Revised 12/22/2000

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

11.0 MANAGEMENT MEASURES

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11.1 PURPOSE OF REVIEW

The purpose of the review is to determine that the management measures will provide reasonable assurance that the IROFS will be available and reliable when needed and thus, satisfy the performance requirements of 10 CFR 70.61.

Management measures are functions, performed by a licensee, generally on a continuing basis, that are applied to items relied on for safety (IROFS) as identified in the ISA Summary, to provide reasonable assurance that the items are available and reliable to perform their functions, when needed. Management measures are applied to IROFS identified in the ISA Summary. The phrase "available and reliable," as used in the revised Part 70, means that, based on the analyzed, credible conditions in the ISA, IROFS will perform their intended safety function when needed to prevent accidents or mitigate the consequences of accidents. Management measures descriptions will be reviewed to determine reasonable assurance of compliance with the Part 70 performance requirements, 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 management measures. The following sections of Chapter 11 address each of the management measures included in the Part 70 definition of

management measures, i.e., configuration management (CM); maintenance; training and qualifications; procedures; audits and assessments; incident investigations; records management; and other QA elements.

The degree to which measures are applied to the IROFS may be chosen by the applicant as a function of the item's importance in terms of meeting the performance requirements as evaluated in the ISA. The review is to determine the adequacy of individual management measures as applied to IROFS. If variations of a particular management measure (a "graded" application) are to be applied to IROFS of differing importance to risk management, then these variations will be reviewed.

11.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary:

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

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

11.3 AREAS OF REVIEW

This section describes the scope of the review and briefly outlines the specific commitments, core elements, safety grading (if applicable), QA and technical information that need to be examined by each technical reviewer. For each management measure, the reviewer should examine the following information submitted by the applicant:

1. Commitments:
   a. to apply the management measures to IROFS identified in the ISA Summary, and
   b. to develop, implement and update (as required) policies, procedures and programs to apply each management measure

2. System Description and Core Elements: descriptions of the principal elements of the policies, programs and methods for applying the management measure including, for example,
   a. implementation approach and strategy
   b. overview of implementation policies, programs and methods
   c. principles and/or core elements of implementation programs and methods
   d. the description of the safety grading method, if applicable, and how different levels of grading are applied within specific management measures
   e. demonstration of how "continuing reasonable assurance" of reliability and availability of the IROFS will be achieved and maintained

f. verification and validation methods
g. relation to other management measures

3. Quality Assurance: if QA is discussed as a component of the management measure (rather than as a separate management measure), a description of which QA elements are being applied to the management measure and, if applicable, what safety grading of QA has been made.

Areas of Review for each management measure are described in the following Sections 11.3.1 through 11.3.8.

11.3.1 Configuration Management (CM)

The review should confirm that the application addresses development and implementation of a CM system that is consistent with the requirements of 10 CFR 70.72(a). The reviewer should examine applicant's description of a CM function that assures consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. The review should also determine that the applicant's CM function captures formal documentation governing changes in the design of the site, structures, processes, systems, equipment, components, computer programs, personnel activities (IROFS), and supporting management measures, and IROFS, as identified and described in the ISA Summary or the applicant's safety program description in the license application. The review should assure that the CM function is adequately coordinated and integrated with the other management measures.

The NRC staff will review the following topic areas within CM: CM policy, design requirements, document control, change control, and CM function assessment.

11.3.2 Maintenance

The review should confirm that the application addresses development and implementation of a maintenance function that provides reasonable assurance that IROFS will be available and reliable to perform their safety functions when required. The staff will review the applicant's description regarding each of the following elements of a maintenance function. The reviewer should review what maintenance elements will be applied to an IROFS, and whether that level of maintenance will reasonably support the applicant's claimed availability and reliability for that IROFS. The following principal elements will be reviewed:

1. Surveillance/monitoring
2. Preventive maintenance (PM)
3. Functional testing
4. Corrective maintenance
5. Work control methods

11.3.3 Training and Qualifications

The review should confirm that the application addresses training of personnel whose activities are relied on for safety. The plan for selection, training, testing, and qualification of these personnel should be described in the application and reviewed by the staff. The review should examine the applicant's plan for training and qualifications with respect to its adequacy to fulfill the objectives for the training identified by the licensee. The review of the training and qualification should address the following training areas:

1. Organization and management of the training function;
2. Position training requirements
3. The core elements of training programs;
4. Organization of instruction, using lesson plans and other training guides;
5. Evaluation of trainee accomplishment;
6. Conduct of on-the-job training;
7. Evaluation of training effectiveness; and
8. Personnel qualification

Part 70 training requirements (reference 70.23(a)(2)) are also addressed in Chapter 4 of this SRP.

11.3.4 Procedures

The review should confirm that the applicant commits to use a process for the preparation, use, and control of written procedures pertaining to IROFS, including the human performance of actions relied on for safety, and the management measures supporting those IROFS. This will include reviewing what the applicant commits to and describes regarding identifying what procedures will be created and controlled, and the preparation, use, and management of change of written procedures.

In general, this review will focus on the applicant's commitments and descriptions relevant to procedures in order to find compliance with 70.22(a)(8) and 70.23(a)(4). Detailed, operator-level procedures at the facility are reviewed, on a sampling basis, during periodic NRC inspections. However, for new license applications or new processes at existing facilities, especially those that involve operations such as highly enriched uranium liquid processes, the licensing review may include reviews of selected detailed specific operating procedures, if available.

11.3.5 Audits and Assessments

The review should confirm that the application addresses the implementation of a system of audits and assessments. The reviewer should examine the applicant's commitments to and description of a system of audits and assessments to develop reasonable assurance that it is structured to (1) audit compliance with regulatory requirements and license commitments, and (2) assess the effectiveness of the management measures activities in achieving the continued availability and reliability of IROFS. An applicant may describe a "corrective action program" which includes the functions of both audits and assessment and incident investigations (see following section 11.3.6). This approach is acceptable and the reviewer should, in that case, review the applicant's description and commitments with regard to the acceptance criteria in this SRP chapter for both audits and assessments and incident investigations.

11.3.6 Incident Investigations

The review should confirm that the application addresses the design and implementation of a function to investigate abnormal events and to implement timely and effective corrective actions. ~~The reviewer should examine~~ the applicant's policy and management structure for investigating abnormal events, and defining and completing appropriate corrective actions. The review should include examining the criteria for appointing investigating personnel , the

methods for determining root causes, the principal elements of procedures for tracking and completing corrective actions, and the policy for documenting the process for the purpose of applying the "lessons learned" to other operations. An applicant may describe a “corrective action program” which includes the functions of both audits and assessment and incident investigations. This approach is acceptable and the reviewer should, in that case, review applicant’s description and commitments with regard to the acceptance criteria in this SRP chapter for both audits and assessments and incident investigations.

11.3.7 Records Management

The review should confirm that the application addresses development of a records management system to collect, store, and assure retrieval of all information pertinent to the safe design and operation of the facility, including the IROFS and associated management measures.

11.3.8 Other QA Elements

The review should confirm that the application addresses the implementation of accepted QA principles in the design, construction, operation, maintenance, and modification of the equipment and activities important to the safety of the licensed facility. In particular, the reviewer should examine the applicant’s description of the application of QA elements to IROFS and the management measures that support the availability and reliability of those IROFS.

If the applicant has established differing levels, or grades, of QA to be applied as a function of risk level, the reviewer should examine the descriptions of these levels and their stated application to specific IROFS.

The reviewer should also examine the applicant’s description of the QA function coordination or integration with other management measures.

11.4 ACCEPTANCE CRITERIA

11.4.1 Regulatory Requirements

10 CFR Part 70 in its entirety is applicable to nuclear fuel manufacturing facilities. Of primary interest in establishing what should be included in an applicant’s license application are 70.22(a)(6), (7), and (8) which require information regarding an applicant’s technical qualifications, proposed equipment and facilities, and proposed procedures to be included in an application. Further, 70.23(a)(2), (3), and (4) state that the Commission’s requirements to approve a license include a determination that applicant’s training and experience, proposed equipment and facilities, and proposed procedures are all adequate to protect health and to minimize danger to life and property.

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

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

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

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

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

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

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

11.4.2 Regulatory Guidance

All regulatory guidance applicable to management measures has been incorporated into the acceptance criteria discussions below. Reference documents to be used for background information are listed in Section 11.7.

11.4.3 Regulatory Acceptance Criteria

The acceptance criteria shown below are the NRC's positions on what commitments and descriptions regarding management measures should be submitted pursuant to 70.22 and Subpart H for review by the staff, in order that the staff can make the determinations required by 70.23 and Subpart H. The reviewer should find the applicant's information acceptable if it provides reasonable assurance that the following acceptance criteria are satisfactorily addressed. The staff will review in order to find reasonable assurance that the proposed management measures will be adequate to assure the availability and reliability, when required, of the IROFS to which they are applied. The over-arching acceptance criterion is that the management measures, as described by the applicant, must collectively support the applicant's claimed availability and reliability for specific IROFS, as reported in the ISA Summary. This reliability must be sufficient to assure that specific postulated accident sequences will be sufficiently unlikely, in accordance with the performance requirements of 10 CFR 70.61.

11.4.3.1 Configuration Management (CM)

The reviewer should determine that the applicant's CM system will be acceptable if the license application satisfies the following criteria:

~~1. The following commitments are made in the license application:~~

a. The applicant commits to establish a CM system that is consistent with the regulatory requirements of 10 CFR 70.72(a).

b. The applicant commits to prepare written procedures to implement the CM system.

c. The applicant commits to track all changes made to IROFS (and supporting management measures) and to maintain consistency among the IROFS design bases, physical configuration and IROFS documentation.

d. The applicant commits to keep the facility ISA, ISA Summary, and supporting documents, up-to-date.

e. The applicant commits to periodically review the efficacy of the CM system and to incorporate improvements, as needed.

2. CM Policy

The applicant's description of CM policy demonstrates the following: (a) the scope of the CM function includes all safety basis documents necessary to assure consistency among the facility safety design requirements, the facility physical configuration, and the facility documentation); (b) the organizational structure and key staff responsibilities assure effective accountability and communication among managers to achieve CM objectives. The CM functional interfaces with maintenance and training and qualification are of particular importance and should be addressed individually.

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

3. Design Requirements

The applicant describes what design requirements and associated design bases are formally established and maintained. Technical management review and approval functions are described. The applicant identifies, in the ISA Summary, the IROFS to be included within the CM function, along with the assignment of any grades or quality levels. However, in the ISA Summary this indication may consist of only an index or category designation. The definition of the individual content of multiple CM levels, if used, should be in the CM Chapter of the application.

Design requirements are recorded and maintained in a manner that correlates each IROFS with its grade, the design requirements, technical topics involved, and associated documentation.

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4. Document Control

The applicant describes how the CM system will capture documents which the applicant relies on for safety. The description includes maintaining and accessing documents, document retention policies, and document retrieval policies. Documents included in the system include, at a minimum, IROFS design requirements; the ISA; ISA Summary; as-built drawings; specifications; procedures that are IROFS or that are relevant to operations involving IROFS; qualification records for personnel performing IROFS related activities; QA; maintenance; audits and assessments; emergency response plans; system modification documents; and assessment reports. For each document within the CM function, the following information should be readily available: revision level, current status, document owner, information regarding implemented changes, and any other information used by the applicant for control and tracking, such as storage location.

5. Change Control

The applicant describes a change process to maintain consistency among the design requirements, the physical configuration, and the facility documentation. The applicant describes the process for identifying proposed changes; for performing appropriate technical and managementreview and approval of proposed changes in IROFS or related management measures; for tracking and implementing changes; for documenting changes, including as-built information; and for assuring availability of current revised documents to the appropriate operating functions.

The applicant also describes a process, within the CM function, for providing reasonable assurance that the ISA and the ISA Summary are systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety-basis changes are properly modified, authoritatively approved, and made available to appropriate personnel. When a change is made in accordance with 10 CFR 70.72, the affected on-site documentation changes will be made within a short enough period to avoid inadvertant access by site personnel of outdated design and other specifications for IROFS.

6. Assessments

The applicant conducts periodic assessments of the CM function to determine the function's effectiveness and to correct deficiencies. Both document assessments and physical assessments (system walkdowns) are conducted periodically. All assessments and follow-ups are documented. Such assessments are systematically planned and conducted in accordance with an overall facility audit and assessment function.

11.4.3.2 Maintenance

The reviewer should determine that the applicant's maintenance function will be acceptable if the license application satisfies the following criteria:

1. The following commitments are made in the license application:

~~a. The applicant commits to develop and implement a maintenance program for IROFS~~ that addresses the core elements of corrective maintenance, preventive maintenance, surveillance/monitoring and functional testing.

b. The applicant commits to prepare written procedures for the maintenance program and to periodically update them, as required.

c. The applicant commits to refer to the facility's incident investigation (or corrective action) program any IROFS' unacceptable performance deficiencies identified by the maintenance program activities.

d. The applicant commits to assure IROFS performance requirements continue to be met during periods of maintenance.

e. The applicant commits to periodically review the efficacy of the maintenance program and to incorporate improvements, as needed.

2. Surveillance / monitoring

For IROFS identified in the ISA Summary, the applicant describes the surveillance function. The surveillance activity should support the determination of performance trends for IROFS, thus providing data useful in determining PM frequencies. The applicant describes a surveillance activity that includes maintaining records of the current surveillance schedule, performance criteria, and test results for all IROFS listed in the ISA Summary.

3. PM

Applicant provides a description of the PM function that includes scheduled periodic refurbishing or replacement to prevent unanticipated failures of IROFS. The description should show that the applicant will consider the results from incident investigations and the failure records required by 70.62(a)(3) in establishing PM schedules. Instrumentation calibration and testing are addressed by the applicant as part of this maintenance activity. The applicant states that it will use functional testing before returning an IROFS to operational status, if necessary, to ensure that an IROFS' availability and reliability will be restored to levels necessary to meet the performance requirements of 70.61.

The methodology or basis used to determine PM frequency is described. Applicant describes how results from incident investigations and identified root causes are used to modify the maintenance function. The applicant describes how the function will be designed to assure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of IROFS because of monitoring or PM. Records showing the PM schedule, and results, for all IROFS subject to this maintenance component, are maintained by the applicant.

4. Functional testing

Applicant includes a general description of the methods used and the commitment to perform functional testing, as needed, of IROFS, after PM or corrective maintenance. These tests should be conducted using applicant-approved procedures. The tests should include compensatory measures while the test is being conducted, unless the process or operation is shut down while the test is being performed. Applicant designs the functional test to include all operational aspects of the IROFS that are important to meeting the performance criteria of 70.61.

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

5. Corrective maintenance

   Applicant provides both a commitment to prompt performance of corrective maintenance on IROFS and describes the general structure and conduct of this function. The description should indicate a planned, systematic, and controlled approach for the repair and replacement activities associated with identified unacceptable performance deficiencies of IROFS. Records will be kept of estimated or actual elapsed time that the IROFS was deficient prior to discovery, as necessary to assist in confirming the claimed overall likelihood of accident sequences in which the IROFS is designed to act to prevent or mitigate consequences, to meet the performance requirements of 70.61.

6. Work control methods

   The applicant provides a description of work-control methods. The applicant should commit to prepare written procedures for work control. Such procedures should address at least the following elements, as applicable: a) authorized work instructions with detailed steps; 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 as needed while performing work on IROFS; h) procedural control of removal of components from service for maintenance and for return to service; and i) notification to operations personnel that repairs have been completed. Other details of maintenance procedure acceptance criteria are addressed in Section 11.4.3.4 of this SRP.

11.4.3.3 Training and Qualification

The reviewer should determine that the applicant's training and qualification function will be acceptable if the license application satisfies the following criteria:

1. The following commitments are in the license application:

   a. Applicant commits to clearly identify the job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training of workers whose actions are identified in the ISA Summary to be relied on for safety.

   b. Applicant commits to provide formal, documented training for each position or activity for which the required performance is relied on for safety; that training should be based on the actual job performance requirements.

   c. Applicant commits to document training procedures so that training is conducted reliably and consistently using current information on the plant configuration, equipment, procedures, and processes.

   d. Applicant commits to assign qualified individuals to conduct the training.

e. Applicant commits to maintain both individual and programmatic training records. These records provide required data on each individual's training, job performance, and qualification, and provide information for both evaluating individual capability and for assessment of the overall training function.

f. Applicant commits to maintain current the training of key personnel through periodic evaluation of job performance and refresher training.

g. Applicant commits to periodically review the training and qualification program and to incorporate improvements, as required, to assure its continued effectiveness.

h. Applicant commits to maintain training documents that are linked to the CM function to provide reasonable assurance that design changes and modifications are accounted for in the training.

The applicant's submittal regarding personnel training and qualification should be acceptable if it includes the following descriptive material in addition to the commitments listed above. The reviewer should note that training requirements under Part 70, section 70.23(a)(2), are more broadly applicable than those for personnel activities directly involved with the performance of IROFS. SRP section 4.4.5 provides specific criteria for training and qualification pertinent to compliance with 10 CFR Parts 19 and 20, and specifically with respect to training for occupational radiation protection at a licensed facility. The reviewer should coordinate with the primary reviewer of Chapter 4 of this SRP to assure an adequate response by the applicant.

2. Organization and Management of Training - The application should describe the organization and responsibilities for the management of training, and describe the formal training required for activities relied on for safety.

The applicant should state that each activity selected for training (initial or continuing) is linked to supporting procedures and training materials. The specific activities selected for training and the link with training materials is be reviewed on an established schedule and updated as necessitated by changes in procedures, facility systems/equipment, or job scope.

3. Position Training Requirements - The applicant should describe the training requirements for personnel in plant positions that perform activities relied on for safety (such activities should be identified in the ISA Summary). Before training, trainees should meet entry-level criteria defined for the position, including minimum educational, technical, experience, and physical fitness (if necessary) requirements.

4. Description of the core elements of training programs. The applicant describes these elements, addressing the methods used to establish training objectives and course content, the organization and conduct of training, the methods used to measure trainee accomplishment of the objectives, the periodic requalification of personnel, as necessary, by training and /or testing, and evaluation of training effectiveness and revision of the training as necessary.

5. Organization of Instruction Using Lesson Plans and Other Training Guides - Applicant's ~~description assures the consistent conduct of training activities based on required learning~~ objectives derived from specific job performance requirements. Plans/guides may be used for in-class training and on-the-job training and if used should include standards for evaluating

acceptable trainee performance. Review and approval requirements should be established for all plans/guides and other training materials before their issue and use.

6. Evaluation of Trainee Accomplishment - Applicant states that 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 - Applicant should describe the general principles applied to the conduct of on-the-job training if on-the-job training is used for activities relied on for safety. Completion of on-the-job training is demonstrated by actual task performance; when the actual task cannot be performed and is "walked-down," the conditions of task performance, references, tools, and equipment will reflect the actual task to the extent possible.

8. Evaluation of Training Effectiveness - Applicant should describe its approach to measuring training effectiveness and revising training when found necessary. This approach should be based, at least in part, on the performance of trained personnel in the job setting. Feedback from trainee performance during training, and from former trainees and their supervisors, is used to evaluate and refine the training. Change actions (for example procedure changes, equipment changes, facility modifications) are monitored and evaluated for their impact on the development or modification of initial and continuing training and are incorporated in a timely manner. This is accomplished with document control through the CM function. Improvements and changes to initial and continuing training are 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. Such commitments should be in the application regarding personnel qualification for managers, supervisors, technical professional staff, construction personnel, plant operators, technicians, maintenance personnel, and other staff required to meet NRC regulations:

a. Managers should have a minimum of a B.S./B.A. or equivalent. Each manager should have either management experience or technical experience in facilities similar to the facility identified in the application.
b. Supervisors should have at least the qualifications required of personnel being supervised, plus, either one additional year of experience supervising the technical area at a similar facility, or, completion of a supervisor training course.
c. Technical professional staff whose actions or judgments are critical to satisfy the performance requirements identified in 10 CFR Part 70 (i.e. related to an IROFS) should have a B.S. in the appropriate technical field and 3 years of experience. Other technical professional staff should have a B.S. in the appropriate technical field and one year of experience.
d. Plant operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations should have completed the applicant's training process or have equivalent experience or training.
e. ~~Candidates for process operators should be required to meet minimum qualifications~~ described in the application.

11.4.3.4 Procedures

The reviewer should determine that the applicant's development, implementation, and control of procedures will be acceptable if the license application satisfies the following criteria:

1. The following commitments are made in the license application:

    a. The applicant commits to using a system of procedures to control all safety important activities (IROFS and the related management control measures described in this Chapter 11). This attribute may be described as part of procedures or as part of QA.

    b. the applicant commits to the following procedure adherence statement: “Activities involving licensed special nuclear material and/or items relied on for safety will be conducted in accordance with approved procedures.”

    c. the applicant commits to periodically review procedures to validate their continued accuracy and usefulness. At a minimum all operating procedures are reviewed every 5 years and emergency procedures are reviewed every year. The applicant also commits to review procedures associated with abnormal events and to refer any identified deficiencies to the incident investigation (or corrective action) program for evaluation and corrective action, if required.

2. The applicant describes the method for identifying, developing, approving, implementing, and controlling operating procedures. The description should provide reasonable assurance that: (a) the technical accuracy of procedures is validated through field tests; (b) procedures are approved by management personnel responsible and accountable for the operation; (c) a mechanism is specified for revising and reissuing procedures in a controlled manner; (d) the QA elements and CM functions at the plant assure that current procedures are available and used at all work locations; and (e) the plant training program trains and retrains the required persons in the use of the correct authorized procedures.

3. The applicant provides a description of its general approach to establishing the content of written procedures. The contents should be complete and comprehensive, and should include the following elements, as appropriate: (a) purpose and applicability (workers, visitors, contractors, etc.) (b) company policies and guidelines governing the procedure; (c) type of procedure; (d) steps for each operating process phase; (e) initial start-up; (f) normal operations; (g) temporary operations; (h) emergency shutdown; (i) emergency operations; (j) normal shutdown; (k) start-up following an emergency or extended downtime; (l) hazards and safety considerations; (m) operating limits; (n) precautions necessary to prevent exposure to hazardous chemicals (resulting from operations with SNM) or to licensed SNM; (o) measures to be taken if contact or exposure occurs; (p) IROFS associated with the process and their functions; and (q) the time frame for which the procedure is valid. It is particularly important that safety limits, operating limits, and IROFS (such as mass limits, moderator exclusion, independent sampling requirements, etc.) be clearly identified as such in operating procedures.

~~4~~ The applicant describes the ~~categories~~ of procedures used ~~at the facility, identifies activities~~ addressed by procedures, and describes what organizations are responsible for which procedures. Appendix A to this chapter provides an example listing of the categories and activities. The appendix is only intended to illustrate the scope and depth of procedures and

is not intended to prescribe any particular organization or categorization of an applicant's procedures.

5. The applicant has formal requirements governing temporary changes to procedures. Such changes should be designed and implemented in accordance with 70.72. The review and approval process is documented. Temporary procedures are issued only when permanent procedures do not exist to: a) direct operations, e.g., during testing, maintenance, and modifications; b) provide guidance in unusual situations not within the scope of permanent procedures; and, c) provide reasonable assurance of orderly and uniform operations for short periods when the plant, a system, or component of a system is not covered by existing permanent procedures. Applicant's description shows that the use of the temporary procedure is limited to a specific period and the procedure requires the same level of review and approval as that for permanent procedures.

6. Applicant's policy on use of, and particularly adherence to, procedures is described.

11.4.3.5 Audits and Assessments

The reviewer should determine that the applicant's audits and assessments function will be acceptable if the license application satisfies the following criteria:

1. The following commitments are made in the license application:

   a. The applicant has committed to conduct internal audits and independent assessments of activities relied on for safety. The applicant commits to and describes policies controlling the audit and assessment function (i.e., at a minimum, the activities to be audited; guidance in conducting the audit or assessment; and the level of management responsibility for reporting and acting on results of audits and assessments).

   b. The applicant commits to use appropriately trained and qualified personnel who have sufficient independence to conduct audits and assessments.

   c. The applicant commits to conduct audits and assessments in accordance with written procedures and checklists.

   d. The applicant commits to document audit and assessment findings in writing and to distribute them to appropriate management members for review. The applicant also commits to refer in a timely manner to the facility incident investigation (or corrective action) program any unacceptable performance deficiencies discovered during an audit for possible corrective action, if required.

   e. The applicant commits to periodically review the audit and assessment procedures and to revise them, as may be needed.

2. Applicant describes an audit activity which will be conducted to verify that operations are being conducted in accordance with regulatory requirements and commitments in the license application. ~~Audits may be conducted utilizing qualified personnel who are involved~~ in the audited activity.

3. Applicant describes how independent groups or individuals not involved in or directly responsible for the licensed activity will conduct assessments, to verify that the health, safety, and environmental compliance functions are effectively achieving their designed purposes.

4. Audits and assessments will be sufficiently broad in scope, including, at least, 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.

5. The approach to prioritizing and tracking identified corrective actions to completion is described.

6. Appropriate documentation of results is retained and examined over time to assure that identified problems and associated causes are tracked to identify trends, repeat occurrences, generic issues, and vulnerabilities before significant problems result.

11.4.3.6 Incident Investigations

The reviewer should determine that the applicant's incident investigation function will be acceptable if the license application satisfies the following criteria:

1. The following commitments are made in the license application:

   a. The applicant commits to design and implement an incident investigation program to identify, examine and remedy abnormal facility events and IROFS' unacceptable performance deficiencies.

   b. The applicant commits to prepare written procedures and to utilize adequately trained and qualified personnel to conduct incident investigations.

   c. The applicant commits to periodically review the incident investigation policies and procedures and to revise them, as may be needed.

2. The applicant describes an investigation process that will determine specific or generic root cause(s) and generic implications, recommend corrective actions, and report to the NRC as required by 10 CFR 70.50 and 70.74. The investigation process should include a prompt risk-informed evaluation. The investigator(s) will be independent from the line function(s) involved with the incident under investigation. Individual members of an investigative team may have responsibility for the functional area provided that they had no involvement in the incident being investigated. The team leader or single investigator is independent of the functional area involved in the incident. The failure records required for IROFS and associated management measures will be reviewed as part of the investigation. The process description should address the following elements:

   a. 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;

b. Criteria for selecting the person who would lead an investigation and for selecting other investigators, for identifying their responsibilities, and criteria for the authority and responsibility of the investigators.

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

3. Identified failures are evaluated, commensurate with their risk significance, to determine the cause(s). Individuals or teams trained in root cause analysis techniques evaluate significant problems using a structured root cause method to identify root and contributing causes and corrective actions to prevent recurrence.

4. Management assures that corrective actions are identified, approved, prioritized, and completed in a timely manner consistent with risk significance.

5. Appropriate, auditable documentation of results is retained and examined over time (at least two years) to assure that identified problems and associated causes are tracked to identify trends, repeat occurrences, generic issues, and vulnerabilities before significant problems result.

11.4.3.7 Records Management

The reviewer should determine that the applicant's records management system will be acceptable if the license application satisfies the following criteria:

1. The following commitments are made in the license application:

   a. The applicant commits to establish and maintain a records management system to collect, store and permit retrieval of records pertaining to IROFS.

   b. The applicant commits to periodically review the records management system procedures and to revise them, as may be needed.

2. Procedures are established and documented specifying the requirements and responsibilities for record selection; verification; protection; transmittal; distribution; retention; maintenance; and disposition; and 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 and 11.6.7 for details on records management). This attribute may be described as part of records management or as part of QA;

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

4. Examples of records that should be included in the system are listed in Appendix B to this SRP Chapter 11. Records are categorized by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records. The procedures for records management should: a) assign responsibilities for records management; b) specify the authority needed for records retention or disposal; c)

specify which records must have controlled access and provide the controls needed; d) provide for the protection of records from loss, damage, tampering, or theft or during an emergency; and e) specify procedures for ensuring that the records management system remains effective.

5. For computer codes/computerized data used for activities relied on for safety, as specified in the ISA Summary, the applicant establishes procedure(s) for maintaining readability and usability of older codes/data as computing technology changes. This could include transcribing the older forms of information (e.g., magnetic tapes) and codes for older computing equipment to contemporary computing media and equipment. Records of IROFS failures must be kept and updated in accordance with 10 CFR 70.62(a)(3). Record revisions necessitated by post-failure investigation conclusions will be made within a short enough period to avoid inadvertant access by site personnel of outdated design and other specifications for IROFS.

11.4.3.8 Other QA Elements

The reviewer should determine that the applicant's QA function will be acceptable if the license application satisfies the following criteria:

The applicant's QA elements should be structured to apply to IROFS and management measures, which may include design features.

QA is one measure that may either be treated as a separate, stand-alone management measur management e or as an integral component of each of the remaining seven management measures. The application may, therefore, describe the facility's overall QA program as a stand-alone management measure, or it may incorporate discussion of QA into the description of individual measures.

QA elements may be applied in proportion to the importance of the item to the achievement of safety (graded approach). Applicants'/licensees' QA elements may differ based on the purpose and complexity of the facility and processes to be controlled. An applicant may choose to apply all QA elements and the highest level to all IROFS. Alternatively, QA may be applied to an IROFS in a graded manner commensurate with the reduction of risk attributable to that IROFS. Some QA functions may be embedded in the design of other management measures, in which case the applicant may reference other areas of the application that present information relevant to QA. QA elements may include one or more of the following elements. Key attributes of QA elements, as described below, should be determined to be appropriately applied by the applicant:

1. The applicant describes the: a) organizational structure; b) functional responsibilities; and c) provides charts showing the interrelationships, and areas of responsibility and authority for all organizations performing activities relied on for safety, including the organization of the applicant and, as applicable, its principal contractors (architect/engineer, constructor, construction manager, and operator). Persons or organizations responsible for ensuring that appropriate QA has been established and for verifying that activities affecting quality have been ~~correctly performed have sufficient authority, access to work areas, and organizational~~ independence to carry out their responsibilities. This attribute may be described as part of QA or as part of Chapter 2, Organization and Administration.

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

3. A design control function is established that includes design inputs, process, analyses, verification, interfaces, changes, and design documentation and records. This attribute may be described as part of QA or as part of CM .

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

5. Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate for the circumstances. This attribute may be described as part of QA or as part of the management measure on procedures.

6. The preparation, issuance, and changes of documents that specify quality requirements or prescribe activities affecting quality are controlled to provide reasonable assurance that the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by authorized personnel. This attribute may be described as part of QA or as part of the management measure on records management.

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

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

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

10. Inspection required to verify conformance of IROFS with requirements is planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results. Personnel qualification programs are established for inspection test personnel. This attribute may be described as part of QA or as part of the management measure on maintenance.

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11. Tests are conducted to verify that IROFS conform to specified requirements and will perform satisfactorily in service. Test requirements are specified in written procedures with provisions included for documenting and evaluating test results. Personnel qualification

programs are established for test personnel. This attribute may be described as part of QA or as part of the management measure on maintenance.

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

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

14. Provisions are made to control the inspection, test, and operating status of IROFS to prevent inadvertent use of nonconforming items or bypassing of inspections and tests. This attribute may be described as part of QA or as part of the management measure on maintenance.

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

16. Provisions are made to provide reasonable assurance that conditions adverse to safety are promptly identified and corrected and that measures are taken to preclude repetition. These actions should be documented and reported to appropriate levels of management. This attribute may be described as part of QA or as part of a corrective action program.

17. Provisions are made for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality for IROFS. This attribute may be described as part of QA or as part of the management measure on records management.

18. Provisions are made for planning and scheduling assessments and audits to verify compliance with and to determine the effectiveness of QA; responsibilities and procedures are identified for assessing, auditing, documenting, and reviewing results and for designating management levels to review assessment and audit results; and provisions are made for incorporating the status of findings and recommendations in management reports. This attribute may be described as part of QA or as part of the management measure on audits and assessments.

19. The applicant's provisions for continuing QA address reviews and updates of QA documents based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA program changes. This attribute may be described as part of QA or as part of the management measure on audits and assessments and/or configuration management.

11.5 REVIEW PROCEDURES

~~This section discusses appropriate review techniques for the application contents.~~ It is generally a procedure that the reviewers use to determine whether the acceptance criteria in Section 11.4 have been met.

11.5.1 Acceptance Review

The primary reviewer should evaluate the application to confirm that it addresses the "Areas of Review" discussed in Section 11.3. If significant omissions are identified, the applicant should be requested to submit additional information before the start of the safety evaluation review.

The applicant may reference information presented elsewhere in the license so long as it is adequately cross-referenced. In such cases the primary reviewer should review the referenced sections to confirm the applicant's commitments to the measure and proposed methods of implementation are acceptable.

11.5.2 Safety Evaluation

After the application is accepted for review in accordance with Section 11.5.1, the primary and secondary reviewers will perform a Safety Evaluation Review (SER) against the acceptance criteria of Section 11.4. If, during the course of the safety evaluation, the reviewers determine a need for additional information, requests for such additional information should be coordinated with the licensing project manager. The reviews for all management measures should be coordinated with the primary reviewer of the ISA Summary.

The primary and secondary reviewers may need to visit the facility to review information in the facility ISA, or, in the case of an existing licensee, to inspect the facility or to discuss licensee performance with resident or region inspection staff. On such visits, selected procedures may be reviewed.

The secondary reviewers will generally be responsible for confirming that the applicant's submission meets the acceptance criteria of Section 11.4. The secondary reviewer has responsibility for confirming that commitments for one management measure are consistent with other sections of the submittal. The secondary reviewer is also responsible for writing the SER input for a particular management measure.

After completing the safety review of each management measure, the primary staff reviewer, with assistance from the other reviewers, should assemble, review, and edit input for the SER as described in Section 11.6.

11.6 EVALUATION FINDINGS

This section presents the staff's conclusions and findings that result from reviews of each area of review described in Section 11.3 of this SRP.

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

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

The staff can document the evaluation as follows:

11.6.1 CM

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

The applicant has suitably and acceptably described its commitment to a proposed CM system, including the method for managing changes in procedures, facilities, activities, and equipment for IROFS. Management-level policies and procedures, including an analysis and independent safety review of any proposed activity involving IROFS, are described that will provide reasonable assurance that the relationship among design requirements, physical configuration, and facility documentation is maintained. The CM management measure includes the principal elements of CM described in the acceptance criteria of the SRP.

11.6.2 Maintenance

The applicant has committed to maintenance of IROFS. The applicant's maintenance commitments contain the basic elements to provide reasonable assurance of the availability and reliability of IROFS, when needed: surveillance and monitoring, corrective maintenance, PM, functional testing, and work control methods . The applicant's maintenance function is proactive, using maintenance records, PM records, and surveillance tests to analyze equipment performance and to seek the root causes of repetitive failures.

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

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

~~The staff concludes that the applicant's maintenance functions~~ provide reasonable assurance that IROFS will be available and reliable as required to meet the performance standards of 70.61.

11.6.3 Training and Qualification

Based on its review of the license application [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] the NRC staff has concluded that the applicant has committed to and adequately described its personnel training and qualification in a manner that (1) satisfies regulatory requirements; and (2) is consistent with the guidance in this SRP.

There is reasonable assurance that implementation of the described training and qualification will result in operations personnel who are qualified to start-up, operate, maintain, and shut down the facility safely. There is also reasonable assurance that the applicant's program will effectively train or qualify other employees who may have responsibilities for design, construction, maintenance, engineering, or other duties that could affect the availability and reliability of IROFS, when needed. The staff concludes that the applicant's plan for personnel training and qualification meets the requirements of Part 70.

11.6.4 Procedures

The application has described a suitably detailed process for the identification, development, approval, and implementation of procedures applicable to IROFS. The staff concludes that the applicant's plan for procedures meets the requirements of Part 70.

11.6.5 Audits and Assessments

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

The staff concludes that the applicant's plan for audits and assessments meets the requirements of Part 70 and provides reasonable assurance that safety functions and management measures will be evaluated periodically and adjusted as necessary.

11.6.6 Incident Investigations

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

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

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

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

11.6.7 Records Management

The staff has reviewed the applicant's records management system against the SRP's acceptance criteria and concluded that the system: (1) will be effective in collecting, verifying, protecting, and storing information about the facility and its design, operations and maintenance will be able to retrieve the information in readable form for the designated lifetimes of the records; (2) will provide a records storage area(s) with the capability to protect and preserve health and safety records that are stored there during the mandated periods, including protection of the stored records against loss, theft, tampering, or damage during and after emergencies; and (3) will provide reasonable assurance that any deficiencies in the records management system or its implementation will be detected and corrected in a timely manner.

11.6.8 Other QA Elements

Based on its review of the license application [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable. The review record should demonstrate the adequacy of the applicant's application of other QA elements when coupled with the management measures and licensee commitments, as applied to IROFS, for design, construction, and operations]. The NRC staff has concluded that the applicant has adequately described the application of other QA elements.

Accordingly, the staff concludes that the applicant's application of QA elements meets the requirements of Part 70 and provides reasonable assurance of protection of public health and safety and of the environment.

11.7 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX A to Chapter 11

CHECKLIST FOR PROCEDURES

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

1. *Management Control Procedures:*

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

2. *Operating Procedures:*

a. System procedures that address startup, operation, shutdown, control of process operations, and recovery after a process upset

Process operations
Ventilation systems
Criticality alarm system

Decontamination operations

Plant utilities (air, other gases, cooling water, fire water, steam)
Temporary changes in operating procedures

b. Abnormal Operation/Alarm Response

Loss of cooling water

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

3. *Maintenance activities that address system repair, calibration, surveillance, and functional testing*

Repair, replacement, calibration, and testing of IROFS

Repair, replacement, calibration, and testing of criticality alarm units

Repair, replacement, calibration, and testing of HVAC and SNM containment systems

Surveillance/monitoring

4. *Emergency Procedures:*

Response to an accidental nuclear criticality
Response to hazardous chemical releases (including uranium hexafluoride)
Response to fires
Response to external events such as tornado, earthquake, extreme precipitation

APPENDIX B to Chapter 11

RECORDS

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

Examples of Records

SRP Chapter

1.0 General Information

Construction records

Facility and equipment descriptions and drawings

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

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

Safety analyses, reports, and assessments

Records of site characterization measurements and data

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

Procurement records, including specifications for IROFS

2.0 Organization and Administration

Administrative procedures with safety implications

Administrative procedures for material control and accounting program

Organization charts, position descriptions, and qualification records

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

QA records

Safety inspections, audits, assessments, and investigations

3.0 Integrated Safety Analysis (ISA), including the ISA Summary

4.0 Radiation Safety

Bioassay data

Personnel exposure records

Contamination records

Radiation training records

5.0 Nuclear Criticality Safety

Nuclear criticality safety procedures

Nuclear criticality safety analyses

Inspections, audits, investigations, and assessments

Incidents, unusual occurrences, or accidents

Training records

6.0 Chemical Safety

Chemical safety procedures

Inspections, audits, investigations, and assessments

Incidents, unusual occurrences, or accidents

Chemical safety analyses

Training records

7.0 Fire Safety

Fire Hazard Analyses

Fire prevention measures, including fire-watch records

Inspection, maintenance, and testing of fire protection equipment

Training records

Pre-fire emergency plans

8.0 Emergency Management

Emergency plan(s) and procedures

Comments on emergency plan from outside emergency response organizations

Emergency drill records

Memorandum of understanding with outside emergency response organizations

Records of actual events

Training records

Inspection and maintenance of emergency response equipment and supplies

9.0 Environmental Protection

Environmental monitoring and release records

Environmental Report and supplements to the Environmental Report, as applicable

10.0 Decommissioning

Decommissioning cost estimates
Financial assurance documents

Site characterization data

Decommissioning procedures

~~Final survey data~~

Decommissioning records

11.0 Management Measures

11.1 Configuration Management

1. Safety analyses, reports, and assessments that support the physical configuration of process designs, and changes thereto
– Validation records for computer software used for safety analysis or material control and accounting
– ISA documents
– Procedures

11.2 Maintenance

– Calibration and testing data for IROFS
– PM records, including surveillance/monitoring records, and trend records and root cause analysis
– Failure records (required by 10 CFR 70.62)
– Corrective maintenance records

11.3 Training and Qualification

– Personnel training and qualification records
– Procedures

11.4 Procedures (Refer to Appendix A for Chapter 11)

– Management control procedures
– Operating procedures
– Maintenance activities procedures
– Emergency procedures

11.5 Audits and Assessments

– Audits and assessments of safety and environmental activities
– Corrective action program records

11.6 Incident Investigations

– Incident investigation policy and procedures
– Root cause analysis
– Investigation reports
– Corrective action records
– Summary list of reportable events for the term of the license -

11.7 Records Management

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

11. 8 Other Quality Assurance Elements

- Inspection records
- Test records