Felix M. Killar, Jr.
DIRECTOR, MATERIAL
LICENSEES & NUCLEAR INSURANCE
Tel: (202) 739-8126

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Mr. Theodore S. Sherr
Chief, Regulatory and International Safeguards Branch
U.S. Nuclear Regulatory Commission
Two White Flint North 8A33
Washington, D.C. 20555

Reference: Comments on the June, 1999 Draft Version of NUREG-1520 '*Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility*': Chapter 11 – Management Measures

Dear Mr. Sherr:

The Nuclear Energy Institute (NEI)[1] and its industry members are undertaking detailed reviews of each chapter of the draft Standard Review Plan (SRP) released on July 16, 1999 as part of SECY-99-147. To provide effective guidance on implementation of 10 CFR 70, we believe the SRP should be concisely written and accurately reflect the 'risk-informed, performance-based' regulatory approach incorporated into the Part 70 rule revisions.

Accompanying this letter are NEI's comments on Chapter 11 ('*Management Measures*') of the draft SRP. The review is presented in two parts: (i) general comments on the sub-chapter, and (ii) specific language (or stylistic) improvements presented on a red-lined version of the draft SRP sub-chapter. In view of the number and complexity of NEI's proposed improvements, a second copy of SRP Chapter 11 has been prepared from which the red-lined text deletions have been removed. This version of draft SRP Chapter 11 will enable you to more clearly understand the improvements which NEI is recommending.

Mr. Theodore S. Sherr

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

NEI is pleased that many improvements to the draft SRP developed in public meetings and workshops and proposed by industry have been incorporated into this latest draft of the SRP. The June, 1999 revision is markedly improved over earlier versions issued in 1998 and we compliment the staff for this accomplishment.

We look forward to working with you and your staff to make NUREG-1520 a clear and concise document that will facilitate implementation of the new provisions of 10 CFR Part 70. Please feel free to contact me should you have any questions concerning the proposed improvements in the attachment to this letter.

Sincerely,

Felix M. Killar, Jr.
Director, Material Licensees and Nuclear Insurance

c. Mr. Marvin S. Fertel
Dr. Carl J. Paperiello, Director NMSS

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COMMENTS ON THE JULY, 1999 DRAFT VERSION OF NUREG-1520
'*STANDARD REVIEW PLAN FOR THE REVIEW OF A LICENSE APPLICATION FOR A FUEL CYCLE FACILITY*'

CHAPTER 11: MANAGEMENT MEASURES

I. General Comments

Introduction

The July 1999 revision of the draft Standard Review Plan (SRP) presents a significant reorganization of the contents of Chapter 11. NEI commends the NRC for consolidating the eight sub-chapters into one '*Management Measures*' chapter with single sections on 'Areas of Review', 'Acceptance Criteria', 'Review Procedures' and 'Evaluation Findings.' This consolidation has resulted in the deletion of some redundant language, duplicate technical references and some prescriptive detail. We are pleased with the corrections made by the staff to clarify the chapter's language, to enhance consistency in the usage of Glossary terms and to purge the chapter of some remaining terminology appropriate to nuclear power plants, but not to fuel cycle facilities. We are particularly encouraged with the inclusion of new language that supports NEI's contention that Quality Assurance (QA) should be viewed not as a separate, stand-alone management measure, but rather an integral component of *any* management measure employed by the licensee.

In spite of this progress, draft SRP Chapter 11 still retains several new and complex programs patterned after those for nuclear power reactors that are not suitable for fuel cycle facilities and which are not mandated by 10 CFR 70. These programs should be deleted from the SRP. The prescriptiveness in discussion of certain management measures must also be addressed. The significant expansion in detailed requirements for 'Audits and Assessments' (§11.4.3.6) in the July 1999 revision of SRP Chapter 11 is puzzling.

Prescriptive and Programmatic Language

NEI wants to ensure that any prescriptive, programmatic criteria included in Chapter 11 without a specific basis in 10 CFR 70 will not become *de facto* regulatory requirements. Although we recognize that the SRP is only intended to be a staff guidance document to ensure consistency in license application reviews, the SRP acceptance criteria can over time become the minimum standards ('lowest rung on the acceptance ladder'). Thus, acceptance criteria and any examples provided to the staff reviewer must be carefully selected and be tailored to the facility risks that the items relied on for safety are designed to prevent or mitigate.

Draft SRP Chapter 11 remains voluminous (46 pages) and contains much material that is repeated from section to section. For example, document control is addressed in the Configuration Management, Quality Assurance, Procedures and Records Management sections. Corrective action programs are addressed in the Quality Assurance, Audits and Assessments and Incident Investigations sections.

These, and other, topics need only be addressed once in Chapter 11. Individual sections of draft SRP Chapter 11 contain very prescriptive statements as to how a particular requirement is to be carried out. For example, section §11.4.3.3 allows little latitude in designing monitoring, preventive maintenance and corrective maintenance programs. Section 11.4.3.6 mandates use of performance indicators and Part 50-type external audits of suppliers of items relied on for safety . Section 11.4.3.7 requires use of 'teams' to investigate abnormal events, requires investigators to be 'independent' and requires use of 'process expert(s)'. Section 11.4.3.1 establishes ASME NQA-1 as the basis for review of a license applicant's quality assurance program, regardless of the level of assurance that may be warranted by the Integrated Safety Analysis (ISA). Finally, §11.4.3.4(9) requires plant managers and technical staff to have university degrees, regardless of their experience or demonstrated expertise. Several sections of draft SRP Chapter 11 introduce new programmatic requirements patterned after those for nuclear power reactors. Draft SRP §11.5.2.4 ('Training and Qualifications') continues to make reference to application of a full performance-based '*systematic approach to training (SAT)*' comparable to what is required in the nuclear power industry; such a level of comprehensive and exhaustive training is not likely to be required by a fuel cycle facility's ISA. Many of the acceptance criteria for the Training and Qualifications management measure are taken directly out of the SAT guidance manual.

Chapter 11 frequently requires a licensee to ***demonstrate*** some action (e.g. §11.3.3: "*…the applicant should demonstrate that items relied on for safety are inspected, calibrated…*" In a license application the applicant can only be expected to "***describe how***" rather than "***demonstrate***" how compliance with a regulatory requirement or standard will be achieved.

Quality Assurance (QA)

Draft SRP Chapter 11 continues to treat QA as a distinct 'management measure'. However, as noted above, revised language in §11.3.1 acknowledges that QA is applicable to ***all*** management measures. For example, §11.3.1 requires an applicant to address "*…the relationship between QA and other management measures…*" and to "*…ensure that the QA function is adequately coordinated and integrated with other management measures…*" NEI supports this application of QA as an "umbrella" function that applies to ***all*** management measures. Unlike nuclear reactor licensees, who are required by 10 CFR 50.34(a)(7) to design and implement a formal QA program in accordance with eighteen of the nineteen NQA-1 criteria listed in 10 CFR Part 50, Appendix B, 10 CFR 70 contains no equivalent requirement. We believe the inherently lower risks to human health and safety and the environment of fuel cycle facilities do not warrant imposition of NQA-1 type QA requirements. The SRP, however, in §11.4.3.1directs the reviewer to examine the 19 components comprising the ANSI/ASME NQA-1 *Quality Assurance Requirements for Nuclear Facility Applications.*

For these reasons NEI recommends that separate treatment of QA in Chapter 11 is not required. We do, however, strongly support the requirement for an applicant (or licensee) to commit to overall QA (§11.3.1). NEI sees very limited areas in a fuel cycle facility's operation to which application of a rigorous NQA-1 QA program would be appropriate. NQA-1 QA ***might***, for example, be appropriate to a criticality accident alarm system (CAAS) or to the usage of soluble poisons. However, for the remaining 99% of plant equipment and operations, management measures to which appropriate, graded levels of QA may be applied, should be quite adequate to provide reasonable assurance that items relied on for safety will be reliable and available when required. In performing an ISA the applicant (or licensee) will have identified items relied on for safety to either prevent an identified, credible accident sequence or to mitigate its consequences. The attributes of a particular engineered safety control will have been evaluated by the ISA methodology to ensure that its physical and engineered attributes (reliability, maintenance needs, operating range, materials of construction, size, etc.) will adequately satisfy the design requirements for the items relied on for safety. Thus, by the very nature of the ISA process, the applicant (or licensee) will be applying QA to developing the safety basis of the facility.

NEI's recommendation that separate consideration of QA not be required is further supported by incorporation of a majority of the §11.4.3.1 NQA-1 QA criteria either in other sections of the license application or as an integral component of other management measures. Appropriate levels of QA will be applied to every licensee safety program, safety control or management measure. Inclusion of a separate QA sub-section of the management measures SRP chapter appears, therefore, to be repetitive and redundant. Assurance of the reliability and availability of items relied on for safety is provided by a combination of management measures and not solely by QA.

Although 10 CFR 70 does not require a licensee to establish a formal QA program (analogous to Part 50), this term is used repeatedly in the QA 'Acceptance Criteria' (§11.4.3.1) section. Reference is also made to the QA Organization (e.g. §11.4.3.6). A reading of this section, and especially of the suggested language in §11.6.1 ('Evaluation Findings') does, however, lay out the contents of a formal QA Program similar in scope and content as that for power reactors. The general requirements of 10 CFR 70.62 to establish and maintain a safety program and to implement appropriate management measures will, by necessity, entail implementation of QA measures appropriate to the safety importance of each item relied on for safety. Comparison of the 19 NQA-1-type QA criteria in §11.4.3.1 with the Chapter 11 management measures and components of a license application indicates that all but three QA criteria are already addressed either in the application or as a management measure. In the following table the license application section or Management Measure onto which each NQA-1 QA criterion can be mapped is indicated. For those three NQA-1 QA criteria that are not specifically addressed, they could be included in Chapter 11 subsection entitled '*Additional Management Measures*'.

Mapping of NQA-1 QA Criteria in a Part 70 License Application		
	NQA-1 Criterion in (§11.4.3.1)	**License Application Section or Management Measure**
1	Organization	Application Chapter 2 ('*Organization and Administration*')
2	QA Program	Formal QA Program not required by 10 CFR 70
3	Design Control	Management Measure: *Configuration Management*
4	Design Bases	Application Chapter 3: ('*ISA Commitments and ISA Summary*') and Baseline Design Criteria of 10 CFR 70.64(a) addressed in various Application chapters
5	Instructions/Procedures	Management Measure: *Procedures*
6	Document Control	Management Measure: *Records Management*
7	Procurement/Purchasing	Management Measure: *Procedures*
8	Control of Materials	Management Measure: *Procedures*
9	Special Processes	**No Comparable Reference**
10	Inspection	Management Measure: *Maintenance*
11	Test Control	Management Measure: *Maintenance*
12	Measuring Equipment	Management Measure: *Maintenance*
13	Handling & Storage	**No Comparable Reference**
14	Inspection, Test and Operating Status	Management Measure: *Maintenance*
15	Nonconforming Materials	**No Comparable Reference**
16	Corrective Action	Management Measure: *Corrective Action Program*
17	QA Records	Management Measure: *Records Management*
18	Audits	Management Measure: *Audits and Assessments*
19	Lessons Learned	Management Measure: *Audits and Assessments* and *Configuration Management*

Rule Clarifications

There exist a few instances where the basis of a 10 CFR 70 regulatory requirement is not accurately stated in the SRP. For example, the first paragraph of §11.4.1 states that 10 CFR 70.62(d) mandates use of several specific management measures. In fact, this citation requires only that an applicant establish management measures. Selection of specific management measures is left to the discretion of the applicant. The one management measure that is required by the regulations is Configuration Management (10 CFR 70.72(a)). On numerous occasions the SRP continues to direct the reviewer to look for the 'safety-grading' of management measures. 10 CFR 70.62(a) and (d) were revised to remove the requirement that management measures ***shall*** be graded; 'safety-grading' is now only an option that the applicant may use. The 'shalls' should be edited to read 'may' to be consistent with the Rule. §11.4.3.5 again improperly interprets the

NRC-OSHA Memorandum of Understanding concerning hazardous chemicals. This section requires the applicant to develop operating procedures "*…to prevent exposure of hazardous chemicals or SNM…*". As we have noted earlier, the correct phrase should be "*…to prevent exposure of hazardous chemicals produced from licensed material…*"

Technical Editing

Draft SRP Chapter 11 lacks consistency in the detail of guidance provided to the reviewer in examining each of the suggested management measures. For example, the areas of review for configuration management constitute 2 pages, whereas that for the corrective action program is only one paragraph (§11.3.7). The latter program is certainly just as important as the former. Review of the maintenance program is similarly addressed in only two paragraphs (§11.3.3), despite the overriding importance of this measure to engineered safety controls. Some sections direct the reviewer to examine commitments (e.g. procedures in §11.5.2.5)), whereas others seek concurrence with prescriptive detailed requirements (e.g. configuration management §11.5.2.2)). Greater uniformity in the approach to evaluate an applicant's management measures is required.

Terminology is frequently incorrectly used or defined. For example, '*Safety Evaluation Report (SER)*' is defined on six separate occasions and 'Configuration Management' is defined five separate times. The Part 50 term 'structures, systems and components' was deleted from the SRP Glossary in preference to the term 'items relied on for safety', and yet it continues to be defined several times and repeatedly used throughout Chapter 11. Consistency is required when referring to 'items relied on for safety'. For example, other terms such as 'safety function', 'safety control', 'safety feature' appear to be used interchangeably when, in fact, the correct term should be 'item relied on for safety.' The new term 'systems important to safety' appears for the first time in guidance for reporting the results of an evaluation (§11.6.2), whereas, if the term is important, it should have been introduced in the 'areas of review' or 'acceptance criteria.' The old term 'management control measures,' which was abandoned in 1998 in favor of the term 'management measures' continues to appear sporadically (e.g. §11.4.3.5). The acceptance criteria continue to direct the reviewer to examine for a "systematic approach to training' such as required for Part 50 licensees. Why does the term 'health and safety (H&S)' continue to be used in §11.6.8 after it is was consistently deleted throughout §11.4.3.8 in the June 1999 revision of SRP Chapter 11?

There persist several terms whose usage should be limited to nuclear power licensees. For example, §11.4.3.5 (3) still requires an applicant to develop procedures for management measures including 'human-system interfaces'; the NRC agreed with NEI in its response of March 19, 1999 that reference to 'human-system interface' should be deleted from the SRP. The QA 'Areas of Review' contains the sentence "*…The applicant's customers and the NRC, under 10 CFR Part 50, may impose product-related QA criteria…*", which may be correct, but is not applicable to the evaluation of Part 70 license applications. These and

numerous other editorial issues must be addressed in a thorough evaluation of this chapter.

Miscellaneous

Several miscellaneous issues continue to be of concern or should be addressed:

(1) *Training and Qualification*: NEI does not understand the need to train a facility in the "*… design, construction…and decommissioning…*" of a facility (§11.6.4). The plant engineers and operators should only be expected to have expertise in the start-up, shutdown, operation and maintenance of the facility. What is the safety benefit of having a plant operator have knowledge of the facility's decommissioning (other than, perhaps, familiarity with the 10 CFR 20.1406 waste minimization practices)?

(2) *Repetitive Requirements*: On several occasions the SRP seems to require the reviewer to perform an analysis that has already been performed in an earlier chapter of the application (e.g. ISA).

(3) *QA Acceptance Criteria*: Although this point is moot if NEI's recommendation that the QA section be deleted, why does the QA discussion in §11.4.3.1 require grading of QA to "*…parallel that for maintenance…*"? Why should QA grading not parallel other management measures? Is the reviewer to infer that grading of other management measures is less important or robust? What is the safety justification to conduct periodic "QA programmatic audits" (§11.4.3.6(3)(a) if the applicant is fulfilling his ISA commitments to maintain the facility's safety bases, items relied on for safety and management measures?

(4) *Design Reconstitution*: Section 11.5.2.2 requires design reconstitution for existing facilities if the current design information is not adequate. This requirement would seem to be redundant in light of the fact that existing licensees must perform an ISA within 4 (or 5) years after the effective date of the revised 10 CFR 70. How could an existing licensee hope to conduct a credible and thorough ISA without using up-to-date "as-built" designs? The example included in §11.5.2.2 is inappropriate ('*The reviewer looks for evidence that the applicant has considered systems interactions…*"). This is the function of the ISA and such interactions will have been thoroughly examined in the search for credible accident sequences and accident initiating events. This example should be deleted.

(5) *Appendix B – Records*: Inclusion of a section on Decommissioning (§10) may prompt the reviewer to search for decommissioning records, when such records will not exist for several decades. Why potentially direct the reviewer to search for 'final survey data' or 'decommissioning records'? NEI recommends that the examples of records be limited to those that a licensee could be reasonably expected to establish and retain during the operating life of the facility.

(6) *Ensure vs. Reasonable Assurance*: Chapter 11 has, for the most part, been purged of the requirement for a management measure to ensure the reliability and availability of a management measure. Replacement of '*ensure*' by '*provide*

reasonable assurance' is commended. There persist, several remaining usages where this change should be effected.

(7) *Technical and Regulatory References*: Chapter 11 continues to reference numerous NRC documents and regulatory guides that are applicable to nuclear power plants, but whose detailed guidance is inappropriate to fuel cycle facilities. For example, NRC Inspection procedures 88062 and 88025, NUREG/CRs 4616 and 5665, NUREG-1220 and 40 CFR 68 are all inappropriate to reference to a reviewer of a Part 70 license application. They should not be cited in NUREG-1520

(8) *Solicitation of Performance Data*: On several occasions the SRP directs the reviewer to examine data on which to base a decision or analysis. Part 70 facilities do not collect or assemble the extensive data that a nuclear reactor operator would. For example, §11.6.3 states that the "…*maintenance function*… *justifies the preventive maintenance intervals in the terms of equipment reliability goals*…" Part 70 licensees do not have the data to provide reliability goals. The SRP should not direct a reviewer to examine a program or new performance goal for which data will be lacking.

II. Recommended Revisions to Draft SRP Chapter 11

General

Several sections of draft SRP Chapter 11 closely parallel regulatory guidance written specifically for nuclear power reactors. The need for such equivalent, complex regulations for fuel cycle facilities can not be justified in view of the inherently lower risks posed to human health and safety by such facilities. These 'reactor-like' requirements should be deleted from Chapter 11. The '*Areas of Review*' and '*Acceptance Criteria*' in several of the remaining sections require revision, particularly to remove highly prescriptive language and requirements.

NEI recommends that Chapter 11 be further restructured in terms of a licensee's **commitments** to select, design, implement and revise (as needed) appropriate management measures. To employ a term introduced at the September 14, 1999 NRC Public meeting on Part 70, the management measure commitments are indeed "future IOUs". Although the basic elements of a management measure – definition, scope, policies (but *not* procedures) to implement or revise – can be sketched out in the application, their full implementation will only be realized as the facility is commissioned and gains an operating history.

NEI also recommends that some additional consolidation of the content of Chapter 11 be undertaken. For example, the direction given the reviewer for each management measure to seek additional information from the applicant, if necessary, could be consolidated into §11.5.1 rather than repeated in the Review Procedure section for each management measure.

NEI's analysis of each management measure discussed in draft SRP Chapter 11 follows:

Configuration Management: Draft §11.3.2 remains far too prescriptive. In the license one should commit to programs and only describe the key elements of such programs. Programs are implemented by procedures that are *not* part of the license.

Draft SRP §11.3.2 (4) states, among other things, that the ISA must be maintained current and that suitable hazard/accident methods be used to establish safety margins of proposed changes. This is a matter that should be addressed solely in the ISA Chapter of the SRP. It should be deleted from Chapter 11. The language in item (4) implies that every change will require a change to the ISA (and possibly, ISA Summary) and that the NRC could expect to see changed pages to these documents. All that might be required for a change, however, is addition of supplemental information to the facility design file (ISA documentation retained at the facility).

Draft SRP §11.4.3.2(6) requires an existing licensee to conduct a design reconstitution to ensure that the facility's configuration is consistent with the

as-built documentation. The commitment of resources to perform the calculations, analyses, updates of engineering drawings and specifications would be excessive and unnecessary and would not result in an significant benefit to safety. The long track record of safe operation of fuel cycle facilities has convincingly demonstrated that their original design configurations were acceptable and that reconstitution is not necessary. To conduct a thorough ISA on an existing facility, a licensee will, by necessity, have had to use "as-built" designs. As this management measure will not have come into force until after the ISA is completed, inclusion of a design reconstitution requirement appears to be redundant.

Draft SRP §11.4.3.2 (1) (paragraph 2) directs that configuration management should initially apply to existing facilities in accordance with the SRP, but be "*…independent of ISA results…*". Pending completion of the ISA a licensee would have to assume that *any* credible accident sequence could be high risk, thereby necessitating identification of a large number of items relied on for safety, all of which would be subject to the configuration management function. Only when the ISA is completed and the higher-risk accident sequences are identified in the ISA Summary, could that smaller set of safety-significant items relied on for safety, which would be subject to the configuration management program, be identified. The draft SRP would then permit a licensee to reclassify items relied on for safety and thereafter reduce the number subject to the configuration management function. This proposed implementation methodology is burdensome and inappropriate for existing facilities. NEI recommends that the configuration management function only be applied to existing facilities once the ISA Summary has been completed and those safety-significant items relied on for safety have been properly identified.

Draft §11.1 contains several instances (e.g.§11.1.6) in which a safety review and analysis of a proposed change to an item relied on for safety is required by the configuration management function. Such a review is, however, part of the ISA process and will be conducted in fulfillment of a licensee's ISA program commitment. The configuration management function is responsible for ensuring that a proposed modification is formally described and recorded, but it is neither responsible for performing the safety evaluation of the proposed modification nor for establishing its safety importance. The draft SRP (§11.5.2.2) also requires examination of interfaces between configuration management and "*…external organizations and functions… [such as]…QA, maintenance, and training (including qualification)…*" These interfaces are not the responsibility of the configuration management program and do not belong in this chapter of the SRP. These interfaces are, instead, implemented as a result of a licensee's binding license commitments to maintain a variety of safety and management systems and functions relied upon to ensure safety (i.e. safety bases). The safety significance of a proposed modification to a facility would

be evaluated by the ISA process and, if judged to be acceptable from a safety viewpoint, formally documented by the configuration management program.

Draft §11.4.3 requires an applicant's commitments and configuration management program to be judged against the stated acceptance criteria. Only one such review is needed. There is no need for a separate 'safety evaluation' review which simply repeats what the 'acceptance review' has already accomplished. Either the acceptance criteria are met, or they are not. This redundancy is not needed and the §11.5.2 'Safety Evaluation' section could be significantly shortened.

There is excessive repetition of the requirements for configuration management amongst sections 11.3.2 ('Areas of Review'), 11.4.3.2 ('Acceptance Criteria') and 11.5.2.2 ('Review Procedures'). NEI recommends that only section 11.4.3.2 retain the detailed requirements and that the configuration management information in the other sections be significantly reduced.

Maintenance: Discussion of the maintenance management measure (§11.4.3.3) creates new requirements patterned after commercial nuclear power plant operation requirements and guidance for maintenance programs. It appears to apply the concepts of preventive and corrective maintenance to "*human performance*" and activities. For example, corrective and preventive maintenance practices are to be applied to items relied on for safety, which are defined in 10 CFR 70.4 to include 'activities of personnel.' This error originates from imprecise use of the term 'safety controls' and should be corrected. The requirement for a nuclear power plant maintenance program is required by specific regulation (10 CFR 50.65). In the absence of a corresponding requirement in 10 CFR 70, the NRC should not attempt to impose an equivalent, highly prescriptive maintenance program either through the SRP or as a license condition.

The acceptance criteria in §11.4.3.3 (4) for functional testing contain a paragraph (p. 11.0-15) of detailed work procedures. NEI concurs with the need for such detailed procedures, but recommends that such detailed information be maintained at the facility and not included in the license application. Any changes in the maintenance procedures, regardless of their safety significance, might have to be evaluated by means of the 10 CFR 70.72 change process and authorized by means of a license amendment. The applicant should be expected to issue a binding license commitment to establish such maintenance work procedures and control methods, but not to include them in the license application. Such procedures and control methods would be available for review and inspection by the NRC at the facility. Maintenance element (f) in §11.4.3.3 (4) requires licensee compliance with the 10 CFR 21 equipment defect and non-compliance reporting requirements. Although encompassing Part 70 licensees, the Part 21 regulatory

requirements are primarily directed towards Part 50 licensees where an equipment defect could have very significant safety implications. In view of the appreciably lower risks posed by fuel cycle facilities and Part 70 licensees' use of their Corrective Action Program maintenance function, we believe that reference to 10 CFR 21 in the SRP should be deleted. Finally, NEI recommends correction of some language in §11.6.3 ('Evaluation Findings') which states that the maintenance management measure should "*…ensure the validity of the ISA…*' How can a maintenance function <u>*ensure*</u> the <u>*validity*</u> of an ISA? (As an aside, a management measure can only be expected to provide reasonable assurance of the availability and reliability of an item relied on for safety.) Similarly, the requirement for the maintenance management measure to "*…(3) link[s] items relied on for safety requiring maintenance to the ISA Summary…*" Maintenance is but one management measure that can be applied to items relied on for safety identified in the ISA Summary, but how this function can 'link' items relied on for safety to the ISA Summary is unclear.

Training and Qualification: Earlier versions of draft SRP Chapter 11 established the elements of a SAT program as the acceptance criterion for licensees' training and qualification programs. The July 1999 revision of Chapter 11 (§11.5.2.4) continues to reference a "*systematic approach to training*" as the 'base case' for a Part 70 training program, but does permit grading of training to reflect the safety importance of a worker's activities to be relied on for safety in accordance with the results of the ISA. Draft SRP Chapter 11 also continues to reference NUREG-1220, Rev. 1 "*Training Review Criteria and Procedures*" as the primary regulatory reference document. In addition, the SRP states that the Staff is to ensure that personnel have the knowledge and skills necessary "*…to design [and] construct [and] decommission…*" the facility. Several of the Areas of Review and Acceptance Criteria (e.g. needs/job analysis, re-testing, development of learning objectives, systematic evaluation of training effectiveness and trainee mastery of learning objectives, etc.) are pure SAT and should not remain in Chapter 11.

The SRP introduces two new programmatic requirements: (i) adoption of SAT as the standard or 'base case' against which a licensee's training program will be judged, and (ii) the requirement that staff be knowledgeable not only in the start-up, shut-down, operation and maintenance of the facility, but also in its design, construction and decommissioning. These concepts have only been applied as a licensing requirement for certain specific job categories at commercial nuclear power plants under 10 CFR 50. There is no requirement in the Part 70 rule that requires such a comprehensive level of staff training as that mandated in the SRP.

Risk-informed, performance-based regulation grants a licensee the latitude to establish the content, detail and comprehensiveness of its staff training and qualification program. The scope of the program will be established based upon the results of the ISA and specifically by the graded level of *risk* associated with each operator task and the required level of responsibility. If the results of the ISA indicate a need for enhanced training of certain equipment operators (i.e. an "unacceptable performance deficiency" exposed by the ISA), due to the licensee's reliance on actions by those operators to prevent excessive radiation exposures, the licensee will determine the most appropriate way to address the training needs (e.g. increase the frequency of the operators' training, expand the content of the training, or impose new qualification requirements). Such actions may be adequate and effective in addressing the identified vulnerability in the context of the licensee's existing training program. A SAT program is unlikely to be warranted.

Imposition of SAT criteria for nuclear power plant operators is required by a specific regulation (10 CFR §50.120) which establishes SAT as a formal regulatory requirement for certain designated categories of personnel. Proposed Part 70 revisions set a new and higher standard for performance (SAT) in the absence of a Part 70 regulation (analogous to Part 50.120) and before the results of an ISA demonstrate the need for that level of performance.

Extreme care should be taken in referring to NUREG-1220, a regulatory guidance document created for nuclear power plant licensees, as the basic regulatory reference for Part 70 facilities.

The SRP does not justify how operator knowledge and skills in "design, construction and decommissioning" activities at non-plutonium licensed fuel cycle facilities enhances health and safety. Adoption of such standards represents a significant departure from current licensing practice and the rulemaking package does not discuss the implications of this change. Different training requirements may be appropriate for new fuel cycle facilities, particularly if a new process or technology is to be used where there is a dearth of operating, safety and performance history. The SRP should differentiate between the staff training and qualification requirements for new and existing fuel cycle facilities.

The Training and Qualifications requirements detailed in the SRP are very prescriptive and cumbersome, are inconsistent with current industry practice and will result in only a marginal positive impact on the effectiveness of facility training programs. Such requirements should only be established by the licensee using the results of the ISA.

Highly prescriptive criteria for both the qualification and training of plant personnel are imposed in §11.4.3.4 (9). For example, plant managers and

technical staff must have university degrees, a performance standard which appears to be equally important as demonstrating proficiency in an individual's area(s) of expertise. Establishment of minimum experience and qualifications for key facility personnel should remain the responsibility of the licensee. Personnel qualifications for facility design and construction extends the NRC's review process well beyond traditional materials licensing practices; training of personnel for decommissioning should be addressed at the time of decommissioning and not in the context of new licenses, renewals or amendments.

There is no mention of 'grading' of the training program in the §11.4.3.4 'Acceptance Criteria', although §11.5.2.4 (Review Procedures) does permit grading of the SAT training program. Application of the grading concept should be included in the discussion of acceptance criteria. A new addition in the July 1999 revision of §11.4.3.4 requires design personnel and construction personnel (in addition to operations personnel) to conduct a needs/job analysis to develop valid task lists for specific jobs. NEI does not understand why design and construction personnel require training in items relied on for safety? Qualified personnel who developed the design bases of the facility, and which were subsequently evaluated by means of the ISA, would seem to have no need for training in administrative controls. Similarly, we do not see the need for construction personnel to have this training. Once the facility is constructed, processes and safety controls will be thoroughly checked against design and construction criteria prior to operation (and payment to the contractors). NEI recommends that design personnel and construction personnel be omitted from the requirement to conduct needs/job analyses

NEI also recommends that the qualifications portion of draft SRP Chapter 11.3 be deleted. The training program should primarily ensure that plant personnel have the knowledge and skills needed to perform any activity that is important to, or relied on for safety (i.e. administrative control) identified in the ISA Summary.

Simplification of the discussion of the training management measure could be achieved by replacement of the prescriptive detail in, for example, sections §11.4.3.4 (1)-(6) by commitments and by omitting the prescriptive educational requirements of §11.4.3.4 (9) items (1)-(5).

Procedures: Discussion of the procedure management measure presents in §11.3.5 what appears to be a reasonable set of procedural criteria. However, the acceptance criteria (§11.4.3.5) turn these reasonable criteria into a bureaucratic nightmare of overly prescriptive detail. The SRP should not prescribe procedure content or imply that the reviewer will include assessment of individual procedures. Procedures should be written, updated and kept at the facility and not be incorporated into the license or evaluated as part of the license application review. This chapter requires procedures

for many activities that are <u>*not*</u> identified in the ISA as items relied on for safety. The SRP incorrectly states that a procedure should contain "*…regulations, policies and guidelines governing the procedure…*" These, in fact, should be covered in the safety and regulatory procedures and *not* in the operating procedure.

Audits and Assessments: Discussion of the audit and assessment management measure has been significantly changed from that included in SECY-99-147. The acceptance criteria (§11.4.3.6) have been expanded to contain unnecessary prescriptive detail. The underlying theme conveyed in the acceptance criteria does not agree with the stated purpose of the audit and assessment management measure ("*…to ensure that items relied on for safety are in accordance with regulatory requirements and license commitments and to ensure that they are available and reliable when needed…*"). The §11.4.3.6 acceptance criteria appear to have been revised to parallel the requirements of this activity for nuclear power reactors as stated in 10 CFR 50, Appendix B, Item XVIII "Audits': "*…audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program…*" For example, whereas §11.3.6 (correctly) states the purpose of audits and assessments, §11.4.3.6 (1)(a) defines the purpose differently to "*…objectively evaluate the effectiveness and proper implementation of QA for items relied on for safety…*" and 3(a) defines the purpose of internal audits to be to "*…evaluate the applicant's internal QA procedures…*" Acceptance criterion 1(b) goes on to state that audits and assessments should be performed in all areas where the requirements of QA are applicable. In fact, QA will be applied to all items relied on for safety and their complementary management measures! Further dwelling on the QA focus of this management measure, criterion 1(m) requires the management measure to only assess "*…the effectiveness of QA…*" and criterion 2(b) focuses on '*QA programmatic audits*". As noted earlier in this letter, NEI supports application of appropriate levels of QA for application to items relied on for safety and management measures. However, QA is but one, albeit important, management measure that should be considered in evaluating the reliability and availability of items relied on for safety. The focus of the audit and assessment management measure should not rest solely with QA.

§11.4.3.6 introduces the concept of 'external audits' that a licensee <u>*may*</u> be required to perform on suppliers' QA procedures. This is a new programmatic requirement applicable to reactor licensees, but not necessarily needed for Part 70 licensees. The SRP should not direct performance of external QA audits in the absence of any regulatory requirement for a formal QA program, of which external audits may be an important component.

Finally, the audit and assessment management measure discussion frequently directs the licensee to use the audit or assessment results to

immediately implement corrective actions (e.g. §11.4.3.6 1(j), 2(e)), whereas any unacceptable performance deficiencies should, in fact, initially be referred to the facility's Corrective Action program to establish what corrective actions, if any, may be warranted. NEI recommends that the CAP referral process be used before any corrective action is undertaken.

NEI recommends that discussion of the audit and assessment management measure revert to the language used in the June 1999 version of the SRP and focus on a licensee's binding license commitments to implement this measure. The prescriptiveness must be reduced and the carry-over of nuclear reactor terminology must be deleted. NEI also recommends that the 'Evaluation Finding' language in the earlier version of SRP Chapter 11.5 be reinstated. The 'Review Procedure' language in the new §11.5.2.6 is far too general and a majority of it should be relocated to §11.5.1 to describe general considerations applicable to all management measures.

Incident Investigations: Systematic investigation of abnormal events and implementation of corrective actions, if required, are activities that will be undertaken by a facility in support of its commitment to ensuring items relied on for safety are available and reliable when required. The discussion of this management measure generally reads well.

The SRP mandates establishment of "teams" to investigate abnormal events and establish their root cause(s). "Teams" is too prescriptive. A risk-based evaluation of the event should be promptly performed and, depending on the complexity and severity of the event, an individual may be all that is required to conduct the evaluation. What is important is the applicant's commitment to establish a *process* to conduct such investigations and to recommend possible corrective actions. NEI recommends instead that a licensee should "…establish *a process* to investigate abnormal events and to determine their *specific or* root cause(s) *and generic implications*…"

NEI recommends that the NRC consider changing the name of the 'Incident Investigation' management measure to read "Corrective Action Program' to more accurately reflect the current industry usage.

Records Management: Discussion of the records management measure outlines requirements for a records management system for the collection, storage and retrieval of facility health and safety information. The proposed system is highly prescriptive and would require, for example, a listing of each record, its retention period, its retention location, conditions of storage, its physical form and the organization responsible for administering the records system. This complexity goes far beyond what 10 CFR 70 requires, is very prescriptive and is too inflexible. NEI recommends that the applicant be required to provide binding commitments to design and implement a records

management system, but not to address the specific procedural details in the license application.

III. Proposed Revisions for SRP Chapter 11

NEI has revised the July 1999 version of draft SRP Chapter 11 to make clear that management measures (and systems of management measures) apply to items relied on for safety.

Chapter 11 has been clarified to state that a reviewer should neither seek nor evaluate individual *procedures* that a licensee will develop to implement a license commitment.

NEI has deleted those sections of Chapter 11 that focus solely on QA. As noted above, QA applies to all management measures.

Each of the seven remaining management measures has been revised to focus on the binding license commitments an applicant will make. We have attempted to balance the NRC's need for information on how a commitment may be put into practice against the force of a license commitment. The SRP must provide guidance within the constraints of which a reviewer can use sound, professional judgement to evaluate whether an applicant has committed to implement adequate management measures to provide reasonable assurance concerning the availability and reliability of items relied on for safety.

Finally, NEI has undertaken some additional technical editing of this SRP chapter to ensure consistent and correct use of Glossary terms, to remove unnecessary prescriptive detail and to consolidate text that is repeated throughout the chapter. Additional technical editing will, doubtlessly, be required before the SRP is finalized.

The attached marked-up version of draft SRP Chapter 11 incorporates NEI's recommended improvements. Comments are also included for text that NEI has recommended for deletion to either point out errors or to explain why NEI feels such text should be deleted.

Ref: I\Files\Part 70\SRP (July 1999) Sec 11.msw

11.0 MANAGEMENT MEASURES

11.1 PURPOSE OF REVIEW

Management measures are functions that are performed by a licensee, generally on a continuing basis, ~~that are applied to items relied on for safety,~~ to provide reasonable assurance [Comment: replace "ensure" by "reasonable assurance". See discussion in introductory text.]~~ensure~~ that ~~the~~ items relied on for safety are available and reliable to perform their functions when needed. The phrase "available and reliable" as defined in 10 CFR 70.4 ~~as used in this rule~~ means that ~~, based upon the analyzed, credible conditions in the Integrated Safety Analysis (ISA),~~ items relied on for safety will perform their intended safety function when needed. A licensee is required by 10 CFR 70.62(a) to establish and implement such management measures to provide continuing assurance of compliance with the performance requirements of 10 CFR 70.61. Management measures are applied to both the administrative and engineered safety controls identified in the ISA Summary that are required to prevent or mitigate the consequences of credible, postulated accident sequences. The robustness of a management measure may be graded in the same way that items relied on for safety may be graded according to their importance to safety. ~~to prevent an accident or mitigate the consequences of an accident. Management measures are implemented to ensure continuous 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 items and the measures.~~ Management measures include, for example, configuration management, maintenance, personnel training and qualifications, procedures, audits and assessments, design and oversight of a corrective action (or incident investigation) program and records management, together with application of appropriate levels of~~and other~~ quality assurance to each ~~elements~~. ~~The degree to which measures are applied to the items is a function of the item's importance in terms of meeting the performance requirements as evaluated in the ISA. In the Chapter 11 discussion that follows, quality assurance includes aspects of configuration management, maintenance, training and qualifications, procedures, and audits and assessments; however, these topic areas are discussed in greater depth in individual sections in this chapter because of their importance and because, in some cases, their applicability is broader in scope than what has been included under quality assurance.~~

Evaluation of an applicant's management measures is necessary to provide reasonable assurance that the applicant has committed to develop and apply adequate measures and controls to both items relied on for safety (engineered safety controls) and activities relied on for safety (administrative safety controls). The evaluation will examine the applicant's proposed management measures and policies for their implementation. ~~The purpose of this review is to determine if the management measures applied to items relied on for safety, as documented in the ISA summary, provide reasonable assurance that the items will be available and reliable to perform their function when needed.~~ The review should also determine whether the measures are applied to the items relied on for safety commensurate with their importance to safety (graded approach). The evaluation will conclude whether the proposed management measures provide reasonable assurance that the regulatory requirements of 10 CFR 70.62(d) ('Management Measures') will be satisfied.

11.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Quality Assurance: Quality Assurance Engineer
Configuration Management: Primary ISA Reviewer, Quality Assurance and Records Management Reviewers
Maintenance: Criticality, Chemical, Fire, Radiation Protection and Environmental Reviewers
Training and Qualification: Training Specialist, Quality Assurance, or Human Factors Reviewers
Procedures: Radiation Protection, Criticality and Fire Protection Engineers, Fuel Cycle Facility Inspector
Audits and Assessments: Quality Assurance Reviewer
Incident Investigations: None
Records Management: Quality Assurance Engineer

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

11.3 AREAS OF REVIEW

[Comment: NEI recommends inclusion of some general, overriding guidance to the reviewer at the beginning of this section 11.3 as to what the evaluation will entail. The level of detail contained in the 'Areas of Review' should be reduced to commitments and to general approaches, policies and strategies on how each commitment will be implemented. Detailed criteria should be confined to the 'Acceptance Criteria' section 11.4]

The evaluation of management measures should focus on their description, their applicability to items relied on for safety and their capability (or suitability) for meeting the regulatory requirements of 10 CFR 70.62(a). The evaluation should address the following three topics:

(1) *Management Measures*: the reviewer should examine the acceptability of an applicant's commitments to develop, implement and update, when required, management measures applicable to the facility's items relied on for safety (including the activities of personnel that are relied on for safety). The applicant may elect to grade the robustness or comprehensiveness of individual management measures commensurate with the relative importance to safety of an item relied on for safety to which they are applied.

(2) *Description of Management Measures*: the reviewer should examine each management measure or combination of measures proposed by an applicant to evaluate its suitability to provide reasonable assurance that an item relied on for safety will be available and reliable when required. The following features of each management measure should be examined:

(i) purpose, safety controls to which it applies (administrative control, augmented administrative control, passive engineered control, active engineered control), description of functions
(ii) implementation approach and strategy
(iii) methods of safety grading its application to items relied on for safety

(iv) how application of the management measure will provide the necessary level of "continuing reasonable assurance" to an item relied on for safety
(v) verification and validation methods of the management measure
(vi) interrelations of individual management measures

(3) *Specific Management Measure Evaluation*: guidance is provided in SRP Chapter 11 for evaluation of seven management measures that are typically applied to fuel cycle facility operations. An applicant should generally be expected to address each of these seven management measures, although additional management measures proposed by the applicant should be considered acceptable if they are judged capable of providing the reasonable assurance that an item relied on for safety will be available and reliable when required.

Prior to conducting the evaluation, the reviewer should first consult the ISA Summary (SRP Chapter 3 - '*Integrated Safety Analysis (ISA) Commitments and ISA Summary*') to gain familiarity with:

(i) items relied on for safety for higher-risk accident sequences (including activities of personnel relied on for safety)
(ii) any safety-grading applied to such items relied on for safety
(iii) commitments to implement and maintain items relied on for safety in a functional state, and
(iv) management measures to be applied to each item relied on for safety

The reviewer should understand that 10 CFR 70.62(a) and (d) permit, but do not require, an applicant to grade management measures commensurate with the reduction in risk attributable to the safety control to which the measures are to be applied.

The applicant will be expected to apply appropriate levels of quality assurance (QA) to each management measure and should explain how such QA measures will be applied. For example, QA applied to maintenance may be reflected in the choice of maintenance instrumentation, procedures and frequency of equipment calibration or selection of equipment capable of measuring a parameter over a process' expected operating range.

The reviewer should examine an applicant's commitments for each of the following management measures:

~~**11.3.1 Quality Assurance**~~

[Comment: separate treatment of QA has been deleted in preference to incorporation of QA considerations into each of the specific management measures. See accompanying text for further explanation.] ~~The application must address the 10 CFR Part 70 requirements with respect to management measures, to include quality assurance elements. 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.~~ [Comment: this guidance has been transferred to the chapter introduction (§11.1).]

~~The reviewer should determine that a complete description of the applicant's application of QA elements to items relied on for safety is included in the application and should examine it in terms of the Acceptance Criteria of this section. The review objective is to obtain reasonable assurance of the implementation of accepted QA principles in the design, construction, operation,~~

~~maintenance, and modification phases of a facility's life. Fundamental to this effort is the applicant's application of QA to the identified items relied on for safety resulting from the ISA and identified in the ISA summary.~~ [Comment: the following sentence is redundant in Chapter 11. QA in preparing the ISA was addressed in an SRP Chapter 3 task.]~~QA would also be applicable to the hazards analysis process in the applicant's ISA.~~

~~The application defines the levels of QA to be applied to items relied on for safety identified by the ISA (SRP Section 3.0). Further, the relationship between QA and other management measures should be described.~~ [Comment: the following sentences are redundant as they just repeat what was done in the ISA Chapter 3. Delete for clarity.]~~The application assigns QA levels to each item relied on for safety. The applicant addresses its approach to determining the relative risk, or relative safety importance, of the various items relied on for safety to be treated by both maintenance and QA. This safety importance ranking will determine the levels of QA to be applied to individual items relied on for safety.~~

~~The reviewer should recognize that facility safety may not be the only criterion for QA at a fuel cycle facility.~~ [Comment: the following sentence with its reference to Part 50 requirements is totally inappropriate for this SRP. What is applicable to a Part 50 licensee, while interesting, has no bearing on the actions of a Part 70 licensee. Delete it.]~~The applicant's customers and the NRC, under 10 CFR Part 50, may impose product related QA criteria. The focus of the review of QA measures per this SRP is limited to ensuring the safety (nuclear safety, chemical safety, fire safety, etc.) of workers and the public, and protecting the environment (i.e., in relation to the performance requirements of 10 CFR 70.61). The review should ensure that the QA function is adequately coordinated and integrated with other management measures.~~

~~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. The reviewer should focus on the management controls applied to criticality, containment of licensed materials, personnel protection, and environmental safety. With the application of graded QA, quality levels commensurate with the risk involved should parallel the same risk levels established for maintenance.~~[Comment: why consider just maintenance in the last sentence? Are not other management measures just as important as maintenance?]

11.3.1~~2~~ Configuration Management

This review should confirm ~~ensure~~ that the applicant has committed to develop and implement a configuration management (CM) system that is consistent with the requirements of 10 CFR 70.72(a). The purpose of this system is to document and track all changes to items relied on for safety and associated management measures. It will also~~a plan for or has implemented an acceptable configuration management (CM) function. Configuration management means ensuring, as part of the safety program, oversight and control of design information, safety information, and modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their function when needed. The reviewer should determine, with reasonable assurance, that the applicant has described and committed to a CM function that~~ assure~~s~~ consistency among the facility design and operational requirements, the physical configuration, and the facility documentation.~~ The reviewer should also determine that the applicant's CM function captures formal documentation governing the design and continued~~

~~modification of those facility structures, systems, and components (SSCs) 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.~~

Specific areas of review should include:

- commitment to establish a CM system to maintain current facility documentation on items relied on for safety and to accurately track all safety-significant changes to such items
- commitment to maintain current documentation on management measures to be applied to items relied on for safety (e.g. training, maintenance) and to accurately track all safety-significant changes to such management measures
- commitment to incorporate a CM system into the facility's organization structure responsible for CM, to prepare written CM procedures and to assign personnel responsible for CM
- policies to implement the CM system, descriptions of CM activities, organizational structure
- description of methods to establish and control documents
- commitment that all changes to procedures, facilities, operations and equipment pertaining to items relied on for safety are recorded in the facility's documentation (including the results of ISA evaluations and analysis by the 10 CFR 70.72 facility change mechanism)
- commitment to maintain consistency among design requirements, physical configuration and facility documentation of all items relied on for safety

~~The NRC staff should review the applicant's descriptions and commitments for CM, focusing on the processes for documenting an established baseline configuration and controlling changes to it to preclude inadvertent degradation of safety~~.[Comment: second half of this sentence "*…focusing…safety*" is not needed and should be deleted.] ~~The reviewers should examine descriptions of the organizational structure responsible for CM activities and the process, procedures~~ [Comment: the SRP should never direct the reviewer to examine "procedures". Detailed procedures should not be expected to be included in a license application.]~~, and documentation required by the applicant for modifying the site~~[Comment: the previous words ("*the site*") should be deleted.] ~~; items relied on for safety and the supporting management measures. The staff review should focus on the applicant's management measures that ensure the disciplined documentation of engineering, installation, and operation of modifications; the training and qualification of affected staff; revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; post-modification testing; and readiness review.~~

~~The NRC staff should review the following:~~

~~1. CM Policy~~

~~The review should cover the applicant's description of overall CM functions, including at least the following topics: (a) the scope of the SSCs~~ [Comment: Consistency in terminology: should be 'items relied on for safety', not SSC] ~~to be included in the CM function (b) objectives of each CM activity, (c) a description of each CM activity, and (d) the organizational structure and staffing interfaces.~~

[Comment: this paragraph is not necessary. The phrase "initially independent of the ISA" is inappropriate (se text for explanation).]~~The review should examine the applicant's establishment of a baseline CM policy applicable to all operations, initially independent of the ISA. The review should also examine the applicant's proposed reduced level of CM that the applicant may propose for certain SSCs~~ [Comment: Consistency in terminology: should be 'items relied on for safety', not SSC] ~~based on the ISA.~~

~~2. Design Requirements~~

~~The review should cover the applicant's demonstration that design requirements~~ [Comment: the phrase "and associated design bases" is inappropriate; 'design requirements' is sufficient.]~~and associated design bases have been established and are maintained by an appropriate organizational unit. The applicant's CM controls on the design requirements and the ISA should be evaluated.~~

~~3. Document Control~~

~~The review should include the applicant's~~ [Comment: the phrase "description of its…" should be inserted before 'methods'. The reviewer should be directed to examine an applicant's description, but not the methods themselves.]]~~methods used to establish and control documents within the CM function.~~

~~4. Change Control~~

~~The review should examine the applicant's commitments to ensure that the CM function maintains~~ [Comment: delete the word "strict"; it is far too stringent.] ~~strict consistency among the design requirements, the physical configuration, and the facility documentation. An important component of this review is the applicant's process, within the CM function,~~[Comment: the following commitment regarding the ISA has been addressed in SRP Chapter 3.] ~~for ensuring that the ISA will be 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 will be properly modified, authoritatively approved, and made available to personnel.~~

~~5. Assessments~~

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

~~Design Reconstitution~~ [Comment: this section (6) should be deleted. See text for explanation and justification.]

~~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/is translated into a fixed baseline design basis from which subsequent changes are measured.~~

11.3.2~~3~~ Maintenance

The review should confirm that the applicant has committed to develop and implement a ~~NRC staff will evaluate the applicant's description of its~~ maintenance function for engineered safety controls. The applicant [Comment: the applicant cannot "*demonstrate*", but can only "*describe how*" the items relied on for safety will be maintained.] should describe how ~~demonstrate that~~ items relied on for safety are inspected, calibrated, tested and maintained, to the level commensurate with the risk, to provide reasonable assurance of their [Comment: delete "ensure" and replace with "provide reasonable assurance of"] ~~ensure~~ their ability to perform their safety functions when required ~~called upon~~. [Comment: the following sentence is unnecessary. Its substance has been stated in the introduction to this section.]~~These items relied on for safety are identified by the applicant in the ISA summary. The staff will review the applicant's description of how each of the following functions is implemented within the site organization. *Note that not every aspect of the four maintenance functions is necessarily required; the applicant is expected to identify the items relied on for safety in the ISA Summary and would justify assigning differing degrees of maintenance to item's relied on for safety based on the item's contribution to the reduction of risk.*~~

Specific areas of review should include:

- commitment to provide adequate maintenance and surveillance of items relied on for safety, including adequate inspection, calibration and testing commensurate with the level of risk to be addressed by the items relied on for safety
- commitment to develop basic components of a maintenance program including one or more of the following components: corrective maintenance, preventive maintenance, surveillance/monitoring and functional testing
- commitment to base the maintenance activities on appropriate written procedures, personnel safety, appropriate training and documentation (records of inspection, surveillance, replacements, etc.)

~~1. Corrective maintenance~~

~~2. Preventive maintenance~~

~~3. Surveillance/monitoring~~

~~4. Functional testing~~

11.3.3~~4~~ Training and Qualifications

[Comment: this section needs to be purged of references to Systems Approach to Training (SAT) guidance (e.g. re-testing, systematic evaluation…, need/job analysis, etc.].]

[Comment: the first sentence is not strictly correct. 10 CFR 70.22(a)(7) states a "…*need [for] procedures to protect health and minimize danger to life and property…*" and 10 CFR 70.23(a)(7) requires "…*protection of environmental values*…" The regulations do not specify the detailed requirements stated in the following statement. As a general editorial comment, general statements such as the following sentence should be confined to the introduction of each section and not be peppered through its subsections.] ~~Part 70 of Title 10 of the Code of Federal Regulations requires that personnel who perform activities relied on for safety be trained, tested, and retested as necessary to ensure 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~~ [Comment: plant personnel should not be expected to know how to design, construct, modify or decommission the plant. Safe operation should be their prime concern.]~~design, construct, start-up, operate, maintain, modify, and decommission the facility in a safe manner. Therefore, the training, testing,~~ [Comment: delete the SAT term "retesting".] ~~retesting, and qualification of these personnel should be described in the application and should be reviewed by the staff. This should include the training, testing, retesting~~[Comment: delete the SAT term "retesting".]~~, and qualification of~~ [Comment: inclusion of these eight job categories is too prescriptive. What is important is that personnel who perform activities relied on for safety should be trained and qualified. Delete the phrase "…managers, supervisors…maintenance personnel, and other…"] ~~managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel, and other personnel who perform activities relied on for safety. The review of the training and qualification should address the following training objectives:~~

Assessment of the applicant's training and qualification system should incorporate the following:

- commitment to implement a training program to make personnel understand and recognize the importance of items relied on for safety and to qualify them to perform activities pertaining to items relied on for safety
- commitment to provide training in items relied on for safety that is commensurate with their importance to risk reduction
- commitment to develop a training program that includes: an organization and management structure, program development, on-the-job and/or classroom instruction, evaluation of trainees and training effectiveness, qualification of personnel and provision to evaluate the continuing effectiveness of the training system
- commitment that personnel will have the knowledge and skills necessary to operate and maintain the facility and items relied on for safety

~~1. Organization and management of the training system~~
~~2. Trainee selection~~
~~3. Conduct of needs/job analysis and identification of tasks for training~~ [Comment: this is a SAT component. Delete as it is not applicable.]
~~4. Development of learning objectives as the basis for training~~ [Comment: this is a SAT component. Delete as it is not applicable.]
~~5. Organization of instruction using lesson plans and other training guides~~

~~6. Evaluation of trainee mastery of learning objectives~~ [Comment: this is a SAT component. Delete as it is not applicable.]
~~7. Conduct of on-the-job training~~ [Comment: should not be limited to 'on-the-job' training. Should encompass classroom or off-site training as well.]
~~8. Systematic evaluation of training effectiveness~~ [Comment: this is a SAT component. Delete as it is not applicable.]
~~9. Personnel qualification~~
~~10. Applicant's provisions for continuing assurance~~

11.3.~~4~~5 Procedures Program

[Comment: the reviewer should not be expected to examine detailed operating and management control procedures. These will be maintained at the facility, but not incorporated into the license. The reviewer should, instead, examine the applicant's commitments to prepare, maintain, distribute and update, as required, such procedures.]

The review should examine ~~NRC staff should review~~ the applicant's process ~~the applicant has developed~~ for the preparation ~~production~~, use and management control of written procedures. This should include the basic elements of identification, development, verification, review and comment resolution, approval, validation, issuance, change control, and periodic review. The applicant will prepare ~~review includes~~ 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 item relied on for safety. Procedures of this type include required actions to protect against ~~ensure~~ nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection; and,

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

The review will not encompass examination of specific, detailed operating and management control procedures, but rather just the applicant's commitment and proposed methodology to prepare, distribute and maintain current such procedures. Detailed procedures will be maintained at the facility and do not constitute part of the license application.

Specific areas of review should include:

- commitment to develop, approve and implement operating procedures and management control procedures applicable to items relied on for safety
- policies and methodologies for procedures pertaining to items relied on for safety and their management measures: identification of the need for a procedure, writing of procedures, approval of procedures (engineering and managerial approval processes), validation and verification of procedures, implementation and distribution of procedures, and procedure revision and re-issuance policies

- identification of items relied on for safety and management measures for which procedures are required
- policies to integrate the procedure and CM management measures
- commitment to develop methods and to verify, validate and periodically evaluate facility procedures and distribute them to appropriate plant personnel

~~The NRC staff should review the following:~~

~~1. The method for identification of the procedures that are needed plant-wide. The ISA summary identifies items relied on for safety~~ [Comment: replace "where" by "including those for which" in the following sentence.] ~~where human actions are important. Procedures should be provided for all necessary steps or operations that are conducted at the facility. Procedures should be provided for every element of management control that is discussed in the SRP sections.~~

~~2. 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, MSDS 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. Includes how procedures are managed within the plant configuration management function.~~

~~4. Method for verifying and validating procedures before use. During procedure development, workers and operators review procedures to ensure they are usable and accurate.~~

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

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

11.3.5~~6~~ Audits and Assessments

The review should determine that the applicant has committed to implement a system of audits and assessments. Audits are designed ~~applicant should describe a system of audits and assessments which consists of two distinct levels~~ [Comment: 'levels' should be replaced by 'types'.]~~of activities: an audit activity structured~~ to monitor compliance with regulatory requirements and license commitments, and ~~an~~ assessments determine ~~activity oriented to determining~~ the effectiveness of management measures to provide reasonable assurance of the~~the activities in achieving applicant-specified objectives that ensure continued~~ availability and reliability of items relied on for safety when required to perform their intended safety functions.

Specific areas of review should include:

- commitment to design and implement a system of internal audits and independent assessments of items relied on for safety
- methods to conduct audits and assessments, to establish their frequencies of performance (based on safety grading of items relied on for safety) and their structure

- commitment to use appropriately qualified personnel to conduct audits and assessments
- commitment to use and analyze audit and assessments results, to report them to facility management and to refer any identified, unacceptable performance deficiencies to the facility corrective action program for resolution

~~The reviewer should examine the applicant's~~ [Comment: replace "presentation with respect to" with "description of" for clarity.]~~presentation with respect to:~~

~~The commitments to audit and assessment activities;~~

~~The use of qualified and independent audit and assessment personnel;~~

~~The general structure of typical audits and assessments;~~

~~The facility procedures to be used to direct and control the audit and assessment activities;~~

~~The planned use of the results of the audit and assessment activities;~~

~~The documentation to record and distribute the findings and recommendations of these audits and assessments; and~~ [Comment: add the words "…*and refer any identified unacceptable* ~~*performwnce*~~*performance deficiencies to the facility corrective action plan for resolution*…" It is not the function of the 'Audit and Assessment' management measure to plan or implement corrective actions.]

~~The planning and implementation of corrective actions based on the findings and recommendations.~~[Comment: this is a function of the Corrective Action Program outlined in §11.3.6.]

11.3.~~6~~7 Corrective Action Program (Incident Investigations)

The ~~NRC staff should~~ review should determine that the applicant~~'s~~ has committed to design and implement a Corrective Action Program (CAP) to investigate abnormal events and to undertake corrective actions to items relied on for safety and/or management measures, if required. ~~policy, procedures,~~[Comment: procedures are not to be included in the license application and do not require review.] ~~and management structure for investigating abnormal events and completing appropriate corrective actions. The review should include the provisions for establishing~~ [Comment: use of the term '*investigating teams*' is too prescriptive. Replace with '*processes to investigate abnormal events*' to allow investigation of an abnormal event of low safety significance.] ~~investigating teams, the methods for determining~~ [Comment: findings of the CAP should not be limited to "root causes". Broaden the applicability of the following phrase be recasting it to read: '…*for determining specific or root cause(s) and any generic implications, and* …"] ~~root causes, and~~ [Comment: insert '*the applicant's*' before 'procedures'.]~~procedures for tracking and completing corrective actions and for documenting the process for the purpose of applying the "lessons learned" to other operations.~~

Specific areas of review should include:

- commitment to develop and implement a CAP to investigate abnormal facility events

and unacceptable performance deficiencies related to items relied on for safety and/or management measures

- commitment to establish CAP policies, to incorporate these policies into the facility's management organization to oversee CAP activities and to assign appropriately trained and qualified personnel to this function
- description of CAP policies:
  - (i) the approach and methods to investigate abnormal events
  - (ii) methods to design, track and complete appropriate corrective actions
  - (iii) methods to determine specific or root cause(s) and generic implications of abnormal events
  - (iv) process to enable "lessons learned" to other items relied on for safety and/or management measures

11.3.~~7~~8 Records Management

The review should determine that the applicant has committed to develop and implement a records management system to collect, store and permit retrieval of facility information such as ISA documentation, maintenance records, CAP investigations and actions, records of facility and operational changes, reports to the NRC and both items relied on for safety and their complementary management measures. ~~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:~~

Specific areas of review should include:

- commitment to establish and maintain a records management system
- policies pertaining to:
  - (i) records handling, storage and retrieval
  - (ii) identification of records to be maintained (for example, training, audits of items relied on for safety, CAP results)
  - (iii) establishment of record retention time frames
- commitment to periodically review the efficacy of the records management system and to revise it, as required, and to correct any identified deficiencies

~~1. The process whereby records, including training, dosimetry, effluents, classified information, facility structures, systems, or components relied on for safety, and failure logs are created, selected, verified, categorized, indexed, inventoried, protected, stored, maintained, distributed, deleted, or preserved.~~ [Comment: final sentence has been incorporated into the introduction of this section. Delete.]~~The review should ensure 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).~~

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

11.4 ACCEPTANCE CRITERIA

[Comment: NEI recommends addition of some general statements at the beginning of §11.4 to be consistent with the style of the other 10 SRP chapters' Acceptance Criteria' sections. Additionally, general statements that are included in the discussion of each management measure (for example, soliciting additional information from the applicant to address any deficiencies, etc.) should be consolidated into this §11.4 introductory section.]

The reviewer should find the applicant's management measures information acceptable if it provides reasonable assurance that the following acceptance criteria are adequately addressed and satisfied.

11.4.1 Regulatory Requirements

[Comment: information in this section is generally far too broad and not strictly accurate. Only specific regulatory citations need to be provided. Recommend deletion of this first 'motherhood' statement.] ~~The requirements for fuel cycle facility management measures, including QA elements, configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, and records management are specified in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," as revised (e.g., Part 70 definitions; 70.62(d)).~~

10 CFR 70.62(d), *Management Measures* ~~*Safety Program and Integrated Safety Assessment,*~~ requires ~~that the~~ an applicant~~'s~~ to establish management measures for application to ~~ensure that~~ engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to §70.61(e) so ~~are maintained to ensure~~ they are available and reliable to perform their function when needed

[Comment: the following citation is not pertinent to the management measures discussion.] ~~The requirement specifically applicable to personnel training and qualification is Code of Federal Regulations, Title 10 (10 CFR), Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," specifically Section 19.12, "Instructions to Workers."~~

The regulation requirement for an applicant to ~~procedures that~~ protect health and minimize danger to life or property is specified in 10 CFR 70.22(a)(8).

[Comment: the following interpretation of the contents of 10 CFR 70.65(b) does not correspond with what is proposed for this section in the Federal Register version of this regulatory citation. Section (b), in fact, does not even mention the term "management measures. Delete this erroneous statement.] ~~The requirements specified in 10 CFR 70.65(b) require organization and management controls to provide reasonable assurance that management systems and structures are in place and effective in planning, implementing, performing audits and assessments, and controlling site operations in a fashion that ensures comprehensive management control and oversight function of the health, safety, and environment.~~

[Comment: although the 'records management' and 'CAP' management measures could bear upon preparation of proper reports to the NRC (required under 10 CFR 70.74), this citation does not

directly apply to management measures and should be deleted.] ~~Incident investigation and reporting required by 10 CFR 70.74(a) and (b).~~

11.4.2 Regulatory Guidance

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

ANSI/ISO/ASQ 9000 series quality management standards.

International Atomic Energy Agency 1995 Safety Guide 50-SG-Q1, "Establishing and Implementing a Quality Assurance Program;" DOE's September 1997 draft "Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C."

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.

~~NUREG-1220, "Training Review Criteria and Procedures," Revision 1, January 1993.~~[Comment: this is primarily ~~regultory~~regulatory guidance that applies to nuclear power plants. It is inappropriate for fuel cycle facility usage. Delete.]

11.4.3 Regulatory Acceptance Criteria

[Comments: (i) separate treatment of QA has been deleted in preference to incorporation of QA considerations into each of the specific management measures. §11.4.3.1 has, therefore, been deleted. See accompanying text for further explanation.]

~~**11.4.3.1 Quality Assurance**~~

~~To be acceptable, the applicant's QA program~~ [Comment: Part 70 does not require establishment of a formal '*QA program'*, Inappropriate terminology.] ~~should be structured to apply appropriate QA measures and controls to items relied on for safety, which may include site design features. QA measures may be applied in proportion to the importance of the item to the achievement of safety (graded approach). QA programs~~ [Comment: Part 70 does not require establishment of a formal '*QA program'*, Inappropriate terminology.] ~~are expected to differ based on the purpose and complexity of the facility and processes to be controlled.~~

~~The ISA summary should identify the items relied on for safety, the degree of their importance to safety, and the related controls that are required for safety. An applicant may choose to apply the highest level of QA and control to all items relied on for safety or may grade its QA in proportion to the importance of the item to the achievement of safety.~~

~~When used, the graded approach for the application of QA should be described and should parallel the maintenance~~ [Comment: Why should it just parallel 'maintenance? Why not other

management measures?] ~~defined and applied by the applicant as described in the application. At a minimum, the same items relied on for safety that are included in the maintenance~~ [Comment: Why should it just parallel 'maintenance? Why not other management measures?]~~program should have appropriate QA controls. When the applicant implements a graded QA program~~[Comment: Part 70 does not require establishment of a formal '*QA program'*, Inappropriate terminology.]~~, the relative risk importance ranking of items relied on for safety, as established within the maintenance~~ [Comment: Why should it just parallel 'maintenance? Why not other management measures?]~~program, should be the same as those used in QA. For each of the items relied on for safety as identified in the ISA summary, but commensurate with the feature's risk level, the applicant may identify and define the applicable level of QA. From that point on, the assignment of QA levels to be used may be based on the graded QA application.~~

~~A checklist for evaluating QA is given below. When QA is graded, the attributes listed below are applied~~ [Comment: why does the SRP mandate that all such NQA-1 "…*attributes listed below [be] applied*…"? This does not concur with the risk-informed approach developed in the Part 70 rule, nor does it address the safety grading which was discussed in the previous paragraph. If an applicant elects to use NQA-1, all 19 criteria may still not be applicable.] ~~collectively only for accident sequences that run the highest level of risk. QA requirements may be reduced by modifying or eliminating attributes based upon evaluations performed and documented in the ISA.~~

~~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). Persons or organizations responsible for ensuring that appropriate QA has been established and verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities.~~

~~2.The applicant commits to meet the applicable requirements of American National Standard Institute/American Society of Mechanical Engineers standard, ANSI/ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications." Alternatively, QA elements applied to items relied on for safety can be developed, and committed to, using one or more of the following documents: 1) ANSI/ASME NQA-1-1994; 2) an appropriate ISO 9000 quality management standard; 3) an appropriate ANSI/ISO/ASQ 9000 quality systems standard; 4) International Atomic Energy Agency 1995 Safety Guide 50-SG-Q1, "Establishing and Implementing a Quality Assurance Program;" 5) DOE's September 1997 draft "Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C;" and/or 6) other documents that provide equivalent QA for such facilities. The commitment may describe the applicant's graded approach to QA, describing controls implemented consistent with an item's importance to safety, or the commitment may describe a QA program~~ [Comment: Part 70 does not require establishment of a formal '*QA program'*, Inappropriate terminology.] ~~applied to all items relied on for safety. The QA function is well-documented, planned, implemented, and maintained to ensure the availability and reliability of items important to safety. It should be functional prior to performing the ISA required by Part 70.~~

~~3.A design control system is established that includes design inputs, process, analyses, verification, interfaces, changes, and design documentation and records (see sections 11.3.2, 11.4.3.2, 11.5.2.2, 11.6.2 for details on configuration management).~~

4.Applicable design bases and other requirements necessary to ensure adequate quality are included or referenced in documents for procurement of items or services relied on for safety. To the extent necessary, suppliers are required to have QA consistent with the quality level of the item or service to be procured.

5.Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate for the circumstances (see sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures).

6.The preparation, issuance, and changes of documents that specify quality requirements or prescribe activities affecting quality are controlled to ensure that the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by authorized personnel (see sections 11.3.2, 11.4.3.2, 11.5.2.2, 11.6.2 for details on configuration management and sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures).

7.Purchased items and services relied on for safety are controlled to ensure conformance with specified requirements.

8.Provisions are made to identify and control items relied on for safety and to ensure that incorrect or defective items are not used.

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

10. Inspection required to verify conformance of items relied on for safety with requirements is planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results (see sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures). Personnel qualification programs are established for Inspection test personnel (see sections 11.3.4, 11.4.3.4, 11.5.4, 11.6.4 for details on training and qualifications).

11. Tests are conducted to verify that items relied on for safety 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 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures). Personnel qualification programs are established for test personnel (see sections 11.3.4, 11.4.3.4, 11.5.4, 11.6.4 for details on training and qualifications).

12. Provisions are made to ensure 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.

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

~~14. Provisions are made to control the inspection, test, and operating status of items relied on for safety to prevent inadvertent use of nonconforming items or bypassing of inspections and tests.~~

~~15. Provisions are made to control the identification, segregation, disposition, and prevention of installation or use of nonconforming items relied on for safety.~~

~~16. Provisions are made to ensure that conditions adverse to safety are promptly identified and corrected and that measures are taken to preclude repetition. These actions should be documented and reported to appropriate levels of management (see sections 11.3.7, 11.4.3.7, 11.5.2.7, 11.6.7 for details on incident investigations and sections 11.3.6, 11.4.3.6, 11.5.2.6, 11.6.6 for details on audits and assessments).~~

~~17. Provisions are made for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality for items relied on for safety (see sections 11.3.8, 11.4.3.8, 11.5.2.8, 11.6.8 for details 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 11.3.6, 11.4.3.6, 11.5.2.6, 11.6.6 for details 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.~~

11.4.3.1~~2~~ Configuration Management

The applicant's CM system ~~reviewers should determine that an applicant's CM function~~ should be ~~is~~ acceptable if it satisfies the following criteria.

- the applicant commits to establish a CM system consistent with the regulatory requirements of 10 CFR 70.72(a)
- the applicant commits to maintain current facility documentation on items relied on for safety and to accurately track all safety-significant changes to such items
- the applicant commits to maintain current documentation on management measures to be applied to items relied on for safety (e.g. training, maintenance) and to accurately track all safety-significant changes to such management measures
- the applicant commits to prepare written policies and procedures to implement CM
- the applicant outlines how the CM system is incorporated into the facility's organizational structure, describes CM activities, specifies the documents to which the CM function will apply (e.g. drawings, PI&Ds, design and procurement specifications, engineering analyses, operating procedures, training records, maintenance records, etc.), and describes technical management review and approval procedures

- the applicant describes how the CM function maintains consistency among the design requirements, the physical configuration and the facility documentation, especially as they apply to items relied on for safety
- the applicant describes a process to document and record all changes to procedures, facilities, operations, the ISA Summary and other ISA-related documentation and equipment pertaining to items relied on for safety, including necessary authorizations
- the applicant commits to periodically assess, in accordance with the Audit and Assessment management measure (§11.4.5) the efficacy of the CM system, to identify possible improvements and to correct any safety-significant deficiencies

1.CM Policy

The applicant's description of overall CM functions describes at least the following topics: (a) the scope of the items relied on for safety [Comment: text in the following parentheses is redundant and should be deleted. Correct consistency in terminology: should be 'items relied on for safety', not SSC]] (SSCs and management measures) to be included in the CM function (coordinate with the Section 3, ISA, reviewer for the application), (b) the objectives of each CM function activity, (c) a description of each CM function activity, and (d) the organizational structure and staffing interfaces. The functional interfaces with maintenance, and training and qualification are of particular importance and should be addressed individually. The SSCs [Comment: Consistency in terminology: should be 'items relied on for safety', not SSC]under CM [Comment: delete 'should'; CM must apply to all items relied on for safety identified in the ISA Summary.]should include all those items relied on for safety as defined by the ISA summary.

[Comment: NEI disagrees with the content of this paragraph that requires an existing licensee to apply full CM activities to all items relied on for safety. Only after the ISA is completed would a licensee be permitted to relax such stringent application of CM for low-safety significant items relied on for safety. An existing licensees should be permitted to continue application of its existing CM policies – which have been approved by the NRC --, without change, until the ISA is completed (within 4 or 5 years), at which time the new CM system can be applied to items relied on for safety of differing degrees of safety significance.] An important element of an applicant's overall CM policy is the establishment of a baseline CM policy applicable to all applicant operations, independent of ISA. That baseline initially includes all the CM functions described in this SRP Chapter. After an ISA is completed and [Comment: Consistency in terminology: should be 'items relied on for safety', not SSC]SSCs are identified that may not be associated with 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 function as applied to those lesser risk design or operational features. In that case, the applicant then, in its description of CM policy, defines the specific attributes of a reduced level or levels of CM that would be applied to selected items relied on for safety, and in the ISA identifies those items that will be assigned the lesser category of CM.

2.Design Requirements

The applicant [Comment: an applicant can not be expected to '…*demonstrate…the establishment and maintenance of design requirements*…", but rather just "…*describe how they will be established and maintained*…" Replace "demonstrate" by "describe how" throughout §11.5 for consistency and accuracy. One *describes* something in an application, but

does not *demonstrate* its efficacy.] ~~demonstrates that design requirements and~~ [Comment: delete "associated design bases". Inappropriate.]~~associated design bases have been established and are maintained by an appropriate organizational unit. The applicant demonstrates that the design requirements and the ISA are kept current and~~ [Comment: delete the following phrase "… *and that suitable…proposed changes…*" as it is not needed.]~~that suitable hazard/accident analysis methods, including controlled computer codes, if used, are available and are properly used to evaluate safety margins of proposed changes. Technical management review and approval procedures are described.~~ [Comment: delete the following sentence as it is redundant.]~~The specific items relied on for safety included in the CM function are identified within the ISA summary report.~~

~~3.~~Document Control

~~The applicant describes an acceptable method to establish and control documents within the CM function, including cataloging the document data base, the information content of the document data base, maintenance and distribution of documents, document retention policies, and document retrieval policies. A list of the types of documents controlled is established and includes key documents, such as drawings, procurement specifications, engineering analyses, operating procedures, training/qualification records, and preventive and corrective maintenance procedures, and maintenance completion records.~~ [Comment: what about corrective action program changes? Why is it excluded?]

~~4.~~Change Control

~~The applicant~~ [Comment: replace "*demonstrates that*" by "*describes how*". See earlier comment above. One describes something in an application, but does not demonstrate its efficacy.] ~~demonstrates that the CM function maintains~~ [Comment: 'strict' is too stringent. Delete this adjective.]~~strict consistency among the design requirements, the physical configuration, and the facility documentation. The applicant describes an acceptable process for identifying and authorizing proposed changes,~~ [Comment: the CM system should not have as a responsibility the "…*performance of technical and safety reviews of proposed changes*…" or of "…*implementing such changes*…" This is a function of the 10 CFR 70.72 facility change mechanism. The CM system will document and record any implemented changes and will mandate that changes and updates to the ISA and ISA Summary are promptly made.].~~performing appropriate technical and safety reviews of proposed changes, approving changes, implementing changes, and documenting changes. The applicant describes an acceptable process, within the CM function, for~~ [Comment: replace 'ensure' by '*provide reasonable assurance*' in the following clause.]~~ensuring that the ISA is systematically reviewed and modified to reflect design or operational changes~~ [Comment: the balance of this sentence is not needed and should be deleted.]~~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.~~

~~5.~~Assessments

~~The applicant confirms that assessments, including initial and periodic examinations of the CM system, are conducted to determine the program's effectiveness and to correct deficiencies. The applicant indicates that such assessments are systematically planned and conducted in~~

~~accordance with an overall facility audit and assessment function (see sections 11.3.6, 11.4.3.6, 11.5.2.6, 11.6.6 for details on audits and assessments) .~~

[Comment: the following section (6) should be deleted. See text for explanation and justification.]
~~6.~~Design Reconstitution ~~[Existing Facilities Only]~~

~~The applicant describes the design reconstitution that 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 reconstituted the current design bases, supporting analyses, requirements, and documentation that support items important to safety. The reconstitution process, including walk-downs, is complete and verifies that the configuration is consistent with as-built facility documentation.~~

11.4.3.~~2~~3 Maintenance

The applicant's maintenance function should be acceptable if it satisfies the following criteria~~ The reviewers should find the applicant's submittal acceptable if the application includes the following~~:

- the applicant commits to design and implement an adequate maintenance system for items relied on for safety that will provide for levels of inspection, calibration and testing commensurate with the safety significance of the item relied on for safety
- the applicant describes an organizational structure for the maintenance function, commits to appoint qualified personnel to take responsibility for this activity and who will develop, approve and modify, as required, maintenance procedures
- the applicant commits to provide sufficient resources to enable the maintenance activities to be properly executed
- the applicant commits to prepare written maintenance policies and procedures for each component of the maintenance system
- the applicant identifies those items relied on for safety to which the maintenance function will apply and describes the methods used to establish differing frequencies, if any, for maintenance of different items relied on for safety
- the applicant describes policies for each maintenance activity including, for example, task work instructions, notification requirements, issuance of maintenance work permits, procedures for use of compensatory measures during the repair or replacement of a safety-significant items relied on for safety, etc.
- applicant describes a process to record the results of all maintenance activities (in coordination with the Records Management management measure), to document all safety-significant referrals made to the CAP and to management, and any recommendations for changes to the design or operation of items relied on for safety
- the applicant describes the basic components of the maintenance program that may include one or more of the following components: surveillance and monitoring, preventive maintenance, corrective maintenance, and functional testing. For each applicable component, the applicant should provide the following information:

  (1) Preventive Maintenance
  - commitment to conduct preplanned and scheduled periodic refurbishing and/or overhauls or items relied on for safety

- description of preventive maintenance activities including, for example, instrumentation calibration and testing, methods used to establish the frequency of preventive maintenance activities and the scope (detail) of such activities

(2) Corrective Maintenance
- commitment to promptly perform corrective actions or repairs on items relied on for safety
- description of the approach and methods for planning and implementing repairs to items relied on for safety

(3) Surveillance and Monitoring
- commitment to design and implement a program to survey and monitor the performance of items relied on for safety
- description of the components of the surveillance and monitoring program including methods used to establish the frequency of such inspections for items relied on for safety having different degrees of safety importance, activities and reporting procedures

(4) Functional testing
- commitment to evaluate the potential impact of all corrective or preventive maintenance, or calibration of, items relied on for safety, and subsequently perform the appropriate post-maintenance functional testing to provide reasonable assurance that the maintenance activity did not adversely impact the reliability of the control
- commitment to perform functional testing after initial installation, and prior to implementation of, new items relied on for safety
- description of functional testing procedures, documentation of test results and the schedule of their performance

- commitment to refer to the facility's CAP any unacceptable performance deficiencies identified in the maintenance activities to identify specific or root cause(s) and generic implications to eliminate or minimize the possibility of their recurrence
- commitment to minimize the unavailability of items relied on for safety which are undergoing preventive or corrective maintenance and to implement appropriate compensatory measures as required during such periods of unavailability
- the applicant commits to periodically assess, in accordance with the Audit and Assessment management measure (§11.4.5), the efficacy of the maintenance system, to identify possible improvements and to correct any safety-significant deficiencies

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

~~1.Surveillance / monitoring~~

~~For items relied on for safety identified in the ISA summary, the applicant describes the surveillance function and its commitment to the organization and conduct of surveillance at a specified frequency, to~~ [Comment: replace 'measure' with 'assess'] ~~measure the degree to which engineered safety functions meet performance specifications. This activity is~~

used in setting preventive maintenance frequencies and the determination of performance trends for items relied on for safety . [Comment: the following sentence has been repeated three times in this §11.4.3.2 and should be deleted. Its substance has been incorporated above as a commitment.] Applicant describes how results from incident investigations, review of the [Comment: NEI considers there no need for the separate '*failure log*' required by 10 CFR 70.62(a)(3) as these performance data have been recorded and addressed by the licensee already.]failure log required by §10 CFR 70.62(a)(3), and [Comment: the following clause should be rewritten so as not to be so prescriptive: "…*identified specific or root cause(s) and generic implications, are used*…"]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 items relied on for safety are maintained by the applicant. [Comment: the following sentence is too prescriptive and must be deleted,]For surveillance tests that can only be done while equipment is 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 items that are relied on for safety. The maintenance function provides a planned, systematic, integrated, and controlled approach for the repair and replacement activities associated with identified failures to items relied on for safety. [Comment: the following sentence is too onerous and prescriptive. Its substance has been addressed in the 'functional testing' write-up. Delete it.]After conducting corrective maintenance and prior to returning an item relied on for safety to operational status, if necessary, a functional test is conducted to ensure that a safety control performs as designed and provides the safety action expected. [Comment: the following clause should be rewritten so as not to be so prescriptive: "…*identified specific or root cause(s) and generic implications, are used*…"] Applicant describes how results from incident investigations and [Comment: the following clause should be rewritten so as not to be so prescriptive: "…*identified specific or root cause(s) and generic implications, are used*…"]identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Contractors that work on or near items relied on for safety identified in the ISA summary receive the same level of training and follow the same [Comment: what are 'work control activities? Definition required?]work control activities as listed above.

3.Preventive maintenance

Applicant provides a description of the preventive maintenance (PM) function that demonstrates a commitment to conduct preplanned and scheduled periodic refurbishing, partial or complete overhaul, for the purpose of ensuring that unplanned outages of selected safety functions [Comment: 'safety function' refers to items relied on for safety?] do not occur. This activity includes using the results of the surveillance component of maintenance and the [Comment: NEI considers there no need for the separate '*failure log*' required by 10 CFR 70.62(a)(3) as these performance data have been recorded and addressed by the licensee already.] failure log required by §70.62(a)(3). Instrumentation calibration and testing is addressed by the applicant as part of this component. The applicant describes how the function will be designed to ensure that the objective of

preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of safety features [Comment: 'safety features' refers to items relied on for safety?]because of monitoring or preventive maintenance. [Comment: the following sentence is too prescriptive and should be deleted.] After conducting PM and prior to returning a safety control to operational status, if necessary, a functional test is conducted to ensure that a safety control performs as designed and provides the safety action expected. The methodology or basis used to determine PM frequency is described. [Comment: the following sentence has been repeated three times in this §11.4.3.2 and should be deleted. Its substance has been incorporated above as a commitment.]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 from recurring. Feedback from the PM and corrective maintenance function is used [Comment: insert the words '*as necessary'* after '*used*'.]to change frequency or scope of the maintenance activity[Comment: insert the words '*as required*' after '*maintenance activity*']. A rationale for deviation from industry standards or vendor recommendations is provided. [Comment: the following sentence addresses issues that should be incorporated into the Records management management measure.]Records showing the PM schedule, and results, for all safety features [Comment: 'safety features' refers to items relied on for safety?]subject to this maintenance component are maintained by the applicant.

4.Functional testing

Applicant includes a description of and commitment to the functional testing of items relied on for safety[Comment: insert "as necessary" here.], for surveillance purposes or if needed after corrective/ preventive maintenance or calibration. These tests are conducted using approved procedures and include compensatory measures while the test is being conducted. The description includes the methods used, the frequency, and the basis for each. Applicant ensures that the functional tests cover all aspects of the [Comment: better use "items relied on for safety" instead of safety control.]safety control. [Comment: the following 3 sentences tell "how" the licensee should act and are inappropriate for inclusion in the SRP. This example sets a prescriptive tone and should be deleted.]As an example, if a level controller is used to actuate a three-way valve and divert flow to an alternate tank, then the level monitor sending unit and the valve, power supplies, utility services, and any corresponding local or control room displays are tested at the same time during the functional test. The intent is to simulate actual upset conditions and demonstrate that the safety control is available and reliable and will function in the field as intended. Applying a milliamp signal across the leads of the level monitor and watching the valve cycle open or close, is not considered an adequate functional test. During startup of new process equipment these functional tests are conducted, documented and maintained for NRC review. Records showing the functional test schedule, and results, for all items relied on for safety subject to this maintenance component, and results, are maintained by the applicant.

[Comment: the following paragraph is inappropriately located in §11.4.3.2 as maintenance is not to be applied to humans whose activities may be relied upon for safety. Discussion of administrative controls should be confined to §11.11.4.3.3 ("Training and Qualification". Delete this sentence.] If any Administrative Control is identified as being an item relied on for safety, the applicant should

~~provide a discussion on how it is assured that this type of item relied on for safety (i.e., administrative control) is available and reliable to perform its intended safety function.~~

[Comment: the following work control methods contain detailed information that will be part of the ISA Documentation that is retained at the facility. The applicant or licensee should commit to developing such work control methods, but inclusion of their details in the license application is inappropriate. Delete this paragraph. Too prescriptive.] ~~The work control methods listed below are applied to the corrective, preventive and functional testing maintenance elements and include (as applicable): a) authorized work instructions with detailed steps and a reminder on the importance of the items relied on for safety identified in the ISA summary; b) parts lists; c) as built or redlined drawings; d) a notification step to the operations function prior to conducting repairs and removing a safety control from service; e) work permits for~~ [Comment: welding and cutting are not activities over which the NRC has jurisdiction. Delete these activities.]~~welding and cutting, confined space or radiation related work; f) replacement with like/kind parts and the control of new or replacement parts to ensure~~ [Comment: reference should not be made to 10 CFR 21. All unacceptable performance deficiencies are addressed in the CAP. See text for discussion.]~~compliance with 10 CFR Part 21; g) compensatory measures while performing work on items relied on for safety; h) procedural control of removal of components from service for maintenance and for return to service; i) ensuring safe operations during the removal of items relied on for safety from service; and j) notification to operations personnel that repairs have been completed. Written procedures for the performance of maintenance includes steps a) through j) (see sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures). All work requests and maintenance procedures include technical and safety discipline reviews and approval, as well as approval by responsible management.~~

[Comment: the following paragraph is redundant and unnecessary. Delete it for clarity.] ~~The four maintenance elements described above are covered by elements of the management measures discussed in SRP Section 11.0. The applicant includes a discussion or provides references, of how the maintenance function utilizes, interfaces with, or is linked to the various management measures. As an example, maintenance workers are trained and qualified to perform their duties and a description of the link between maintenance and the training and qualification function is described.~~

11.4.3.3~~4~~ Training and Qualification

[Comment: many of NEI's comments pertaining to §11.4.3.3 concern purging the guidance of Systems Approach to Training (SAT) terminology. The very prescriptive guidance in item (9) on educational requirements for certain facility positions should also be deleted. There appears to be no mention of the grading of training programs in this section; safety grading comparable to that permitted in the maintenance function (for items relied on for safety) should be included instead of the inordinate attention afforded SAT principles.]

The applicant's ~~The NRC reviewers should find the applicant's~~ submittal regarding personnel training and qualification should be acceptable if it satisfies the following criteria: ~~provides reasonable assurance that the regulatory review criteria below are adequately addressed and satisfied. In addition to the regulatory review criteria given below, SRP Subsections 4.1.5.4 and 4.1.5.6 provide specific criteria for training and qualification for radiation safety personnel. Thus, some of the information specified below may be found in other sections of the SRP and incorporated by reference.~~

- the applicant commits to adequately train plant personnel in the start-up, operation and maintenance of the facility to provide reasonable assurance that any personnel whose activities are identified in the ISA Summary to be relied upon for safety will be capable of performing such activities promptly and effectively
- the applicant outlines an organizational structure to plan, direct and evaluate training, assigns responsibility for training to appropriately qualified individuals, describes how training programs and their contents will be developed, outlines the training needs for different positions or activities for which the required performance is relied on for safety and explains what measures will be used to judge the success of training programs
- the applicant describes any grading of training programs that may have been implemented to make the training thoroughness and rigor commensurate with the functional responsibility and importance to safety of a position
- the applicant describes the minimum education and qualifications for personnel whose activities are relied on for safety
- the applicant commits to use training personnel who are knowledgeable in training methods, in the facility's safety programs, and in the facility's items relied on for safety described in the ISA Summary
- the applicant commits to clearly define the function, responsibility, authority and accountability of personnel involved in the management, supervision and conduct of training
- the applicant commits to implement and document procedures so that training is conducted reliably and consistently, and that training in activities relied on for safety uses well-organized and current safety information (maintained by the facility's CM)
- the applicant commits to establish and maintain training records appropriate to judge an individual's fitness and capability to perform activities relied on for safety
- the applicant explains how training guides will be prepared and how they will provide reasonable assurance of the consistent conduct of training activities and how classroom and on-the-job training will be used and coordinated
- the applicant commits to maintain current the training of personnel through periodic testing of personnel, refresher training and instruction in activities that may be relied on for safety
- the applicant commits to periodically evaluate the effectiveness of the training program to provide reasonable assurance that it conveys the required skills and knowledge and to implement changes, if required, to increase its effectiveness to correct any deficiencies

~~1. Organization and Management of Training - The organization and management of training are acceptable if the~~ [Comment: delete from the following list of activities "design', 'construction' and 'decommissioning'. Training should focus on activities related to the operation of the facility.]~~design, construction, start-up, operation, maintenance, modification, and decommissioning of the facility are organized, staffed, and managed to facilitate planning, directing, evaluating, and controlling a~~ [Comment: delete 'systematic' as too prescriptive and suggestive of the SAT concept.] ~~systematic training process that fulfills job-related training needs. Formal training should be provided for each position or activity for which the required performance is relied on for safety. The application should state what training will be conducted and which personnel will be provided this training.~~

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

1. ~~Line management is responsible for the content and effective conduct of the training.~~
2. ~~The job function, responsibility, authority and accountability of personnel invoilved in managing, supervising and implementi~~ng training is clearly defined.

~~3. Performance-based training is used as the primary management tool for analyzing, designing, developing, conducting and evaluating training~~[Comment: this is SAT. Delete.]

4.. ~~Procedures are documented and implemented to ensure that all phases of training are conducted reliably and consistently.~~

5. ~~Training documents are linked to the configuration management system to ensure that design changes are accounted for in the training.~~

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

7. ~~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 fitness for intended duty.~~

~~2. Trainee Selection - Trainee selection is acceptable if minimum requirements for trainees are specified for candidates whose activities are relied on for safety 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.~~

~~3.~~ [Comment: this criterion is SAT. the first sentence is far too prescriptive and detailed. Delete.]~~Conduct of Needs/Job Analysis and Identification of Tasks for Training - The conduct of needs/job analysis and identification of tasks for training are acceptable if the tasks required for competent and safe job performance are identified, documented, and included in the training.~~

[Comment: why are design and construction personnel now included? Their involvement is limited to a time when there are no activities relied on for safety. Delete.]~~Design personnel, construction personnel, operations personnel, training staff, and other subject matter experts, as appropriate, should have conducted or should conduct a needs/job analysis to develop a valid task list for specific jobs. The jobs treated in this manner should include - as a minimum - those responsible for managing, supervising, performing, and verifying the activities specified in the ISA summary as preventing or mitigating accident sequences. Each task selected for training (initial or continuing) from the facility-specific task list should be matrixed to supporting procedures and training materials. The facility-specific list of tasks selected for training and the comparison to training materials should be reviewed on an established schedule and updated as necessitated by changes in procedures, facility systems/equipment, or job scope.~~

~~4.~~ [Comment: this criterion is SAT. Delete.] ~~Development of Learning Objectives as the Basis for Training - The development of learning objectives as the basis for training is acceptable if learning objectives that identify training content and define satisfactory trainee performance are derived from job performance requirements. Learning objectives should state the knowledge, skills, and abilities the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity. Learning objectives should be sequenced based on their relationship to each other.~~

5. Organization of Instruction Using Lesson Plans and Other Training Guides - [Comment: revise the first sentence to read: "…*Lesson plans and other training guides should provide guidance to ensure the consistent conduct of training activities…*" As written the original sentence is SAT.]The organization of instruction using lesson plans and other training guides is acceptable if the plans/guides are based on the 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 proper trainee performance. Review and approval requirements should be established for all plans/guides and other training materials before their issue and use.

6. [Comment: this criterion is SAT. Delete.] Evaluation of Trainee Mastery of Learning Objectives - The evaluation of trainee mastery of learning objectives is acceptable if trainees are evaluated periodically during training to determine their progress toward mastery of job performance requirements and at the completion of training to determine their mastery of job performance requirements.

7. Conduct of [Comment: delete "on-the-job" as training can also occur in classrooms. Too limiting.] On-the-Job Training - The conduct of on-the-job training is acceptable if on-the-job training used for activities required by the ISA are fully described. [Comment: delete "on-the-job"] On-the-job training should be conducted using well-organized and current [Comment: delete "performance-based" as SAT.] performance-based training materials. [Comment: delete "on-the-job"] 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 [Comment: delete "on-the-job"] 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. Systematic Evaluation of Training Effectiveness - A systematic evaluation of training effectiveness and its relation to [Comment: delete "on-the-job"]on-the-job performance is acceptable if it [Comment: replace "ensure" by "provides reasonable assurance"]ensures that the training program conveys [Comment: replace "all" by "the". Less onerous.]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 programs should be conducted periodically by qualified individuals to identify program strengths and weaknesses. [Comment: the balance of this paragraph is overly prescriptive and should be deleted.]Feedback from trainee performance during training and from former trainees and their supervisors should be used to evaluate and refine the training. Change actions (for example procedure changes, equipment changes, facility modifications) should be monitored and evaluated for their impact on the development or modification of initial and continuing training and should be incorporated in a timely manner. This should be accomplished through the configuration management system (see sections 11.3.2, 11.4.3.2, 11.5.2.2, 11.6.2 for details on configuration management). Improvements and changes to initial and continuing training should be systematically initiated, evaluated, tracked, and incorporated to correct training deficiencies and performance problems.

9. Personnel Qualification - [Comment: to reduce the prescriptiveness of this paragraph, replace the first sentence as follows: "…*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 an authority of the respective personnel."] ~~The following commitments should be in the application regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel and other staff required to meet NRC regulations:~~

[Comment: delete the following six overly-prescriptive requirements.]

~~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.~~

~~Supervisors should have at least the qualifications required of personnel being supervised with either one additional year experience supervising the technical area at a similar facility or should have completed the supervisor training.~~

~~Technical 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. item relied on for safety) should have a B.S. in the appropriate technical field and three years experience. Other technical staff should have a B.S. in the appropriate technical field and one year experience.~~

~~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.~~

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

~~10. Applicant's Provisions for Continuing Assurance – The applicant's provisions for continuing assurance of personnel training and qualification are acceptable if the submittal addresses periodic~~ [Comment: replace '*retesting*' by '*training and/or testing*'.]~~retesting of personnel as necessary to~~ [Comment: replace 'ensure' by '*provide reasonable assurance*']~~ensure 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~~5 Procedures Program

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

- the applicant commits to develop, approve and implement operating and management control procedures applicable to items relied on for safety
- the applicant describes methods to identify the need for a procedure, to write and approve procedures (engineering and managerial approval processes), to verify and validate procedures, to implement and distribute procedures and to revise and re-issue procedures, as required. The applicant also describes methods to assess the technical accuracy of procedures and the personnel responsible for verification and approval

- the applicant commits to the following procedure adherence: "Activities involving licensed special nuclear material and/or items relied on for safety will be conducted in accordance with approved procedures."
- the applicant commits to periodically review procedures to validate their continued accuracy and usefulness. The applicant also commits to review any relevant procedures associated with abnormal events and to refer any perceived deficiencies to the CAP for evaluation and corrective action, if required
- the applicant describes items relied on for safety and management measures for which procedures are required
- the applicant describes policies to promote the integration of the procedures and CM management measures

Appendix A provides examples of facility operations and activities for which procedures may be required.

[Comment: Items (1) through (3) suggest that the reviewer will examine actual procedures. This is not required by the reviewer. These 3 items should, therefore, be deleted.]

~~1. Procedures are written or planned for the~~ [Comment: replace "conduct of all operations involving" by "operation of"]~~conduct of all operations involving controls identified in the ISA summary as items relied on for safety and for all management control systems supporting those controls.~~

~~2. Operating procedures contain the following elements: (a) purpose of the activity; (b) regulations, polices, and guidelines governing the procedure; (c) type of procedure; (d) steps for each operating process phase; (e) initial startup; (f) normal operations; (g) temporary operations; (h) emergency shutdown; (I) emergency operations; (j) normal shutdown; (k) startup following an emergency or extended downtime; (l) hazards and safety considerations; (m) operating limits (n) precautions necessary to prevent exposure of hazardous chemicals~~ [Comment: insert "…*produced from licensed material*…" after '*chemicals*']~~or licensed special nuclear material; (o) measures to be taken if contact or exposure occurs; (p) items relied on for safety associated with the process and their functions;~~ [Comment: why single out items relied on for safety in (p). This whole section addresses items relied on for safety.]~~(q) time frame for which the procedure is valid.~~

~~3. Management~~ [Comment: replace "control procedures" by "measures".]~~control procedures contain elements reflecting the important elements of the functions described in the applicable chapters of this SRP. Procedures exist to manage the following activities: a) design; b) configuration management; c) procurement; d) construction; e) radiation safety; f) maintenance; g) human-systems interface;~~ [Comment: 'human-system interfaces was deleted from the SRP. Delete this phrase.]~~h) quality assurance; i) training and qualification; j) audits and assessments; k) incident investigations; l) records management; m) criticality safety; n) fire safety; o) chemical process safety; and p) reporting requirements.~~

~~4.~~ [Comment: item (4) is identical to item (5). Delete item (4).]~~The applicant's method for identifying the procedures includes using ISA findings and conclusions to identify needed procedures. Process operating procedures provide specific direction regarding administrative controls to ensure process operational safety.~~

5. The applicant describes the method for identifying, developing, approving, implementing, and controlling operating procedures[Comment: insert after 'procedures' the following "*…based on the results of the ISA…*"]. This method includes, as a minimum, that (a) operating limits and controls 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 quality assurance and configuration management programs at the plant ensure that current procedures are available and used at all work locations; and (h) the plant training program ensures that the required persons are trained in the use of the latest procedures available.

6. The applicant includes the following commitment regarding procedure adherence: "Activities involving licensed special nuclear material and/or items relied on for safety will be conducted in accordance approved procedures".

7. The applicant describes the types of procedures used during facility operation. These will typically include management control, operating, maintenance, and emergency procedures. The applicant provides information regarding the procedure categories used at the facility. The applicant develops procedures for site wide safe work practices to provide for the control of processes and operations with licensed special nuclear material and/or items relied on for safety 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. Procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA and 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 topics of administrative procedures; system procedures that address startup, operation, and shutdown; abnormal operation/alarm response; maintenance activities that address system repair, calibration, inspection and testing; and emergency procedures. Appendix A provides an acceptable listing of the items to be included under each topic.

8. Applicant reviews procedures following unusual incidents, such as an accident, unexpected transient, significant operator error, or equipment malfunction, or following [Comment: delete "any" and change 'modification' to "modifications"] any modification to a system [Comment: add "as appropriate" after 'system'.]and revises procedures as needed.

9. Applicant ensures technical accuracy of procedures and that they can be performed as written. The discussion identifies who is responsible for verification. The verification process ensures that the technical information is included and correct, [Comment: the balance of this sentence is too prescriptive and should be deleted.]including formulas, set points, 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 ensures that the operating limits and controls identified in the ISA are specified in the procedures and that quality assurance 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 approve new procedures and changes to existing procedures.

10. Documents are distributed in accordance with applicable distribution lists. A process is used to limit the use of outdated procedures. Copies are available to appropriate personnel. Issuance and distribution of procedures is documented and refers to the Records Management function.

11. The applicant has formal requirements governing temporary changes. Temporary changes do not involve a change to the ISA [Comment: delete the balance of this clause.]or involve an item relied on for safety. 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) ensure orderly and uniform operations for short periods when the plant, a system, or component [Comment: meaning: item relied on for safety?] 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 time frame for use of the temporary procedure and includes the same level of review and approval as that for permanent procedures.

12. [Comment: the content of item (12) is part of the maintenance management measure and need not be repeated here. Parts (a) and (b) are far too prescriptive. Delete the entire item.]Maintenance procedures involving items relied on for safety 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) prior to performing work and upon completion of maintenance work. The discussion includes potential degradation of items relied on for safety during the planned maintenance.

    c. Control of work by [Comment: replace “comprehensive” by “adequate”] comprehensive procedures to be followed by maintenance technicians. Maintenance procedures are reviewed by the various safety disciplines 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 configuration management function to ensure like/kind replacement and adherence to 10 CFR 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, criticality, fire, chemical, environmental or [Comment: delete the following phrase.]human-systems interface issues).

13. Applicant conducts periodic reviews of procedures to ensure their continued accuracy and usefulness and establishes the time frame for reviews of the various types of procedures. At a minimum all operating procedures are reviewed every 5 years and emergency procedures are reviewed every year. 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.

11.4.3.56 Audits and Assessments

[Comment: NEI is unclear why the NRC staff significantly expanded upon the Acceptance Criteria for Audits and Assessments in the July 1999 revision of Chapter 11.5. A majority of the added text is unnecessarily prescriptive, adopts the Part 50 regulatory focus on '*audits and assessments of QA*' rather than on the availability and reliability of items relied on for safety – the whole purpose of Chapter 11 -- and should be deleted. See the accompanying text for further discussion of NEI's concerns.]

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

- the applicant commits to design and implement a system of internal audits and independent assessments of items relied on for safety
- the applicant describes methods to conduct audits and assessments, to establish their frequencies of performance (based on safety grading of items relied on for safety) and their scope and structure. The applicant should also describe policy directives covering the audit and assessment functions (e.g. activities to be audited, schedules, guidance in conducting the audit or assessment, assigned responsibilities for each phase of the work, procedures for recording results of each audit or assessment, etc.)
- the applicant commits to use appropriately qualified personnel to conduct audits and assessments. The applicant should describe the qualifications and responsibilities of key individuals responsible for the overall direction and conduct of audits and assessments, and identify organizational responsibilities
- the applicant describes any performance indicators that may have been developed for items relied on for safety and that can be used to facilitate scheduled audits and assessments
- the applicant commits to conduct audits and assessments in accordance with written procedures and checklists
- the applicant commits to document report findings and recommendations and to distribute them to appropriate management for review. The applicant also commits to

refer to the CAP any unacceptable performance deficiencies that may be discovered during an audit or assessment for possible corrective action, if required.

- the applicant commits to periodically review the audit and assessment procedures and to upgrade them, if required

~~Audits and Assessments - General: Audits and assessments are acceptable if:~~

a. ~~Internal audits, external audits and assessments~~ [Comment: replace "are" by "may be" to comply with the regulations.]~~are conducted by the applicant with a graded approach based on the results of the integrated safety analysis required by 10 CFR §70.62.~~ [Comment: the following sentence does not accurately reflect the purpose of 'Audits and Assessments' that was stated in §11.3.6. The following purpose applies instead to Part 50 audits and assessments of QA. Delete.]~~Audits and assessments should objectively evaluate the effectiveness and proper implementation of QA for items relied on for safety and address the technical adequacy of the items being audited/assessed.~~

b. ~~The applicant describes, commits to, and justifies a frequency and scope of audits and assessments that address items relied on for safety.~~ [Comment: the following sentence is incorrect. Audits and assessments are to be performed where the ISA directs, not where QA is an issue.]~~Audits and assessments should be performed in all areas where the requirements of QA are applicable. Audits and assessments should be regularly scheduled on the basis of the status and the safety significance of the items being audited/assessed and should be initiated early enough to ensure the implementation of effective QA.~~

c. ~~Policy directives are established for audits and assessments. For each activity to be audited/assessed, the policy directives cover schedules, guidance for conducting the audit or assessment, assigned responsibilities, and procedures for recording the results of the audit or assessment and ensuring that identified deficiencies are corrected in a timely and effective manner.~~ [Comment: refer to the CAP.]

d. ~~The applicant identifies the position title, qualifications, and responsibilities of the manager responsible for the overall success of the audits and assessments. Other organizational responsibilities for audits and assessments may be identified by the applicant.~~

e. ~~Training and qualification requirements for audit and assessment personnel are described. (SRP Section 11.4 addresses training and qualification requirements in detail.)~~

f. ~~Each audit and assessment team has authority to investigate any aspect of the audited/assessed items and has access to all relevant information.~~

g. ~~Performance indicators~~ [Comment: definition of this PI term may be appropriate.]~~are established so that audits and assessments can determine the degree to which selected items relied on for safety are meeting the applicant's objectives to protect (1) the health and safety of the public and workers and (2) the environment.~~

h. ~~Audits and assessments are conducted according to written procedures/ checklists.~~

i. [Comment: the following item is unnecessarily prescriptive. Delete.] ~~Audits and assessments include detailed walk-downs of the area, including out-of-the-way and limited-access areas, with accurate, documented descriptions of deficiencies.~~

j. ~~On-the-spot corrective actions~~ [Comment: better to refer deficiencies to the CAP for thoughtful and considered review and corrective action, if required.]~~are provided for, with appropriate documentation.~~

k. ~~Audit and assessment results are reviewed with management having responsibility in the area audited/assessed.~~ [Comment: item (k) is repetitive of item (m). Delete.]

l. ~~Reports of findings and recommendations are documented and distributed to appropriate management for review and response. As described in SRP Section 11.3, a management corrective action program~~ [Comment: agree that the 'Incident Investigation' management measure should be re-named CAP.]~~is administered to ensure timely and effective corrective action.~~

m. ~~Audit and assessment deficiency data are analyzed and~~ [Comment: replace "trended" by "tracked"] ~~trended. Resultant reports, which indicate quality trends and the effectiveness of QA~~[Comment: "effectiveness of QA" is not a primary objective of audits and assessments management measure. Delete.]~~, are given to appropriate management for review, response, corrective action, and follow-up.~~

~~2. Audits: Audits are acceptable if, in addition to the acceptance criteria in 11.7.4.3.1 above,~~

a. ~~Audit personnel have no direct responsibility for the items they audit.~~

b. ~~Audits are led by appropriately qualified and certified audit personnel from the QA organization.~~ [Comment: but why just consider QA? A knowledgeable person in the Items relied on for safety would seem to be a paramount necessity.]

c. ~~Audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.~~

d. ~~Both technical and~~ [Comment: "QA programmatic audits are not required by the regulations for Part 70.]~~QA programmatic audits are performed to provide a comprehensive independent verification and evaluation of procedures and activities affecting the quality~~ [Comments: what constitutes the "quality" of an item relied on for safety?]~~of items relied on for safety.~~

e. ~~Auditing organizations schedule and conduct appropriate follow-up to ensure timely and effective corrective action.~~ [Comment: refer first to the CAP for consideration.]

3. ~~Internal Audits: Internal audits are acceptable if, in addition to the acceptance criteria in 11.7.4.3.2 above,~~

a. ~~Both technical and~~ [Comment: what is the regulatory requirement or justification for "QA programmatic audits"?] ~~QA programmatic audits are performed to verify and evaluate the applicant's internal QA, procedures, and items.~~

b. ~~Audit reports are issued to appropriate management on a timely basis~~

c. ~~Reports on the status of audit finding corrective actions are issued periodically to appropriate management~~

d. ~~During facility operation, internal audits address compliance with selected operating limits.~~

4. [Comment: NEI is particularly concerned with the implication that a Part 70 licensee must conduct audits of its suppliers. This is a new and unnecessary programmatic requirement. Delete.] ~~External Audits: External audits are acceptable if, in addition to the acceptance criteria in 11.7.4.3.2 above,~~

   a. ~~Both technical and QA programmatic audits are performed to verify and evaluate suppliers' QA, procedures, and items.~~

   b. ~~Audit reports are issued to appropriate internal and external management on a timely basis.~~

   c. ~~Reports on the status of audit finding corrective actions are issued periodically to appropriate internal and external management~~

5. ~~Assessments: Assessments are acceptable if, in addition to the acceptance criteria in 11.7.4.3.1 above, responsible management personnel or qualified, but not necessarily certified, personnel (designated by responsible management) with no direct responsibility for the items being assessed perform the assessments.~~

6. ~~Applicant's Provisions for Continuing Assurance: The applicant's provisions for continuing audits and assessments is acceptable if the submittal addresses reviews and updates of the description of its audits and assessments based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other changes that should be reflected in the description of its audits and assessments to keep it current.~~

11.4.3.~~6~~7 Corrective Action Program (Incident Investigations)

The reviewer should determine that the applicant's commitments to design and implement a CAP are ~~applicant's description and commitments in the application will be~~ acceptable if the reviewer finds reasonable assurance of the following:

- the applicant commits to design and implement a CAP to investigate abnormal facility events and unacceptable performance deficiencies in items relied on for safety and/or management measures

- the applicant commits to establish CAP policies, to provide a management organization to oversee CAP activities, and assign appropriately trained and qualified personnel to this function
- the applicant provides a description of CAP policies including:
  - (i) the overall plan (or approach) and methods to investigate abnormal events
  - (ii) the timing of investigations (generally to be initiated as soon as practicable) and scope of investigations (generally to be determined by the safety significance of the event and the complexity of the process involved)
  - (iii) methods to develop, implement and track appropriate corrective actions through their completion
  - (iv) methods to determine specific or root cause(s) and generic implications of abnormal events
  - (v) methods to document investigations and corrective actions that were implemented
  - (vi) process to enable "lessons learned" to other items relied on for safety and/or management measures

~~1. The applicant will establish~~ [Comment: replace the following text to read "…*will establish a process for investigating abnormal*…" Expecting a commitment to use "teams" is inappropriate.] ~~teams to investigate abnormal events that may occur during operation of the facility, to determine~~ [Comment: replace the following text to read: "…*the specific or root cause(s) and generic implications of the event*…"]~~the root cause(s) of the event, and to recommend corrective actions.~~ [Comment: delete the balance of this item (1) and replace with: "…*The scope and timing of the investigation will be determined by the safety significance of the event and the complexity of the process involved. Investigations shall, however, be initiated as soon as practicable, commensurate with the safety of the investigative personnel after the event has been brought under control.*"]~~These teams will be independent from the line function(s) involved with the incident under investigation. Investigations will begin within 48 hours of the abnormal event, or sooner, depending on the safety significance of the event. The failure log required for items relied on for safety should be reviewed as part of the investigation.~~

~~2. The applicant will monitor and document corrective actions through completion.~~

~~3.~~ [Comment: item (3) is far too prescriptive Delete the second sentence in its entirety and replace "…*maintain documentation so that*…" by "…*The applicant will apply "lessons learned" to future operation of the facility.*".]~~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 to accident sequences already considered in the ISA, and actions will be taken to ensure that the ISA includes 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, and that policy or procedure contains the following elements:~~

~~1. A documented plan for investigating an abnormal event.~~ [Comment: delete the next sentence. Not applicable to this section.]~~This plan is separate from any required Emergency Plan. The investigation of an abnormal event should commence as soon as~~ [Comment:

replace “possible” by “practicable”]possible, commensurate with the safety of the investigative team, after the event has been brought under control.

2. A description of the [Comment: replace “functions” by “minimum”]functions, qualifications, and responsibilities of the [Comment: delete “management”]management person who would lead the investigative team and those of the other [Comment: replace “team members” by “supporting personnel”.]team members, the scope of the team's authority and responsibilities, and assurance of cooperation of management.

3. [Comment: replace the first words of this sentence as follows: “…*Assurance the investigative personnel have authority to*…”]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: this is an issue for §11.4.3.7. Relocate.]

5. Guidance for the [Comment: replace “team” by “personnel”]team conducting the investigation on how to apply a reasonable, systematic, structured approach to determine [Comment: replace the following text to read: “…*the specific or root cause(s) and generic implications of the problem*…”]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. [Comment: erroneous statement. These reports will be maintained at the facility for NRC review.]Requirements to make available to NRC original reports of investigative teams, on request.

7. A system for monitoring to ensure completion of [Comment: insert the word “any” here.]appropriate corrective measures.

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 upon the following acceptance criteria:

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

2. The functions, responsibilities, and scope of authority of investigating [Comment: replace “teams” by “personnel”.]teams are documented in the plan.

3. Qualified internal or external investigators are appointed [Comment: change the balance of this sentence to read: “…*and should include at least one process expert and at least one individual trained in root cause analysis, as appropriate.”*]to serve on investigating teams. The teams will include at least one process expert and at least one team member will be trained in root cause analysis.

4. The applicant commits to prompt investigation of any abnormal events, and precursors to abnormal events (such as undetected failure of [Comment: replace “controls” by “items relied on for safety”]controls).

~~5. The investigation process and investigating~~ [Comment: replace "teams" by "personnel".] ~~team are independent of the line management and participants are assured of no retribution from participating in investigations.~~

~~6. A reasonable, systematic, structured approach is used to determine the~~ [Comment: replace the following text to read: "…*the specific or root cause(s) and generic implications of the abnormal events*…"] ~~root cause(s) of abnormal events.~~

~~7. Auditable records and documentation related to abnormal events, investigations, and root cause~~ [Comment: replace "analysis" by "analyses"] ~~analysis are maintained. For each abnormal event, the incident report should include a description, contributing factors,~~ [Comment: replace the following text to read: "…*the specific or root cause(s) and generic implications and findings*…"] ~~root cause analysis, and findings and recommendations. Relevant findings are reviewed with all affected personnel.~~

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

11.4.3.~~7~~8 Records Management

The ~~reviewer will find the~~ applicant's records management system should be ~~for records~~ acceptable if it satisfies the following criteria:

- the applicant commits to establish and maintain a records management system to collect, store and permit retrieval of facility information such as ISA documentation, maintenance records for items relied on for safety, CAP investigations and corrective actions, records of facility operational changes and information on items relied on for safety and their complementary management measures
- the applicant should outline policies pertaining to:
  - (i) records handling, storage, security and retrieval
  - (ii) identification of records to be maintained (to comply with regulatory requirements)
  - (iii) establishment of record retention time frames
  - (iv) technical specifications for record preparation and storage

- commitment to review the efficacy of the records management system and to revise it, as required, and to correct any identified deficiencies

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

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

~~3. Records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage.~~

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

5. The organization and procedures are in place to promptly detect and correct any deficiencies in the [Comment: "H&S" was consistently deleted from §11.3.8 and the old §11.7.4.3. Why does it persist here?]H&S records management system or its implementation.

Examples of records that should be included in the system are listed in Appendix B. [Comment: delete the balance of this paragraph. It provides specific procedural information that does not need to be included in a license application.]Records are categorized by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records. The procedures should: a) assign responsibilities for records management; b) specify the authority needed for records retention or disposal; c) specify which records must have controlled access and provide the controls needed; d) provide for the protection of records from loss, damage, tampering, or theft or during an emergency; and e) specify procedures for ensuring that the records management system remains effective.

For computer codes/computerized data relied on for safety, the applicant establishes procedure(s) for maintaining readability and usability of older codes/data as computing technology changes. This could include transcribing the older forms of information (e.g., punched cards or paper tapes) and codes for older computing equipment to contemporary computing media and equipment.

11.5 REVIEW PROCEDURES

[Comment: NEI recommends addition of some general statements at the beginning of §11.5 to be consistent with the style of the other 10 SRP chapters' Acceptance Criteria' sections. Additionally, general statements that are included in the discussion of each management measure (for example, soliciting additional information from the applicant to address any deficiencies, or stating for each maintenance measure "…*after determining that the application is acceptable…*" etc.) should be consolidated into this §11.5 introductory section.]

11.5.1 Acceptance Review

The primary reviewer should evaluate the application to confirm determine that 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.

In discussing a management measure, the applicant may elect to incorporate information from other sections of the application. This approach is acceptable, so long as the information is adequately cross-referenced. The reviewer may wish to consult any such referenced sections to confirm that the applicant's commitments to management measures are adequate and acceptable.

11.5.2 Safety Evaluation

The ~~After the~~ primary reviewer will perform a safety evaluation against the Acceptance Criteria in Section 11.4. Assessment of renewal or amendment applications should be coordinated with the facility's NRC inspector and should include review of inspection reports. Any concerns identified by the inspector should be addressed and resolved by the applicant. If, during the course of the safety evaluation, the primary reviewer determines a need for additional information, the primary reviewer should coordinate a request for additional information with the licensing project manager. After completing the safety review of each management measure, the primary staff reviewer, with assistance from the other reviewers, should prepare input for the Safety Evaluation Report (SER) as described in Section 11.6 using the acceptance criteria from Section 11.4.

~~determines that the application is acceptable for review in accordance with Section 11.5.1, above, the primary and secondary reviewers should perform a safety evaluation against the acceptance criteria described in Section 11.4~~. Review procedures for each criterion are discussed in the sections below.

[Comment: NEI has recommended deletion of sections of the SRP that treat QA separately from other management measures. See text for discussion.]

~~**11.5.2.1 Quality Assurance**~~

~~After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the primary staff reviewer should confirm that the applicant (and the applicant's principal contractors') QA commitments are consistent with other sections of the submittal. The secondary reviewer is also responsible for integrating the QA input into the Safety Evaluation Report (SER). The secondary reviewer should review the QA 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, maintenance, and configuration management are coordinated and that QA is an integral part of everyday work activities. The review should provide reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of QA and will make needed adjustments on a timely basis. The staff is to look for and measure the effectiveness of QA design, not just the existence of appropriate elements.~~

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

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

~~Staff Reviewers of SRP Chapters 3 through 15 should determine whether items within their areas of review that are relied on for safety are specified to be within the appropriate level of the applicant's QA program.~~

~~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. The staff or applicant may also propose license conditions to ensure QA meets the acceptance criteria. The review should result in a determination that there is reasonable assurance that the applicant's (and the applicant's principal contractors') QA will provide reasonable assurance that items relied on for safety will perform their safety function 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 SER Section 11.6.1 using the acceptance criteria from SER Section 11.4.1.~~

11.5.2.1~~2~~ Configuration Management

[Comment: there is no need to repeat the detailed acceptance criteria of §11.4.3.1 in this section. Concise equivalents are appropriate.]

The reviewer should confirm that the applicant's proposed CM provides reasonable assurance of compliance with the requirements of 10 CRR 70.72(a). The CM system should be capable of documenting and tracking all changes to items relied on for safety and management measures. The applicant's description of how the CM system is incorporated into the facility's organizational structure, descriptions of methods to establish and control documents, commitments to assign responsibility for CM to adequately trained personnel and to commit sufficient resources to enable the CM system to function effectively should be assessed. The reviewer must be convinced that the elements of the CM system are capable of maintaining consistency among the design requirements, physical configuration and facility documentation for all items relied on for safety and their management measures.

~~1. CM Policy Management~~

~~The primary reviewer should consider whether the CM plan acceptably states management commitments, gives the policy directive, and defines key responsibilities, terminology, and equipment scope.~~ [Comment: the conduct of immediate corrective actions should not be directed by the CM system. Rather, evaluation of unacceptable performance deficiencies and proposals for corrective actions should remain as a task of the CAP. Delete the following sentence.] ~~The method for initiating immediate corrective actions should be reviewed.~~ [Comment: the following sentence is not required. What is the "…*dependence on CM of items relied on for safety*…"? The function of the CM function is to retain in a current state the documentation that pertains to items relied on for safety. This does not constitute "dependency" between the two. Delete this sentence.] ~~The secondary reviewers should examine the ISA summary and the ISA as needed for the identification of dependence on CM of items relied on for safety. Appropriate interfaces both within the CM function and with~~ [Comment: what is inferred by "external organizations and functions"?] ~~external organizations and functions should be examined. In particular, the functional interfaces with~~ [Comment: replace "QA" by "management measures"] ~~QA, maintenance, and training (including qualification) should be examined. The reviewers should look for the applicant's identification of required databases and the rules for their maintenance.~~ [Comment: the following sentence should be deleted. Reviewers should not examine any procedures as

part of the application review.]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 statements of requirements proceeds logically from the design basis. The design basis is a set of facts, about the systems covered by CM, that has been reviewed and approved by appropriate authority within the organization. The reviewers should verify that specific personnel are assigned the responsibility for maintaining the design bases and requirements. [Comment: delete the following 2 sentences. They are overly prescriptive and unnecessary and go beyond what is to be included in a license application.]These may be the same personnel that maintain the ISA and controlled computer codes. The reviewers should verify that the items relied on for safety to be listed under CM are clearly defined in the requirements documents, along with the assignment of any grades or quality levels. The grades or quality levels, if specified, are based on the qualitative risk associated with postulated [Comment: insert the word "credible" before "accident".]accident sequences in which the items relied on for safety are required to function. This part of the review should be coordinated with the ISA primary reviewer. [Comment: the following sentence erroneously states that all items relied on for safety are specified in the ISA Summary. Delete these two following sentences.]The ISA summary specifies all items relied on for safety, and the applicant should have indicated in the ISA what level of CM attributes are applied to a particular item. However, in the ISA 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 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. This includes design requirements, the ISA, as-built drawings, specifications, all safety-important operating procedures, procedures involving training, [Comment: replace "QA" by "assurance measures"] QA, maintenance, audits and assessments, emergency 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. 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 ensure that the description of change control within the CM function commits to acceptable methods in place for: (a) the identification of changes in configurations relied on for safety; (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 QA. [Comment: the following sentence is redundant and

inappropriate for inclusion in license application guidance. This refers to ISA documentation maintained at the facility.] ~~Post-modification~~ [Comment: insert the word "functional" before "testing".]~~testing of hardware (or procedure drills or walk-throughs) may be done in conjunction with periodic equipment performance monitoring and normal maintenance functions.~~

~~5. Assessments~~

[Comment: the content of this item (5) could be better included into the "Audits and Assessment" management measure discussion.]~~The primary reviewer should ensure that both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function. The primary reviewer should ensure that all assessments and follow-ups are documented. These reports can provide a supporting basis for future changes. The primary reviewer should assure that assessments will include at least a sampling level of reviews of safety systems from design requirements through implementation.~~

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

[Comment: as NEI has mentioned earlier the requirement to address design reconstitution is inappropriate for inclusion in the CM system description. The following text discusses ISA requirements which have been addressed in SRP Chapter 3 and which do not need to be addressed again.] ~~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 SSCs. 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 looks for evidence that the applicant has considered system interactions, such as heavy overhead equipment falling on sensitive equipment below, the effect of leaks and electrical problems on nearby equipment, and difficulties of inspection and maintenance. The reviewer will seek evidence that the need for design bases reconstitution was investigated, that reconstitution was accomplished as necessary, and that new or revised documentation was properly incorporated into the CM function. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP.~~

11.5.2.2~~3~~ Maintenance

[Comment: the first sentence is redundant (provides absolutely no guidance on 'review procedures') and should be deleted.] ~~If the applicant's submittal is acceptable, the reviewer conducts the review of the applicant's maintenance function with respect to the acceptance criteria.~~ The reviewer will evaluate the applicant's description of how the maintenance function will coordinate and utilize 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.

An acceptable maintenance function ~~includes descriptions~~ [Comment: "demonstrations are not made in the SRP or license application.]~~and demonstrates~~ describes the applicant's ~~adequate~~ commitments to the following: corrective maintenance, preventive maintenance, surveillance/monitoring, and functional testing. [Comment: the following sentence has been consolidated into §11.5.1 and should be deleted here.] ~~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.~~

11.5.2.~~3~~4 Training and Qualification

[Comment: the first sentence is redundant (provides absolutely no guidance on 'review procedures') and should be deleted.] ~~After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 11.4, recognizing that the rigor and formality of a~~ [Comment: purge this section of SAT references such as the following: "*…systematic approach to training…*"] ~~systematic approach to training and the required personnel qualification may be graded to correspond to the hazard potential of the facility and to the complexity of the training needed.~~ 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 and in agreement with ongoing activities. The secondary reviewer should also integrate the personnel training and qualification input into the ~~Safety Evaluation Report (~~SER~~)~~.

[Comment: the reviewer was directed to do this at the beginning of the chapter. This sentence is repetitive and should be deleted.]~~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: the following sentence has been consolidated into §11.5.1 and should be deleted here.]~~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. The staff or applicant may also propose license conditions to ensure that the personnel training and qualification meet the acceptance criteria.~~ The review should result in a determination that there is reasonable assurance that the applicant's personnel training and qualification will provide for ~~ensure that only~~ properly trained and qualified personnel to ~~will~~ perform activities relied on for safety.

[Comment: the content of the following sentence has already been included in §11.5.2 and need not be repeated here. Delete.] ~~When the safety evaluation is complete, the primary 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.~~

11.5.2.~~4~~5 Procedures Program

[Comment: the substance of the first two sentences has been relocated to §11.5.2 and need not be repeated here.] ~~Upon acceptance of the application for review, the primary reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria listed in section 11.4. The reviewer will document in a safety evaluation report that the applicant has committed to the following:~~

The reviewer should confirm that the applicant's commitments to establish a process for the preparation, use and management control of written procedures applicable to items relied on for safety are adequate. The reviewer should examine proposed policies to write, approve, validate, distribute, implement and verify procedures. Finally, the reviewer should assess the proposed integration of the procedures and CM management measures, and the applicant's commitment to develop methods to periodically evaluate and update facility procedures, as required.

[Comment: there is no need to repeat verbatim the acceptance criteria in this section. Delete.]

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

~~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 items relied on for safety or other environmental, safety, and health concerns need not be controlled with the stringency applied to operating procedures or management control procedures associated with controls specified by the ISA summary. The applicability of less stringent procedure control should be specified to avoid misunderstandings in implementation.~~

~~4. Changes to operating, management control, or maintenance procedures are reviewed and approved~~ [Comment: the following phrase "…by an independent multi-disciplinary safety review team…" is unnecessarily prescriptive. Delete.]~~by an independent multi-disciplinary safety review team and controlled by the configuration management function.~~

~~5. The applicant includes a statement to follow approved procedures while processing licensed special nuclear material.~~

~~6. Procedures exist for the notification of operations personnel before and after maintenance is performed on items relied on for safety and activities are controlled by procedures.~~

[Comment: the substance of this sentence has been relocated to §11.5.2. Delete this sentence.] ~~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.~~

11.5.2.~~5~~6 Audits and Assessments

[Comment: this section is terribly verbose, repetitive of ideas that are expressed elsewhere and not especially enlightening to the reviewer. Its substance can be condensed into three sentences. The sentences are very confusing and the expression muddled.]

[Comment: the substance of the following sentence has been relocated to §11.5.2 and there is no need to repeat it here. Delete.]~~After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the primary reviewer will perform a safety evaluation against the acceptance criteria described in Section 11.4.~~ The review should determine whether the applicant has adequately planned for audits and assessments ~~to be accomplished~~ and whether necessary policies, personnel, procedures, and instructions will be in place to provide reasonable assurance that audits and assessments can be properly executed in a timely manner. [Comment: there is no need to conduct audits at the design phase of the plant. This is part of the ISA process. Delete.] ~~begin audits and assessments early; that is, during the design of items relied on for safety.~~

[Comment: the substance of the following two sentences has been relocated to §11.5.2 and there is no need to repeat it here. Delete.]~~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 items relied upon for safety.

[Comment: no substance in these sentences. Delete.]~~The secondary reviewer should confirm that the applicant's audit and assessment commitments are consistent with other sections of the submittal. The secondary reviewer is also responsible for integrating the audit and assessment input into the Safety Evaluation Report (SER).~~

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

[Comment: the substance of the following two sentences has been relocated to §11.5.2 and there is no need to repeat it here. Delete.]~~On the basis of its review, the staff may request that the applicant provide additional information or modify the application to meet the acceptance criteria in SRP Subsection 11.7.4. The staff or applicant may also propose license conditions to ensure audits and assessments meet the acceptance criteria.~~ The review should determine that ~~result in a determination that there is reasonable assurance that~~ the applicant's audits and assessments ~~of the applicant and the applicant's principal contractors will provide additional assurance that~~ of items relied on for safety will provide reasonable assurance that they will perform satisfactorily when required ~~in service and that activities relied on for safety will be performed satisfactorily~~.

[Comment: the substance of the following two sentences has been relocated to §11.5.2 and there is no need to repeat it here. Delete.] ~~The final step in the review is the primary reviewer's writing~~

~~of a Safety Evaluation Report (SER) input that summarizes the conduct of the review, identifies what material in the application forms the basis for a finding of reasonable assurance with respect to the regulatory requirements, and presents any recommendations for license conditions that are necessary to conclude that reasonable assurance is achieved.~~

[Comment: the substance of the following two sentences has been relocated to §11.5.2 and there is no need to repeat it here. Delete.] ~~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 section.~~

11.5.2.~~6~~7 Corrective Action Program (Incident Investigations)

The primary reviewer will verify that the applicant has described an adequate~~a comprehensive~~ incident investigation process ~~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 reviewer will consult with the NRC inspection staff and review any historical information regarding the adequacy of the applicant's incident investigation process. [Comment: the substance of the following sentence has been relocated to §11.5.2 and there is no need to repeat it here. Delete.] ~~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.~~

11.5.2.~~7~~8 Records Management

The reviewer will review the applicant's records management system to determine the adequacy of the policies [Comment: detailed procedures and practices need not be described in the license.], ~~procedures, and practices~~ for the collection, storage and retrieval of facility information such as ISA documentation, maintenance records, CAP investigations and actions, records of facility and operational changes and items relied on for safety.] 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. 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 records for controls or high risk accidents sequences.

[Comment: the substance of the following sentence has been relocated to §11.5.2 and there is no need to repeat it here. Delete.] ~~On the basis of the review, the reviewer may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria presented in Section 11.4 of this SRP.~~

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 outstanding issues, the reviewer documents the review as described above and includes a list of open issues that require resolution prior to the staff's position finding of reasonable assurance. For partial reviews, revisions, and process changes, the reviewer will use applicable sections of the acceptance criteria and the SER will be written to reflect what portions were not reviewed and the significance, if any. Upon completion of the review, NRC staff may impose temporary or one-time license conditions to authorize short duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.

The staff can document the evaluation as follows:

~~**11.6.1 Quality Assurance**~~

[Comment: as noted earlier, NEI recommends that separate treatment of QA is not required. Delete this section. As an aside, why does the NRC cite the 19 NQA-1 acceptance criteria in §11.4.3, but only reference eight in this section. Are the remaining QA criteria of lesser concern?] ~~*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 that the adequacy of the applicant's~~ [Comment: there are no regulatory requirements for a QA program. Delete this terminology.]~~QA program, as applied to items relied on for safety, for design, construction, operations] *the NRC staff has concluded that the applicant has adequately described its~~ [Comment: there are no regulatory requirements for a QA program. Delete this terminology.]~~*QA program (and the* [Comment: there are no regulatory requirements for a QA program. Delete this terminology.]~~*QA program of its principal contractors). The staff concludes further that:*~~

~~*1. The applicant has established and documented a commitment for an organization responsible for developing, implementing, and assessing the management controls for ensuring safe facility operations in accordance with the criteria in Section 11.4 of this SRP.*~~

~~*2. The applicant has established and documented a commitment for QA, and the administrative controls for staffing, performance, assessing findings, and implementing corrective actions are in place.*~~

~~*3. The applicant has developed a process for preparation and control of written administrative plant procedures, including procedures for evaluating changes to procedures, items, tests, and processes relied on for safety. A process for review, approval, and documentation of procedures will be implemented and maintained.*~~

~~*4. The applicant has established and documented a surveillance, test, and inspection program to ensure satisfactory in-service performance of items relied on for safety. Specified standards or criteria and testing steps have been provided.*~~

~~*5. Periodic independent audits are conducted to determine the effectiveness of the management controls. Management controls 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 controls have been provided for evaluation of the effectiveness of training against predetermined objectives and criteria.*~~

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

~~*8. QA covers the items relied on for safety, as identified in the ISA summary, and controls are established to prevent hazards from becoming pathways to higher risks and accidents.*~~

~~*Accordingly, the staff concludes that the applicant's*~~ [Comment: there are no regulatory requirements for a QA program. Delete this terminology.]~~*QA program (and the*~~ [Comment: there are no regulatory requirements for a QA program. Delete this terminology.]~~*QA program of its principal contractors) meets the requirements of 10 CFR Part 70 and provide reasonable assurance of protection of public health and safety and of the environment.*~~

11.6.1~~2~~ Configuration Management

The staff has reviewed the Configuration Management (CM) function for (name of facility) according to Section 11of the Standard Review Plan. [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 documenting ~~*managing*~~ *changes to* ~~*in procedures, facilities, activities, and equipment for*~~ *items relied on for safety* ~~*systems important to safety*~~*. The applicant's proposed CM provides reasonable assurance of compliance with the requirements of 10 CFR 70.72(a). The CM system is capable of documenting and tracking all changes to items relied on for safety and management measures. The applicant's description of how the CM system is incorporated into the facility's organizational structure, descriptions of methods to establish and control documents, commitments to assign responsibility for CM to adequately trained personnel, and commitment of sufficient resources to enable the CM system to function effectively are assessed to be acceptable. The applicant's CM system should be capable of maintaining consistency among the design requirements, physical configuration and facility documentation of all items relied on for safety and their management measures.* [Comment: the following sentence pertains to the 10 CFR 70.72(a) facility (as opposed to documentation) change process. It should be deleted.] ~~*Management level policies and procedures, including an analysis and independent safety review of any proposed activity involving systems important to safety, are described that will ensure that the relationship 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.*~~

[Comment: there is again no need to reproduce again these detailed comments on the CM system. Delete.]

~~*1. CM Management*~~

~~*The organizational structure, procedures, and responsibilities necessary to implement configuration management 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 adequately describe systems important to safety.*~~

~~*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 items relied on for safety systems important to safety. This includes appropriate CM controls to assure configuration verification, functional tests, and accurate documentation for equipment or procedures that have been modified.*~~

11.6.2~~3~~ Maintenance

The applicant has committed to maintenance of items relied on for safety. The applicant's maintenance commitments contain the basic elements to provide reasonable assurance of their [Comment: replace 'ensure' by "reasonable assurance".] ~~*ensure*~~ *availability and reliability: corrective maintenance, preventive maintenance, functional testing, equipment calibration, work control, and management measures for items relied on for safety. The applicant's maintenance function is proactive, using maintenance records, preventive maintenance records, and surveillance tests to analyze equipment performance and to seek the root causes of repetitive failures.*

The surveillance activities described in this section of the application provide reasonable assurance that ~~*ensure the*~~ [Comment: surveillance activities can not ensure the validity of the "*ISA examination*" (whatever that is).] ~~*validity of the ISA by examination and calibration and testing of the*~~ *equipment that monitors items relied on for safety will be adequately calibrated and tested.* ~~*process safety parameters and acts to prevent or mitigate accident consequences.*~~

[Comment: the following paragraph contains far too detailed information that is inappropriate for inclusion in the application. Delete.] ~~*The maintenance function: (1) is based on approved procedures; (2) employs work control methods that properly consider personnel safety, awareness of facility operating groups,*~~ [Comment: replace "quality assurance" by "management measures".]~~*quality assurance, and the rules of configuration management; (3) links items relied on for safety requiring maintenance to the ISA summary;*~~ [Comment: fuel cycle facilities do not have the data required to establish reliability goals. Delete item (4).]~~*(4) justifies the preventive maintenance intervals in the terms of equipment reliability goals; (5) provides for training that emphasizes importance of ISA or ISA summary identified controls, regulations, codes, and personal safety; and (6) creates documentation that includes*~~ [Comment: delete "detailed"] ~~*detailed records of*~~ [Comment: delete "all"]~~*all surveillance, inspections, equipment failures, repairs, and replacements.*~~

The staff concludes that the applicant's maintenance functions meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public are protected.

[Comment: the substance of this paragraph has been included in §11.5.2 and need not be repeated here. Delete.] ~~In cases where the SER is drafted in advance of resolving all outstanding maintenance issues, the reviewer documents the review as described above and includes a list of open issues that require resolution prior to the staff's position finding of reasonable assurance. For partial reviews, revisions, and process changes, the reviewer will use applicable sections of the acceptance criteria and the SER will be written to reflect what portions were not reviewed and the maintenance significance, if any. Upon completion of the review, NRC staff may impose temporary or one-time license conditions to authorize short duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.~~

11.6.~~3~~4 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 that (1) satisfy regulatory requirements, (2) are consistent with the guidance in this SRP, and (3) are acceptable.*

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

11.6.~~4~~5 Procedures Program

The application has described a suitably detailed process for the development, approval, and implementation of procedures. Special attention has been paid to items relied on for safety. ~~*, as well as to systems important to the health of plant workers and the public and to the protection of the environment.*~~ [Comment: deleted text is redundant.]

11.6.56 Audits and Assessments

Based on its review of the license application, [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] *the NRC staff has concluded that the applicant has adequately described its audits and assessments program. The staff has reviewed the applicant's plans for the conduct of audits and assessments and finds them acceptable.*

The staff concludes that the applicant's plans for audits and assessments meets the requirements of 10 CFR Part 70 and provides reasonable assurance of protection of (1) the health and safety of the public and workers and (2) the environment.

11.6.67 Corrective Action Program (Incident Investigations)

The applicant has committed to incorporating a corrective action program into the facility's and established an organizational structure responsible for performing incident investigations of abnormal events that may occur during operation of the facility, determining the specific or root cause(s) and generic implications of the event, and recommending corrective actions for providing reasonable assurance of for ensuring a safe facility and safe facility operations in accordance with the acceptance criteria of Section 11 Subsection 11.4 of the SRP.

The applicant has committed to the monitoring, and documentation and tracking ing 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 CAP or incident investigation process complies with applicable NRC regulations and is adequate.

11.6.78 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 health and safety (H&S) aspects of the facility and its operations, and will be able to retrieve the information in readable form and in a timely fashion for the designated lifetimes of the records. ; (2) will provide a records storage area(s) with the capability to protect and preserve H&S 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 ensure that any deficiencies in the H&S records management system or its implementation will be detected and corrected in a timely manner.

11.7 REFERENCES

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

Proposed Revision to Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* as revised.

[Comment: this reference is totally inappropriate and objectionable for Part 70 licensees. Delete.] ~~NUREG-1324, *Proposed Method for Regulating Major Materials Licensees*, Section 3.2.6, Configuration Management, U.S. Nuclear Regulatory Commission, 1992.~~

DOE-STD-1073-93, *DOE Standard: Guide for Operational Configuration Management Function,* Parts I and II, Department of Energy

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

Code of Federal Regulations, Title 29, Part 1910.119, *Process Safety Management of Highly Hazardous Chemicals*, U.S. Government Printing Office, Washington D.C., as revised.

[Comment: this is a reference that provides guidance for nuclear power reactors and is totally inappropriate for Part 70 licensees. Delete.]~~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.~~

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.

[Comment: this is a reference that provides guidance for nuclear power reactors and is totally inappropriate for Part 70 licensees. Delete.] ~~U.S. Nuclear Regulatory Commission, Inspection Procedure 88062, *Maintenance and Inspection*, dated January 16, 1996.~~

[Comment: this is a reference that provides guidance for nuclear power reactors and is totally inappropriate for Part 70 licensees. Delete.] ~~U.S. Nuclear Regulatory Commission, Inspection Procedure 88025, *Maintenance and Surveillance Testing*, dated May 23, 1984.~~

[Comment: this is a reference that provides guidance for nuclear power reactors and is totally inappropriate for Part 70 licensees. Delete.] ~~NUREG-1220, Rev.1, *Training Review Criteria and Procedures*, U.S. Nuclear Regulatory Commission, January 1993.~~

[Comment: this is a reference that provides guidance for nuclear power reactors and is totally inappropriate for Part 70 licensees. Delete.]~~U.S. Nuclear Regulatory Commission, NUREG/CR-4616, *Root Causes of Component Failures Program: Methods and Applications*, December 1986.~~

[Comment: this is a reference that provides guidance for nuclear power reactors and is totally inappropriate for Part 70 licensees. Delete.] ~~U.S. Nuclear Regulatory Commission, NUREG/CR-5665, *A Systematic Approach to Repetitive Failures*, February 1991.~~

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

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

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

ISO 9000 quality management standard.

ANSI/ISO/ASQ 9000 quality systems standard.

International Atomic Energy Agency 1995 Safety Guide 50-SG-Q1, “Establishing and implementing a Quality Assurance Program;”

DOE,“Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C,” September 1997 draft.

Appendix A: CHECKLIST FOR PROCEDURES

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

[Comment: NEI recommends addition of several procedures to this checklist, as well as deletion of others that are not necessary, inapplicable or covered elsewhere in the license application.]

1. Management Control Procedures:

   Training
   Audits and Assessments
   Incident Investigations
   Records Management
   Configuration Management
   Quality Assurance
   ~~Equipment control (lockout/tagout)~~ [Comment: Delete. Covered elsewhere]
   ~~Shift turnover~~ [Comment: Delete. Not needed.]
   ~~Work Control~~ [Comment: Delete. Covered elsewhere]
   Management control
   Industrial Safety
   Nuclear Materials Management
   Procedure management
   Nuclear criticality safety
   Fire protection
   Radiation protection
   Radioactive waste management
   Maintenance
   Environmental protection
   Chemical process safety
   Operations
   ~~Calibration control~~ [Comment: this procedure is covered under "maintenance". Delete.]
   ~~Preventive maintenance~~ [Comment: this procedure is covered under "maintenance". Delete.]

2. Operating Procedures

   a. System of p~~P~~rocedures that a~~A~~ddresses Startup, Operation, Shutdown Control of Process Operations and Recovery After a Process Upset

      Process Operations
      Ventilation Systems
      Criticality alarm~~s~~ System
      Shift routines, shift turnover and operating practices
      Decontamination operations
      ~~Uranium recovery~~ [Comment: Included in "process operations" above. Delete.]
      Plant Utilities (air, other gases, cooling water, fire water, steam)

Temporary changes in operating procedures

b. Abnormal Operation/Alarm Response:

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

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

Repairs and preventive repairs of items relied on for safety
Testing of criticality alarm units
Calibration of items relied on for safety
HEPA filter maintenance
Functional testing of items relied on for safety
Relief valve replacement/testing
Surveillance/monitoring
Pressure vessel testing
~~Non-fired pressure vessel testing~~ [Comment: Delete as covered above.]
Piping integrity testing
Containment device testing

4. Emergency Procedures:

Accidental Nuclear ~~Response to a~~ criticality
Hazardous ~~process~~ chemical releases (including UF_6) and spills
Fires
Loss of Power or Water

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 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. Furthermore, 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 ~~structures, systems, or components,~~ [Comment: change to ensure consistency in usage of defined terminology.] relied on for safety as specified by the facility configuration management system

Records of facility changes and associated integrated safety analyses, as specified by the facility c

Safety analyses, reports~~,~~ and assessments

~~Records of s~~Site characterization measurements and data

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

Procurement records, including specifications for items relied on for safety

2.0 Organization and Administration

Administrative procedures with safety implications

Change control records for material control and accounting program

Organization charts, position descriptions~~,~~ and qualifications records

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

Management Measure ~~Quality Assurance~~ records

2.0 Organization and Administration (continued)

Safety inspections, audits, assessments~~,~~ and investigations

Safety s~~S~~tatistics and trends

3.0 Integrated Safety Analysis

4.0 Radiation Safety

Personnel Bioassay data

Personnel Exposure records

Radiation protection (and contamination control) records

Radiation protection training records

Radiation work permits

5.0 Nuclear Criticality Safety

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

Nuclear criticality safety analyses

Nuclear criticality safety evaluations

~~Records pertaining to n~~Nuclear criticality safety inspections, audits, investigations~~,~~ and assessments

~~Records pertaining to n~~Nuclear criticality safety incidents, unusual occurrences~~,~~ or accidents

~~Records pertaining to nuclear criticality safety analyses~~

6.0 Chemical Safety

Chemical process safety procedures and plans

~~Records pertaining to c~~Chemical process inspections, audits, investigations~~,~~ and assessments

Diagrams, charts~~,~~ and drawings

~~Records pertaining to c~~Chemical process safety incidents, unusual occurrences, and~~or~~ accidents

Chemical process safety reports and analyses

Chemical process safety training

7.0 Fire Safety

Fire Hazards Analys~~e~~is

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

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

~~Records pertaining to f~~Fire protection training and retraining of emergency response teams

Pre-fire emergency plans

8.0 Emergency Management

Emergency plan~~(~~s~~)~~ and procedures

Comments on emergency plans from outside emergency response organizations

Emergency exercise~~drill~~ records

Memorand~~a~~um of understanding with outside emergency response organizations

~~Records of a~~Actual emergency response events

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

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

9.0 Environmental Protection

Environmental release and monitoring records

Environmental Report and Supplements to the Environmental Report, as applicable

10. 0 Decommissioning [Comment: a section on Decommissioning should not be given as an example in a license application evaluation manual. Where will the reviewer find "final survey data"? Where will decommissioning procedures be detailed? Delete all references except those pertaining to the DFP.]

~~Decommissioning records~~

Financial assurance documents

Decommissioning cost estimates

~~Site characterization data~~

~~Final survey data~~

Decommissioning procedures

11.0 Management Measures ~~Control Systems~~

[Comment: delete this section on QA]
~~11.1 Quality Assurance~~

~~- audit and assessment records~~
~~- inspection records~~
~~- test records~~
~~- corrective action records~~

11.~~2~~1 Configuration Management

~~-~~ s~~S~~afety analyses, reports~~,~~ and assessments that support the physical configuration of process designs, and changes to those designs
~~-~~ v~~V~~alidation and verification of records for computer software used for safety analys~~e~~i~~s~~s or MC&A [Comment: for uniformity, should define this acronym.]
- ISA documents, including process descriptions, plant drawings and specifications, ~~purchase specifications for items relied on for safety~~ [Comment: far too prescriptive]
- approved, current operating procedures ~~and emergency operating procedures~~ [Comment: already addressed in SRP Chapter 9]

11.~~2~~3 Maintenance

- ~~failure log (required by 70.62)~~ [Comment: see NEI letter on 10 CFR 70 changes]
~~-~~ p~~P~~reventive maintenance ~~records~~, including trending and root cause analys~~e~~i~~s~~
~~-~~ c~~C~~alibration and testing data for items relied on for safety
~~-~~ c~~C~~orrective maintenance ~~records~~

11.34 Training and Qualification

- pPersonnel training and qualification records
- pProcedures

11.45 Procedures

- sStandard operating procedures
- fFunctional test procedures

11.56 Audits and Assessments
- aAudits and assessments of safety and environmental activities

11.67 Corrective Action Program (Incident Investigations)

- iInvestigations reports
- cChanges recommended by investigation reports, how and when implemented
- sSummary of reportable events for the term of the license
- iIncident investigation policy

11.78 Records Management

- pPolicy
- mMaterial storage records
- records of rReceipt, transfer and disposal of radioactive material

PROPOSED REVISION OF SRP (NUREG-1520) CHAPTER 11
INCORPORATING RECOMMENDATIONS
OF THE
NUCLEAR ENERGY INSTITUTE
(NOVEMBER, 1999)

11.0 MANAGEMENT MEASURES

11.1 PURPOSE OF REVIEW

Management measures are functions that are performed by a licensee, generally on a continuing basis, to provide reasonable assurance that items relied on for safety are available and reliable to perform their functions when needed. The phrase "available and reliable" as defined in 10 CFR 70.4 means that items relied on for safety will perform their intended safety function when needed. A licensee is required by 10 CFR 70.62(a) to establish and implement such management measures to provide continuing assurance of compliance with the performance requirements of 10 CFR 70.61. Management measures are applied to both the administrative and engineered safety controls identified in the ISA Summary that are required to prevent or mitigate the consequences of credible, postulated accident sequences. The robustness of a management measure may be graded in the same way that items relied on for safety may be graded according to their importance to safety. Management measures include, for example, configuration management, maintenance, personnel training and qualifications, procedures, audits and assessments, design and oversight of a corrective action (or incident investigation) program and records management, together with application of appropriate levels of quality assurance to each .

Evaluation of an applicant's management measures is necessary to provide reasonable assurance that the applicant has committed to develop and apply adequate measures and controls to both items relied on for safety (engineered safety controls) and activities relied on for safety (administrative safety controls). The evaluation will examine the applicant's proposed management measures and policies for their implementation. The review should also determine whether the measures are applied to the items relied on for safety commensurate with their importance to safety (graded approach). The evaluation will conclude whether the proposed management measures provide reasonable assurance that the regulatory requirements of 10 CFR 70.62(d) ('Management Measures') will be satisfied.

11.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Quality Assurance: Quality Assurance Engineer
Configuration Management: Primary ISA Reviewer, Quality Assurance and Records Management Reviewers
Maintenance: Criticality, Chemical, Fire, Radiation Protection and Environmental Reviewers
Training and Qualification: Training Specialist, Quality Assurance, or Human Factors Reviewers

Procedures: Radiation Protection, Criticality and Fire Protection Engineers, Fuel Cycle Facility Inspector
Audits and Assessments: Quality Assurance Reviewer
Incident Investigations: None
Records Management: Quality Assurance Engineer

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

11.3 AREAS OF REVIEW

The evaluation of management measures should focus on their description, their applicability to items relied on for safety and their capability (or suitability) for meeting the regulatory requirements of 10 CFR 70.62(a). The evaluation should address the following three topics:

(4) *Management Measures*: the reviewer should examine the acceptability of an applicant's commitments to develop, implement and update, when required, management measures applicable to the facility's items relied on for safety (including the activities of personnel that are relied on for safety). The applicant may elect to grade the robustness or comprehensiveness of individual management measures commensurate with the relative importance to safety of an item relied on for safety to which they are applied.

(5) *Description of Management Measures*: the reviewer should examine each management measure or combination of measures proposed by an applicant to evaluate its suitability to provide reasonable assurance that an item relied on for safety will be available and reliable when required. The following features of each management measure should be examined:

(vii) purpose, safety controls to which it applies (administrative control, augmented administrative control, passive engineered control, active engineered control), description of functions
(viii) implementation approach and strategy
(ix) methods of safety grading its application to items relied on for safety
(x) how application of the management measure will provide the necessary level of "continuing reasonable assurance" to an item relied on for safety
(xi) verification and validation methods of the management measure
(xii) interrelations of individual management measures

(6) *Specific Management Measure Evaluation*: guidance is provided in SRP Chapter 11 for evaluation of seven management measures that are typically applied to fuel cycle facility operations. An applicant should generally be expected to address each of these seven management measures, although additional management measures proposed by the applicant should be considered acceptable if they are judged capable of providing the reasonable assurance that an item relied on for safety will be available and reliable when required.

Prior to conducting the evaluation, the reviewer should first consult the ISA Summary (SRP Chapter 3 - '*Integrated Safety Analysis (ISA) Commitments and ISA Summary*') to gain familiarity with:

(v) items relied on for safety for higher-risk accident sequences (including activities of personnel relied on for safety)
(vi) any safety-grading applied to such items relied on for safety
(vii) commitments to implement and maintain items relied on for safety in a functional state, and
(viii) management measures to be applied to each item relied on for safety

The reviewer should understand that 10 CFR 70.62(a) and (d) permit, but do not require, an applicant to grade management measures commensurate with the reduction in risk attributable to the safety control to which the measures are to be applied.

The applicant will be expected to apply appropriate levels of quality assurance (QA) to each management measure and should explain how such QA measures will be applied. For example, QA applied to maintenance may be reflected in the choice of maintenance instrumentation, procedures and frequency of equipment calibration or selection of equipment capable of measuring a parameter over a process' expected operating range.

The reviewer should examine an applicant's commitments for each of the following management measures:

11.3.1 Configuration Management

This review should confirm that the applicant has committed to develop and implement a configuration management (CM) system that is consistent with the requirements of 10 CFR 70.72(a). The purpose of this system is to document and track all changes to items relied on for safety and associated management measures. It will also assure consistency among the facility design and operational requirements, the physical configuration, and the facility documentation.

Specific areas of review should include:

- commitment to establish a CM system to maintain current facility documentation on items relied on for safety and to accurately track all safety-significant changes to such items
- commitment to maintain current documentation on management measures to be applied to items relied on for safety (e.g. training, maintenance) and to accurately track all safety-significant changes to such management measures
- commitment to incorporate a CM system into the facility's organization structure responsible for CM, to prepare written CM procedures and to assign personnel responsible for CM
- policies to implement the CM system, descriptions of CM activities, organizational structure
- description of methods to establish and control documents
- commitment that all changes to procedures, facilities, operations and equipment pertaining to items relied on for safety are recorded in the facility's documentation (including the results of ISA evaluations and analysis by the 10 CFR 70.72 facility change mechanism)
- commitment to maintain consistency among design requirements, physical configuration and facility documentation of all items relied on for safety

11.3.2 Maintenance

The review should confirm that the applicant has committed to develop and implement a maintenance function for engineered safety controls. The applicant should describe how items relied on for safety are inspected, calibrated, tested and maintained, to the level commensurate with the risk, to provide reasonable assurance of their ability to perform their safety functions when required.

Specific areas of review should include:

- commitment to provide adequate maintenance and surveillance of items relied on for safety, including adequate inspection, calibration and testing commensurate with the level of risk to be addressed by the items relied on for safety
- commitment to develop basic components of a maintenance program including one or more of the following components: corrective maintenance, preventive maintenance, surveillance/monitoring and functional testing
- commitment to base the maintenance activities on appropriate written procedures, personnel safety, appropriate training and documentation (records of inspection, surveillance, replacements, etc.)

11.3.3 Training and Qualifications

Assessment of the applicant's training and qualification system should incorporate the following:

- commitment to implement a training program to make personnel understand and recognize the importance of items relied on for safety and to qualify them to perform activities pertaining to items relied on for safety
- commitment to provide training in items relied on for safety that is commensurate with their importance to risk reduction
- commitment to develop a training program that includes: an organization and management structure, program development, on-the-job and/or classroom instruction, evaluation of trainees and training effectiveness, qualification of personnel and provision to evaluate the continuing effectiveness of the training system
- commitment that personnel will have the knowledge and skills necessary to operate and maintain the facility and items relied on for safety

11.3.4 Procedures Program

The review should examine the applicant's process for the preparation, use and management control of written procedures. This should include the basic elements of identification, development, verification, review and comment resolution, approval, validation, issuance, change control, and periodic review. The applicant will 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 item relied on for safety. Procedures of this type include required actions to protect against nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection; and,

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

The review will not encompass examination of specific, detailed operating and management control procedures, but rather just the applicant's commitment and proposed methodology to prepare, distribute and maintain current such procedures. Detailed procedures will be maintained at the facility and do not constitute part of the license application.

Specific areas of review should include:

- commitment to develop, approve and implement operating procedures and management control procedures applicable to items relied on for safety
- policies and methodologies for procedures pertaining to items relied on for safety and their management measures: identification of the need for a procedure, writing of procedures, approval of procedures (engineering and managerial approval processes), validation and verification of procedures, implementation and distribution of procedures, and procedure revision and re-issuance policies
- identification of items relied on for safety and management measures for which procedures are required
- policies to integrate the procedure and CM management measures
- commitment to develop methods and to verify, validate and periodically evaluate facility procedures and distribute them to appropriate plant personnel

11.3.5 Audits and Assessments

The review should determine that the applicant has committed to implement a system of audits and assessments. Audits are designed to monitor compliance with regulatory requirements and license commitments, and assessments determine the effectiveness of management measures to provide reasonable assurance of the availability and reliability of items relied on for safety when required to perform their intended safety functions.

Specific areas of review should include:

- commitment to design and implement a system of internal audits and independent assessments of items relied on for safety
- methods to conduct audits and assessments, to establish their frequencies of performance (based on safety grading of items relied on for safety) and their structure
- commitment to use appropriately qualified personnel to conduct audits and assessments
- commitment to use and analyze audit and assessments results, to report them to facility management and to refer any identified, unacceptable performance deficiencies to the facility corrective action program for resolution

11.3.6 Corrective Action Program (Incident Investigations)

The review should determine that the applicant has committed to design and implement a Corrective Action Program (CAP) to investigate abnormal events and to undertake corrective actions to items relied on for safety and/or management measures, if required.

Specific areas of review should include:

- commitment to develop and implement a CAP to investigate abnormal facility events and unacceptable performance deficiencies related to items relied on for safety and/or management measures
- commitment to establish CAP policies, to incorporate these policies into the facility's management organization to oversee CAP activities and to assign appropriately trained and qualified personnel to this function
- description of CAP policies:
    (v) the approach and methods to investigate abnormal events
    (vi) methods to design, track and complete appropriate corrective actions
    (vii) methods to determine specific or root cause(s) and generic implications of abnormal events
    (viii) process to enable "lessons learned" to other items relied on for safety and/or management measures

11.3.7 Records Management

The review should determine that the applicant has committed to develop and implement a records management system to collect, store and permit retrieval of facility information such as ISA documentation, maintenance records, CAP investigations and actions, records of facility and operational changes, reports to the NRC and both items relied on for safety and their complementary management measures.
Specific areas of review should include:

- commitment to establish and maintain a records management system
- policies pertaining to:
    (iv) records handling, storage and retrieval
    (v) identification of records to be maintained (for example, training, audits of items relied on for safety, CAP results)
    (vi) establishment of record retention time frames
- commitment to periodically review the efficacy of the records management system and to revise it, as required, and to correct any identified deficiencies

11.4 ACCEPTANCE CRITERIA

The reviewer should find the applicant's management measures information acceptable if it provides reasonable assurance that the following acceptance criteria are adequately addressed and satisfied.

11.4.1 Regulatory Requirements

10 CFR 70.62(d), *Management Measures* requires an applicant to establish management measures for application to engineered and administrative controls and control systems that are

identified as items relied on for safety pursuant to §70.61(e) so they are available and reliable to perform their function when needed

11.4.2 Regulatory Guidance

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

ANSI/ISO/ASQ 9000 series quality management standards.

International Atomic Energy Agency 1995 Safety Guide 50-SG-Q1, "Establishing and Implementing a Quality Assurance Program;" DOE's September 1997 draft "Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C."

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.

11.4.3 Regulatory Acceptance Criteria

11.4.3.1 Configuration Management

The applicant's CM system should be acceptable if it satisfies the following criteria.

- the applicant commits to establish a CM system consistent with the regulatory requirements of 10 CFR 70.72(a)
- the applicant commits to maintain current facility documentation on items relied on for safety and to accurately track all safety-significant changes to such items
- the applicant commits to maintain current documentation on management measures to be applied to items relied on for safety (e.g. training, maintenance) and to accurately track all safety-significant changes to such management measures
- the applicant commits to prepare written policies and procedures to implement CM
- the applicant outlines how the CM system is incorporated into the facility's organizational structure, describes CM activities, specifies the documents to which the CM function will apply (e.g. drawings, PI&Ds, design and procurement specifications, engineering analyses, operating procedures, training records, maintenance records, etc.), and describes technical management review and approval procedures
- the applicant describes how the CM function maintains consistency among the design requirements, the physical configuration and the facility documentation, especially as they apply to items relied on for safety
- the applicant describes a process to document and record all changes to procedures, facilities, operations, the ISA Summary and other ISA-related documentation and equipment pertaining to items relied on for safety, including necessary authorizations
- the applicant commits to periodically assess, in accordance with the Audit and Assessment management measure (§11.4.3.5) the efficacy of the CM system, to identify possible improvements and to correct any safety-significant deficiencies

11.4.3.2 Maintenance

The applicant's maintenance function should be acceptable if it satisfies the following criteria:

- the applicant commits to design and implement an adequate maintenance system for items relied on for safety that will provide for levels of inspection, calibration and testing commensurate with the safety significance of the item relied on for safety
- the applicant describes an organizational structure for the maintenance function, commits to appoint qualified personnel to take responsibility for this activity and who will develop, approve and modify, as required, maintenance procedures
- the applicant commits to provide sufficient resources to enable the maintenance activities to be properly executed
- the applicant commits to prepare written maintenance policies and procedures for each component of the maintenance system
- the applicant identifies those items relied on for safety to which the maintenance function will apply and describes the methods used to establish differing frequencies, if any, for maintenance of different items relied on for safety
- the applicant describes policies for each maintenance activity including, for example, task work instructions, notification requirements, issuance of maintenance work permits, procedures for use of compensatory measures during the repair or replacement of a safety-significant items relied on for safety, etc.
- applicant describes a process to record the results of all maintenance activities (in coordination with the Records Management management measure), to document all safety-significant referrals made to the CAP and to management, and any recommendations for changes to the design or operation of items relied on for safety
- the applicant describes the basic components of the maintenance program that may include one or more of the following components: surveillance and monitoring, preventive maintenance, corrective maintenance, and functional testing. For each applicable component, the applicant should provide the following information:

(5) Preventive Maintenance
- commitment to conduct preplanned and scheduled periodic refurbishing and/or overhauls or items relied on for safety
- description of preventive maintenance activities including, for example, instrumentation calibration and testing, methods used to establish the frequency of preventive maintenance activities and the scope (detail) of such activities

(6) Corrective Maintenance
- commitment to promptly perform corrective actions or repairs on items relied on for safety
- description of the approach and methods for planning and implementing repairs to items relied on for safety

(7) Surveillance and Monitoring
- commitment to design and implement a program to survey and monitor the performance of items relied on for safety
- description of the components of the surveillance and monitoring program including methods used to establish the frequency of such inspections for items relied on for safety having different degrees of safety importance, activities and reporting procedures

(8) Functional testing
    - commitment to evaluate the potential impact of all corrective or preventive maintenance, or calibration of, items relied on for safety, and subsequently perform the appropriate post-maintenance functional testing to provide reasonable assurance that the maintenance activity did not adversely impact the reliability of the control
    - commitment to perform functional testing after initial installation, and prior to implementation of, new items relied on for safety
    - description of functional testing procedures, documentation of test results and the schedule of their performance

- commitment to refer to the facility's CAP any unacceptable performance deficiencies identified in the maintenance activities to identify specific or root cause(s) and generic implications to eliminate or minimize the possibility of their recurrence
- commitment to minimize the unavailability of items relied on for safety which are undergoing preventive or corrective maintenance and to implement appropriate compensatory measures as required during such periods of unavailability
- the applicant commits to periodically assess, in accordance with the Audit and Assessment management measure (§11.4.3.5), the efficacy of the maintenance system, to identify possible improvements and to correct any safety-significant deficiencies

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:

- the applicant commits to adequately train plant personnel in the start-up, operation and maintenance of the facility to provide reasonable assurance that any personnel whose activities are identified in the ISA Summary to be relied upon for safety will be capable of performing such activities promptly and effectively
- the applicant outlines an organizational structure to plan, direct and evaluate training, assigns responsibility for training to appropriately qualified individuals, describes how training programs and their contents will be developed, outlines the training needs for different positions or activities for which the required performance is relied on for safety and explains what measures will be used to judge the success of training programs
- the applicant describes any grading of training programs that may have been implemented to make the training thoroughness and rigor commensurate with the functional responsibility and importance to safety of a position
- the applicant describes the minimum education and qualifications for personnel whose activities are relied on for safety
- the applicant commits to use training personnel who are knowledgeable in training methods, in the facility's safety programs, and in the facility's items relied on for safety described in the ISA Summary
- the applicant commits to clearly define the function, responsibility, authority and accountability of personnel involved in the management, supervision and conduct of training

- the applicant commits to implement and document procedures so that training is conducted reliably and consistently, and that training in activities relied on for safety uses well-organized and current safety information (maintained by the facility's CM)
- the applicant commits to establish and maintain training records appropriate to judge an individual's fitness and capability to perform activities relied on for safety
- the applicant explains how training guides will be prepared and how they will provide reasonable assurance of the consistent conduct of training activities and how classroom and on-the-job training will be used and coordinated
- the applicant commits to maintain current the training of personnel through periodic testing of personnel, refresher training and instruction in activities that may be relied on for safety
- the applicant commits to periodically evaluate the effectiveness of the training program to provide reasonable assurance that it conveys the required skills and knowledge and to implement changes, if required, to increase its effectiveness to correct any deficiencies

11.4.3.4 Procedures Program

The applicant's process for developing and implementing procedures should be acceptable if it satisfies the following:

- the applicant commits to develop, approve and implement operating and management control procedures applicable to items relied on for safety
- the applicant describes methods to identify the need for a procedure, to write and approve procedures (engineering and managerial approval processes), to verify and validate procedures, to implement and distribute procedures and to revise and re-issue procedures, as required. The applicant also describes methods to assess the technical accuracy of procedures and the personnel responsible for verification and approval
- the applicant commits to the following procedure adherence: "Activities involving licensed special nuclear material and/or items relied on for safety will be conducted in accordance with approved procedures."
- the applicant commits to periodically review procedures to validate their continued accuracy and usefulness. The applicant also commits to review any relevant procedures associated with abnormal events and to refer any perceived deficiencies to the CAP for evaluation and corrective action, if required
- the applicant describes items relied on for safety and management measures for which procedures are required
- the applicant describes policies to promote the integration of the procedures and CM management measures

Appendix A provides examples of facility operations and activities for which procedures may be required.

11.4.3.5 Audits and Assessments

The applicant's submittal regarding audits and assessments should be acceptable if it satisfies the following:

- the applicant commits to design and implement a system of internal audits and independent assessments of items relied on for safety
- the applicant describes methods to conduct audits and assessments, to establish their frequencies of performance (based on safety grading of items relied on for safety) and their scope and structure. The applicant should also describe policy directives covering the audit and assessment functions (e.g. activities to be audited, schedules, guidance in conducting the audit or assessment, assigned responsibilities for each phase of the work, procedures for recording results of each audit or assessment, etc.)
- the applicant commits to use appropriately qualified personnel to conduct audits and assessments. The applicant should describe the qualifications and responsibilities of key individuals responsible for the overall direction and conduct of audits and assessments, and identify organizational responsibilities
- the applicant describes any performance indicators that may have been developed for items relied on for safety and that can be used to facilitate scheduled audits and assessments
- the applicant commits to conduct audits and assessments in accordance with written procedures and checklists
- the applicant commits to document report findings and recommendations and to distribute them to appropriate management for review. The applicant also commits to refer to the CAP any unacceptable performance deficiencies that may be discovered during an audit or assessment for possible corrective action, if required.
- the applicant commits to periodically review the audit and assessment procedures and to upgrade them, if required

11.4.3.6 Corrective Action Program (Incident Investigations)

The reviewer should determine that the applicant's commitments to design and implement a CAP are acceptable if the reviewer finds reasonable assurance of the following:

- the applicant commits to design and implement a CAP to investigate abnormal facility events and unacceptable performance deficiencies in items relied on for safety and/or management measures
- the applicant commits to establish CAP policies, to provide a management organization to oversee CAP activities, and assign appropriately trained and qualified personnel to this function
- the applicant provides a description of CAP policies including:
  - (vii) the overall plan (or approach) and methods to investigate abnormal events
  - (viii) the timing of investigations (generally to be initiated as soon as practicable) and scope of investigations (generally to be determined by the safety significance of the event and the complexity of the process involved)
  - (ix) methods to develop, implement and track appropriate corrective actions through their completion
  - (x) methods to determine specific or root cause(s) and generic implications of abnormal events
  - (xi) methods to document investigations and corrective actions that were implemented
  - (xii) process to enable "lessons learned" to other items relied on for safety and/or management measures

11.4.3.7 Records Management

The applicant's records management system should be acceptable if it satisfies the following criteria:

- the applicant commits to establish and maintain a records management system to collect, store and permit retrieval of facility information such as ISA documentation, maintenance records for items relied on for safety, CAP investigations and corrective actions, records of facility operational changes and information on items relied on for safety and their complementary management measures
- the applicant should outline policies pertaining to:
  - (v) records handling, storage, security and retrieval
  - (vi) identification of records to be maintained (to comply with regulatory requirements)
  - (vii) establishment of record retention time frames
  - (viii) technical specifications for record preparation and storage

- commitment to review the efficacy of the records management system and to revise it, as required, and to correct any identified deficiencies

Examples of records that should be included in the system are listed in Appendix B.

11.5 REVIEW PROCEDURES

11.5.1 Acceptance Review

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

In discussing a management measure, the applicant may elect to incorporate information from other sections of the application. This approach is acceptable, so long as the information is adequately cross-referenced. The reviewer may wish to consult any such referenced sections to confirm that the applicant's commitments to management measures are adequate and acceptable.

11.5.2 Safety Evaluation

The primary reviewer will perform a safety evaluation against the Acceptance Criteria in Section 11.4. Assessment of renewal or amendment applications should be coordinated with the facility's NRC inspector and should include review of inspection reports. Any concerns identified by the inspector should be addressed and resolved by the applicant. If, during the course of the safety evaluation, the primary reviewer determines a need for additional information, the primary reviewer should coordinate a request for additional information with the licensing project manager. After completing the safety review of each management measure, the primary staff reviewer, with assistance from the other reviewers, should prepare input for the Safety Evaluation Report (SER) as described in Section 11.6 using the acceptance criteria from Section 11.4.

Review procedures for each criterion are discussed in the sections below.

11.5.2.1 Configuration Management

The reviewer should confirm that the applicant's proposed CM provides reasonable assurance of compliance with the requirements of 10 CRR 70.72(a). The CM system should be capable of documenting and tracking all changes to items relied on for safety and management measures. The applicant's description of how the CM system is incorporated into the facility's organizational structure, descriptions of methods to establish and control documents, commitments to assign responsibility for CM to adequately trained personnel and to commit sufficient resources to enable the CM system to function effectively should be assessed. The reviewer must be convinced that the elements of the CM system are capable of maintaining consistency among the design requirements, physical configuration and facility documentation for all items relied on for safety and their management measures.

11.5.2.2 Maintenance

The reviewer will evaluate the applicant's description of how the maintenance function will coordinate and utilize 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.

An acceptable maintenance function describes the applicant's commitments to the following: corrective maintenance, preventive maintenance, surveillance/monitoring, and functional testing.

11.5.2.3 Training and Qualification

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 and in agreement with ongoing activities. The secondary reviewer should also integrate the personnel training and qualification input into the SER.

The review should result in a determination that there is reasonable assurance that the applicant's personnel training and qualification will provide for properly trained and qualified personnel to perform activities relied on for safety.

11.5.2.4 Procedures Program

The reviewer should confirm that the applicant's commitments to establish a process for the preparation, use and management control of written procedures applicable to items relied on for safety are adequate. The reviewer should examine proposed policies to write, approve, validate, distribute, implement and verify procedures. Finally, the reviewer should assess the proposed integration of the procedures and CM management measures, and the applicant's commitment to develop methods to periodically evaluate and update facility procedures, as required.

11.5.2.5 Audits and Assessments

The review should determine whether the applicant has adequately planned for audits and assessments and whether necessary policies, personnel, procedures, and instructions will be in place to provide reasonable assurance that audits and assessments can be properly executed in a timely manner.

The reviewers should focus on audits and assessments of items relied upon for safety.

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

The review should determine that the applicant's audits and assessments of items relied on for safety will provide reasonable assurance that they will perform satisfactorily when required.

11.5.2.6 Corrective Action Program (Incident Investigations)

The primary reviewer will verify that the applicant has described an adequate incident investigation process 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 reviewer will consult with the NRC inspection staff and review any historical information regarding the adequacy of the applicant's incident investigation process.

11.5.2.7 Records Management

The reviewer will review the applicant's records management system to determine the adequacy of the policies. 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. 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 records for controls or high-risk accidents sequences.

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. 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 outstanding issues, the reviewer documents the review as described above and includes a list of open issues that require

resolution prior to the staff's position finding of reasonable assurance. For partial reviews, revisions, and process changes, the reviewer will use applicable sections of the acceptance criteria and the SER will be written to reflect what portions were not reviewed and the significance, if any. Upon completion of the review, NRC staff may impose temporary or one-time license conditions to authorize short duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.

The staff can document the evaluation as follows:

11.6.1 Configuration Management

The staff has reviewed the Configuration Management (CM) function for (name of facility) according to Section 11of the Standard Review Plan. [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 documenting changes to items relied on for safety . The applicant's proposed CM provides reasonable assurance of compliance with the requirements of 10 CFR 70.72(a). The CM system is capable of documenting and tracking all changes to items relied on for safety and management measures. The applicant's description of how the CM system is incorporated into the facility's organizational structure, descriptions of methods to establish and control documents, commitments to assign responsibility for CM to adequately trained personnel, and commitment of sufficient resources to enable the CM system to function effectively are assessed to be acceptable. The applicant's CM system should be capable of maintaining consistency among the design requirements, physical configuration and facility documentation of all items relied on for safety and their management measures.

11.6.2 Maintenance

The applicant has committed to maintenance of items relied on for safety. The applicant's maintenance commitments contain the basic elements to provide reasonable assurance of their availability and reliability: corrective maintenance, preventive maintenance, functional testing, equipment calibration, work control, and management measures for items relied on for safety. The applicant's maintenance function is proactive, using maintenance records, preventive maintenance records, and surveillance tests to analyze equipment performance and to seek the root causes of repetitive failures.

The surveillance activities described in this section of the application provide reasonable assurance that the equipment that monitors items relied on for safety will be adequately calibrated and tested.

The staff concludes that the applicant's maintenance functions meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public are protected.

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 that (1) satisfy regulatory requirements, (2) are consistent with the guidance in this SRP, and (3) are acceptable.*

There is reasonable assurance that implementation of the described training and qualification will result in personnel who are qualified and competent to, start-up, operate and maintain the facility safely. The staff concludes that the applicant's plan for personnel training and qualification meet the requirements of 10 CFR Part 70.

11.6.4 Procedures Program

The application has described a suitably detailed process for the development, approval, and implementation of procedures. Special attention has been paid to items relied on for safety.

11.6.5 Audits and Assessments

Based on its review of the license application, [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] *the NRC staff has concluded that the applicant has adequately described its audits and assessments program. The staff has reviewed the applicant's plans for the conduct of audits and assessments and finds them acceptable.*

The staff concludes that the applicant's plans for audits and assessments meet the requirements of 10 CFR 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 Corrective Action Program (Incident Investigations)

The applicant has committed to incorporating a corrective action program into the facility's organizational structure responsible for performing incident investigations of abnormal events that may occur during operation of the facility, determining the specific or root cause(s) and generic implications of the event, and recommending corrective actions for providing reasonable assurance of safe facility operations in accordance with the acceptance criteria of Section 11 of the SRP.

The applicant has committed to the monitoring, documentation and tracking 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 CAP or 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 will be effective in collecting, verifying, protecting, and storing information about the health and safety aspects of the facility and its operations, and will be able to retrieve the information in readable form and in a timely fashion for the designated lifetimes of the records.

11.7 REFERENCES

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

Proposed Revision to Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* as revised.

DOE-STD-1073-93, *DOE Standard: Guide for Operational Configuration Management Function,* Parts I and II, Department of Energy

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

Code of Federal Regulations, Title 29, Part 1910.119, *Process Safety Management of Highly Hazardous Chemicals*, U.S. Government Printing Office, Washington D.C., as revised.

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

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

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

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

ISO 9000 quality management standard.

ANSI/ISO/ASQ 9000 quality systems standard.

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

DOE,"Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C," September 1997 draft.

Appendix A: CHECKLIST FOR PROCEDURES

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

1. Management Control Procedures:

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

2. Operating Procedures

   a. System of procedures that addresses Startup, Operation, Shutdown Control of Process Operations and Recovery After a Process Upset

      Process Operations
      Ventilation Systems
      Criticality alarm System
      Shift routines, shift turnover and operating practices
      Decontamination operations
      Plant Utilities (air, other gases, cooling water, fire water, steam)
      Temporary changes in operating procedures

   b. Abnormal Operation/Alarm Response:

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

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

Repairs and preventive repairs of items relied on for safety
Testing of criticality alarm units
Calibration of items relied on for safety
HEPA filter maintenance
Functional testing of items relied on for safety
Relief valve replacement/testing
Surveillance/monitoring
Pressure vessel testing
Piping integrity testing
Containment device testing

4. Emergency Procedures:

Accidental Nuclear criticality
Hazardous chemical releases (including UF_6) and spills
Fires
Loss of Power or Water

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 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. Furthermore, 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 as specified by the facility configuration management system

Records of facility changes and associated integrated safety analyses, as specified by the facility configuration management system

Safety analyses, reports and assessments

Site characterization measurements and data

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

Procurement records, including specifications for items relied on for safety

2.0 Organization and Administration

Administrative procedures with safety implications

Change control records for material control and accounting program

Organization charts, position descriptions and qualifications records

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

Management Measure records

2.0 Organization and Administration (continued)

Safety inspections, audits, assessments and investigations

Safety statistics and trends

3.0 Integrated Safety Analysis

4.0 Radiation Safety

Personnel Bioassay data

Personnel Exposure records

Radiation protection (and contamination control) records

Radiation protection training records

Radiation work permits

5.0 Nuclear Criticality Safety

Nuclear criticality safety procedures

Nuclear criticality safety analyses

Nuclear criticality safety evaluations

Nuclear criticality safety inspections, audits, investigations and assessments

Nuclear criticality safety incidents, unusual occurrences or accidents

6.0 Chemical Safety

Chemical process safety procedures and plans

Chemical process inspections, audits, investigations and assessments

Diagrams, charts and drawings

Chemical process safety incidents, unusual occurrences, and accidents

Chemical process safety reports and analyses

Chemical process safety training

7.0 Fire Safety

Fire Hazards Analyses

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

Inspection, maintenance and testing of fire protection equipment

Fire protection training and retraining of emergency response teams

Pre-fire emergency plans

8.0 Emergency Management

Emergency plans and procedures

Comments on emergency plans from outside emergency response organizations

Emergency exercise records

Memoranda of understanding with outside emergency response organizations

Actual emergency response events

Training and retraining of personnel involved in emergency preparedness functions

Inspection and maintenance of emergency response equipment and supplies

9.0 Environmental Protection

Environmental release and monitoring records

Environmental Report and Supplements to the Environmental Report, as applicable

10. 0 Decommissioning

Financial assurance documents

Decommissioning cost estimates

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 to those designs
Validation and verification of records for computer software used for safety analyses or MC&A
ISA documents, including process descriptions, plant drawings and specifications

11.2 Maintenance

Preventive maintenance, including trending and root cause analyses
Calibration and testing data for items relied on for safety
Corrective maintenance

11.3 Training and Qualification

Personnel training and qualification
Procedures

11.4 Procedures

Standard operating procedures
Functional test procedures

11.5 Audits and Assessments

Audits and assessments of safety and environmental activities

11.6 Corrective Action Program (Incident Investigations)

Investigations
Changes recommended by investigation reports, how and when implemented
Summary of reportable events for the term of the license
Incident investigation policy

11.7 Records Management

Policy
Material storage
Receipt, transfer and disposal of radioactive material