to submit additional information or modify the submittal to meet the~~ identified SRP 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~~. 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.~~2.~~1 ~~CM~~

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1. ~~CM Policy~~**Configuration Management**

The ~~primary~~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 ~~policy~~program directive, and defines key responsibilities, terminology, and equipment scope. ~~The secondary reviewers should examine the ISA Summary and the ISA, as needed, to assure that identified IROFS will be subject to the CM function. Appropriate~~

(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 ~~should be examined~~. In particular, the review should examine functional interfaces with QA, maintenance, and training (including qualification~~) should be examined.~~).

(5) The reviewer~~s~~ should look for the ~~applicant's~~applicant's identification of ~~required~~necessary databases and the rules for their maintenance. ~~The reviewers should examine implementing procedures for the CM function.~~

11.5.1.2 Design Requirements

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

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

(4) The reviewer~~s~~ should verify that ~~the~~ IROFS to be listed under CM will be clearly defined in the requirements documents, along with the assignment of any grades or quality levels. ~~This~~The reviewer should coordinate this part of the review ~~should be coordinated~~ with the ISA primary reviewer. ~~The ISA Summary should specify all IROFS, and the applicant should have indicated in the ISA Summary what level of CM attributes is applied to a particular item. However, in the ISA Summary this indication may consist of~~

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~~only an index or category designation. The definitions of the multiple CM levels, if used, should be in the CM section of the application. The primary reviewer for the CM section~~

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 ~~primary~~ reviewer should evaluate the ~~applicant's material showing that the CM system will capture~~application to determine whether the CM system captures documents that are relevant and important to safety. ~~The~~These documents should include the design requirements, the ISA, the ISA ~~Summary~~summary, as-built drawings, specifications, all ~~safety~~ operating procedures important ~~operating procedures~~to safety, procedures involving training, maintenance ~~and~~ , audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and other documents that the applicant deems ~~to pertain~~pertinent to the CM function.

(2) The ~~primary~~ reviewer should ~~determine whether~~examine information describing a controlled document database ~~is~~ 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 ~~primary~~ reviewer should ~~be able to find~~verify that the description of change control within the CM function commits to ~~have~~ acceptable methods for (~~a~~1) the identification of changes in configurations that are IROFS, (~~b~~) 2) technical and management review of changes, and (~~c~~) 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 ~~primary~~ reviewer should ~~be able to find~~verify that both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function~~. The primary reviewer should be able to find~~ and that all assessments and follow-ups will be documented. ~~These reports can provide a supporting basis for future changes.~~

11.5.1.6 Design Reconstitution (Existing Facilities Only)

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

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(1) The ~~primary~~ reviewer ~~examines~~should examine the ~~applicant's~~ applicant's description of work to establish, organize, and document design requirements and design bases for items for which design information was not available before the application was submitted. ~~Of particular importance are~~ This includes the methods used to evaluate, verify, and validate reconstituted design data for IROFS. ~~For existing facilities, the design requirements and physical configuration may have greatly changed according to the demands of a changed mission. If documentation has not kept pace, it will be necessary for the applicant to walk down systems, update drawings and specifications, perform new calculations and analyses, and otherwise rebuild the design bases.~~

(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. ~~On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP.~~

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

11.5.2~~.2~~ Maintenance

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

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

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

11.5.~~2~~.3 Training and Qualification

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

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(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 ~~qualification~~qualifications of personnel who will perform activities relied on for safety.

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

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

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

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

11.5.~~2.~~4 Procedures

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

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

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~~3. Policy and administrative procedures, noncrucial operating 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.~~

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

~~5. The applicant includes a statement to follow approved procedures while processing licensed SNM.~~

~~6.~~(7) Procedures exist for the notification of operations personnel before and after maintenance is performed on IROFS, and activities are controlled by procedures.

~~When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the procedures input for the SER, as described in Section 11.6, using the acceptance criteria from Section 11.4.3.4~~(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~~.2~~.5 Audits and Assessments

~~After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the secondary~~ The reviewer will ~~perform a safety evaluation against the acceptance criteria described in Section 11.4. The review should~~ determine whether the applicant has adequately planned for audits and assessments to be accomplished and whether necessary ~~policies~~programs, personnel, and procedures~~, and instructions~~ will be ~~in place to begin audits and assessments early, that is, during the design of IROFS.~~ established.

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

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

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

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

~~When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the audits and assessments input for the SER, as described in Section~~ **11.**~~6, using the acceptance criteria from Section 11.4.3.~~**5**~~.~~

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~~11.5.2~~.6 Incident Investigations

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

For existing facilities, the ~~primary~~ reviewer ~~will~~ should 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.~~

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~~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

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~~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.~~

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 ~~as well~~, particularly the storage areas for records ~~for~~ related to IROFS for high-consequence ~~accident~~ accident sequences.

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~~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~~Quality Assurance Elements

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~~After the primary reviewer has determined that the application is acceptable for review in accordance with Section 11.5.1, above, the primary~~ The reviewer should ~~confirm that~~evaluate

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

~~The secondary reviewer should also determine that the applicant has specified the QA elements criteria, the basis for choosing the criteria and the proposed method for implementation. If the applicant references other sections of the application when describing its QA elements, the reviewer should review these other sections of the application to determine the applicant's commitment to the QA elements and the proposed method for implementation.~~

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

~~Staff reviewers of SRP Chapters 3 through 11 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 review should result in a determination that there is reasonable assurance that the applicant's (and the applicant's principal contractors') QA elements will provide reasonable assurance that IROFS will perform their safety functions in a satisfactory manner.~~The reviewer will document in the SER the results of the following:

~~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.~~(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.

~~**11.6 EVALUATION FINDINGS**~~ (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.

~~*** Note: This is a proposed revision to Chapter 11 of NUREG-1520 ***~~

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(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

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The ~~staff's~~staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of ~~Section~~ Section 11.4.1 and that the ~~regulatory acceptance criteria in Section 11.4.3 have been~~ 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'~~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 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 ~~should be written~~ to reflect ~~what~~ only the portions of the submittal that were ~~not~~ reviewed ~~and the safety significance, if any.~~.

~~The staff can document the evaluation as follows:~~The following sections present examples of staff documentation for the SER.

11.6.1 ~~CM~~Configuration Management

The staff has reviewed the CM function for ~~{~~[name of facility~~}~~] according to ~~Section~~ 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 ~~that~~ 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 ~~assure~~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 ~~this SRP.~~NUREG-1520. The assessments are expected to verify and ~~assure~~ensure the adequacy of the CM function.

6. Design Reconstitution (Existing Facilities Only)

The applicant has adequately described ~~that~~ the design reconstitution~~, if required, has been done.~~ 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, ~~preventive 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

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~~Summary~~ 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~~ summary to identify IROFS that require maintenance and ~~at what~~ determine the level of maintenance needed, (4~~)~~) justifies the PM intervals in ~~the~~ terms of the equipment reliability goals, (5~~)~~) provides for training that emphasizes the importance of IROFS identified in the ISA ~~Summary identified IROFS~~summary, regulations, codes, and ~~personal~~ 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~~ 10 CFR Part 70~~,~~ and provide reasonable assurance ~~that the~~ of public health and safety ~~of the worker~~ and the ~~public are provided for~~protection of the environment.

11.6.3 ~~———~~Training and Qualification

Based on its review of the license application [~~Insert~~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 the regulatory requirements~~, (2)~~ and is consistent with the guidance in this SRP~~) and (3) is acceptable~~.

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

11.6.5 ~~———~~Audits and Assessments

Based on its review of the license application [~~Insert~~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~~applicant's plan for audits and assessments and finds it acceptable.

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The staff concludes that the ~~applicant's~~applicant's plan for audits and assessments meets the requirements of ~~10 CFR Part~~ 10 CFR Part 70 and provides reasonable assurance of protection of the health and safety of the public ~~and~~, 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 ~~Subsection~~ 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~~ 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~~promptly.

11.6.8 ~~——~~Other ~~QA~~Quality Assurance Elements

Based on its review of the license application [~~Insert~~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~~applicant's use of other QA elements, as applied to IROFS, for design, construction, and operations~~] the~~]. 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 ~~further that~~the following:

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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 ~~this SRP~~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. ~~Specified standards or criteria and testing steps have been provided.~~

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

6. Training requirements have been established and documented to provide employees with the skills to perform their jobs safely. Management measures have been provided for 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~~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~~applicant's use of other QA elements ~~(and the applicable QA elements of its principal contractors)~~ meets the requirements of
~~10 CFR Part~~ 10 CFR Part 70 and provides reasonable assurance of protection of public health and safety and of the environment.

11.7 ~~REFERENCES~~References

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