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U.S. NUCLEAR REGULATORY COMMISSION STANDARD REVIEW PLAN OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

11.0 MANAGEMENT MEASURES

11.1 PURPOSE OF REVIEW

[General comments on §11.1:

- (1) This section contains far too much redundancy. For example, 'grading' of management measures is discussed three different times (last sentences in ¶1, ¶2, ¶4) and the purpose of the review is unnecessarily stated twice (1st sentences ¶1 and ¶4).
- (2) Some licensees prefer to see management measures "support" (rather than be "applied to") IROFS to provide a measure of assurance that they will be available and reliable when needed.]
- (3) The continued inclusion of Appendix C in its present form is questioned. The Appendix states that each sentence of the SRP must be analyzed and addressed in a license application – an unrealistic expectation. A simple paragraph in §11.1 clarifying what level of detail in the information describing Management Measures is recommended. Appendix C was to have been prepared using excerpted sections from existing licenses to clarify what detailed information would be expected to enable the revised Part 70 requirements to be satisfied. However, Appendix C fails to fulfill this industry expectation. A separate document with sample text submissions for each management measure has, instead, been prepared for licensee guidance.]
- (4) The statements addressing '*management measure grading*' should clearly state that '*grading*' also means that not all eight management measures may necessarily have to be used to support an IROFS. '*Grading*' also refers to the robustness or thoroughness of a an individual management measure supporting an IROFS.]
- (5) References to "risk management" and the risk of accident sequences continue throughout §11.1 (and the entire Chapter 11). Industry has always supported this approach – considering the overall and comparative *risk* of accident sequences. However, the NRC objected to this approach at the June 2000 public meeting, and directed that the SRP should examine and rank accidents in terms of their "consequences" as is stated in the 10 CFR 70.61 rule language. Should the NRC not want to think in terms of risk, an editing of Chapter 11 is required to expunge all references to this term.]

Management measures are functions, performed by a licensee, generally on a continuing basis, that ~~support are applied to~~ items relied on for safety (IROFS), to provide reasonable assurance that the items are available and ~~reliable able~~ [Comment: for consistency with Rule language and with the following sentence, replace 'able' by 'reliable'] to perform their functions, when needed. The phrase "available and reliable," as used in the revised Part 70, means that, based on the analyzed, credible conditions in the ISA, IROFS will perform their intended safety functions when needed to prevent accidents or mitigate the consequences of accidents. Management measures will be ~~developed implemented to provide reasonable assurance of compliance with the performance requirements,~~ considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the ~~IROFS items~~ and the supporting management measures. The following discussion

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addresses each of the management measures included in the Part 70 definition of management measures, i.e., configuration management (CM); maintenance; training and qualifications; procedures; audits and assessments; incident investigations; records management; and other QA elements. ~~[Comment: consolidate the following sentence into a separate paragraph that addresses 'grading' (below).] The degree to which measures are applied to the items may be a function of the item's importance in terms of meeting the performance requirements as evaluated in the ISA.~~

~~[Comment: the following paragraph addresses management measure grading]. Management measures supporting an IROFS may be graded commensurate with the importance of the IROFS to facility safety. The license applicant should describe methods used to decide which management measures should be applied to an IROFS and how the robustness and comprehensiveness of each selected management measure is developed.~~

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

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

~~To provide additional explanation of the context and level of detail considered sufficient to support staff review, further description of an acceptance criterion for maintenance is provided in Appendix C. The description explains what a reviewer would expect to find in an application, responding to each sentence of the criterion in the SRP (Section 11.4.3.2 Maintenance, item 1, Surveillance/Monitoring). [Comment: see introductory comments.]~~

~~[Comment: duplicate statement of purpose. Delete following sentence.] The purpose of this review is to enable the staff to conclude, with reasonable assurance, that the management measures applied to IROFS, as documented in the ISA Summary, provide reasonable assurance that the items will be available and able to perform their functions, when needed, consistent with the performance requirements of 10 CFR 70.61. [Comment: delete redundant "grading" text.] If a graded approach is used, the review should also determine whether the measures applied to the IROFS commensurate with the IROFS' importance to safety.~~

11.2 RESPONSIBILITY FOR REVIEW

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Primary: Licensing Project Manager

Secondary:

Configuration Management: Primary ISA Reviewer, QA and Records Management Reviewers

Maintenance: Criticality, Chemical, Fire, Radiation Protection, and Environmental Reviewers

Training and Qualification: Training Specialist, QA Reviewer

Procedures: Radiation Protection, Criticality and Fire Protection Engineers, Fuel Cycle Facility Inspector

Audits and Assessments: QA Reviewer

Incident Investigations: Inspection Specialist

Records Management: QA Reviewer

QA: Quality Assurance Engineer

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

11.3 AREAS OF REVIEW

11.3.1 Configuration Management (CM)

This review should ~~confirm provide reasonable assurance~~ [Comment: this is a requirement of §70.72(a) and so more than “reasonable assurance” is needed.] that the applicant has committed to develop and implement a CM ~~System 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 System function must that assures consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. ~~[Comment: this paragraph is superfluous. CM must (obviously) be coordinated with other management measures to achieve the goals stated in the previous sentence.]~~ The review should also determine that the applicant’s CM function captures formal documentation governing the design and continued modification of the site structures, processes, systems, equipment, components, IROFS computer programs, personnel activities, and supporting management measures, as identified and described in the ISA. The review should assure that the CM function is adequately coordinated and integrated with the other management measures.

The NRC staff should review the applicant's descriptions of, and commitments to, 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 facility site [Comment: modifying the facility is the issue rather than modifications to the “site”]; and descriptions of the various levels of CM to be applied to IROFS designated in the ISA Summary. The staff review should focus on the applicant’s CM measures that provide

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reasonable assurance of the disciplined documentation of: engineering, installation, and operation of modifications; ~~the~~ training and qualification of affected staff; ~~the~~ revision and distribution of operating, ~~test, calibration, surveillance,~~ [Comment: these three activities are usually included in maintenance or operating procedures and need not be separately listed.] and maintenance procedures and drawings; post-modification (or functional) testing; and readiness review.

The NRC staff should review the following:

1. CM System Policy

[Comment: 'policy' should be replaced by 'process' or system', a less prescriptive term. §70.72(a) uses "configuration management **system**" in its references to CM. There are many references to CM System elsewhere in Chapter 11 (e.g. §11.4.3.3(1)(4)). Recommend consistent use of "CM System" throughout Chapter 11.]

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; [Comment: 70.72 states that CM must apply to all IROFS. There is, therefore, no need to include the preceding (a) comment] (b) descriptions and objectives of each CM activity; (c) a description of each CM activity; and (d) the organizational structure and staffing interfaces [Comment: "staffing interfaces" is overly prescriptive.]

The review should examine the applicant's establishment of a CM system policy applicable to all operations, in accordance with 10 CFR 70.72. [Comment: unnecessary citation. Everything dealing with CM is in 70.72. Delete for clarity and reduced redundancy.]

2. Design Requirements

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

3. Document Control

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

4. Change Control

The review should examine the applicant's commitments to provide reasonable assurance that the CM system 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." [Comment: superfluous citation. Delete for clarity and reduced redundancy.]

5. Assessments

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The review should examine the applicant's commitments to conduct ~~initial and~~ [Comment: "initial" would seem to have no meaning here (?)] periodic assessments of the CM System function, to determine its the function's effectiveness, and to correct deficiencies, consistent with the acceptance criteria for "Audits and Assessments."

~~6. Design Reconstitution [Existing Facilities Only]~~

~~The review should examine the applicant's discussion of design reconstitution of the current design basis that has been done for the purpose of the application, and how that reconstitution was translated into a fixed baseline design basis from which subsequent changes will be measured. [Comment: we wonder whether this section is needed. If the NRC will be approving the ISA Summary for an existing plant, presumably the information and design basis on which the ISA was conducted will have been examined. Approval of the ISA Summary implies that the design bases were deemed to be satisfactory. Therefore, there would appear to be no need for this Item (6).]~~

11.3.2 Maintenance

The NRC staff will evaluate the applicant's description of its maintenance function. The reviewer will examine the applicant's commitments to inspect, calibrate, test and maintain IROFS to a level commensurate with the items' safety significance [Comment: the NRC prefers deletion of references to "risk reduction"] ~~importance to risk reduction, to provide reasonable assurance of their ability to perform their safety functions when required. [Comment: the following statement is obvious and is redundant, Delete.]~~ ~~The applicant identifies these IROFS in the ISA summary.~~ The staff will review the applicant's description of how each of the following four elements of a maintenance program are functions ~~is implemented, within the site organization.~~ Note that not every aspect of each of the four maintenance functions is necessarily required; the applicant should specify which maintenance elements will be applied to an IROFS. ~~is expected to identify the IROFS in the ISA Summary and would justify assigning differing degrees of maintenance to individual IROFS, based on the item's contribution to the reduction of risk.~~

1. Corrective maintenance

- a. A commitment to promptly perform corrective actions to correct remediate IROFS unacceptable performance deficiencies; ~~and~~
- ~~b. A description of the approach and methods for planning and implementing repairs to IROFS with the objective of eliminating or minimizing the recurrence of unacceptable performance deficiencies. [Comment: far too prescriptive. The foregoing commitment should be adequate for the reviewers' purposes. Delete.]~~

2. Preventive maintenance (PM)

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

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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. [Comment: far too prescriptive. The foregoing (a) commitment should be adequate for the reviewers' purposes. Delete.]~~

3. Surveillance/monitoring

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

~~b. A description of the components of the surveillance and monitoring program including methods used to establish the frequency of such inspections for IROFS having different degrees of safety importance. [Comment: far too prescriptive. Seeking information on the "components of the surveillance and monitoring" programs should not be required. The part (a) commitment should be adequate for the reviewers' purposes. Delete.]~~

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 IROFS; ~~and~~

~~b. A general description of functional testing, and the test results documentation. [Comment: far too prescriptive. The part (a) commitment should be adequate for the reviewers' purposes. Delete.]~~

11.3.3 Training and Qualifications

Part 70 requires that personnel who perform activities relied on for safety be trained ~~and tested,~~ [Comment: testing is currently rarely required at Part 70 facilities. Demonstration of proficiency through actions and exercises is preferred.] as necessary, to provide reasonable assurance that they understand, recognize the importance of, and are qualified to perform these activities in a manner that adequately protects: (1) the health and safety of the public and workers; and (2) the environment. As appropriate for their authority and responsibilities, these personnel should have the knowledge and skills necessary to design, operate, and maintain the facility in a safe manner. Therefore, the training, testing, and qualification of these personnel should be described in the application. [Comment: the balance of this paragraph is obvious and need not be stated in such a prescriptive manner. Delete for clarity.] ~~and should be reviewed by the staff. This should include the training, testing, and qualification of all personnel who perform activities relied on for safety. The review should examine the applicant's training and qualifications based on the adequacy to fulfill the objectives for the training identified by the licensee, especially when human factors are relied on for safety.~~ The review of the training and qualification should address the following training areas:

1. Organization and management of ~~the training function~~ [Comment: may be no single function];
2. Analysis and identification of functional areas requiring training;
3. Position training requirements
4. Development of the basis for training, including objectives;
- ~~5. Organization of instruction, using lesson plans and other training guides; [Comment:~~

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~~redundant as covered in Item (1). Delete.]~~

~~6. Evaluation of trainee learning; [Comment: redundant as covered in Item (8). Delete.]~~

7. Conduct of on-the-job training;

8. Evaluation and continuing assurance of training effectiveness;

9. Personnel qualification; ~~and~~

~~10. Applicant's provisions for continuing assurance, including the needs for retraining or reevaluation of qualification. [Comment: redundant as covered in Item (8). Delete.]~~

11.3.4 Procedures

The review should examine the applicant's process for the preparation, use, and ~~management~~ [Comment: control may extend beyond management control.] control of written procedures. [Comment: the following sentence is too detailed and prescriptive. Matters are already covered by the first sentence. Delete for clarity.] ~~This should include the basic elements of identification; development; verification; review and comment resolution; approval; validation; issuance; change control; and periodic review.~~ The applicant should prepare two general types of procedures for use at the facility:

1. Procedures used to directly control process operations, commonly called "operating procedures." These are procedures for workstation operators and should include directions for normal operations as well as off-normal events caused by human error or failure of an IROFS. Procedures of this type include required actions to provide reasonable assurance of nuclear criticality safety; chemical safety; fire protection; radiation protection; -emergency planning; and environmental protection [Comment: emergency planning and environmental protection are generally covered in other site plans and procedures.]; and,
2. Procedures used for activities that support the process operations, ~~which are commonly referred to as "management control procedures."~~ These are procedures used to define manage the conduct of activities such as CM; radiation safety; maintenance; ~~human systems interface;~~ [Comment: references to this topic were to have been deleted from the SRP.] QA; training and qualification; audits and assessments; incident investigations; record-keeping; and reporting.

The actual ~~operating~~ [Comment: not just operating procedures.] procedures are not part of the license and would not normally be reviewed for technical adequacy ~~for low-risk processes~~ [Comment: in accordance with NRC direction, references to the "risk" of a process should be deleted and expressed in terms consistent with §70.61.], since this aspect is addressed by the inspection function. [Comment: the following sentence should be relocated to §11.5 'Review Procedures' as it tells how the license application should (or could) be conducted. It applies not only to CM.] ~~For new licenses or processes, especially those that involve high-risk operations~~ [Comment: see forgoing comment.], such as some highly enriched uranium liquid processes or some mixed-oxide processes, the licensing review may include a site visit, to make an adequate safety determination, at which time some procedures may be reviewed.

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

1. ~~The method for identification of the procedures that are needed plant-wide. The ISA Summary identifies IROFS where human actions are important.~~ Procedures should be

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provided for all necessary steps or operations that are conducted at the facility with licensed material and with IROFS. ~~Procedures should be provided for every element of management control that is discussed in the SRP sections;~~

- ~~2. [Comment: recommend deleting this Item (2) as not every listed element is given in every plant procedure. Some will be in operating procedures while others will be in administrative procedures and some will be in neither.] Essential elements that are generic to all procedures including: criticality; chemical process and fire safety; warning notes; reminders or pertinent information regarding specific hazards or concerns which include station limits; Materials Safety Data Sheet availability; special precautions; radiation and explosive hazards; and special personal protective equipment;~~
3. The method for creating and controlling procedures within plant management control systems. ~~This includes how procedures are managed within the plant GM function; [Comment: redundant comment. The licensee has been instructed to address the complementary nature of all management measures with one another. Delete.]~~
4. Method for verifying and validating procedures before use. [Comment: delete this second sentence as it is more along the lines of "how to" do something – too prescriptive. The matter addressed in this sentence is not part of a license application review.] ~~During procedure development, workers and operators review procedures to provide assurance that they are usable and accurate.~~
5. The method and schedule for periodically reverifying and revalidating procedures; and
6. The method for ensuring that current procedures are available to personnel. ~~and that personnel are qualified to use the latest procedures. [Comment: this issues is covered under the "Training and Qualification" management measure. Delete here for clarity.]~~

11.3.5 Audits and Assessments

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

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

1. The commitments to audit and assessment activities;
2. The use of qualified ~~and independent~~ audit and assessment personnel; [Comment: personnel do not always have to be "independent". In fact many root cause analysis procedures require participation of the operators and facility staff that may have committed the error.]

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- ~~3. The general structure of typical audits and assessments; [Comment: covered in §11.3.4.]~~
- ~~4. The facility procedures to be used to direct and control the audit and assessment activities~~
- ~~5. The planned use of the results of the audit and assessment activities; [Comment: covered in (7) below.]~~
- ~~11.6. The documentation to record and distribute the findings and recommendations of these audits and assessments; and~~
7. The planning and implementation of corrective actions based on the findings and recommendations.

11.3.6 Incident Investigations

The NRC staff should review the applicant's policy, ~~procedures, [Comment: review of detailed procedures is not part of the license review. Delete.]~~ and management structure for investigating abnormal events and completing appropriate corrective actions. The review should include the provisions for establishing investigating teams, the methods for determining root causes, ~~and procedures for tracking and completing corrective actions [Comment: review of detailed procedures is not part of the license review. Delete.]~~ and for documenting the process for the purpose of applying the "lessons learned" to other operations. An applicant may describe a "corrective actions program" which includes the functions of both audits and assessment and incident investigations. This approach is acceptable and the reviewer should, in that case, review the applicant's description and commitments with regard to the acceptance criteria in this SRP chapter for both audits and assessments and incident investigations.

11.3.7 Records Management

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

1. The process whereby records - training records; dosimetry records; effluents records; records of classified information; records concerning facility IROFS; and records of their failure - are ~~managed, created; selected; verified; categorized; indexed; inventoried; protected; stored; maintained; distributed; deleted; or preserved. [Comment: overly prescriptive. Delete.]~~ The review should provide reasonable assurance that the records management function is adequately coordinated and integrated with other management measures.
2. The handling and control of various kinds of records and the methods of recording media that comprise the records (including contaminated and classified records); and
3. The physical characteristics of the records storage area(s) with respect to the preservation and protection of the records for their designated lifetimes.

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11.3.8 Other QA Elements

[Comments:

- (1) the rule uses the term "other QA elements" (§70.4). However, licensees generally simply refer to "QA" or to "QA measures". Industry recommends that such a simplified term be used throughout the language of §11.4.3.8.]
- (2) we reiterate, for the record, our contention that QA is an integral and inseparable element of all management measures and that separate treatment should not be expected. The July 2000 revision of Chapter 11 somewhat addresses this concern by allowing the applicant to comment on QA measures that will be applied to each of the other §70.4 management measures. However, directing an applicant to address all 19 NQA-1 type requirements – whether on a graded basis or otherwise -- is unwarranted.]

The reviewer should evaluate how the applicant proposes to apply QA to IROFS and their supporting management measures. application must address the Part 70 requirements with respect to management measures, to include other QA elements. [Comment: the following sentence is an unnecessary repetition of material in §11.1. Delete for clarity and reduced redundancy.] 10 CFR 70.62(d) requires that each applicant or licensee shall establish management measures to provide continuing assurance of compliance with the performance requirements of 10 CFR 70.61.

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

The application defines ~~the QA elements including any grading of and~~ the levels to be applied to IROFS identified ~~in by~~ the ISA ~~(SRP Section 3.0) Summary. [Comment: the following sentence is identical to the last sentence in the following paragraph. All management measures add "quality" to IROFS and no other relation need be defined.]~~ Further, ~~the relationship between QA and other management measures should be described. The applicant determines QA grading will be determined by~~ the relative risk, or relative safety importance, of ~~an the various IROFS, to determine the QA elements and their levels requirements to be applied to them.~~ individual IROFS.

[Comment: the following sentences add nothing to the SRP. Application of QA to licensee products is not of concern in license application reviews. (The next sentence that has not been struck out states the purpose to a "T"). The review should recognize that facility safety may not be the only area requiring QA elements at a fuel cycle facility. The applicant's customers and the NRC, under 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. [Comment: the following parenthetical is obvious and should be deleted for clarity's sake.] (i.e., in relation to the performance requirements of 10 CFR 70.61). The review should provide reasonable assurance that the application of QA function is appropriately adequately coordinated and integrated with other management measures.

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

11.4 ACCEPTANCE CRITERIA

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

11.4.1 Regulatory Requirements

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

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

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

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

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

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

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

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

11.4.2 Regulatory Guidance

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[Comment: The NRC has enough regulations and regulatory guidance documents on QA, that there should be no compelling need to cite non-NRC documents. References to NQA-1 should be deleted.]

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

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

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

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

~~5.1.~~ U.S. Nuclear Regulatory Commission, "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities", Federal Register 54 (No. 53), 11590-11598, March 21, 1989.

~~6.2.~~ U.S. Nuclear Regulatory Commission, "Training Review Criteria and Procedures," NUREG-1220, Revision 1, January 1993.

11.4.3 Regulatory Acceptance Criteria

11.4.3.1 Configuration Management (CM)

1. CM System Policy

The applicant's description of ~~the overall~~ CM ~~System functions~~ confirms its application to all IROFS and describes at least the following topics: (a) ~~the scope of the IROFS and management measures to be included in the CM function (coordinate with the Section 3, ISA, reviewer for the application), [Comment: §70.72 allows no flexibility as suggested in (a). The CM Systems will apply to all IROFS. Item (a) should be revised to specify any CM grading applied to IROFS. Revise accordingly, and delete the two additional references to grading elsewhere in this §11.4.3.1.]~~ assignment of CM grades (or quality levels) to IROFS and how such grades were established, (b) the objectives of each CM activity, (c) a description of each CM activity, and (d) the organizational structure and staffing interfaces. The functional interfaces with maintenance and training and qualification are of particular importance and should be addressed individually. [Comment: Following sentence is obvious. See comment earlier in this paragraph.] ~~The IROFS under CM should include all those IROFS as defined by the ISA Summary.~~

An important element of an applicant's overall CM System policy is the establishment of a

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baseline ~~CM policy~~ applicable to all new facilities or new processes at existing facilities, in accordance with 10 CFR 70.64. That baseline ~~may~~ 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 ~~[Comment: in accordance with NRC preferences to not address “risk”, the terminology applicable to accidents should be changed as noted] high-consequence events high-risk accident sequences~~, as defined by the ISA Summary ~~or the ISA~~, the applicant may choose to reduce or eliminate certain features of the CM ~~System function~~ as applied to those lesser-~~consequence 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.

The design process leading to drawings and other statements of requirements proceeds logically from the design basis. ~~[Comment: sentence not needed. Content already expressed in first sentence of §11.4.3.1. Delete.] IROFS to be listed under CM are clearly defined in the ISA Summary, along with the assignment of any grades or quality levels. The applicant should have indicated in the ISA Summary what level of CM attributes is applied to a particular item. However, in the ISA Summary, this indication may only consist of an index or category designation. The definition of the multiple CM levels, if used, should be in the CM description within the application.~~

2. Design Requirements

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

~~[Comment: following sentence is too prescriptive and detailed. It doesn't contribute anything. Delete.] A design control function is established that includes design inputs, process, analyses, verification, interfaces, changes, and design documentation and records (see Sections 11.3.1, 11.5.2.1, and 11.6.1 for details on CM). This attribute may be described as part of CM or as part of the management measure on QA.~~

3. Document Control

The applicant describes an acceptable method to establish and control documents within the CM ~~System~~. ~~[Comment: balance of this sentence is unnecessarily prescriptive. Delete.] function, including cataloging the document data base, the information content of the document data base, maintaining and distributing documents, document retention policies, and document retrieval policies.~~ The applicant describes how CM will capture documents that are ~~[Comment: what is a “document...relied on for safety”? Clarify as noted.] important to safety, relevant and relied on for safety.~~ ~~[Comment: the following sentence is very prescriptive and dictates how the licensee should operate. Existing licensees frequently do not operate as is prescribed in the following sentence. Licensees often do not have a separately identified “CM function”, but rather integrate CM – including all of the elements & attributes in this sentence -- within several functions. Delete.] This may include design requirements; the ISA; as-built drawings; specifications; procedures involving training; QA; maintenance; audits and assessments; emergency operating procedures; emergency response plans; system modification documents; assessment reports; operating procedures;~~

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~~and others that the applicant may deem part of CM.~~ The document database is used to control documents and track document change status.

4. Change Control

The applicant describes how the CM System function will maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. The applicant commits to an acceptable process for identifying and authorizing proposed changes; for performing appropriate technical, management, and safety reviews of proposed changes in IROFS; for tracking and implementing changes; and for documenting changes. [Comment: text in parentheses is superfluous. This paragraph contains enough detail and prescription without the need for the text in parenthesis. Delete.] ~~(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 System function, for providing reasonable assurance that the ISA and ISA Summary are is systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety-basis changes are properly modified, authoritatively approved, and made available to personnel. When a change is made in accordance with 10 CFR 70.72, the affected on-site documentation must be made within [Comment: 5 days is totally unrealistic – especially if there is minor safety significance to the change. Current licensee practice is 30 days.] ~~five thirty working~~ days [10 CFR 70.72(e) states “promptly”].

5. Assessments

The applicant confirms that ~~initial and~~ [Comment: the need for an initial assessment is not clear.] periodic assessments of the CM System function will be ~~are~~ conducted to determine the ~~system'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 System function.~~ All assessments and follow-ups are documented. These reports can provide a basis for future changes. The applicant indicates that such assessments are systematically planned and conducted in accordance with an overall facility audit and assessment program function (see sections 11.3.5. and 11.4.3.5 in Chapter 11 for details on audits and assessments)-.

[Comment: as noted in our comments for §11.3.1 (6), we question the need for the following section. The design basis as reported in the ISA serves as the benchmark for all future changes. Any design reconstitution will have been completed before the ISA is done. Delete.]

~~6. Design Reconstitution [Existing Facilities Only]~~

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

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11.4.3.2 Maintenance

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

1. Surveillance / monitoring

For IROFS identified in the ISA Ssummary, the applicant describes the surveillance function and its commitment to the organization and conduct of surveillance at a specified frequency. The surveillance activity should support the determination of performance trends for IROFS, thus providing data useful in determining PM frequencies. Applicant describes how results from incident investigations, review of the records of failure of IROFS and management measures log [Comment: a "log" is no longer required. Delete this term.] required by 10 CFR 70.62(a)(3), and identified root causes, are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Records showing the current surveillance schedule, performance criteria, and test results for all IROFS listed in the ISA Summary are maintained by the applicant. For surveillance tests that can only be done while IROFS listed in the ISA Summary are out of service, proper compensatory measures are prescribed for the continued normal operation of a process.

2. Corrective maintenance

Applicant provides the documented approach used to perform corrective actions or repairs on IROFS. The maintenance function provides a planned, systematic, integrated, and controlled approach for the repair and replacement activities associated with identified unacceptable performance deficiencies of IROFS. [Comment: the following sentence is repeated in Item (4) below and is redundant here. It is not part of Corrective Maintenance. Delete for clarity.] ~~After conducting corrective maintenance and before returning an IROFS to operational status, if necessary, a functional test is conducted to provide reasonable assurance that the safety control performs as designed and provides the safety action expected.~~

3. PM

Applicant provides a description of the PM function that demonstrates a commitment to conduct preplanned and scheduled periodic refurbishing, or partial or complete overhaul, for the purpose of ensuring that unanticipated loss(es) of IROFS do not occur. This activity includes using the results of the surveillance component of maintenance and the records of failure of IROFS and management measures ~~failure log~~ [Comment: a "log" is no longer required. Delete this term.] required by 70.62(a)(3). Instrumentation calibration and testing are addressed by the applicant as part of this component. The applicant describes how the function will be designed to assure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of IROFS because of monitoring or PM. [Comment: the following sentence is repeated in Item (4) below and is redundant here. It is not part of PM. Delete for clarity.] ~~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

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basis used to determine PM frequency is described. Applicant describes how results from incident investigations and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause(s) from recurring. Feedback from PM, corrective maintenance, and incident investigations is used, as appropriate, to modify the frequency or scope of the PM activity. [Comment: the following sentence is unnecessarily prescriptive. The license applicant will be stating how the PM will be designed, and used, not defend why he is not adhering to some other standard or suggestion for PM. Delete for consistency.]~~A rationale for deviation from industry standards or from vendor recommendations for PM is provided.~~ Records showing the PM schedule, and results, for all IROFS subject to this maintenance component, are maintained by the applicant.

4. Functional testing

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

For illustrative purposes only, the following scenario is provided:

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

As necessary, during start-up of new process equipment, functional tests are conducted, documented, and maintained, for NRC review. Records showing the dates of functional tests schedule, [Comment: use of the word "schedule" suggests that Functional Testing is conducted at regular time intervals, similar to PM. This sentence would have appeared to be copied from the PM section without having the necessary modifications made. Correct as suggested.] and results, for all IROFS subject to this maintenance component, are maintained by the applicant.

[Comment: the purpose of the following paragraph is to refer assessment of activities relied on for safety to the "Training and Qualifications" section of Chapter 11.] Administrative controls are often identified as IROFS. The applicant should describe how the Training and Qualification management measure will be used to provide reasonable assurance that plant personnel will be trained to perform activities relied on for safety when required. ~~provide a general discussion about how these IROFS are assured to be available and reliable to perform their intended safety function over extended periods of operation. Specific management measures and how they are applied should be described.~~

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[Comment: the following paragraph contains very detailed information that a licensee could use in structuring maintenance programs and procedures. As the reviewer will generally not be reviewing or approving actual procedures or detailed program components, the need for the following paragraph is not apparent. Suggest it be deleted. Several editorial comments are, however noted should it remain in §11.4.3.2]

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 Ssummary; 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; [Comment: combine (h) and (i) for simplicity.] h) procedural control of removal of IROFS components from service for maintenance and for return to service; ~~i) ensuring safe operations during the removal of IROFS from service;~~ and ij) notification to operations personnel that repairs have been completed. Written procedures for the performance of maintenance include, as applicable, [Comment: add the suggested words to balance this sentence contents with those of the 3rd sentence above.] steps a) through ij). The details of maintenance procedure acceptance criteria are addressed in Section 11.4.3.2 of this SRP. [Comment: following sentence is already covered under the "procedures" section. Delete.] ~~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 test, or surveillance/monitoring activities listed above for the maintenance function.

[Comment: content of this sentence is repeated in the introduction to §11.4.3.2. Delete for clarity.] ~~The four maintenance elements described above are covered by elements of the management measures discussed in SRP Section 11.0.~~ The applicant should include a discussion of, or provide references to, how the maintenance function uses, interfaces with, or is linked to the various management measures. As an example, since maintenance workers are trained and qualified to perform their duties, a description of the link between maintenance and the training and qualification programs function should be described.

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

[Comment: the content of Items (1)-(4) really addresses procedures that will be developed and maintained at the facility, but that will not be included in the license application. We would recommend that this latest addition to Chapter 11 be deleted. In any case, a few improvements to reduce redundancy are noted below.]

1. [Comment: combine the content of Item (1) with Item (2) for simplification and clarity and to eliminate redundancy.] ~~Inspection required to verify conformance of IROFS with~~

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~~requirements is planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results. (see Sections 11.3.4, 11.5.2.4, 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). This attribute may be described as part of maintenance or as part of the management measure on QA.~~

- ~~2. Inspections and Tests are conducted to verify that IROFS conform to specified requirements and will perform satisfactorily in service. Inspection and Test requirements are specified in written procedures with provisions included for documenting and evaluating test results. (see Sections 11.3.4, 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). This attribute may be described as part of maintenance or as part of ~~the management measure on~~ QA.~~
3. Provisions are made to provide reasonable assurance that tools, gauges, instruments, and other measuring devices are properly identified, controlled, and calibrated ~~and adjusted~~ at specified intervals, to maintain performance within required limits. This attribute may be described as part of maintenance or as part of ~~the management measure on~~ QA.

~~4. [Comment: Item (4) is addressed in the CM program. Delete Item (4) to reduce redundancy.] 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 maintenance or as part of the management measure on QA.~~

11.4.3.3 Training and Qualification

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

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

The following commitments should be in the application regarding organization and

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management of training:

1. ~~Line management is responsible~~ Responsibility for the content and effective conduct of the training and management of the training program is clearly defined. [Comment: Licensees all organize their training programs differently and "line management" may not hold this responsibility. For clarity, combine (1) and (2).]
 - ~~2.~~ The job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training is clearly defined.
 - ~~3.2.~~ Performance-based Training is used as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.
 - ~~4.3.~~ Procedures are documented and implemented to provide reasonable assurance that all phases of training are conducted reliably and consistently.
 - ~~5.4.~~ Training documents are linked to the CM system to provide reasonable assurance that design changes and modifications s are accounted for in the training.
 - ~~6.5.~~ Exemptions from training are granted to trainees and incumbents only when justified, documented, and approved by management.
 - ~~7.6.~~ Both programmatic and individual training records are maintained. These records, support management information needs and provide required data on each individual's training, job performance, and qualification.

2. Analysis and Identification of Activities for Which Requiring Training is Required - analysis and identification of [Comment: "activities" do not require training, rather it is "personnel" who require training. Correct the English.] activities for which requiring training is required is acceptable if the activities required for competent and safe job performance are identified, documented, and addressed by the training.

Design, construction, operations, training, and other subject matter experts, as appropriate, should conduct an analysis to identify activities requiring training. The activities treated in this manner should include - as a minimum - those for ~~managing, supervising,~~ performing, and verifying the activities relied on for safety specified in the ISA Summary. [Comment: balance of sentence is obvious. Delete.] ~~as preventing or mitigating accident sequences-~~ [Comment: the balance of this paragraph is too prescriptive and specific. For example, requiring "matrixing to supporting procedures" dictates to the licensee "how to do" the activity. Delete the following sentence.] Each activity selected for training (initial or continuing) from the facility-specific activities should be matrixed to supporting procedures and training materials. ~~The facility-specific activities selected for training and the comparison with training materials should be reviewed on an established schedule and updated as necessitated by changes in procedures, facility systems/equipment, or job scope.~~

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

4. Development of the Basis for Training Including Objectives - The development of the basis for training including the objectives is acceptable if the basis identifies training content, defines satisfactory trainee performance standards or achievement levels and identifies objectives from the analysis of activities and performance requirements. [Comment: following sentence is repetitive and superfluous. Delete.] ~~Objectives should state the knowledge, skills, and abilities~~

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~~the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve on completion of the training activity.~~

5. [Comment: this paragraph provides useful information to the licensee, but as the reviewer will not be examining lesson plans or training guides, is there need for it in this §11.4.3.3? Consider deleting.] Organization of Instruction Using Lesson Plans and Other Training Guides - Lesson plans and other training guides should provide guidance to assure the consistent conduct of training activities, and should be based on required learning objectives derived from specific job performance requirements. Plans/guides should be used for in-class training and on-the-job training and should include standards for evaluating acceptable trainee performance. Review and approval requirements should be established for all plans/guides and other training materials before their issue and use.

6. Evaluation of Trainee Accomplishment - The evaluation of trainee proficiency 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. [Comment: the bottom line is proficiency to perform. Emphasize this.]

7. [Comment: same comment as for Item (5): this paragraph provides useful information to the licensee, but as the reviewer will not be examining lesson plans or training guides, is there need for it in this §11.4.3.3? Consider deleting this Item (7).] Conduct of On-the-Job Training - ~~The conduct of o~~On-the-job training is acceptable when if on-the-job training used for activities relied on for safety required by the ISA Summary are fully described. On-the-job training should be conducted using well-organized and current training materials and be. ~~On-the-job training should be~~ conducted by designated personnel who are competent in the program standards and methods of conducting the training. Completion of on-the-job training should be by actual task performance. When the actual task cannot be performed and is therefore "walked-down," the conditions of task performance, references, tools, and equipment should reflect the actual task to the extent possible.

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

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

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technicians, maintenance personnel, and other staff required to meet NRC regulations:

1. Managers should have a minimum of a B.S./B.A. or equivalent. Each manager should have either management ~~experience~~ or technical experience in facilities similar to the facility identified in the application.
2. Supervisors should have at least the qualifications required of personnel being supervised, plus, either one additional year of experience supervising the technical area at a similar facility, or, completion of a supervisor training course.
3. [Comment: this provision is too restrictive. A licensee should be able to hire college graduates to do this work. Similarly, licensees have good experience using Co-op and summer students to perform safety-significant jobs.] Technical professional staff identified in the ISA Summary whose actions ~~or judgments are critical to satisfy the performance requirements identified in 10 CFR Part 70 (i.e. related to an IROFS) are relied on for safety~~ should have a B.S. in the appropriate technical field and 3 years of experience. Other technical professional staff should have a B.S. in the appropriate technical field ~~and one year of experience~~.
4. Construction personnel, plant operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations should have completed the applicant's training process or have equivalent experience or training.
5. Candidates for process operators should be required to meet minimum qualifications described in the application. Candidates for job functions other than process operators should also be required to meet minimum qualifications, but these minimum qualifications need not be described in the application. [Comments: Item (5) is too restrictive. Safety-related requirements, but not necessarily process operator requirements, should be stated in the application.]

10. Applicant's Provisions for Continuing Assurance - The applicant's provisions for continuing assurance of personnel training and qualification are acceptable if the submittal addresses periodic requalification of personnel, as necessary, [Comment: the bottom line is "job performance" – and not testing.] by job performance and proficiency training and/or testing, to provide reasonable assurance that they continue to understand, recognize the importance of, and are qualified to perform their activities that are relied on for safety.

11.4.3.4 Procedures Development and Implementation

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

1. Activities affecting quality are prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate for the circumstances (see Sections 11.3.4, 11.5.2.4, and 11.6.4 for details on procedures). This attribute may be described as part of the procedures or as part of ~~the management measure on QA~~.

[Comment: the following three additions to §11.4.3.4 are already covered by the CM system and elsewhere under different management measures. They are unnecessarily prescriptive for QA.] ~~Procedures are written or planned for the operation of IROFS and for all management measures supporting those controls.~~

~~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 procedures or as part of the management measure on QA.~~

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~~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 procedures or as part of the management measure on QA.~~

2. ~~[Comment: if every operator procedure contained this much requested information, the operator would be overwhelmed and unlikely to be able to conduct safety significant activities. For example, the operator does not need to know regulations, policies, etc. Emergency safety issues may be described in a procedure, but not in every procedure as is suggested by this Item (2). The overly prescriptive nature of this Item (2) must be reduced.] A system of operating, safety and administrative procedures addresses~~ Operating procedures contain the following elements: (a) purpose of the activity; (b) regulations, polices, and guidelines governing the procedure; (c) type of procedure; (d) steps for each operating process phase; (e) initial start-up; (f) normal operations; (g) temporary operations; (h) emergency shutdown; (l) 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. ~~[Comment: note that procedures are not in the license application and will not be examined at this time. Delete the following sentence.] It is particularly important that safety limits and IROFS (such as mass limits, moderator exclusion, independent sampling requirements, etc.) be clearly identified as such in the procedure for the operators.~~
3. ~~[Comment: first sentence is redundant – it says nothing. Delete.] Procedures reflect the important elements of the functions described in the applicable chapters of this SRP.~~ Procedures exist to direct the following activities: a) design; b) CM; c) procurement; d) construction; e) radiation safety; f) maintenance; g) QA elements; h) training and qualification; i) audits and assessments; j) incident investigations; k) records management; l) criticality safety; m) fire safety; n) chemical process safety; and o) reporting requirements.
4. The applicant describes the method for ~~identifying,~~ developing, approving, implementing, and controlling operating procedures. ~~Identifying needed procedures includes consideration of ISA results. [Comment: the balance of this paragraph is very prescriptive and, while it provides useful information to the licensee in developing a procedure, as procedures are not included in, or reviewed, the following list of checklist items should be deleted.]~~The method includes, as a minimum, that: (a) operating limits and IROFS are specified in the procedure; (b) procedures include required actions for off-normal conditions of operation, as well as normal operations; (c) if needed, safety checkpoints are identified at appropriate steps in the procedure; (d) procedures are validated through field tests; (e) procedures are approved by management personnel responsible and accountable for the operation; (f) a mechanism is specified for revising and reissuing procedures in a controlled manner; (g) the QA elements and CM functions at the plant provide reasonable assurance that current procedures are available and used at all work locations; and (h) the plant training program trains the required persons in the use of the latest procedures available.
5. The applicant includes the following commitment regarding procedure adherence:

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“Activities involving licensed special nuclear material and/or IROFS will be conducted in accordance with approved procedures.”

6. The applicant describes the types of procedures used during facility operation. These will typically include management control, operating, maintenance, and emergency procedures. ~~[Comment: the following sentence is redundant and should be deleted.] The applicant provides information regarding the procedure categories used at the facility.~~ The applicant develops procedures for site-wide safe work practices to provide for the control of processes and operations with licensed SNM and/or IROFS and/or hazardous chemicals produced from licensed materials. These safe work practices apply to workers, visitors, contractors, and vendors. ~~An acceptable identification discussion clearly states areas for which a procedure is required. [Comment: the following sentence is very prescriptive – micro-management by the NRC of licensee actions.] Procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA ISA Summary. The applicant provides a listing (in an appendix) of the types of activities that are covered by written procedures. The listing includes The license applicant should list~~ the topics of administrative procedures; system procedures that address start-up, operation, and shutdown; abnormal operation/alarm response; maintenance activities that address system repair, calibration, inspection, and testing; and emergency procedures. Appendix A to this chapter provides an acceptable listing of the items to be included under each topic.
7. Applicant reviews procedures after unusual incidents, such as an accident, ~~[Comment “unexpected transients” is a term not used by fuel fabricators. Delete.] unexpected transient~~, significant operator error, or equipment malfunction, or after any modification to a system, and revises procedures, as needed.
8. Applicant ensures technical accuracy of procedures applied to IROFS and/or licensed material and that they can be performed as written. The discussion identifies who is responsible for verification. ~~[Comment: the following sentences provide too detailed requirements.. Delete.] The verification process provides reasonable assurance that the technical information is included and correct, including formulas, set points, and acceptance criteria, and includes either a walk-down of the procedure in the field, or a table-top walk-through. The review process includes technical, cross-discipline reviews by affected organizations. This process includes both new procedures and procedure changes. The review provides reasonable assurance that the operating limits and IROFS identified in the ISA Summary are specified in the procedures and that QA requirements are identified and included in operating procedures. The applicant describes who can approve procedures and includes the approval level for each procedure type. At a minimum, responsible management, along with the safety disciplines, approves new procedures and changes to existing procedures.~~
9. Documents containing procedures are distributed in accordance with applicable distribution lists. A process is used to limit the use of outdated procedures. ~~[Comment: the following two sentences provide prescriptive details inappropriate for the application review. They should be deleted for clarity.] Copies are available to appropriate personnel. Issuance and distribution of procedures are documented and refer to the~~

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~~Records Management function.~~

10. The applicant has formal requirements governing the review, approval and use of temporary changes to procedures. Temporary procedure changes do not involve a change to the ISA or ISA Summary. ~~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 reasonable assurance of orderly and uniform operations for short periods when the plant, a system, or component of a system is performing in a manner not covered by existing permanent procedures, or has been modified or extended in such a manner that portions of existing procedures do not apply. The discussion includes establishment of a timeframe for use of the temporary procedure and includes the same level of review and approval as that for permanent procedures.

11. Maintenance procedures involving IROFS commit to the topics listed below for corrective, preventive, functional testing after maintenance, and surveillance maintenance activities:
 - a. Pre-maintenance activity requires reviews of the work to be performed, including procedure reviews for accuracy and completeness;

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

 - c. Control of work by comprehensive procedures to be followed by maintenance technicians. Maintenance procedures are reviewed by the appropriate various safety disciplines, as required. ~~[Comment: the following list of five items is unnecessary for inclusion in this section – far too prescriptive.] including criticality, fire, radiation, industrial, and chemical process safety. The procedures describe, as a minimum the following:~~
 - ~~i. Qualifications of personnel authorized to perform the maintenance or surveillance;~~

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

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

 - ~~iv. Tracking and records management of maintenance activities;~~

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

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12. Applicant conducts periodic reviews of procedures to assure their continued accuracy and usefulness and establishes the timeframe for reviews of the various types of procedures. At a minimum all operating procedures are reviewed every 5 years and emergency procedures are reviewed every two years. [Comment: why is not review on a 2-year cycle appropriate in some cases? Too prescriptive.] [-Comment: the following sentence says nothing and should be deleted.] ~~The applicant describes the use and control of procedures.~~ Provisions allow for operations to stop and place the process in a safe condition if a step of a procedure cannot be performed as written. Guidance identifies the manner in which procedures are to be implemented. Routine procedural actions that are frequently repeated might not require the procedure to be present. Procedures for complex jobs or dealing with numerous sequences where memory cannot be trusted may require valve alignment check sheets, approved operator aids, or in-hand procedures that are referenced directly, when the job is conducted.

11.4.3.5 Audits and Assessments

The NRC reviewers should find the applicant's submittal regarding audits and assessments acceptable if it satisfies the following: provides reasonable assurance that the regulatory review criteria below are adequately addressed and satisfied. [Comment: consistency in SRP language.]

1. The applicant should describe policy directives covering the audit and assessment function (i.e., at a minimum, the activities to be audited; audit frequency; guidance in conducting the audit or assessment; ~~assigned responsibilities for each phase of the work;~~ and procedures for recording the results and recommending actions to be taken).
2. The applicant has committed to conduct internal audits and independent assessments of activities significant to plant safety and environmental protection;
3. Audits will be conducted to verify that operations are being conducted in accordance with regulatory requirements and commitments in the license application;
4. Independent assessments will be conducted by ~~off-site groups or~~ [Comment: unnecessarily prescriptive.] individuals not involved in the licensed activity, to verify that the health, safety, and environmental compliance functions are effectively achieving their designed purposes;
5. Audits and assessments will be conducted for the areas of radiation safety; nuclear criticality safety; chemical safety; fire safety; environmental protection; emergency management; QA; CM; maintenance; training and qualification; procedures; incident investigation; and records management; and
6. Qualified personnel [Comment: personnel "without direct responsibility" are not always required. The licensee should avail himself of all technical expertise, especially that of plant personnel highly knowledgeable of the facility's operations.] ~~without direct responsibility for the function and area being audited or assessed~~ will be used. The staff positions and committees responsible for audits and assessments are specified. The levels of management to which results are reported, and the systems or processes to address findings, recommendations and to provide corrective actions, are also described.

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7. ~~[Comment: the content of this Item (7) are all repeated from above. Delete this redundancy.] Provisions are made for planning and scheduling assessments and audits to verify compliance with and to determine the effectiveness of QA; responsibilities and procedures are identified for assessing, auditing, documenting and reviewing results and for designating management levels to review assessment and audit results; and provisions are made for incorporating the status of findings and recommendations in management reports (see Sections 11.3.5, 11.5.2.5, and 11.6.5 for details on audits and assessments). This attribute may be described as part of audits and assessments or as part of the management measure on QA.~~
78. The applicant's provisions for continuing QA address reviews and updates of QA documents based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA program changes. This attribute may be explained as part of audits and assessments or as part of ~~the management measure on~~ QA.

11.4.3.6 Incident Investigations

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

1. The applicant will establish a process to investigate abnormal events that may occur during operation of the facility, to determine their specific or generic root cause(s) and generic implications, to recommend corrective actions, and to report to the NRC as required by 10 CFR 70.50 and 70.74. The investigation process should include a prompt risk-based evaluation and, depending on the complexity and severity of the event, an individual may be all that is required to conduct the evaluation. ~~[Comment: the following sentence is unnecessarily prescriptive and should be deleted. Note that self-assessments are usually undertaken by the group that committed the violation – a good practice even if there is no involvement of an independent entity.]~~The investigator(s) will be independent from the line function(s) involved with the incident under investigation. ~~[Comment: Investigations should begin only within 72 hours (to allow for weekends).]~~ Investigations will begin within ~~72~~ 48 hours of the abnormal event, or sooner, depending on the safety significance of the event. ~~The failures of log required for IROFS and management measures, if relevant,~~ should be reviewed as part of the investigation.
2. The applicant will monitor and document corrective actions, through completion; and
3. The applicant will maintain documentation so that "lessons learned" may be applied to future operations of the facility. Details of the event sequence will be compared with accident sequences already considered in the ISA, and the ~~ISA and~~ ISA Summary will be modified ~~accordingly, to include the evaluation of the risk associated with accidents of the type actually experienced.~~

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

~~[Comment: of the following seven items, several are very prescriptive, in that they tend to~~

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specify the content of procedures. Recommend revision.]

1. A documented plan for investigating an abnormal event. This plan is separate from any required Emergency Plan. The investigation of an abnormal event should begin as soon as possible, commensurate with the safety of the investigative team, after the event has been brought under control;
2. A description of the functions, qualifications, and responsibilities of the management person who would lead the investigative team of qualified internal and external investigators (including experts in root cause analysis) and those of the other team members; the scope of the team's authority and responsibilities; and assurance of cooperation of management;
3. Assurance of the team's authority to obtain all the information considered necessary, and independence from responsibility for or to the functional area involved in the incident under investigation;
4. Procedures requiring maintenance of all documentation relating to abnormal events for 2 years or for the life of the operation, whichever is longer; [Comment: too long a period. 5 years may be reasonable for a license commitment.]
5. Guidance for personnel conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the root cause(s) of the problem. The level of investigation should be based on a graded approach relative to the severity of the incident;
- ~~6. Requirements to make available, to the NRC, original investigation reports on request; and [Comment: unnecessary item. The NRC has the right to review all work and reports at the facility.]~~
- ~~6.7. A system for monitoring ~~to ensure~~ 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; [Comment: this item (1) is already addressed in item (1) above. Delete redundancy.]~~
- ~~2. The functions, responsibilities, and scope of authority of investigators and/or teams are documented in the plan; [Comment: this item (2) is already addressed in item (2) above. Delete redundancy.]~~
- ~~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; [Comment: this item (3) is already addressed in item (2) above. Delete redundancy.]~~
4. The applicant commits to prompt investigation of any abnormal events, and precursors to abnormal events (such as undetected failure of IROFS); [Comment: How does one detect an

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“undetected” event or failure? Delete the last part of this item (4).]

~~5.—The investigation process and investigating team are independent of the line management, and participants are assured of no retribution from participating in investigations; [Comment: this requirement can not be generalized as written. In some cases line management should do their own review. Most root cause analysis methods require the participation of operations personnel.]~~

~~11.6.~~ A reasonable, systematic, structured approach is used to determine the root cause(s) of abnormal events;

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

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

11.4.3.7 Records Management

The reviewer will find the applicant’s records management system ~~for records-~~ [Comment: simplify the language for clarity.] acceptable if it satisfies the following criteria:

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

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

3. [Comment: this item (3) imposes new requirements. How much rigor is really appropriate for LEU fuel fabrication facilities?] Records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage;

4. Procedures are established and documented specifying the requirements and responsibilities for a record management system. [Comment: the balance of this sentence is unnecessarily detailed and prescriptive. Delete for consistency.] ~~selection; verification; protection; transmittal; distribution; retention; maintenance; and disposition; 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, 11.5.2.7, and 11.6.7 for details on records management).~~ This attribute may be described as part of records management or as part of ~~the management measure on~~ QA; and

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

~~6.—[Comment: delete item (6). This item is repeated verbatim in Item (6) of §11.4.3.8 and should be included in the QA section. Delete this redundancy.] The preparation, issuance~~

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~~and changes of documents that specify quality requirements or prescribe activities affecting quality are controlled to provide reasonable assurance that the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by authorized personnel (see Sections 11.3.1, 11.5.2.1, and 11.6.1 for details on CM and sections 11.3.4m 11.5.2.4 and 11.6.4 for details on procedures). This attribute may be described as part of records management or as part of the management measure on QA. [Comment: the order of the following two sentences should be reversed.]~~ Examples of records that should be included in the system are listed in Appendix B to Chapter 11. Records are categorized by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records. - ~~[Comment: the following sentence is too detailed, vague and prescriptive and is covered in Item (4) above. Review and approval of procedures is not included in assessment of the license application and so detailed information on what should be in the procedures is redundant and unnecessary. Delete for clarity.]~~ ~~The procedures should: a) assign responsibilities for records management; b) specify the authority needed for records retention or disposal; c) specify which records must have controlled access and provide the controls needed; d) provide for the protection of records from loss, damage, tampering, or theft or during an emergency; and e) specify procedures for ensuring that the records management system remains effective.~~

~~[Comment: unclear how a computer code or computerized data could support an activity relied on for safety.]~~ 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.- ~~[Comment: delete following sentence as unnecessarily detailed and prescriptive.] This could include transcribing the older forms of information (e.g., punched cards or paper tapes) and codes for older computing equipment to contemporary computing media and equipment.~~ Records of IROFS failures must be kept and updated in accordance with 10 CFR 70.62(a)(3). Record revisions necessitated by post-failure investigation conclusions should be made within thirty five working days [10 CFR 70.62(a)(3) states “promptly”].~~[Comment: 5 days is unrealistically short and inconsistent with current licensee practice.]~~

11.4.3.8 Other QA Elements

Comments:

- (1) the rule uses the term “other QA elements” (§70.4). However, licensees generally simply refer to “QA” or to “QA measures”. Industry recommends that such a simplified term be used throughout §11.4.3.8.]
- (2) we reiterate, for the record, our contention that QA is an integral and inseparable element of all management measures and that separate treatment should not be expected. The July 2000 revision of Chapter 11 somewhat addresses this concern by allowing the applicant to comment on QA measures that will be applied to each of the other §70.4 management measures. However, directing an applicant to address all 19 NQA-1 type requirements – whether on a graded basis or otherwise -- is unwarranted.
- (3) Industry believes that much of §11.4.3.8 is superfluous. A simple statement such as “QA should be applied in accordance with the procedures described above.” Should be

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appropriate.]

(4) Some statement should be included stating that “grading” of QA includes both the selection of appropriate QA elements (not all may be appropriate to a particular IROFS) as well as the thoroughness/comprehensiveness of the selected QA element.

To be acceptable, the applicant's QA ~~elements~~ should be structured to support apply appropriate measures to IROFS, which may include site design features. QA ~~elements~~ may be graded applied in accordance with proportion to the importance of the IROFS item to the achievement of safety. ~~(graded approach). [Comment: following statement is repetitive – goes without saying. Delete for clarity.] Applicants'/licensees' QA elements are expected to differ based on the purpose and complexity of the facility and processes to be controlled.~~

[Comment: the following paragraph simply repeats the “grading” discussion in the previous paragraph again – whose application to all management measures was also discussed in the introduction to this chapter. Delete this redundancy.] The ISA summary should identify the IROFS, the degree of their importance to safety, and their related activities that are required for safety. The applicant's selection of QA elements to be applied to an IROFS, and the applicant's grading and level of the QA elements may be proportional to the importance to safety of the IROFS. An applicant may choose to apply all QA elements and the highest level to all IROFS, or may grade the application in proportion to the importance of the item to the achievement of safety.

[Comment: for the third time in §11.4.38, the “grading” concept is again stated. Delete this redundancy. Note also that this sentence erroneously states that risk ranking is determined by the “maintenance function”, when, in fact, such ranking is done by the ISA team.] All IROFS should have all appropriate QA elements applied. If the applicant grades the application of QA elements, the relative risk importance ranking of IROFS, as established within the maintenance function, should parallel those used in for QA elements.

A checklist for evaluating the application of QA ~~elements~~ is given below. [Comment: again, more redundant statements addressing “grading”. Reference to risk is not supported by the NRC. Delete.] ~~If the application of QA is graded, the attributes described for each element listed below are applied for accident sequences based on the highest level of risk.~~ The application of QA ~~elements~~ may be reduced by modifying or eliminating either the number of elements or the attributes within each element, based on evaluations performed and documented in the ISA. Attributes of QA ~~elements~~ are as follows are provided below:

[Comment: already addressed in license chapter 2. No special additional treatment is needed. Recommend deleting this paragraph. Specific errors commented upon, however.] 1. The applicant describes the: a) organizational structure; b) functional responsibilities; and c) ~~charts of the lines, interrelationships, and areas of~~ responsibility and authority for all organizations performing activities relied on for safety, including the organization of ~~the applicant and, as applicable,~~ its principal contractors (architect/engineer, constructor, construction manager, and operator), as applicable. Persons or organizations responsible for ensuring that appropriate QA has been established and for verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities. This attribute may be described as part of QA or as part of

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Chapter 2, Organization and Administration:

~~[Comment: this item has already been covered. No bearing. Recommend deletion.]~~ 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. ~~[Comment: the following sentence contains too much detail and is unnecessary. Delete.]~~ ~~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. See references in Section 11.7 (e.g., ANSI/ASME NQA-1).~~

~~[Comment: CM is part of the management system and need not be redefined here again. Delete.]~~ 3. ~~A design control function is established that includes design inputs, process, analyses, verification, interfaces, changes, and design documentation and records (see Sections 11.3.1, 11.4.3.1, 11.5.2.1, and 11.6.1 for details on CM). This attribute may be described as part of QA or as part of the management measure on CM, configuration management.~~

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; ~~[Comment: there is general limited applicability of this provision. It closely resembles item (7) below. Remove redundancy.]~~

~~[Comment: this item just re-discusses procedures and should not be in this §11.4.3.8. Delete.]~~ 5. ~~Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate for the circumstances (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). This attribute may be described as part of QA or as part of the management measure on procedures.~~

~~6. [Comment: Item (6) is a repetition of item (6) of §11.4.3.7. Delete this redundancy. Furthermore, there is no need to re-discuss or re-define CM – done previously. Delete.]~~ ~~The preparation, issuance, and changes of documents that specify quality requirements or prescribe activities affecting quality are controlled to provide reasonable assurance that the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by authorized personnel (see Sections 11.3.1, 11.4.3.1, 11.5.2.1, and 11.6.1 for details on CM and sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). 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. ~~[Comment: why are duplicate procedures required to identify IROFS? Done already.]~~

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

9. Measures are established to maintain the acceptability of special processes used in the course of construction, maintenance, modifications, and testing of IROFS 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; Comment: the content of Item (9) has been discussed in many other areas of Management Measures and is really redundant here.

~~10. Comment: matter already discussed under Maintenance management measure. No further discussion her is warranted. Delete. Inspection required to verify conformance of IROFS with requirements is planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). Personnel qualification programs are established for inspection test personnel (see Sections 11.3.3, 11.4.3.3, 11.5.2.3, and 11.6.3 for details on training and qualifications). This attribute may be described as part of QA or as part of the management measure on maintenance.~~

~~11. Comment: matter already discussed under Maintenance management measure. No further discussion her is warranted. Delete. 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). 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. Comment: matter already discussed under Maintenance management measure. No further discussion her is warranted. Delete. 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. Comment: matter already discussed under Maintenance management measure. No further discussion her is warranted. Delete. 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;

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16. ~~[Comment: matter already discussed under Corrective Action Planning. No further discussion her is warranted. Delete.] 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. Comment: Amen for 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). This attribute may be described as part of QA or as part of a corrective action plan~~

17. ~~[Comment: matter already discussed under Records management measure. No further discussion her is warranted. Delete.] 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). 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 (see Sections 11.3.5, 11.4.3.5, 11.5.2.5, and 11.6.5 for details on audits and assessments). This attribute may be described as part of QA or as part of the management measure on audits and assessments.

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 ~~CM~~configuration management.

11.5 REVIEW PROCEDURES

~~[Comment: this section should simply state that the reviewer is to determine that management measures have met the acceptance criteria of §11.4. The current text in this section adds very little value or guidance to the reviewer. There is a high degree of repetitiveness and redundancy that should be deleted.]~~

~~This section should address **procedures** – i.e. how will the review of each management measure be performed – and should avoid stating **what** should be reviewed (handled in §3 and §4.)~~

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.

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

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

11.5.2 Safety Evaluation

After the primary reviewer determines that the application is acceptable for review in accordance with Section 11.5.1, above, the primary and secondary reviewers should perform a ~~s~~Safety ~~E~~evaluation ~~R~~review (SER) [Comment: first use and definition of this term.] against the acceptance criteria described in Section 11.4. Review procedures for each criterion are discussed in the sections below. If deficiencies are identified, the applicant should be requested to submit additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP. The reviews for ~~e~~ all management measures should be coordinated with the primary reviewer of the ISA Summary.

11.5.2.1 CM

[Comment: there is a noticeable disparity amongst the length of individual sections of §11.5.2. Why does CM warrant almost 2 pages of repeated information, whereas Maintenance just requires a quarter page summary? Surely, maintenance is of greater safety significance than CM – but one would not conclude this from the §11.5.2.1 presentation. Much more uniformity is required in this section. CM is a glaring example of a topic that must be significantly cut down to size. The excessive redundancy must be removed.]

1. CM System Policy Management

The primary reviewer should consider whether the CM ~~System plan~~ acceptably states management commitments, gives the policy directive, and defines key responsibilities, ~~terminology~~, and equipment scope. The secondary reviewers should examine the ISA Summary ~~and the ISA, as needed~~, to assure that the applicant has committed to apply CM to IROFS identified in the ISA Summary. ~~identified IROFS will be subject to the CM function.~~ [Comment: the balance of this paragraph specifies "what" should be reviewed and is inappropriate content for §11.5. Delete.] ~~Appropriate interfaces both within the CM function and with external organizations and functions should be examined. In particular, the functional interfaces with QA, maintenance, and training and (including qualification) should be examined. The reviewers should look for the applicant's identification of required databases and the rules for their maintenance. The reviewers should examine implementing procedures for the CM function.~~

2. Design Requirements

The primary reviewer should confirm that the design process leading to drawings and other

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statements of requirements proceeds logically from the design basis. ~~[Comment: the following sentence is a definition and not a procedure. Delete.] 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. [Comment: following sentence is far too prescriptive. Delete.] The reviewers should verify that specific personnel are assigned the responsibility for maintaining the design bases and requirements. [Comment: the following sentences state "what" should be reviewed and are not procedures. Delete.] The reviewers should verify that the IROFS to be listed under CM will be clearly defined in the requirements documents, along with the assignment of any grades or quality levels. This part of the review should be coordinated with the ISA primary reviewer. The ISA Summary should specify all IROFS, and the applicant should have indicated in the ISA Summary, what level of CM attributes is applied to a particular IROFS item. However, in the ISA Summary this indication may consist of only an index or category designation. The definition of the individual content of multiple CM levels, if used, should be in the CM Chapter of the application. The primary reviewer for the CM Chapter is responsible for determining that appropriate levels of CM are applied to IROFS of differing safety significance. [Comment: correct English expression.] to determine if the reduced levels the applicant would apply to safety items for lesser risk accident sequences are adequate.~~

3. Document Control

The primary reviewer should evaluate the applicant's material showing that the CM system will capture documents that are relevant and important to safety. ~~[Comment: the following sentences state "what" is to be reviewed and do not discuss procedures. Delete.] The documents should include design requirements; the ISA; the ISA Summary; as-built drawings; specifications; all safety-important operating procedures; procedures involving training, maintenance, audits and assessments; emergency response plans and operating procedures; emergency response plans; system modification documents; assessment reports; and others, as necessary, that the applicant may deem part of the CM function. The primary reviewer should determine whether a controlled document database is used to control documents and track document change status. [Comment: the following sentence is not a procedure. Delete.] Rules of storage for originals or master copies of documents within the CM function follow the guidance of "Records Management."~~

4. Change Control

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

5. Assessments

The primary reviewer should ~~confirm be able to find~~ that both document assessments and physical assessments (system walkdowns) will be conducted periodically, to check the

adequacy of the CM System function. ~~The primary reviewer should be able to find that All assessments and follow-ups will be documented in. These reports that can provide a supporting basis for future changes.~~

~~11. Design Reconstitution (Existing Facilities Only)~~

~~Design reconstitution may be necessary for existing facilities if current design information is not adequate. The primary reviewer examines the applicant's description of work to establish, organize, and document design requirements and design bases for items for which design information was not available before the application was submitted. Of particular importance are the methods used to evaluate, verify, and validate reconstituted design data for IROFS. For existing facilities, the design requirements and physical configuration may have greatly changed according to the demands of a changed mission. If documentation has not kept pace, it will be necessary for the applicant to walk down systems, update drawings and specifications, perform new calculations and analyses, and otherwise rebuild the design bases. The reviewer will seek evidence that the need for design bases reconstitution was investigated, that reconstitution was accomplished as necessary, and that new or revised documentation was properly incorporated into the CM function. [Comment: the following sentence is a general statement already presented in the introduction to this chapter. Delete this redundancy.] 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. [Comment: the balance of this sentence has been stated previously in §11.5.2. Delete this redundancy.], using the regulatory acceptance criteria from SRP Section 11.4.3.1.

11.5.2.2 Maintenance

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

[Comment: this paragraph does not discuss procedures, but rather defines the management measure program. Repetitive and unnecessary in §11.5. Delete.] ~~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

[Comment: recommend stating the procedures more clearly.] The primary reviewer evaluates

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~~the adequacy of the applicant's training and qualification program to ensure that personnel whose activities are relied on for safety will be knowledgeable in how to perform such activities when required, performs a safety evaluation against the acceptance criteria described in Section 11.4, 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 training needed. The review should evaluate the adequacy of training and qualification on the basis of how well it fulfills the objectives for the training as identified by the applicant, especially when human activities factors are relied on for safety. The review should determine whether the applicant has adequately planned for the training and personnel qualification to be accomplished and whether necessary policies, procedures, and instructions will be in place and appropriate training and qualification will be accomplished before personnel begin activities relied on for safety. The reviewers should focus on the training and qualification of personnel who will perform activities relied on for safety.~~

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

~~[Comment: this is an example of excessive and unneeded "checks and balances". Delete this paragraph.] To what does "ongoing activities" refer? The supporting reviewer should become familiar with the applicant's personnel training and qualification commitments and determine whether ongoing activities are in agreement with them.~~

~~[Comment: this paragraph does not explain procedures – rather it is the goal of the review. Therefore, inappropriate for this §11.5. Delete.] The review should result in a determination that there is reasonable assurance that the applicant's personnel training and qualification will result in only properly trained and qualified personnel performing activities relied on for safety.~~

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

11.5.2.4 Procedures

~~[Comment: remove the first clause – already stated in §11.5.2. Delete redundancy.] On acceptance of the application for review, the secondary reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria for procedures listed in Section 11.4. The secondary reviewer will document in an SER that the applicant has committed to the following:~~

~~[Comment: the following 6 items are not procedures, but are rather areas to be reviewed by the reviewer. Thus, they are inappropriate for inclusion in the "Review Procedures" section and should be deleted.]~~

- ~~1. IROFS identified in the ISA Summary are highlighted in safety procedures (including procedures that constitute administrative controls for safety) [Comment: consistency with Rule language required.]. There may be several levels of requirements within procedures for diagnosing and correcting process upsets, dealing with abnormal~~

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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. [Comment: sentence adds nothing. Delete.]~~

- ~~2. Procedures important to safety are independently verified and validated before use, and this is documented in a policy on procedures.~~
- ~~3. Policy and administrative procedures, non-crucial operating procedures, and other non-operational procedures that do not impact IROFS or other environmental, safety, and health concerns need not be controlled with the stringency applied to operating procedures or management control procedures associated with IROFS specified in the ISA Summary. The applicability of less stringent procedure control should be specified to avoid misunderstandings in implementation.~~
- ~~4. Changes to operating, management measure, or maintenance procedures are reviewed and approved by an independent multi-disciplinary safety review team and controlled by the GM function.~~
- ~~5. The applicant includes a statement to follow approved procedures while processing licensed SNM.~~
- ~~6. Procedures exist for the notification of operations personnel before and after maintenance is performed on IROFS, and activities are controlled by procedures. [Comment: this should already be understood. Delete.]~~

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

11.5.2.5 Audits and Assessments

~~[Comment: the idea in the first part of this sentence is already stated in §11.5.2. Delete redundancy.] After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the secondary reviewer will perform a safety evaluation against the acceptance criteria described in Section 11.4. The review should determine whether the applicant has adequately planned for audits and assessments in accordance with the acceptance criteria in §11.4 to be accomplished and whether necessary policies, personnel, procedures, and instructions will be in place to begin audits and assessments early, that is, during the design of IROFS.~~

~~[Comment: the substance of this paragraph applies to all management measure reviews and has been relocated to §11.5.2. Delete here as repetitious.] If the applicant references other sections of the application when describing its audits and assessments, the primary reviewer should review these other sections of the application to determine the applicant's commitment to overall audits and assessments and the proposed method for implementation. The reviewers should focus on audits and assessments of IROFS.~~

The secondary reviewer should confirm that the applicant's audit and assessment

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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.

~~[Comment: this statement conveys a blanket lack of confidence in the licensee. This paragraph introduces another “check & balance” that would not appear to be needed. Delete this paragraph.] 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.~~

~~[Comment: the following paragraph does not outline a procedure and is, therefore, inappropriate for inclusion in this §11.5. Delete.] 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 the necessary additional assurance that IROFS will perform satisfactorily in service and that activities relied on for safety will be performed satisfactorily.]~~

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

11.5.2.6 Incident Investigations

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

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

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

11.5.2.7 Records Management

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

For fuel cycle facilities that are parts of larger organizations, certain documents may be retained or stored at a site other than the plant site. ~~[Comment: too much detail. Delete this example.] For example, master drawings for structures might be kept in the engineering department of the headquarters of the parent company.~~ The reviewer may choose to review the physical characteristics of these offsite record storage areas, as well, particularly for

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records for IROFS or high-risk accident sequences [Comment: the NRC prefers no usage of the term "high-risk accident sequence. Replace.]

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

11.5.2.8 Other QA Elements

[Comment: see §11.4.3.8, ¶1.2.3.& item 12: the statement in this §11.5.2.8 should be simply that the review determines that these acceptance criteria are adequately addressed.] After the primary reviewer has determined that the application is acceptable for review in accordance with Section 11.5.1, above, ~~T~~the primary reviewer should confirm that the applicant's (and the applicant's principal contractors') QA ~~element~~ commitments are consistent with other sections of the submittal and. ~~The secondary reviewer should review the QA elements information with respect to the acceptance criteria in Section 11.4. The secondary staff reviewer should determine whether the applicant has adequately planned the work to be accomplished and whether necessary policies, procedures, and instructions either are in place or will be in place before work starts. The review is based on an assessment of the material presented. It should provide reasonable assurance that the applicant's QA elements, maintenance, and CM are coordinated and that the QA elements are an integral part of everyday work activities. [Comment: the following sentence does not describe a procedure and should, therefore, be deleted.] The review should provide reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of QA elements and will make needed adjustments on a timely basis. The staff is to look for and measure the effectiveness of the QA elements design, not just the existence of appropriate elements.~~

The secondary reviewer should also determine that the applicant has specified ~~the~~ QA ~~elements~~ criteria, ~~and~~ the basis on which the criteria were selected and how they are apportioned within the sections of the application as well as the proposed method for implementation. [Comment: the following issue was addressed in §11.5.2 and need not be repeated here again. Delete.] 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.

[Comment: this is far too detailed – too many reviewers. See previous comment for §11.5.2.5.] The supporting reviewers should become familiar with the applicant's (and principal contractors') QA elements commitments and determine whether ongoing activities are in agreement with them.

Staff Reviewers of SRP Chapters 3 through 1145 [Comment: a Freudian slip? Unintended application of MOX SRP criteria to Part 70 licensees?] should determine whether IROFS within their areas of review are assigned ~~specified to be within the~~ appropriate QA ~~elements~~ and appropriate grading level.

[Comment: the following paragraph does not outline a procedure, but rather states an

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~~acceptance criterion. Inappropriate for §11.5. Delete]. The review should result in a determination determine that there is reasonable assurance that the applicant's (and the applicant's principal contractors') QA, when coupled with the other management measures and licensee commitments elements will provide reasonable assurance that IROFS will perform their safety functions in a satisfactory manner.~~

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

11.6 EVALUATION FINDINGS

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

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

The staff can document the evaluation as follows:

11.6.1 CM

The staff has reviewed the CM ~~System 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 ~~[Comment: too detailed. Delete.] , including an analysis and independent safety review of any proposed activity involving IROFS,~~ are described that will provide reasonable assurance that the relationship ~~between among~~ ~~[Comment: for comparison of more than 2 items, "among" should always be used rather than "between"]~~ design requirements, physical configuration, and facility documentation is maintained as part of a new activity or change in an existing activity involving licensed material. The management measures will include (or do include) the following elements of CM:

1. CM Management

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

2. Design Requirements

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

3. Document Control

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

4. Change Control

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

5. Assessments

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

~~6. [Comment: as noted earlier, there is no need for this section as soon as the ISA is completed. Delete.] Design Reconstitution [Existing Facilities Only]~~

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

11.6.2 Maintenance

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

The surveillance/monitoring, PM and functional testing activities described in the license application provide reasonable assurance that IROFS, identified in the ISA Summary, will be

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available and reliable to prevent or mitigate accident consequences.

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

The staff concludes that the applicant's maintenance functions ~~meet the requirements of Part 70, and~~ provide reasonable assurance that engineered safety controls will be available and reliable when required. [Comment: make the assertion more specific – i.e. meeting the performance standards of §70.61.] ~~the health and safety of the worker and the public are provided for.~~

11.6.3 Training and Qualification

Based on its review of the license application [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] the NRC staff has concluded that the applicant has adequately described and assessed its personnel training and qualification in a manner that (1) satisfies regulatory requirements; and (2) is consistent with the guidance in this SRP. ~~and (3) is acceptable. [Comment: what does "is acceptable" mean? If the program satisfies the regulatory requirements (item (1), then is not the program acceptable? Delete redundancy.]~~

There is reasonable assurance that implementation of the described training and qualification will result in personnel who are qualified and competent to ~~design, construct,~~ start-up, operate, maintain, and modify, ~~and decommission~~ [Comment: current plant personnel should not be expected to be knowledgeable in how to design, build or decommission the facility. Narrow down the responsibilities.] the facility safely and to perform activities relied on for safety. The staff concludes that the applicant's plan for personnel training and qualification meet the requirements of Part 70.

11.6.4 Procedures

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

11.6.5 Audits and Assessments

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

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~~[Comment: the content of the following sentence is stated in the next paragraph. Delete the following sentence to reduce redundancy.] The staff has reviewed the applicant's plan for audits and assessments and finds them acceptable.~~

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

11.6.6 Incident Investigations

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

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

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

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

11.6.7 Records Management

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

11.6.8 Other QA Elements

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

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1. The applicant has established and documented a commitment for an organization responsible for developing, implementing, and assessing the management measures for providing reasonable assurance of safe facility operations in accordance with the criteria in Section 11.4 of this SRP;
2. The applicant has established and documented a QA commitment ~~for QA elements~~, and the administrative measures for staffing, performance, assessing findings, and implementing corrective actions are in place;
3. The applicant has developed a process for preparation, revision and control of written administrative plant procedures, ~~including procedures for evaluating changes to procedures, items and tests~~. A process for review, approval, and documentation of procedures will be implemented and maintained;
4. The applicant has established and documented surveillances, tests, and inspections to provide reasonable assurance of satisfactory in-service performance of IROFS. Specified standards or criteria and testing steps have been provided;
5. Periodic independent audits are conducted to determine the effectiveness of the management measures. Management measures will provide for documentation of audit findings and implementation of corrective actions;
6. Training requirements have been established and documented to provide employees with the skills to perform their jobs safely. Management measures have been provided for evaluation of the effectiveness of training against predetermined objectives and criteria; [Comment: but these are not management measures as defined in §70.4. Clarify by changing the terminology.]
7. The organizations and persons performing safety-related 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. Management measures QA elements cover the IROFS, as identified in the ISA ~~s~~Summary, and measures are established to prevent hazards from becoming pathways to higher risks and accidents.

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

11.7 REFERENCES

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

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- ~~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 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," U.S. Government Printing Office, Washington, DC.
- 4.1. U.S. Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Government Printing Office, Washington, DC.
- 5.2. 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.
- 6.3. 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.
- 7.4. 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.~~
- 10.5. U.S. Nuclear Regulatory Commission, "A Systematic Approach to Repetitive Failures," NUREG/CR-5665, February 1991.
- 11.6. U.S. Nuclear Regulatory Commission, "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities," Federal Register 54 (No. 53), 11590-11598, March 21, 1989.
- 12.7. U.S. Nuclear Regulatory Commission, "Guide to NRC Reporting and Recordkeeping Requirements," NUREG-1460, Rev. 1, July 1994.
- 13.8. U.S. Nuclear Regulatory Commission, "Maintenance and Inspection," Inspection Procedure 88062, January 16, 1996.
- 14.9. U.S. Nuclear Regulatory Commission, "Maintenance and Surveillance Testing," Inspection Procedure 88025, May 23, 1984.
- 15.10. U.S. Nuclear Regulatory Commission, "Proposed Method for Regulating Major Materials Licensees," Section 3.2.6, 'Configuration Management,' NUREG-1324, 1992.
- ~~16. U.S. Nuclear Regulatory Commission, "Proposed Revision to Code of Federal Regulations,~~

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~~Title 10, Part 70, 'Domestic Licensing of Special Nuclear Material,' as revised. [Comment: same as reference #4 above. Delete redundancy.]~~

~~17.11.~~ U.S. Nuclear Regulatory Commission, "Root Causes of Component Failures Program: Methods and Applications," NUREG/CR-4616, December 1986.

~~18.12.~~ U.S. Nuclear Regulatory Commission, "Suggested Guidance Relating to Development and Implementation of Corrective Action," Information Notice 96-28, May 1966.

~~19.13.~~ U.S. Nuclear Regulatory Commission, "Training Review Criteria and Procedures," NUREG 1220, Rev. 1, January 1993.

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APPENDIX A

CHECKLIST FOR PROCEDURES

[General Comment: recommend that this list of procedures be pared down to those important, macro-level procedures identified in the Acceptance Criteria. Some specific comments on the proposed list are noted below.]

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

~~Equipment control (lockout/tagout)~~ [Comment: far too prescriptive.]

~~Shift turnover~~ [Comment: far too prescriptive.]

~~Work Control~~ [Comment: far too prescriptive.]

Procedure management

Nuclear criticality safety

Fire protection

Radiation protection

Radioactive waste management

Maintenance

Environmental protection

Chemical process safety

Operations

~~Calibration control~~ [Comment: covered under "maintenance" procedure above.]

~~Preventive maintenance~~ [Comment: covered under "maintenance" procedure above.]

2. Operating Procedures:

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

Process Operations

Ventilation Systems

Criticality alarms Systems

~~Shift routines, shift turnover, and operating practices~~

Decontamination operations

~~Uranium recovery~~ [Comment: covered under "process operations" above.]

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Plant ~~Utility Systems 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

Repairs/~~replacement, calibration and testing -and preventive repairs~~ of items relied on for
safety (IROFS)

~~Repairs/replacement and t~~esting of criticality alarm units

~~Calibration of IROFS~~

~~High Efficiency Particulate (HEPA) filter maintenance~~ Repair/replacement and testing of
ventilation and containment systems

~~Functional testing of IROFS~~ [Comment: covered above, as revised. Delete.]

~~Relief valve replacement/testing~~ [Comment: covered above, as revised. Delete.]

Surveillance/monitoring

~~Pressure vessel testing~~ [Comment: covered above, as revised. Delete.]

~~Non-fired pressure vessel testing~~ [Comment: covered above, as revised. Delete.]

~~Piping integrity testing~~ [Comment: covered above, as revised. Delete.]

~~Containment device testing~~ [Comment: covered above, as revised. Delete.]

4. Emergency Procedures:

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

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APPENDIX B

RECORDS

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

Examples of Records

SRP Chapter

1.0 General Information

Construction records

Facility and equipment descriptions and drawings

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

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

Safety analyses, reports, and assessments

Records of site characterization measurements and data

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

Procurement records, including specifications for IROFS

2.0 Organization and Administration

Administrative procedures with safety implications

Change control records for material control and accounting program

~~Organization charts, P~~osition descriptions, and personnel qualification records
[Comment: organization charts is too prescriptive.]

Safety and health compliance records, medical records, personnel exposure

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records, etc.

QA records

Safety inspections, audits, assessments, and investigations

~~Safety statistics and trends~~ [Comment: too prescriptive. Delete.]

3.0 Integrated Safety Analysis

4.0 Radiation Safety

Bioassay data

Exposure records

Radiation protection ~~(and contamination control)~~ records [Comment: goes without saying. Delete.]

Radiation training records

~~Radiation work permits~~ [Comment: covered in "Radiation Protection" records above.]

5.0 Nuclear Criticality Safety

Nuclear criticality ~~safety control-written~~ procedures ~~and statistics~~

Nuclear criticality safety analyses

~~Records pertaining to nuclear criticality~~ inspections, audits, investigations, and assessments [Comment: the heading of this Appendix already states "records". No need to repeat here.]

~~Records pertaining to nuclear criticality~~ incidents, unusual occurrences, or accidents [Comment: the heading of this Appendix already states "records". No need to repeat here.]

~~Records pertaining to nuclear criticality safety analyses~~ [Comment: Covered above.]

6.0 Chemical Safety

[Comment: all strikeouts are covered by the Section Heading. Reduce redundancy.]

~~Chemical process safety~~ Procedures and plans

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~~Records pertaining to chemical process~~ inspections, audits, investigations, and assessments

Diagrams, charts, and drawings

~~Records pertaining to chemical process~~ incidents, unusual occurrences, or accidents

~~Chemical process safety~~ Reports and analyses

~~Chemical process safety~~ Training

7.0 Fire Safety

Fire Hazard Analysis

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

~~Records pertaining to~~ inspection, maintenance, and testing of fire protection equipment

~~Records pertaining to fire protection~~ Training and retraining of response teams

Pre-fire emergency plans

8.0 Emergency Management

Emergency plan(s) and procedures

Comments on emergency plan from outside emergency response organizations

Emergency drill records

Memorandum of understanding with outside emergency response organizations

Records of actual events

~~Records pertaining to the~~ Training and retraining of personnel involved in emergency preparedness functions

~~Records pertaining to the~~ inspection and maintenance of emergency response equipment and supplies

9.0 Environmental Protection

Environmental release and monitoring records

Environmental Report and supplements to the Environmental Report, as applicable

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10.0 Decommissioning

- Decommissioning records
- Financial assurance documents
- Decommissioning cost estimates
- Site characterization data
- Final survey data
- Decommissioning procedures

11.0 Management Measures

11.1 Configuration Management

- Safety analyses, reports, and assessments that support the physical configuration of process designs, and changes thereto to those designs.
- Validation records for computer software used for safety analysis or material control and accounting
- Integrated Safety Analysis (ISA) documents, ~~including process descriptions, plant drawings and specifications, purchase specifications for IROFS~~ [Comment: too detailed. This information is referenced in the ISA.]
- ~~Approved, current Operating procedures and emergency operating procedures~~ [Comment: material out of place – covered elsewhere.]

11.2 Maintenance

- ~~- Failure log (required by 10 CFR 70.62) [Comment: no longer required]~~
- PM records, ~~including trending and root cause analysis~~ [Comment: too prescriptive]
- Maintenance, cCalibration and testing data for IROFS
- Corrective maintenance records

11.3 Training and Qualification

- Personnel training and qualification records
- Procedures

11.4 Procedures

- Standard operating procedures
- ~~Maintenance Functional~~ test procedures [Comment: functional testing is part of maintenance.]

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11.5 Audits and Assessments

- Audits and assessments of safety and environmental activities

11.6 Incident Investigations

- Investigation reports
 - ~~- Changes recommended by investigation reports, how and when implemented~~
[Comment: corrective action documents]
 - ~~- Summary of reportable events for the term of the license~~ [Comment: Why? NRC has this information as a matter of public record.]
- Incident investigation policy

11.7 Records Management

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

11.8 Other Quality Assurance Elements

- Inspection records
- Test records
- Corrective action records

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APPENDIX C

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

[Comment: as noted earlier, industry believes that Appendix C in its existing form should be deleted or significantly revised to clarify what information (and level of detail) should be included in a license application discussion of Maintenance.]

As an example of how Appendix C could be revised, NEI has reviewed existing NRC-approved licenses for fuel cycle facilities in the area of "Maintenance". Individual licensee maintenance programs are described at a high-level and focus on the necessary core elements. As the NRC has endorsed this approach, and as the revised Part 70 requirements are not intended to impose significantly new regulatory burdens, an acceptable maintenance program should continue to focus on these high-level program goals with a minimum of detailed supporting information. An example of a license application submittal on maintenance is provided below and includes descriptions in the areas of: (i) program purpose, (ii) policy statement (core elements of the program), (iii) organizational structure, (iv) records, (v) measurement of program efficacy, and (vi) coordination with other management measures.

(This example contains more detail than may be required and uses terminology (e.g. personnel positions and organizations) that may not be appropriate to all licensees.)

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

MAINTENANCE MANAGEMENT MEASURE

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

Policy Overview: The maintenance program will support IROFS listed in ISA Summary and facility processes that involve handling or processing of licensed material. Grading of the maintenance program will be in accordance with the risk the IROFS or safety system is to protect against. Grading will be reflected, for example, in the frequency of surveillance of the IROFS, the thoroughness of the preventive maintenance, quality assurance applied to replacement IROFS components or the frequency of the functional testing of the IROFS. Preventive maintenance (PM) will be applied through use of maintenance planning and control computer programs to establish the frequency of PM activities, to initiate work orders for programmed maintenance and to record details of the execution of the work orders. PM will apply to engineered controls and other equipment such as plant air compressors and emergency generators, fire detection and fire control, natural gas valves, nuclear

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criticality detection, pressure relief valves and steam boilers. The frequency of PM and instrumentation calibration will be based upon manufacturers' recommendations, prior operating experience and safety importance of the IROFS or equipment. PM will include specified calibration and re-calibration or relevant systems that will be initiated and controlled by the maintenance planning and control computer programs. Surveillance/monitoring will be conducted by electronic monitoring of IROFS and operator inspections of their availability and operability. In the event an IROFS or safety system must be removed from service for inspection, compensatory measures including, for example, replacement with an equivalent IROFS, will be implemented. The frequency of surveillance and the use of redundant, back-up electronic monitoring systems will be graded based upon manufacturers' maintenance recommendations, the documented performance trends and the safety importance of the IROFS. Corrective maintenance will be promptly initiated upon discovery of any IROFS unacceptable performance deficiency and will address any recommendations originating from any Corrective Action Program analysis. Each report of an unacceptable performance deficiency will be recorded and if a recurring problem is apparent, it will be referred to the CAP. Functional Testing will be conducted on a periodic basis on IROFS and other facility safety systems including, for example, plant-wide Fire Alarm System and Criticality Alarm System, plant-wide Hazard Warning System, specified safety-related interlocks on process equipment and hydrogen and natural gas line leak tests. When an IROFS component is repaired or replaced, the component will be field-tested to assure that it is likely to perform its desired function when called upon to do so. If the performance of a repaired or replaced IROFS component could be different from that of the original component, the IROFS will be field-tested to assure that it is likely to perform its desired function when called upon to do so. All maintenance activities will be conducted using written maintenance work orders authorized by the Manager of Maintenance Engineering that outline the safety system or IROFS to be worked on, identify potentially impacted IROFS and any required compensatory measures to be implemented, test procedures and acceptable ranges of test parameter results, documentation requirements for test results and other relevant information.

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

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

Maintenance Program Efficacy: A formal review of the efficacy of the Maintenance Program will be conducted under the auspices of the Manager of Maintenance Engineering and the Manager of Regulatory Compliance every two years. Deficiencies in any element of the Maintenance Program resulting from this review and identified in the annual Licensee Performance Reviews will be investigated and

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changes to the Maintenance Program developed for approval by the Manager of Process Engineering . Modifications to the CM system policy and procedures will be promptly implemented.

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