Response to Comments - Chapter 11 - General

Comment No.	Source	Comment	Disposition
11.1 General	NEI	Programs that are not suitable for fuel cycle facilities and which are not mandated by 10 CFR 70 should be deleted from the SRP.	Agree. However, all of the management measures addressed in Ch. 11 are mandated by the Part 70 definition (§70.4) of management measures.
11.2 General	NEI	The prescriptiveness in discussion of certain management measures must be addressed.	Disagree. An SRP should be more prescriptive than a rule otherwise it would not be useful to an NRC reviewer. Prescriptiveness in an SRP assures more consistency and uniformity among reviewers. Regardless of how prescriptive an SRP is, it is still only guidance.
11.3 General	NEI	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. Want to assure that SRP acceptance criteria do not become defacto minimum acceptable standards.	Agree. Acceptance criteria and examples provided to the staff reviewer will be reviewed to ensure that they are tailored to the facility risks that the items relied on for safety are designed to prevent or mitigate. The SRP intro will clearly state that the SRP normally contains the maximum set of acceptance criteria, not the minimum, and are subject to reduction by application of ISA results.
11.4 General	NEI	Document control, corrective action, and other topics need only be addressed once in Chapter 11.	Agree. Efforts are being made to eliminate duplication.
11.5 General	NEI	Selection of specific management measures should be left to the discretion of the applicant.	Disagree. The §70.4 definition of “Management Measures” states; “Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements.”
11.6 General	NEI	The ‘shalls’ (regarding the grading of management measures) should be edited to read ‘may.’	Agree. This will be done.

Response to Comments - Chapter 11 - General

Comment No.	Source	Comment	Disposition
11.7 General	NEI	Greater uniformity in the approach to evaluate an applicant's management measures is required. Some sections direct reviewer to examine commitments (11.5.2.5), other sections seek compliance with prescriptive detailed requirements (11.5.2.2)	Disagree. Each of the referenced sections direct the reviewer to confirm that the applicant's submitted material is consistent with specified acceptance criteria.
11.8 General	NEI	Terminology is frequently incorrectly used or defined. Editorial issues must be addressed in a thorough evaluation of this chapter (11).	Agree. Examples provided will be revised as appropriate. Exceptions are (1) appropriate use of terms such as safety function and (2) guidance regarding a systematic approach to training. An attempt is being made to eliminate the editorial issues.
11.9 General	NEI	Repetitive requirements. SRP seems to require reviewer to perform an analysis required by an earlier chapter of the application (for example, ISA).	Reviewers review analyses performed by applicants/licensees and perform analyses only when required for confirmation purposes. In some cases, a Chapter 11 reviewer may review a given analysis from a perspective that is different from that of the reviewer of an earlier chapter of the SRP.
11.10 Genaral		There are several usages where "Provide reasonable assurance" should replace "ensure."	Agree. "Provide reasonable assurance" will replace "ensure" as appropriate.
11.11 General		Several (cited) references are inappropriate and should not be cited in NUREG-1520.	Disagree. References are listed for general but pertinent background information to augment a reviewer's knowledge of NRC work that has been done that may be relevant to the technical issues under review. References are listed separately from Regulatory Guidance, and are not intended to define or promote any specific NRC position to be taken by a reviewer.

Response to Comments - Chapter 11 - General

Comment No.	Source	Comment	Disposition
11.12 General		Some additional consolidation of Chapter 11 should be undertaken.	Agree. The guidance given reviewers to seek additional information from the applicant, when required, will be consolidated into 11.5.1 and 11.5.2. Also, the guidance regarding license conditions will be consolidated into 11.5.2.
11.13 General		Reactor-like requirements should be deleted from Chapter 11.	Agree. See response to 11-1 and 11-3 above.
11.14 General		With respect to §11.3.2(4) - This section implies that every change will require a change in the ISA, and that NRC would expect to see changed pages to the documents.	Agree in part. §11.3.2(4) will be revised to show that only "as appropriate" changes are expected. However, the CM sections in chapter 11 are the appropriate sections to discuss management of change, particularly document control, of the ISA Summary and ISA. The ISA chapter describes what the ISA Summary is and how to produce it from an ISA, not how to maintain its accuracy over time given expected design changes.
11.15 General		Chapter 11 should be restructured in terms of a licensee's commitments to select, design, implement, and revise (as needed) appropriate management measures.	Disagree. Management measures are specified in Part 70 and licensees do not have the authority to select them. However, the last paragraph of SRP Section 11.3.1 (and elsewhere in the SRP) guides the staff reviewer to determine the applicant's commitment to overall QA.

Response to Comments - Chapter 11 - QA

Comment No.	Source	Comment	Disposition
11.1-QA	NEI	Separate treatment of QA in Chapter 11 is not required. Inclusion of a separate QA sub-section of the management measures SRP chapter appears to be repetitive and redundant.	Disagree. The §70.4 definition of "Management Measures" states; "Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements." §70.62(d) requires each applicant or licensee to establish management measures. SRP Chapter 11 appropriately addresses each specified management measure, including quality assurance.
11.2-QA	NEI	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.	Agree. Thus SRP Chapter 11 addresses all of the management measures listed in §70.4.
11.3-QA	NEI	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. .	Partially agree. A "QA program" is an acceptable, efficient way of describing how "other quality assurance elements" (required by the rule), are implemented.
11.4-QA	NEI	Reference is also made to the QA Organization (e.g. §11.4.3.6).	"QA Organization" will be eliminated from SRP Chapter 11.
11.5-QA	NEI	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.	Agree. However, the acceptance criteria differ. Where appropriate, the SRP guides the QA reviewer to refer to the appropriate SRP chapter that also addresses the management measure being reviewed.
11.6-QA	NEI	"The applicant's customers and the NRC, under 10 CFR Part 50, may impose product-related QA criteria" should be deleted (implied).	Disagree. The statement is a reminder to reviewers of the potential for conflicting QA commitments that might require investigation as part of the review.

Response to Comments - Chapter 11 - QA

Comment No.	Source	Comment	Disposition
11.7-QA	NEI	QA grading should not just parallel maintenance.	Agree. The same risk grading scheme should be applied across all management measures, i.e., a given IROF established as having risk level A should be risk level A for QA, configuration management, maintenance, and all other management measures. The attribute of risk level is inherent to a particular IROF by virtue of its required performance accident sequences. The risk importance is independent of management measures applied to assure its reliability and availability.
11.8-QA	NEI	What is the safety justification to conduct periodic "QA programmatic audits" if the applicant is fulfilling its ISA commitments?	The ISA summary commitment extends only to the application of a QA management measure to a particular IROF. The audit commitment provides assurance that the QA management measure is maintained competent.

Response to Comments - Chapter 11 - Configuration Management

Comment No.	Source	Comment	Disposition
11.1-CM	NEI	The example “The reviewer looks for evidence that the applicant has considered systems interaction...” should be deleted	Disagree. In 11.5.2.2 (Review Procedures) for CM, the reviewer is directed to look for reasonable assurance that design reconstitution has been adequately addressed by the applicant. Since CM starts with a known design basis, its importance to CM should be obvious The fact that an adequate ISA could not be performed without an accurate design basis establishes the responsibility for NRC to review what applicant has done to assure the accuracy of the design basis. the text referred to by NEI will be moved to the ISA, Chapter 3, in the SRP.
11.2-CM	NEI	Section 11.3.2 remains far too prescriptive.	Disagree. However, wording that implies procedure review will be deleted from 11.3.2.
11.3-CM	NEI	Draft 11.3.2 Item 4 requires an existing licensee to conduct a design reconstitution to ensure that the facility’s configuration is consistent with 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 a 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	Disagree. 1. The SRP contains no requirements. 2.While IROFS identified by an ISA Summary may not be identified for some time to come, every licensee has equipment already identified to the NRC as important to safe operation and has claimed to have effective configuration control in their plant. A long track record of “safe” operation does not justify a set of design records, whether public or private, that do not accurately reflect either the design safety requirements or the as-built configuration that is being operated. The reviewer is instructed to look for evidence of “...design reconstitution that has been done for the purpose of the application.” This means that the licensee is expected to have done whatever reconstitution was necessary to establish the current safety basis. The reviewer is to look for evidence

Response to Comments - Chapter 11 - Configuration Management

Comment No.	Source	Comment	Disposition
		redundant.	that the licensee recognized the necessity to at least consider whether any reconstitution was necessary, and then to do what was necessary. 3. The SRP is instruction to reviewers on what to look for in an application and the necessity to include this information in the SRP is independent of the timing of actual performance by a licensee - it is dependent on when the SRP needs to be published.
11.4-CM	NEI	The CM function should 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.	Disagree. See NRC response to 11.3-CM above.
11.5-CM	NEI	§11.1 should not contain instances in which a safety review and analysis of a change to an item relied on for safety is required by the CM function. [Note that the SRP does not contain “requirements”]	Disagree. The CM function is established to provide a systematic assurance that activities like safety analyses and identification of IROFS for proposed changes are completed, that such activities are properly recorded, and that the effects of the changes are accurately transferred into all other appropriate plant activities. The CM function does not define how a safety review is performed or define how safety importance is assigned. Sections 11.3.2, Item 4 “Change Control”, 11.4.3.2, Item 4 “Change Control”, and 11.5.2.2, Item 4 “Change Control” properly state the SRP positions for the CM function.

Response to Comments - Chapter 11 - Configuration Management

Comment No.	Source	Comment	Disposition
11.6-CM	NEI	§11.5.2.2 should not require examination of interfaces between CM and "...*external organizations and functions....*" [Note that the SRP does not contain "requirements"]	Disagree. The reviewer is directed to assure that the CM function is in fact coordinated with other management measures with which it shares data, or from which it obtains data, such as maintenance records, or training and qualification records. This is consistent with the purpose of the CM function of coordinating the safety requirements (established by engineering design), the as-built physical configuration, and current facility records of the first two. Minor revisions to selected sections will be made to reinforce and clarify these points.
11.7-CM	NEI	There should not be redundancy nor excessive repetition of CM requirements in SRP Chapter 11. [Note that the SRP does not contain "requirements"]	Agree in part. Some repetition is considered necessary for clarity and emphasis. The Chapter 11 sections on CM will be revised to improve the clarity and to eliminate unnecessary repetition.

Response to Comments - Chapter 11 - Maintenance

Comment No.	Source	Comment	Disposition
11.1 Maint.	NEI	Prescriptive and Programmatic Language Individual sections of draft SRP Chapter contain very prescriptive statements...., For example, section 11.4.3.3 allows little latitude in designing monitoring, preventive maintenance and corrective maintenance programs	Disagree. Section 11.4.3.3 describes aspects of a maintenance function considered necessary for items relied on for safety. Applicant may propose reduction or elimination of some criteria for certain IROFS based on risk results of the ISA. SRP is written to inform reviewers and industry of what is important to ensuring availability and reliability of IROFS for which failure is required to be "highly unlikely."
11.2 Maint.	NEI	Technical Editing Draft SRP Chapter 11 lacks consistency in the detail of guidance provided to the reviewer in Section 11.3 "Areas of Review"...Review of the maintenance program is addressed in only two paragraphs.	Disagree. Areas of Review introduces the topics that are further addressed in Section 11.4, "Acceptance Criteria". Section 11.3.3 content is adequate to meet this objective.
11.3 Maint.	NEI	Miscellaneous: Item 7. Technical and Regulatory References NRC Inspection Procedures 88062,88025 and 40 CFR Part 68 are all inappropriate to reference to a reviewer of a Part 70 license application	Disagree. The referenced procedures and regulation contain information relevant to the review of management measures described in a Part 70 license application. References are not used as acceptance criteria, or even regulatory guidance, but provide background information to reviewers and the industry.

Response to Comments - Chapter 11 - Maintenance

Comment No.	Source	Comment	Disposition
11.4 Maint.	NEI	Miscellaneous: 8. Solicitation of Performance Data The SRP directs a 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, section 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 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.	Disagree. The maintenance function relates to items relied on for safety. In order to provide continuous compliance with the performance requirements of 10 CFR Part 70.61, which require an unlikelihood of failure of IROFS, an equipment reliability goal must be selected. A preventive maintenance (surveillance) schedule can be selected to verify that the reliability goal is met. Over time, the surveillance will either confirm the selected reliability goal or show that improvement in the IROFS is necessary.
11.5 Maint.	NEI	Discussion of the maintenance management measure section 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" activities.	Disagree. Maintenance function criteria are based on generally accepted practices used in industries where operating process integrity and highly assured containment of product is necessary. The industry chooses the use of administrative controls; the NRC must evaluate applicant's commitment to ensure the availability and reliability, through maintenance, of any given control, whether engineered or administrative. Section 11.4.3.3 also refers to the training and qualifications management measure as the means of assuring administrative controls. Text editing will clarify these points.
11.6 Maint.	NEI	The acceptance criteria in section 11.4.3.3(4) for functional testing contain a paragraph of detailed work procedures. NEI concurs with the need for detailed procedures, but recommends that such detailed information be maintained at the facility and not included in the license application.	Agree in part. Agree that detailed procedures would be maintained at the facility. However, the functional test methods and criteria should be described to provide the NRC with an overview of how this maintenance function would be conducted by the licensee. Minor modifications will be made to the section.

Response to Comments - Chapter 11 - Maintenance

Comment No.	Source	Comment	Disposition
11.7 Maint.	NEI	Although encompassing Part 70 licensees, the Part 21 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...(NEI) recommends that the reference to 10 CFR Part 21 should be deleted.	Disagree. Equipment defect in an IROFS could have very significant safety implications. Part 21 applies to Part 70 licensees and has particular significance when pertaining to UF_6 valves, cylinders, shipping containers etc...
11.8 Maint.	NEI	NEI recommends correction of some language in section 11.6.3, “Evaluation Findings”, which states that the “surveillance activities...ensure the validity of an ISA...” Similarly, the requirement for the maintenance management measure to ”link items relied on for safety requiring maintenance to the ISA Summary...” is not understood.	Agree in part. The statements will be clarified to show that it is availability and reliability of IROFS that are to be ensured; the statement about linking IROFS to the ISA Summary will be revised.
11.9 Maint.	NEI	NEI has proposed an extensive rewrite of the entire July 1999 version of draft SRP Chapter 11, including the portions pertaining to maintenance.	Agree in part. The NEI recommendations for revised text concerning the maintenance management measures will be revised as deemed appropriate, generally in accordance with the comment dispositions recorded in these tables.

Response to Comments - Chapter 11 - Training and Qualifications

Comment No.	Source	Comment	Disposition
11.1 T&Q	NEI	Training and qualification requirements are too comprehensive, prescriptive and cumbersome.	Disagree. Training and qualification requirements should be established, as necessary for the activity, based on safety and risk.
11.2 T&Q	NEI	SRP training and qualification Areas of Review and Acceptance Criteria include "*systematic approach to training, (SAT)"* terms or concepts which are not necessary or appropriate.	Disagree in part. Training and qualification requirements should be established for the activity, as necessary, based on safety and risk. The concepts and terms are typical of those used for training and qualification program planning and implementation in a variety of applications. The SRP Section 11.3.3 will be reworded to delete specific reference to job analysis and for clarification.
11.3 T&Q	NEI	Omit design and construction personnel from the requirement to conduct needs/job analyses..	Disagree. Training and qualification requirements should be established, as necessary for the activity, based on safety and risk. Section 11.3.3 will be reworded for clarification and specific reference to job analysis deleted.
11.4 T&Q	NEI	Question why plant engineers and operators should be expected to have expertise in design, construction, and decommissioning.	Agree to delete "construction", "startup", and "decommissioning" to the referenced SRP Section 11.6.4. Will add "manage" to the list of expected competencies.
11.5 T&Q	NEI	Delete qualifications portion of SRP chapter 11.3.	Disagree. Qualification requirements should be established for the activity, as necessary, based on safety and risk.
11.6 T&Q	NEI	Delete prescriptive criteria for qualification and training of plant personnel in SRP Section 11.4.3.4(9)	Disagree. Qualification requirements should be established for the position and/or activity, as necessary, based on safety and risk.

Response to Comments - Chapter 11 - Procedures

Comment No.	Source	Comment	Disposition
11.1-Pro	NEI	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.	Disagree. The detail presented in the SRP does not, and is not intended to, dictate the specific text of procedures, or to require a reviewer to review and approve specific procedures. The direction to the reviewer concerns what applicant commitments should be sought in the license application regarding (1) the scope of topics to be covered by plant procedures, and (2) the scope of topics to be addressed within procedures. Plant procedures include more than just operating procedures. As noted elsewhere in the responses to comments, detail provided for the understanding and knowledge of the reviewer is necessary in an SRP to both define and limit the scope of reviewer action.
11.2-Pro	NEI	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 not identified in the ISA as items relied on for safety.	Agree in part. It is not the intent of this section of the SRP to require the review of specific operating procedures as part of the licensing review. However, written operating procedures are currently required and will continue to be required for all activities at the facilities that involve the use of licensed material.
11.3-Pro	NEI	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.	Disagree. Operating procedures are the main tools that operations personnel use to safely run the facility and they should clearly identify the safety and regulatory requirements. This does not mean that all regulations, policies and company guidelines must be placed in full text into related procedures. Where certain relevant safety information important to the successful conduct of the procedure, such should be incorporated into the procedure. Placing this type of information into the SOPs will further explain to the operator why he/she is required

Response to Comments - Chapter 11 - Audits and Assessments

Comment No.	Source	Comment	Disposition
			to perform specific functions.

Comment No.	**Source**	**Comment**	**Disposition**
11.1-A&A	NEI	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.	Disagree, the audit and assessment management measure discussion ***does not*** frequently direct the licensee to use the audit or assessment results to immediately implement corrective actions. The sections cited in the comment are appropriate and only suggest that an A and A program is acceptable if "On-the-spot corrective actions are provided for, with appropriate documentation; i.e., the option of immediate corrective action is available, and, audit organizations schedule and conduct appropriate follow-up to ensure timely and effective corrective action."
11.2-A&A	NEI	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.	Agree in part. Section 11.5.6 "Evaluation Findings" from Jun 2, 1999 SECY 99-147 will be inserted in the "Evaluation Findings" Section of the new draft SRP

Response to Comments - Chapter 11 - Incident Investigation

Comment No.	Source	Comment	Disposition
11.1-Inc I	NEI	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…"	Agree. Will revise SRP accordingly.
11.2-Inc I	NEI	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.	Disagree. CAP is important but it is the second part of a two step process to identify and correct problems at the facilities. A CAP program is utilized for both the correction of items discovered by the A&A function and through events. Therefore, it should remain a separate and independent function.

Response to Comments - Chapter 11 - Records Management

Comment No.	Source	Comment	Disposition
11.1 RM	NEI	Examples of records should be limited to those that a licensee could be reasonable expected to establish and retain during the operating life of a facility.	Disagree. Just as design and construction records of an operating plant should meet SRP Chapter 11 guidance, final survey and decommissioning records should also meet the guidance as they become available.