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June 16, 2020

Revision to Sargent & Lundy (S&L)
Topical Report SL-TR-1A
Quality Assurance (QA) Program

United States Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555-0001
Attention: Leslie Perkins

On June 8, 2020, Ms. Leslie Perkins of the NRC forwarded to me the Final Safety Evaluation for Revision 25 of S&L's Nuclear Quality Assurance Program Topical Report, SL-TR-1A.

In accordance with the direction in the June 8th letter and the direction on the NRC website, Sargent & Lundy is submitting a final revision of the topical report with an approved ("-A") designation. This topical report is non-proprietary.

If you have any questions, please contact me at 312.735.8676.

Best Regards,

Randall L. Kurtz
Quality Assurance Director

RLK:arm
Enclosure



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QUALITY ASSURANCE PROGRAM

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SUMMARY OF CHANGES

Revision 25

Sargent & Lundy is submitting this Revision 25 of SL-TR-1A. The justifications for the changes in Revision 25 are as follows.

1. (Chapter 07.03, Page 07-5) "NRC Audits" was revised to "NRC Inspections" to align with the verbiage used in NRC regulatory guidance.
2. (Chapter 07.04, Page 07-5) The chapter was revised to include an extension for periodic external audits/surveys which may be exercised during exigent conditions.

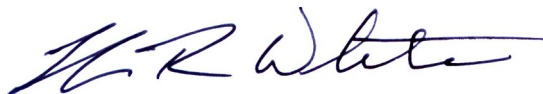
STATEMENT OF POLICY

The Sargent & Lundy LLC (S&L) Nuclear Quality Assurance Program and procedures described herein provide control of S&L design, procurement, and inspection activities which affect the quality of important to safety nuclear plant structures, systems, and components. In the areas of quality and quality assurance, it is S&L policy that designs be in accordance with applicable quality assurance requirements and that procurement documents require that materials, equipment, or services furnished meet or exceed the design criteria.

The Quality Assurance Program and procedures are included in the document control system and are available to persons responsible for implementing the program. These documents are maintained current in accordance with a standard operating procedure.

S&L personnel assigned to a nuclear plant project are required to become familiar with the policies and provisions of the S&L Nuclear Quality Assurance Program and procedures. Compliance with the S&L Nuclear Quality Assurance Program and procedures is mandatory for personnel directly or indirectly associated with implementation.

In the event of conflict between the requirements of the S&L Nuclear Quality Assurance Program and other procedural documents, the S&L Nuclear Quality Assurance Program shall take precedence.



T. R. White
Chairman and CEO

SARGENT & LUNDY LLC
NUCLEAR QUALITY ASSURANCE
PROGRAM
TOPICAL REPORT
SL-TR-1A

**APPROVED
BY:**



R. L. KURTZ

QUALITY ASSURANCE MANAGER



T. R. WHITE

CHIEF EXECUTIVE OFFICER

REVISION 25

DATE: June 12, 2020

From: [Perkins, Leslie](#)
To: [KURTZ, RANDALL L](#)
Cc: [Morey, Dennis](#)
Subject: Final Safety Evaluation for Sargent & Lundy, LLC Nuclear Quality Assurance Program Topical Report SL-TR-1, Revision 25 (EPID: L-2020-TOP-0027)
Date: Friday, June 5, 2020 5:18:00 PM

Dear Mr. Kurtz,

By letter dated May 14, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20132A261), Sargent & Lundy, LLC (S&L) submitted S&L "Nuclear Quality Assurance Program," Topical Report SL-TR-1, Revision 25. By email dated May 28, 2020, the NRC issued its draft safety evaluation (SE) for the S&L "Nuclear Quality Assurance Program," Topical Report SL-TR-1, Revision 25. (ADAMS Accession No. ML20148M255). By email dated June 1, 2020 (ADAMS Accession No. ML20154K711) S&L responded with no comments on the draft SE.

The final SE (ADAMS Accession No. ML20154K718) addresses the applicability of the S&L "Nuclear Quality Assurance Program," TR SL-TR-1, Revision 25.

The NRC staff has found that "Nuclear Quality Assurance Program," TR SL-TR-1, Revision 25, is acceptable for referencing in licensing applications to the extent specified and under the limitations delineated in the TR and the final SE. A copy of the final SE and this email are in ADAMS as publicly available.

According to the guidance provided on the NRC website, we request that S&L publish accepted non-proprietary version of the TR within three months timeframe after this final SE is issued by NRC.

The accepted versions shall incorporate this letter and the final SE after the title page. Also, they must contain historical review information, including NRC RAI questions and your responses. The accepted versions shall include an "-A" (designating accepted) following the TRs identification symbol.

If future changes to the NRC's regulatory requirements affect the acceptability of this TR, S&L will be expected to revise the TR appropriately. Licensees referencing this TR would be expected to justify its continued applicability or evaluate their plants using the revised TR.

If you have any questions, please feel free to contact me at 301-415-2375 or by email.

Leslie Perkins
Project Manager, Licensing Projects Branch
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation
e-mail: Leslie.Perkins@nrc.gov
Phone: 301-415-2375

Office of Nuclear Reactor Regulation Minimal Revisions Review Topical Report Final Safety Evaluation for Sargent & Lundy, LLC, "Nuclear Quality Assurance Program," Topical Report SL-TR-1, Revision 25			
Topical Report Information		Review Information	
Report Number: Topical Report SL-TR-1 Title: Sargent & Lundy, LLC Nuclear Quality Assurance Program Topical Report SL-TR-1, Revision 25 EPID: L-2020-TOP-0027 Docket No.: 99900507		Division/Branch: DRO/IQVB Project Manager: Leslie Perkins Reviewers: Jonathan Ortega-Luciano	
Determination of Minimal Revisions			
Is this the review of very limited scope?	Yes	<input checked="checked" type="checkbox"/> X	No <input type="checkbox"/>
Does the TR change maintain the original SE conclusions?	Yes	<input checked="checked" type="checkbox"/> X	No <input type="checkbox"/>
Do the staff methods for establishing the original conclusions remain unaffected?	Yes	<input checked="checked" type="checkbox"/> X	No <input type="checkbox"/>
If any of the above questions are answered no, a simplified safety evaluation cannot be used.			
1. Introduction			
<p>By letter dated May 14, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20132A261), Sargent & Lundy, LLC (S&L), requested approval of proposed changes to its "Nuclear Quality Assurance [(QA)] Program," Topical Report (TR) SL-TR-1 (hereafter referred to as the QATR). The proposed change was considered a change to an NRC-accepted QATR from non-licensees (i.e., architect/engineers, nuclear steam supply system (NSSS) suppliers), in accordance with Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," 50.4(b)(7)(ii).</p> <p>The proposed change extends the supplier audit frequency from once every three years (i.e., triennial) for the supplier audits and surveys affected by exigent conditions. The increased period between supplier audits or surveys will be supplemented by analysis or evaluation of supplier performance as prescribed in this safety evaluation (SE). The change is applicable to supplier audits or surveys implemented to meet the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 for supplier audit frequency for exigent conditions, as described in the S&L QATR.</p> <p>Currently, the S&L QATR, Revision 24, Section 07.04 of Chapter 07.00, "Control of Purchased Material, Equipment and Services," requires the following:</p> <p style="margin-left: 40px;">Audits of suppliers are conducted per Chapter 18.0 and implementing procedures at maximum three-year intervals, except as stipulated below, to assure compliance with quality requirements. Supplier audits include auditing of suppliers' certificates of conformance when these certificates are used as a basis for accepting the item or service.</p> <p style="margin-left: 40px;">Audits of suppliers, after award of a contract, and annual evaluations of suppliers are not necessary for procurement actions when the items or related services are of the following:</p> <p style="margin-left: 80px;">a. relatively simple and standard in design, manufacture and test, and</p>			

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<p>b. adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.</p> <p>For the following case, audits and annual evaluations of suppliers are also not necessary. S&L may accept short-term engineering and consulting services, such as qualification testing or a design performed by a consultant which will be independently verified by S&L, by technical verification of data produced as discussed in Section 03.04, by surveillance of the activity by a design engineer or a QA engineer, and/or by review of objective evidence for conformance to the procurement document requirements, such as by review of a stress report, as discussed in Section 03.04.</p> <p>S&L submitted the QATR, Revision 25 and requested a modification to Section 07.04 to add QA control that could be applied under exigent conditions. The new modified Section 07.04 adds the following:</p> <p>During exigent conditions, an extension of 25 percent may be applied to the triennial frequency for external audits/surveys where performance is not feasible. Priority shall be given to completing audits/surveys of affected suppliers in order of the expiration of the triennial audit frequency. Exigent conditions include, but are not limited to;</p> <ul style="list-style-type: none"> a. declaration of a national emergency, b. severe localized or national weather conditions, or c. localized outbreak of a severe health concern to the public. <p>Prior to utilizing the exigent condition extension, basic component suppliers shall confirm that a quality assurance program meeting Appendix B to 10 CFR Part 50 continues to be implemented. Commercial suppliers shall confirm programmatic controls related to the activity affecting quality continue to be maintained.</p> <p>During exigent conditions, if a contract or contract modification significantly modifies a supplier's scope, the supplier shall provide written justification that the change(s) are adequately addressed by its quality assurance program controls. Audits/surveys performed during exigent conditions shall reset the 'clock' for the particular activity. The date the activity is performed shall be the basis for the new triennial audit/survey frequency.</p> <p>Exigent conditions, such as the national emergency caused by COVID-19, impacts S&L's ability to complete external supplier audits and surveys within the frequency specified in its QA</p>	

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<p>program that complies with Appendix B to 10 CFR Part 50. Exigent conditions have restricted both domestic and international travel and restricted access to supplier facilities. The proposed change to the S&L's QATR would provide an extension of the external audit frequency for supplier audits and surveys that need to be completed during exigent conditions.</p> <p>The NRC staff has reviewed the modification of S&L's QATR that would be implemented in the event of exigent conditions for QA program changes submitted under 10 CFR 50.4(b)(7)(ii).</p> <p>Details of the NRC staff's evaluation are summarized below.</p> <p>2. Regulatory Basis</p> <p>The NRC's regulatory requirements related to QA programs are set forth in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, and 10 CFR 50.4(b)(7), Quality Assurance related submission, Item (ii). The regulation at 10 CFR 50.4(b)(7)(ii) states, in part, "a change to an NRC-accepted quality assurance topical report from non-licensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, contractors, etc.) must be transmitted to the NRC Document Control Desk."</p> <p>The regulatory requirements for QA program audits of suppliers is set forth in Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Licensees contractually impose these requirements upon their suppliers. Criterion VII requires establishing measures for assuring that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel reprocessing plant site prior to installation or use of such material and equipment.</p> <p>Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 3 (ADAMS Accession No. ML003739981) identifies the ASME's Standard, NQA-1 (NQA-1-1983 through the NQA-1a-1983 Addenda), "Quality Assurance Requirements for Nuclear Facility," as an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50 with some exceptions which are discussed in the Regulatory Position section of RG 1.28, Revision 3. In 2002, the NRC issued an SE (ADAMS Accession No. ML023440300), in which the staff concluded that NQA-1-1994 was equivalent to NQA-1-1983 and continued to conform to the regulatory positions of RG 1.28, Revision 3. Also, under RG 1.28, Revision 3, Regulatory Position 3.2, a licensee may apply a 90-day grace period to annual evaluations and</p>	

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<p>audits of suppliers (approved via SE, ADAMS Accession No. ML101820108). Further, the grace period does not allow the supplier audit "clock" to be reset forward. However, the "clock" can be reset backwards by the supplier audit activity being performed early.</p> <p>3. Technical Evaluation</p> <p>In evaluating the adequacy of the proposed change, the NRC staff considered the guidance of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," RG 1.28 (Revision 3), and ASME NQA-1. The guidance in RG 1.28, Regulatory Position 3.2, "External Audits," states in part, that audits of a supplier's QA program should be performed on a triennial basis.</p> <p>The extension of the audit frequency during exigent conditions as proposed by S&L will provide for greater flexibility in its consideration of other similar events, such as the ongoing COVID-19 pandemic. The current national emergency limiting domestic and international travel will result in S&L not meeting its contractual commitment imposed by licensees associated with the external audit frequency. As the duration of the current national emergency is unknown, the NRC agrees an overall extension of 25 percent to the triennial audit frequency for impacted supplier audits and surveys may be implemented for exigent conditions.</p> <p>During exigent conditions, S&L may continue to use suppliers that have exceeded the maximum allowed audit or survey time based on the conditions set forth in Chapter 07.00, "Control of Purchased Material, Equipment and Services," within the QATR, Revision 25. The NRC staff found that the proposed and existing descriptions provided in Chapter 07.00, as amended, are consistent with the following NRC staff's considerations for allowing extensions to the periodicity of audits and surveys for suppliers during exigent conditions:</p> <ol style="list-style-type: none"> a. There is verification that the supplier is still implementing a quality assurance program that meets Appendix B to 10 CFR Part 50. <ol style="list-style-type: none"> i. For suppliers with delinquent surveys, the entity shall ensure that the suppliers have maintained adequate documented programmatic controls in place for the activity affecting quality. b. The alternative method of the 25 percent extension discussed above is applicable to domestic and international suppliers. c. Receipt inspection and industry operating experience are reviewed on an ongoing basis as the information becomes available and documented. The results of the review are promptly considered for the effects on a supplier's continued qualification and adjustments made as necessary, including corrective actions. 	

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<p>d. If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of 12 months since the last audit or survey, an annual documented evaluation shall be performed and include, as appropriate, the following:</p> <ul style="list-style-type: none"> i. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions. ii. Results of previous source verifications, audits, survey and receiving inspection activities. iii. Operating experience of identical or similar products furnished by the same supplier. iv. Results of audits and inspections from other sources (e.g., customer, ASME, or NRC inspection). <p>e. If the contract or a contract modification significantly enlarges the scope or changes the methods or controls for activities performed by the same supplier, the supplier will provide documented justification that the change(s) are adequately addressed by its quality assurance program controls.</p> <p>The overall 25 percent extension for audits or surveys would only be applicable to exigent conditions. A determination of exigent conditions would be based on S&L's prudent judgement.</p> <p>The above frequency extension for supplier audits or surveys during exigent conditions is an alternative to the 90-day grace period allowed under RG 1.28. The general 90-day grace period alternative will remain unchanged for conditions of a minor administrative nature. Examples of conditions of a minor administrative nature would include, but not limited to: 1) staffing limitations preventing a timely audit to be completed and 2) scheduling conflicts by either the vendor, supplier, or sub-tier supplier.</p> <p>As previously stated, the expectation for the use of the 25 percent frequency extension would be limited to implementation for exigent conditions. The expectation would be that S&L attempts to maintain the current triennial audit or survey period. Unlike the existing alternative on the use of a grace period, S&L would not have to reset the "clock" backwards when the audit or survey is finally performed to the original date the audit or survey should have been performed. The date that the audit or survey is finally performed would be the start of the new triennial audit or survey frequency. The NRC staff considered that should events of a severe nature occur closely together, the requirement for not allowing the "clock" to be reset forward would result in an additional potential scheduling constraint on completing audits or surveys in a timely manner.</p> <p>The NRC staff considered the maturity of S&L's QA program and its supply chain oversight in determining this allowance of a 25 percent extension for audits and surveys to be completed from the date of the expiration of the triennial audit or survey frequency. The NRC staff also</p>	

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<p>considered the potential risk significance of extending the audit and survey frequency by 25 percent. Based on the maturity of S&L's QA program, the expected short duration that S&L will be under an exigent condition, and S&L's continuous monitoring of ongoing and previous supplier performance, the NRC staff determined that there is minimal risk associated with implementing the extended audit and survey frequencies during exigent conditions. Therefore, the NRC concluded that the conditions stated above ensure that reasonable assurance of the quality of items and services will continue to be maintained during this extension period.</p> <p>4. Conclusion</p> <p>The NRC staff concluded that there is reasonable assurance that S&L's QATR will continue to meet the requirements of Appendix B to 10 CFR Part 50 while implementing the 25 percent extension of audit and survey frequencies during exigent conditions. Therefore, the NRC staff found S&L's proposed changes in the QATR, Revision 25, to be an acceptable method for extending audit frequencies during exigent conditions.</p> <p>Principal Contributor: Jonathan Ortega-Luciano</p> <p>Date: June 4, 2020</p>			
ADAMS Accession Nos: Package: ML20154K709; Transmittal Email: MLML20154K721; Response Email: MLML20154K71; SE: ML20154K718			
Approval	Printed Name	Signature	Date
Technical Branch Chief	Kerri Kavanagh	/RA/ by Paul Prescott for	6/4/2020
Projects Branch Chief	Dennis Morey	/RA/ by Michael Orenak for	6/3/2020



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May 14, 2020

Proposed Revision to Sargent & Lundy (S&L)
Topical Report SL-TR-1
Quality Assurance (QA) Program

United States Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555-0001
Attention: Leslie Perkins

On May 11, 2020, Sargent & Lundy (S&L) submitted Proposed Revision 25 of SL-TR-1 (Accession Number ML20132A261) to the NRC in accordance with 10 CFR 50.4(b)(7)(ii). S&L requests the enclosed submittal replaces the submittal of May 11, 2020 in its entirety. Please provide a safety evaluation of the enclosed revision to SL-TR-1.

This revised submittal is also non-proprietary.

If you have any questions, please contact me at 312.735.8676.

Best Regards,

Randall L. Kurtz  Digitally signed by Randall L. Kurtz
Date: 2020.05.15 10:34:55 -05'00'

Randall L. Kurtz
Quality Assurance Director

RLK:arm
Enclosure

00.00 INTRODUCTION

This Sargent & Lundy LLC (S&L) Nuclear Quality Assurance Program was established by management policy. It is intended to be used to assure the quality of engineering and design analyses for the construction, operation or decommission of nuclear plants and gaseous diffusion plants, and of the design and construction of radioactive material packaging and of independent spent fuel storage installations (ISFSIs). The program is employed where the structures, systems and/or components are classified as important to safety insofar as they prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. Safety-related structures, systems and components of nuclear power plants controlled by this Quality Assurance Program are identified in the Safety Analysis Report (usually Section 3.2) and in more detailed lists developed in response to NRC Generic Letter 83-28 or 10 CFR 50.34 (f) (3) (ii) referenced by 10 CFR 52.47(a) (8), 10 CFR 52.79 (a) (17), 10 CFR 52.137 (a) (8) and 10 CFR 52.157 (f) (12). Quality assurance commitments for other types of important to safety items, as found in licensees' or U.S. Department of Energy contractors' quality assurance programs and other licensing basis documents, are specified to S&L in contract documents. Project instructions or project work plans shall delineate the applicability of this program to these other types of items.

S&L intends to provide engineering and design services for new nuclear power plants. S&L will not construct these plants nor provide large-scale inspection services.

The applicable criteria in this program shall be applied in a graded approach to radioactive material packaging and ISFSIs. The application shall be to an extent that is commensurate with the importance to safety, such as described in Appendix A of Regulatory Guide 7.10 (see item h in this chapter), or its equivalent for ISFSIs, such as the classification system described in

NUREG/CR-6407 titled "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety."

The applicable criteria in this program shall be applied in a graded approach to operating gaseous diffusion plants to an extent that is commensurate with the importance to safety and is consistent with the quality assurance program implemented by the United States Enrichment Corporation (USEC), or its successor, in accordance with 10 CFR 76.93.

To implement the program, standard operating procedures have been prepared. Revisions to the Nuclear Quality Assurance Program and the standard operating procedures will be made, in accordance with a standard operating procedure, for any of the following reasons:

- a. the program or standard operating procedures may be incomplete, unclear or incorrect;
- b. the resolution of a nonconformance may require change to some portion of the program or standard operating procedures;
- c. the personnel implementing or auditing the program or standard operating procedures determine that the program and/or procedures do not effectively control a work function;
- d. the standards, codes, regulatory requirements, or organization may be changed.

S&L policy makes compliance with the S&L Nuclear Quality Assurance Program and implementing procedures mandatory for all personnel performing activities relating to safety.

For limited scope projects, such as modification work for operating plants, implementation of various elements of this Nuclear Quality Assurance Program will depend on S&L's assigned responsibilities on the project.

The S&L Nuclear Quality Assurance Program, as represented herein, complies with Title 10 of the Code of Federal Regulations, Part 50, Appendix B, titled "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and with Part I and Subparts 2.4, 2.5, 2.7, and 2.8 of Part II of the 1994 Edition of ASME NQA-1 titled "Quality Assurance Requirements for Nuclear Facility Applications" with the following exceptions:

- (1) S&L deviates from the Introduction to Part I of NQA-1 in the following definitions:
 - (a) Commercial Grade item – See the current definition in 10 CFR 21.3.
 - (b) Nonconformance – A condition of, or affecting, a structure, system, or component in which there is a failure to meet requirements or licensee commitments (NRC GL 91-18, Revision 1).
- (2) A general grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general grace period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early.
- (3) Lead auditors shall have participated in a minimum of five QA audits within a period of time not to exceed three years prior to the date of qualification, one audit of which is a nuclear QA audit within the year prior to

qualification or for individuals with related industry experience, demonstrated ability to properly implement the audit process, to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification.

The Parts of NQA-1 to which S&L commits as listed above contain useful guidance concerning design and construction-related activities associated with new plants or modifications and shall be applied to those activities occurring during the operational and decommissioning phases that are comparable to related activities occurring during initial plant design and construction. Considerable care is required in assessing which operational and decommissioning phase activities are comparable in nature and extent to activities normally associated with design and construction.

For design activities for which Section III of the ASME Boiler and Pressure Vessel Code permits a supplier not accredited by ASME to perform these activities, the evaluation of an S&L supplier's program shall include an evaluation of compliance with Appendix B to 10 CFR 50. (See Paragraph 04.01.e of this program for additional information).

S&L is committed to meeting and implementing the applicable provisions of the following requirements except as indicated below and/or as these provisions may be modified by a commitment in an applicable SAR or design control document (DCD):

- a. Regulatory Guide 1.8, May 2000 – Qualification and Training of Personnel for Nuclear Power Plants (ANSI/ANS-3.1 - 1993 – Selection, Qualification, and Training of Personnel for Nuclear Power Plants) with the following exceptions:

- (1) S&L commits to Part I of the 1994 Edition of ANSI/ASME NQA-1 in lieu of the 1983 Edition.
- (2) Alternatives to the education and experience requirements, such as experience other than at a nuclear-fueled electric power production plant, shall be evaluated and documented by the Chief Executive Officer for the Quality Assurance Manager, by the Quality Assurance Manager for an individual providing quality assurance supervision and other members of the Quality Assurance Division, and by the responsible manager for other personnel in lieu of the applicable plant manager.

Qualification requirements for the Quality Assurance Manager are established in a position description which includes the following prerequisites:

- (1) Management experience through assignments to responsible positions.
- (2) Knowledge of QA regulations, policies, practices, and standards.
- (3) Experience working in QA or related activity in reactor design, construction, or operation or in a similar high technological industry.

Note that a client may elect to qualify S&L personnel, such as those reporting directly to a plant manager, in accordance with the client's quality assurance program. In this case, the personnel qualification requirements in this program, SL-TR-1A, do not apply to these S&L personnel.

- b. Regulatory Guide 1.26, March 2007 - Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants.

- c. Regulatory Guide 1.29, July 2016 - Seismic Design Classification for Nuclear Power Plants.
- d. Regulatory Guide 1.127, February 2016 – Criteria and Design Features for Inspection of Water Control Structures Associated with Nuclear Power Plants.
- e. Regulatory Guide 1.231, January 2017 – Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants.
- f. NRC Regulatory Issue Summary 2000-18, Guidance on Managing Quality Assurance Records in Electronic Media,” October 23, 2000. S&L uses the guidance in this summary except that the versions of the approved Nuclear Information and Record Management Association, Inc. (NIRMA) Technical Guides have been updated. See Chapter 17.00 for further details.
- g. NRC Letter to All Holders of Operating Licensees and Construction Permits for Nuclear Power Reactors, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (Generic Letter 89-02), March 21, 1989.
- h. NRC Letter to All Holders of Operating Licenses and Construction Permits for Nuclear Power Reactors, “Licensee Commercial-Grade Procurement and Dedication Programs (Generic Letter 91-05), April 9, 1991.
- i. Regulatory Guide 7.10, March 2005 - Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material.

S&L takes exception to Regulatory Position C.3.3 concerning the independence of design verifiers. Instead, S&L follows the provisions of

the 1994 Edition of ANSI/ASME NQA-1 as detailed above and as further described in Section 03.04 of this program.

The Topical Report is reviewed annually for continuing conformance to regulatory requirements and industry codes and standards. Changes in the Topical Report are submitted to the Nuclear Regulatory Commission in accordance with 10 CFR 50.4 (b)(7)(ii). Any reductions in commitments to the NRC contained in this Topical Report must be accepted by the NRC before implementation.

01.00 ORGANIZATION

- 01.01 S&L organizational structure and functional responsibility assignments are based on the recognition of quality assurance as an inter-disciplinary process with quality-related activities being performed by individuals at all levels. The responsibilities of persons implementing quality-related requirements are established, assigned, and documented. Assignments are such that:
- a. attainment of quality objectives is accomplished by individuals assigned responsibility for specifying quality or performing work to quality assurance procedures;
 - b. verification of conformance to established quality requirements is accomplished by project personnel who are independent of those responsible for establishing or performing the activity;
 - c. personnel performing key quality assurance functions have direct access to management.

S&L's management organizational structure is shown in Figure 01.01-1, Sargent & Lundy Management Organization Chart. Company services are organized into business groups and functional support groups. The business groups are Nuclear Power Technologies and other business groups as determined by the Chief Executive Officer. The functional support groups are Operations and Financial. The Chief Executive Officer exercises administrative control over the directors of business groups, as well as the Chief Operations Officer and the Chief Financial Officer and General Counsel. Although the individual groups are distinct entities, the management and execution of their respective functions and responsibilities may involve staff sharing with other groups.

The Director of the Nuclear Power Technologies business group oversees nuclear services provided for operating and decommissioning plants and other specialized projects.

In a similar fashion, the directors of the other business groups oversee services provided within their areas of responsibilities.

The Chief Operations Officer exercises administrative control over the Chief Information Officer, the Director of Engineering, the Construction Support Director, the Design Director, and the Manager of the Administrative Services Division. The Chief Information Officer exercises administrative control over the Assistant Chief Information Officer and the Computer Services Division. The Assistant Chief Information Officer is responsible for information management including enterprise content management support services (refer to Chapter 17.00 for control of quality assurance records). The Computer Services Division is responsible for the configuration control of software used in production, including the filing of software verification and validation documentation.

The Chief Financial Officer and General Counsel exercises administrative control over the Director of Legal Services and the Human Resource Director. The Director of Legal Services exercises administrative control over the Managers of the Commercial Division, which reviews contracts with clients, and the Procurement Division, which issues procurement documents to suppliers. The Human Resources Division is responsible for aspects of access authorization and fitness for duty.

The Quality Assurance Manager reports to the Chief Executive Officer.

Personnel from the Chief Operations Officer's staff and the appropriate support services divisions in the Financial Group normally report to the director of these two functional support groups. However, some personnel from these two groups may be temporarily assigned to projects controlled by a director of a

business group, as required, to perform the necessary technical and administrative functions pertaining to design, engineering, procurement, and inspection. The Director of Engineering is responsible for establishing processes, methods and techniques for achieving technical objectives. The director of a business group has overall responsibility for the technical adequacy and acceptability of S&L nuclear engineering and design work within the responsibility of the group, and for providing feedback to the Director of Engineering on the effectiveness of the engineering processes, methods, and techniques.

Project Instructions and governing company standards are established to control quality-related activities. These instructions and governing company standards are reviewed by Quality Assurance for conformance to this program's requirements before issuance.

Within a business group, a project organization is established for each project in which S&L has essentially all the engineering responsibility and for services projects (or tasks) for units under construction, in operation or in decommissioning which may have been engineered by others. The size and composition of the project organization is dependent on the project responsibilities such as described by the project work plan. Since S&L serves a wide variety of clients with different service requirements, different project organizations may be established to best accommodate the scope of work.

For each project, the project organization is comprised of qualified individuals. In cases where an onsite design engineering and/or services project organization is required and falls under the cognizance of the QA Program, organizational charts, functional descriptions of responsibilities and relationships, job descriptions of key personnel positions, or equivalent forms of documentation are prepared showing the lines of responsibility. Delegation of authority passes from the responsible Director of a business group and Project

Director through the Project Manager to Senior Project Engineers and responsible engineers and consultants.

The responsibility for implementation of the S&L Quality Assurance Program on a project is assigned to the Project Manager. The project team provides the S&L interface with the client and major contractors, and establishes the technical requirements on the project to assure compliance with applicable codes, standards, and regulations. In project matters, the Senior Project Engineers report to the Project Manager, who reports to the Project Director, who represents S&L management on the project.

Interfacing relationships and lines of communication among S&L, the client, vendors, and major contractors on a project are established by and/or described in documents such as, but not limited to, the scope of work, the project work plan, procurement documents, and project instructions. Internal interfaces within S&L are established in company standards and procedures, project instructions, and quality assurance procedures.

The Chief Executive Officer establishes quality assurance policy and objectives. The Chief Executive Officer has delegated to the Quality Assurance Manager responsibility for providing and maintaining the Quality Assurance Program, for providing programmatic policy and direction on quality assurance, and for coordinating and verifying its implementation on projects.

Quality Assurance, as indicated in Figure 01.01-1, S&L Management Organization Chart, is independent of any S&L project organization. The Chief Executive Officer ensures that the size of the Quality Assurance Division is commensurate with its duties and responsibilities. The Quality Assurance Manager has the authority and organizational freedom to identify quality problems within S&L, recommend or provide solutions and verify their implementation, and to stop unsatisfactory work or otherwise control further processing of a nonconforming item until the proper disposition of the

unsatisfactory condition has been achieved. S&L personnel are required to bring to the attention of the Quality Assurance Manager conditions which may merit stop-work consideration. The Quality Assurance Manager provides expertise as applicable in interpretation of quality assurance requirements in codes and standards, in regulations, in NRC Regulatory Guides and in the Quality Assurance Articles, Section III, Rules for Construction of Nuclear Facility Components, ASME Boiler and Pressure Vessel Code.

The responsibilities and functions of the Quality Assurance Manager include, but are not limited to:

- a. developing for management approval by the Chief Executive Officer standard operating procedures necessary for implementation of the program;
- b. recommending to the Chief Executive Officer desirable changes in the Nuclear Quality Assurance Program;
- c. reviewing procedures, governing company standards, and instructions prepared by groups, departments, divisions, and project organizations for conformance to the Nuclear Quality Assurance Program and procedure requirements;
- d. interfacing with clients and the Nuclear Regulatory Commission on audits and quality assurance matters;
- e. interfacing with project organizations and support divisions to assist in the implementation of quality assurance requirements on a project;
- f. maintaining and controlling the distribution of the Nuclear Quality Assurance Program, standard operating procedures, and revisions thereto;

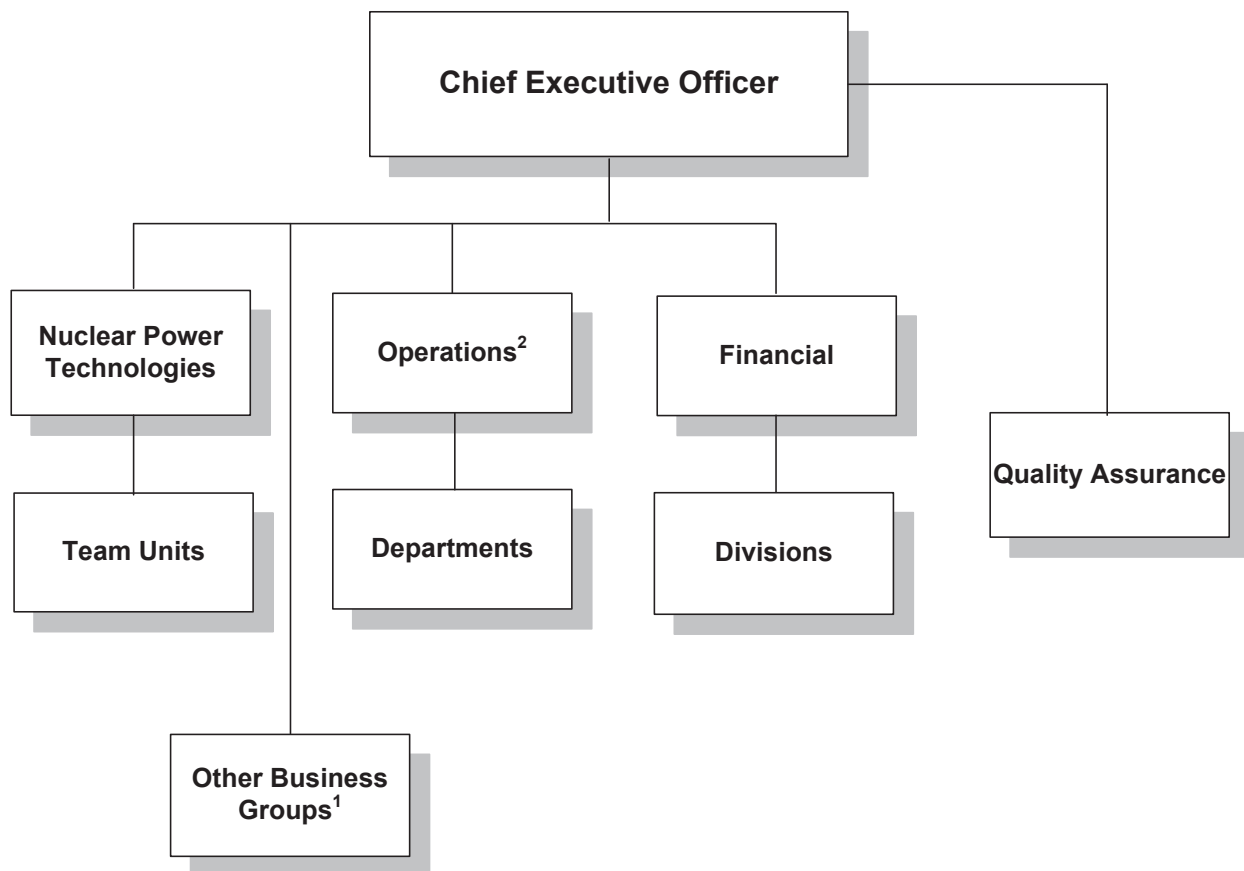
- g. training and instructing S&L personnel performing quality-related activities in the implementation of the Nuclear Quality Assurance Program and standard operating procedures;
- h. developing and conducting audits and surveillance on design, procurement and other activities of S&L personnel assigned to a home office and to the field;
- i. providing quality assurance input in S&L procurement documents;
- j. reviewing, evaluating and reporting on S&L suppliers' quality assurance programs and/or procedures;
- k. conducting certain types of inspection as specified in Chapter 10.00 of the Program and in implementing procedures;
- l. conducting audit and surveillance of suppliers' compliance to their approved quality assurance programs;
- m. performing an overview of software verification and validation documentation. This review is performed after the responsible design organization has completed and documented the testing to demonstrate proper performance.
- n. providing direct quality assurance services as requested by clients, including such services as preparation of QA programs and procedures, auditing and surveillance of the client's organization and its suppliers, and training of client personnel in quality assurance activities;
- o. furnishing qualified personnel to clients for assistance in quality-related activities.

Where portions of engineering investigations and design work such as soil borings, laboratory testing or hydrology assessments are performed by a

consultant or subcontractor, S&L assures that the technical services consultant or subcontractor either 1) has a quality assurance program conforming to applicable portions of 10CFR Part 50, Appendix B and ANSI/ASME NQA-1-1994 and that the technical services consultant or subcontractor is acceptably implementing its program, or 2) their commercial grade services are dedicated in accordance with 10 CFR 21 or 10 CFR 50.55(e), as applicable. The consultant's or subcontractor's program is reviewed by the Quality Assurance Division for compliance with these regulations and ANSI/ASME NQA-1-1994 prior to initiation of quality related activities.

When responsible for procurement, S&L delegates, or a client may delegate the Quality Assurance Manager authority to identify supplier quality control problems and to stop unsatisfactory work or otherwise control further processing of an item by a supplier.

Sargent & Lundy Management Organization Chart
Figure 01.01-1



¹Other Business Groups and their area of responsibility are determined by the Chief Executive Officer.

²Configuration control of software used in production, including filing of software verification and validation documents, is the responsibility of the Operations functional support group.

02.00 QUALITY ASSURANCE PROGRAM

- 02.01 This Quality Assurance Program has been established in accordance with the requirements of 10 CFR Part 50, Appendix B.

This program has also been established to meet the relevant requirements of 10 CFR 52 titled "Licenses, Certifications, and Approvals for Nuclear Power Plants." These requirements are 10 CFR 52.17 (a) (1) (xi) and 10 CFR 52.18 for early site permits; 10 CFR 52.47 (a) (19) and 10 CFR 52.48 for standard design certifications; 10 CFR 52.79 (a) (25) and, as applicable, 10 CFR 52.79 (a) (27) and 10 CFR 52.81 for combined licenses; 10 CFR 52.137 (a) (19) and 10 CFR 52.139 for standard design approvals; and 10 CFR 52.157 (f) (17) and 10 CFR 52.159 for manufacturing licenses.

During the preparation of the Program and the standard operating procedures, steps are taken to verify that the S&L Nuclear Quality Assurance Program and procedures responds to each of the applicable criteria of 10 CFR Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants; 10 CFR 71, Subpart H, Quality Assurance; 10 CFR 72, Subpart G, Quality Assurance; 10 CFR 76.93, Quality Assurance; and to the requirements of the applicable Regulatory Guides, Regulatory Issue Summary, NRC Generic Letters and quality assurance industry standards referenced in Chapter 00.00, Introduction (except as noted therein). NRC Regulatory Guides are reviewed for suitability and used as appropriate for S&L activities. The Generic Letters are used in conjunction with current regulations.

Those responsible for defining the content of the Nuclear Quality Assurance Program are the Chief Executive Officer and the Quality Assurance Manager. The Quality Assurance Manager is responsible for approval of this Quality Assurance Program and implementing procedures. The Chief Executive Officer provides senior management approval of this Quality Assurance Program and the standard operating procedures.

The Nuclear Quality Assurance Program is made available to personnel responsible for quality-related work through controlled distribution in accordance with a standard operating procedure.

Since this program is included in the document control system, S&L personnel who receive the program electronically are provided with a master list so that they can verify that they are working with the current issue of the program. S&L personnel and other organizations who receive controlled hard copies of this program are required to acknowledge receipt of the program and revisions.

To implement the Nuclear Quality Assurance Program and comply with the standard operating procedures, the Chief Operations Officer, Director of Engineering, Department/Division Managers and Project Managers establish standards, procedures, and instructions for the control of quality-related activities. Specific implementing procedures are established to control activities in compliance with the requirements of the program.

S&L policy, as established by the Chief Executive Officer, makes compliance with this Nuclear Quality Assurance Program mandatory for all personnel performing quality-related activities.

- 02.02 Safety-related structures, systems and components for a project are identified, and design and procurement activities are controlled by the Nuclear Quality Assurance Program and the implementing procedures.

The Nuclear Quality Assurance Program and procedures are in effect prior to initiation of activities affected thereby.

- 02.03 S&L standards and procedures provide for the documentation and dissemination of management policies and practices for the control of activities affecting the quality of nuclear safety-related structures, systems and components. Each process owner (see Paragraph 02.06.c of this program), project manager, and organizational manager generates, as necessary,

standards and/or procedures covering his/her areas of responsibility. These standards/procedures establish design, performance, fabrication, installation or operation requirements for a system, structure or component; or establish methods for controlling activities within a department or division. Such standards/procedures are applied to the work performed by personnel qualified in the applicable process who are working on a project or within the related department or division.

The mandatory requirements for nuclear quality-related activities are delineated in the standards/procedures. When a deviation from such requirements is necessary, appropriate review and approval of the proposed deviation is required and is documented.

- 02.04 S&L quality-related activities meet the requirements of the client, S&L, applicable codes and standards, and regulatory agencies.
- 02.05 The development and use of software for quality-related activities are controlled by the Nuclear Quality Assurance Program, including Supplements 3S-1 and 11S-2, and Subpart 2.7 of ANSI/ASME NQA-1-1994. Software is developed in defined sequential phases as part of a software life cycle. Engineering analysis software is verified for correctness and feasibility of software functions and for achievement of requirements for each phase within the assumptions and limitations stated in the software documentation. Prior to use, software is validated by documented testing to demonstrate proper performance. Test requirements and acceptance criteria are provided or approved by the responsible design organization. A variety of typical problems is used in the validation process. Results are checked against known solutions, solutions obtained from other verified and validated software, and/or hand calculations.

Procedures require software used for engineering design or analysis applications to be uniquely identified. Engineering analysis software, which will

not be individually verified and validated for each application, is listed in the S&L online configuration management database. To the extent appropriate, controls are established to prevent unauthorized changes to verified and validated software files. Temporary changes to listed software may be authorized in special circumstances. However, all such changes are required to be validated and documented.

02.06 To assure that appropriate skills are utilized in the performance of quality-related activities:

- a. Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of this Quality Assurance Program, project instructions, and procedures.
- b. Personnel in the Quality Assurance Division, as well as technical specialists who assist with audits, are trained and qualified in the principles, techniques, and requirements of the activity being performed.
- c. The technical and administrative processes used to produce deliverables have been defined. Each of these processes has a formal description.

Personnel who perform quality-related activities are required to be qualified in the applicable process. A standard operating procedure describes the different qualification levels and what activities each level authorizes the person to perform. Records are maintained of the process description and personnel qualifications.

- d. Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, re-examining, and/or re-certifying as determined by management or program commitment.

In accordance with 10 CFR 52.79 (a) (33), personnel associated with the operating phase of combined licenses shall be trained and qualified in

accordance with 10 CFR 50.120 titled “Training and Qualification of Nuclear Power Plant Personnel” derived from a systems approach to training as defined in 10 CFR 55.4, as these are applicable to contractor personnel. [The NRC has determined that, based on a sample review of process descriptions, individual training records, and standard operating procedures that S&L’s personnel qualification certification and training program is consistent with the requirements of 10 CFR 50.120 and 10 CFR 55.4, as well as the guidance in ANS 3.1–1993 (Section 00.00 of this program) regarding qualification of contractor personnel and establishment of a program based on the five elements of a systems approach to training, as defined in 10 CFR 55.4 (reference letter from S. Dembek (NRC) to R. Kurtz (S&L) dated January 2, 2004)].

- 02.07 Differences of opinion between Quality Assurance and other S&L organizations are resolved by the Chief Executive Officer. Resolution is documented.
- 02.08 Management biennially assesses the adequacy of this QA Program's overall implementation on projects which are in the operational or decommissioning phases. Management assesses the adequacy of this QA Program’s overall implementation on projects which are in the construction phase annually or at least once during the life of the activity, whichever is shorter. These assessments are initiated by the Chief Executive Officer. The management team is led by an S&L owner and consists of senior level personnel, such as Project Managers and Senior Project Engineers, with expertise in the engineering disciplines. The report of the assessment is approved by the Chief Executive Officer and is distributed to the responsible management for action.

03.00 DESIGN CONTROL

03.01 The design of structures, systems and components is planned and controlled by governing company standards and procedures, project instructions, and standard operating procedures. Design processes are prescribed, accomplished and documented in accordance with these various procedures, which establish the responsibilities and interfaces of each organizational unit that has an assigned design function. Responsibilities are described for preparing, reviewing and approving design documents such as design criteria, drawings, calculations, software, procurement documents and procedures. Included are measures to assure that:

- a. applicable design inputs, such as design bases, commitments of the SAR, regulatory requirements, and codes and standards, are identified, documented and their selection is reviewed and approved. Additionally, separate design criteria documents are prepared for new structures and new systems which specify, in qualitative or quantitative terms, the requirements to be met or objectives to be achieved by the specific design; such design criteria documents are prepared, when appropriate, for new components within existing systems. The adequacy with which the design criteria documents are translated into procurement documents, drawings and instructions is determined by system and structure design reviews, when appropriate, that are performed in accordance with a standard operating procedure.
- b. responsibility is assigned for inclusion in the design documents of appropriate quality requirements and standards;
- c. deviations, including the reasons thereof, from quality requirements and standards as well as design changes are identified, approved and documented. Design change control is at the same level as applied to the original design.

03.02 Safety-related structures, systems and components are classified in accordance with procedures. Selection of parts, materials and components for suitability of application is made after adequate reviews have been performed. Catalogue items when included in S&L design are reviewed for suitability of application by the appropriate engineering division. Reviews of these items may include any or all of the following: historical performance data and records, valid industry standards and specifications, prototype testing programs, and design reviews.

03.03 During design, controls and reviews are applied for such aspects as physics, seismic, stress, thermal, hydraulic and accident analysis; associated software; compatibility of materials; accessibility for in-service inspection and testing; maintenance and repair; quality standards; and specifying functional criteria in accordance with design and standard operating procedures. When appropriate, acceptance/rejection criteria are included in design documents.

The company performs modifications that may affect the function of safety-related structures, systems, or components in a manner to assure quality at least equivalent to that specified in original design bases and requirements, materials specifications, and inspection requirements.

03.04 Verification of design is accomplished by performing design reviews, alternate calculations, or a qualification testing program. Procedural control is established for design documents that reflect the commitments of the SAR or DCD; this control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, software, system descriptions, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams,

structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

The following provisions are included if the verification method is only by test:

- a. Procedures provide criteria that specify when verification should be by test.
- b. Prototype, component, or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreversible.
- c. Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

Procedures are established to assure that verified computer codes are certified for use and that their use is specified.

Procedures are established and described requiring a documented check to verify the dimensional accuracy and completeness of design drawings and specifications.

The extent of the verification is to be consistent with the importance of the design activity to plant safety, complexity of design, degree of standardization, state of the art and similarity with previously proven design.

Procedures provide guidance and specify methods for performing design verification. Design verification reviews are performed by qualified personnel or groups other than those who performed the original design. This verification

may be performed by the preparer's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or provided the supervisor is the only individual in the organization competent to perform the verification.

After satisfactory resolution of the reviewer's comments, the document is approved and becomes a record of design verification and is subject to audit. The appropriate engineering personnel responsible for the review assure that:

- a. design characteristics can be controlled, inspected and tested;
- b. inspection and test criteria are identified.

In addition to the design reviews made prior to the issue for use of individual design documents, broader system and structure design reviews are performed for complete plant design projects prior to initial fuel loading. These broader reviews are performed after the design documents have been adequately developed. For design modification work for operating plants, in addition to the design reviews of individual documents, broader system and structure reviews or other methods of design verification may be performed when applicable to the project scope of work. During the system and structure design reviews, design documents are reviewed against requirements of the applicable design criteria and/or other supporting documents in accordance with procedures established by the engineering department conducting the reviews. Responsibility to initiate and to follow through on any required changes is assigned to appropriate project personnel.

Errors and deficiencies in approved design documents, including design methods (such as computer codes), that could adversely affect structures, systems, and components important to safety are documented; and action is taken to assure that all errors and deficiencies are corrected.

Deviations from specified quality standards are identified and procedures are established to ensure their control.

Procurement documents indicate those drawings and other design documents to be submitted by suppliers to S&L for review. When S&L is responsible for procurement, S&L and the supplier assure that established measures are implemented for the control, handling and approval of supplier generated documents. The supplier's design documents are reviewed by the appropriate engineering organization in accordance with a standard operating procedure, for conformance to procurement documents and for compatibility with interfacing equipment, structures, systems, etc.

- 03.05 The Project Manager is responsible for project coordination within S&L. Interfacing activities among organizational units, including groups of dedicated process specialists, within S&L are identified and controlled by means of standard operating procedures. These procedures provide for the preparation of design documents by qualified individuals and design verification by individuals who are independent of the preparer. Also, the procedures provide for the following:
- a. reviewing documents for accuracy and technical adequacy prior to release;
 - b. approving documents, by authorized personnel, for use;
 - c. distributing documents to their intended points of use;
 - d. determining that the correct revision of these documents is being used;
 - e. requiring systems for identification of quality assurance records and a control system to clearly indicate their applicability, accountability and status;

- f. subjecting significant changes to documents to the same degree of control as the original;
- g. establishing retention periods for quality assurance records and a mechanism for their transmittal to the client, if required.

Interactions between S&L and outside organizations which provide designs, specifications, data, and/or technical direction are defined as external interfaces. The identification of external interfaces is described in documents such as scope of work, procurement documents, and standard operating procedures.

Procedures provide for control, collection, storage, handling, maintenance and retrieval of the following documents, and revisions thereto:

- a. Nuclear Quality Assurance Program
- b. Standard Operating Procedures
- c. S&L standards
- d. Project instructions
- e. Design documents
- f. Other quality assurance records

The Nuclear Quality Assurance Program is supplemented by procedures covering requirements for distribution of design documents. Subsequent issues of documents follow the same distribution requirements as the original, unless another distribution is approved. When S&L is responsible for the distribution of design documents, status lists are prepared and distributed in accordance with documented procedures to prevent inadvertent use of obsolete documents.

- 03.06 The design change control procedure requires documentation of the change and approval by the cognizant project engineer. The cognizant project engineer is charged with the responsibility for defining all other design documents affected by the change, and for resolving and coordinating changes with other project engineers whose design is affected. Design changes affecting external interfaces are identified and reviewed with the affected external organization(s) and documented in accordance with established procedures.

Design changes identified by field organizations are generally the result of unexpected construction conditions. The field organization generates a document which identifies the conditions and may propose a method of correction. When directed by the client, S&L engineering and design personnel review safety-related design changes. When a proposed design change or a method of correcting a design problem does not comply with approved design basis documents, it is the responsibility of S&L to provide an alternate solution to the problem. Approved design changes will then be incorporated, where appropriate, into the affected design documents.

Advance approval of field design changes may be authorized by responsible S&L personnel when the timing cannot be met for conducting a full review of the design changes. In such cases, the full review of the design changes is conducted by the time the affected design documents are approved and issued for use, and prior to the start of fuel loading, for a plant under construction, or prior to relying upon the component, system or structure to perform its function, for a plant in the operating or decommissioning phase. The authorization and issuance of advanced approval of field design changes are controlled in accordance with procedures.

- 03.07 Control of quality-related activities between S&L and the client during the phase out of design and procurement is in accordance with this program and

implementing standard operating procedures. Transfer of applicable manuals, records and documents is in accordance with procedures and is auditable.

03.08 The design control measures described in this Chapter shall be applied to items which are part of radioactive material packages or ISFSIs such as the following:

- a. Criticality physics, radiation shielding, stress, thermal, and accident analyses;
- b. Compatibility of materials;
- c. Accessibility for inservice inspection, maintenance, and repair;
- d. Features to facilitate decontamination; and
- e. Delineation of acceptance criteria for inspections and tests.

Changes in the conditions specified in the package approval or the ISFSI license require NRC approval.

04.00 PROCUREMENT DOCUMENT CONTROL

04.01 Procedures are established to verify that a statement of scope of the work to be performed and applicable regulatory requirements, design bases, and other requirements necessary to assure quality are included or referenced in S&L originated documents for procurement of equipment, materials, components and services. The following information and requirements are included in procurement documents as appropriate:

- a. applicable regulatory, standard, and code requirements; drawings and standard specifications;
- b. test and inspection requirements;
- c. acceptance/rejection criteria;
- d. requirements for fabrication and special requirements, such as cleaning, packaging, handling, shipping and normal or extended field storage;
- e. requirements for the supplier's quality assurance program identification of quality requirements including reference as applicable to 10 CFR Part 50, Appendix B, ANSI/ASME N45.2, ANSI/ASME NQA-1, ASME Section III, 10 CFR 21 and 10 CFR 50.55 (e);
- f. documentation requirements - suppliers will prepare and submit documentation that identifies the purchased material or equipment and the code, standard, or specification met by the item(s). When S&L is responsible for procurement, the supplier will submit to the client or S&L, drawings, specifications, procedures, subtier procurement documents, inspection and test records, personnel and procedure qualifications, chemical and physical property test results for materials, and certificates

of conformance and compliance, as applicable, for review and/or comment;

- g. records control - identification of quality assurance records to be controlled, maintained, retained and/or delivered to the site prior to use or installation. Retention times and disposition requirements are specified for records to be retained;
- h. source surveillance and audit - provisions for access to supplier and his subsuppliers' facilities, and records for source surveillance and/or audit by purchaser or authorized representative;
- i. lower-tier procurements - extension by the supplier of applicable requirements to subsuppliers, including access by the purchaser or his designated representative, to facilities, procedures, and records;
- j. nonconformances - provisions for the supplier to submit nonconformances together with their recommended disposition (use as is, rework or repair) including the technical justification to S&L for review and approval and, if required, recommendation of disposition to the client;
- k. establishment of hold or witness points in conjunction with the supplier.

04.02 Procurement documents are prepared, reviewed and approved by the appropriate disciplines and issued in a sequence of steps prescribed in accordance with standard operating procedures prior to release for fabrication, construction or installation of items or performance of services.

Revisions are made following the same sequence as for the original document. When S&L is responsible for issuing procurement documents for bid or for purchase and these documents reference a procurement specification, control is maintained by the procurement document and supplements thereto

referencing the applicable revision of the procurement specification.

Procurement documents used for bid contain necessary quality assurance/quality control requirements. Procedures also require that all safety-related references in the procurement document are current and correct.

The following reviews of procurement documents are required to be accomplished and documented:

- a. examination by the responsible preparer for format, standards, editing and uniformity;
- b. for procurement documents containing technical requirements, review by a qualified engineer (independent of the preparer) for technical adequacy, correct use of design bases, applicable regulatory requirements and adequate acceptance/rejection criteria, as applicable;
- c. review for compatibility by an engineer of each applicable interfacing discipline;
- d. review by qualified Quality Assurance personnel to determine that quality requirements are adequately and correctly stated, inspectable and controllable; and that records to be retained, controlled and maintained are identified.

A change and/or revision to a procurement document is subject to the same level of review and approval as the original document.

04.03 Procurement documents require suppliers to have and implement a quality assurance program for purchased materials, equipment and services to an extent consistent with their importance to safety. Concurrence by qualified S&L personnel with supplier quality assurance programs is required prior to initiation

of quality-related activities, when S&L is responsible for procurement or upon request by a client.

Suppliers of basic components and, as necessary, of commercial grade items and services are evaluated in accordance with quality assurance procedures prior to contract award to assure that technical and quality assurance requirements of the procurement documents can be met.

- 04.04 If spare or replacement parts are purchased, such purchases will be based on either an existing prepared, reviewed and approved procurement document or a new procurement document prepared, reviewed and approved in accordance with standard operating procedures. These purchases are subject to present Nuclear Quality Assurance Program controls, to codes and standards and to technical requirements equal to or better than the original technical requirements, or as required to preclude repetition of defects.

05.00 INSTRUCTIONS, PROCEDURES AND DRAWINGS

- 05.01 Activities affecting quality shall be prescribed by documented instructions, procedures or drawings of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures or drawings. Procedures and instructions clearly assign responsibilities and describe the required sequence of actions in the preparation, review, approval, revision and control of documents. Standard operating procedures require that interfacing divisions review and comment on changes.
- 05.02 Applicable government regulations and industry codes and standards, as developed by NRC, ASTM International, ACI, ASME, ANSI, IEEE and other recognized organizations, are specified where applicable. These codes, standards, etc., incorporate both qualitative and quantitative acceptance criteria and are identified and referenced in design criteria, analyses, specifications, and other engineering documents.

Where necessary, design instructions, procedures, and drawings indicate the required sequential order of activities. Quantitative criteria, such as standard practices for dimension, identification and selection of tolerances, and qualitative criteria, such as comparative workmanship samples and visual standards, are specified in the appropriate documents as criteria for determining quality compliance.

In accordance with standard operating procedures, project instructions are prepared to provide for the following:

- a. client requirements not addressed in a standard operating procedure;
- b. clarification and/or additional information for use with a standard operating procedure;

- c. alternative methods, approved by the Chief Executive Officer or a Group Director, to standard operating procedures for addressing programmatic requirements.

A project instruction shall not conflict with the Nuclear Quality Assurance Program.

06.00 DOCUMENT CONTROL

- 06.01 Procedures and practices are established to control the issuance of design documents, instructions, and procedures, including changes thereto, which prescribe activities affecting quality.

The Nuclear Quality Assurance Program and implementing procedures include measures which provide assurance that documents, including changes, are reviewed for adequacy and inclusion of quality requirements, approved for release by authorized personnel, and distributed for use at the location where the prescribed activity is performed. The groups and/or individuals responsible for these activities are identified.

Those participating in an activity are made aware of and use proper and current instructions, procedures, drawings, specifications, codes and standards for performing the activity. Participating organizations have procedures for control of these documents and changes thereto, to preclude the possibility of use of outdated or inappropriate documents. Master lists are distributed on a regular basis or made available electronically so that recipients can verify that they are working with current issue of this program, procedures and drawings. Master lists of other activities are provided on a timely basis.

- 06.02 Document control measures provide for:
- a. reviewing documents and their revisions for adequacy and inclusion of quality requirements prior to release for use;
 - b. identifying individuals or organizations responsible for preparing, reviewing, approving, and issuing documents and revisions thereto;

- c. identifying and maintaining current the proper documents and their status, e.g., "preliminary," "approved for construction," "approved for bids," etc., as appropriate;
- d. coordinating and controlling interface documents;
- e. assuring availability of documents at the onset of work for which they are needed;
- f. establishing current and updated document distribution lists for hard copy distributions;
- g. obsoleting, recalling, or in some manner identifying documents not intended for current use.

Changes to documents are reviewed and approved with a degree of control commensurate with the original document by the same organizations that performed the original review and approval unless other qualified organizations are specifically designated by S&L management. However, nontechnical editorial changes to design documents may not require that the revised document receive the same review and approval as the original document. In such cases, these types of changes and the person who can authorize such a decision are delineated in the procedure controlling issuance of the document. Reviewers have access to pertinent background information upon which to base the review, and have an adequate understanding of the requirements and intent of the original document.

The Nuclear Quality Assurance Program and implementing procedures require that approved changes be reviewed for applicability to related instructions, procedures, drawings, and other appropriate documents, and that those affected documents be changed through controls consistent with the original

issue. Approved changes are required to be traceable as well as implemented by all organizations involved.

- 06.03 The scope of the S&L document control system includes procedures and instructions for such activities as construction, modification, installation, test and inspection, procurement documents, nonconformance reports, manuals, design documents (e.g., calculations, drawings, specifications and analyses), and documents related to computer codes and as-built information.

07.00 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

07.01 Implementing procedures to the Nuclear Quality Assurance Program establish measures to assure that purchased items and services are clearly and adequately specified in procurement documents and that suppliers are capable of producing items and furnishing services, whether purchased directly or through subsuppliers, which conform to procurement document requirements. These procedures include provisions for supplier evaluation, review of procurement requirements, and surveillance of the supplier, when S&L is responsible for the procurement or requested by the client.

Results of evaluations performed on suppliers prior to contract award are documented, and available for audit.

Evaluation of procurement sources is performed by S&L engineering and quality assurance personnel, as appropriate. Recommendation of procurement sources is based on these evaluations. The evaluations cover review of capabilities and facilities for technical, manufacturing, erecting, installing, and quality performance, and include any or all of the following as appropriate:

- a. historical performance data, particularly in product quality and on-time performance;
- b. review and comment on supplier quality assurance program and procedures;
- c. source audits to verify supplier implementation of his quality assurance program, as required;
- d. source qualification programs.

The quality assurance programs of potential suppliers are evaluated to determine compliance with the applicable criteria of 10 CFR Part 50, Appendix B, with ANSI/ASME N45.2 or NQA-1 and applicable Regulatory Guides, with ASME Section III, Divisions 1 and 2, and with other ANSI Standards. The evaluation is accomplished prior to an award by S&L or submittal of the recommendation letter to the client, as applicable, and thereby precedes initiation of quality-related activities. Proposals from bidders are reviewed by S&L in accordance with approved quality assurance procedures by personnel with the appropriate process qualifications and Quality Assurance. The evaluation of proposals includes review for bidder capability to meet Nuclear Quality Assurance Program requirements in procurement documents.

S&L may recommend to the client that an audit be performed, prior to award of purchase order or contract, to evaluate current implementation of the supplier quality assurance program. Preaward meetings with suppliers to resolve any questions are held prior to any recommendation for purchase, when required.

When S&L is responsible for procurement or when S&L is requested by the client, S&L assures that procurement documents require the successful bidder to submit the following, as applicable, to S&L for review by personnel with the appropriate process qualifications in accordance with procedures:

- a. special process procedures such as, but not limited to, welding, heat treating, nondestructive examination;
- b. recommended supplier inspection point program;
- c. appropriate documentation as established by applicable codes, standards, regulations, and procurement documents;
- d. notices of nonconformances and deviations;
- e. test procedures in accordance with applicable codes and standards;

- f. documentation of quality of any commercial, "off-the-shelf" items.

In those cases where the original item is found to be commercially "off the shelf," or without specifically identified technical and nuclear quality assurance requirements, spare and replacement parts may be similarly procured, but care shall be exercised to ensure at least equivalent performance. In cases where the QA requirements of the original item cannot be determined, an engineering evaluation shall be conducted by qualified individuals to establish the requirements and controls. This evaluation shall ensure that interfaces, interchangeability, safety, form, fit, and function are not adversely affected or contrary to applicable regulatory or code requirements. The results of this evaluation shall be documented.

- 07.02 On client request or per procurement requirements, surveillances are performed in facilities of suppliers furnishing materials, parts, components, or services to assure compliance with quality requirements. Surveillances are conducted by qualified personnel in accordance with documented procedures that specify the characteristics or processes to be witnessed or verified and accepted, the method of surveillance and documentation required, and those responsible for implementation of the procedure.

When appropriate, provisions are established by procedures for the identification of mandatory inspection hold points.

S&L supplier surveillances may include but are not limited to monitoring of in-process manufacturing, witnessing of tests, inspections and nondestructive examinations (per inspection point programs), monitoring of conformance to accepted welding procedures and a review of supporting documentation thereof, monitoring of control and calibration of measuring equipment, surveillance of heat treating processes, and observation of packing and shipping activities. As requested by the client, or as determined by S&L, supplier surveillances may include review of pertinent supplier documentation

during fabrication, shipping and final inspection, review of documentation to be shipped to a plant or construction site, and review of completed project checklists and release tags prior to release of equipment for shipping.

The intervals and depth of the surveillances are determined by client or S&L requirements, but are consistent with the relative importance, complexity, and quantity, and the frequency of procurement of the item or service being furnished.

07.03 Evaluations of basic components suppliers such as a supplier of safety-related software are documented and take into account the following, where applicable:

- (a) Receipt inspection, operating experience, and supplier evaluation programs are reviewed on an ongoing basis as the information becomes available to S&L. The results of the review are promptly considered for effect on a supplier's continued qualification and adjustments of supplier audit plans, as warranted. Additionally, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- (b) If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of 12 months, an annual evaluation shall be performed as follows:
 - (1) review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective action.
 - (2) results of previous source verifications, audits, and receiving inspections.
 - (3) operating experience of identical or similar products furnished by the same supplier.

- (4) results of audits from other sources (e.g., customer, ASME, or NRC inspections).

07.04 Audits of suppliers are conducted per Chapter 18.0 and implementing procedures at maximum three-year intervals, except as stipulated below, to assure compliance with quality requirements. Supplier audits include auditing of suppliers' certificates of conformance when these certificates are used as a basis for accepting the item or service.

Audits of suppliers, after award of a contract, and annual evaluations of suppliers are not necessary for procurement actions when the items or related services are all of the following:

- a. relatively simple and standard in design, manufacture and test, and
- b. adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.

For the following case, audits and annual evaluations of suppliers are also not necessary. S&L may accept short-term engineering and consulting services, such as qualification testing or a design performed by a consultant which will be independently verified by S&L, by technical verification of data produced as discussed in Section 03.04, by surveillance of the activity by a design engineer or a QA engineer, and/or by review of objective evidence for conformance to the procurement document requirements, such as by review of a stress report, as discussed in Section 03.04.

During exigent conditions, an extension of 25% may be applied to the triennial frequency for external audits/surveys where performance is not feasible. This 25% extension is applicable to domestic and international suppliers. Priority shall be given to completing audits/surveys of affected suppliers in order of the expiration of the triennial audit frequency.

Exigent conditions include, but are not limited to;

- a. declaration of a national emergency,
- b. severe localized or national weather conditions, or
- c. localized outbreak of a severe health concern to the public.

Prior to utilizing the exigent condition extension, basic component suppliers shall confirm that a quality assurance program meeting Appendix B to 10CFR Part 50 continues to be implemented. Commercial suppliers shall confirm programmatic controls related to the activity affecting quality continue to be maintained.

During exigent conditions, if a contract or contract modification significantly modifies a supplier's scope, the supplier shall provide written justification the change(s) are adequately addressed by its quality assurance program controls.

Audits/Surveys performed during exigent conditions shall reset the 'clock' for the particular activity. The date the activity is performed shall be the basis for the new triennial audit/survey frequency.

- 07.05 S&L suppliers may install safety-related items in a nuclear plant or, for financial reasons, S&L may elect to purchase a safety-related item and transfer ownership to a client at the point of receipt at the site, in a client's warehouse, or at some other time prior to installation.

In this case of ownership transfer, there shall be a written agreement with the client delineating the division of responsibility for quality assurance. In the case where S&L or its suppliers conduct receiving inspection of items, the inspection is performed in accordance with the client's QA program and implementing procedures, or Chapter 10.00 of this program and implementing procedures.

Receiving inspections ensure that:

- a. materials, components, or equipment are properly identified and correspond to the identification of the purchase document and the receiving documentation;
- b. materials, components, equipment and acceptance records satisfy the inspection instructions prior to installation or use;
- c. damaged items are reported.

If an S&L supplier will be installing safety-related items in a nuclear plant or if ownership is to be transferred, receipt inspection also ensures that specified inspection, test and other records (such as certificates of conformance attesting that the material, components, and equipment conform to specified requirements), are available at the nuclear plant prior to installation, use or ownership transfer.

S&L receiving inspections for other items do not include responsibility for availability of inspection, test and other records at plant sites prior to installation or use of the corresponding equipment. This function is assumed by the client.

07.06 When S&L will be supplying records for purchased items to a client, the following records shall be furnished:

- a. Documentation that identifies the purchased items and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item.
- b. Documentation identifying any procurement requirements that have not been met.
- c. A description of those nonconformances from the procurement requirements dispositioned “use-as-is” or “repair.”

08.00 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

- 08.01 S&L does not normally engage in direct activities which require a quality assurance program for identification and control of materials, parts, and components. However, as discussed in Chapter 07.00, S&L suppliers may install safety-related items or S&L may transfer ownership of a safety-related item to a client prior to installation.

In these cases of supplier installation or of ownership transfer, procedures are established for the identification and control of materials, parts, and components, including partly fabricated assemblies. Identification is maintained on the items or in documents traceable to the items. Controls are established to assure that only correct and accepted items are transferred to a client. Any items which are nonconforming at the time of transfer are identified to the client as such. Items which are nonconforming prior to installation or the transfer are controlled in accordance with Chapter 15.00 of this program or the client's program as agreed with the client. Procedures are used to assure proper identification for items in storage. Materials and parts important to the function of safety-related structures, systems, and components are identified so that the identification can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, nonconformance reports, and physical and chemical mill test reports.

Requirements are established in procurement documents for a system of identification and control of materials, parts, and components so that, if required, traceability from procurement, through installation, to end use is assured. S&L procedures provide for identification requirements during generation of drawings and procurement documents. Measures are established to ensure that the use of incorrect or defective items is avoided. Identification and control of materials, parts, and components are primarily a

function of the various fabricators, constructors and material suppliers. Supplier quality assurance programs address the requirement that location and method of identification shall not degrade the item.

On client request, audits or surveillances are performed at supplier facilities to assure proper identification, and control of materials, parts, and components in accordance with procurement documents. Proper identification and control is also included as part of inspections.

09.00 CONTROL OF SPECIAL PROCESSES

09.01 S&L does not engage in direct activities which require a quality assurance program for control of special processes. Control of special processes is the function of the various suppliers. However, when S&L is responsible for procurement or upon request by a client, S&L provides for the review and surveillance of special processes procedures and special processes performance of suppliers engaged in fabricating and furnishing equipment, components, and systems. This is done by qualified S&L personnel whose work is assigned, performed, reported, and reviewed in accordance with documented procedures. S&L personnel who review and provide surveillance on special processes are qualified as needed, and certified in accordance with applicable codes, standards, and S&L training programs. Qualifications and certifications are documented, filed, kept current, and are auditable.

Requirements are established in procurement documents to assure that special processes such as welding, heat treating, cleaning, and nondestructive examination are performed under adequate controls and that procedures governing these processes are established in accordance with applicable codes and specifications. Surveillances permit direct observation of special processes, thereby checking adherence to supplier procedures. Included during these surveillances is verification of the qualifications and certifications of inspectors and operators. Adequacy is determined for the storage, maintenance, and retrievability of qualification records of processing procedures and certification of personnel.

10.00 INSPECTION

10.01 S&L inspects certain types of items and activities in conjunction with plant design, construction, or modification but is not responsible for overall inspection programs. In certain cases, an S&L supplier will install safety-related equipment. The timing, need, and scope of S&L's inspection activities are normally determined by individual clients on a project basis. However, S&L may provide guidance on inspection programs in accordance with project requirements and pertinent codes, standards, and regulatory documents and will incorporate appropriate inspection requirements into design and procurement documents.

A program establishes the inspections to be performed (source, in-process, final, receipt, maintenance, modification, inservice, and operations). The inspection program may be implemented by or for the organization performing the activity inspected.

Inspections are conducted at plant and construction sites and at client/supplier premises or elsewhere to ascertain compliance of items and activities with procurement documents and other specified requirements. S&L's inspection services and related activities may include the following:

- a. verification of installed condition and/or location of structures, systems, or components to determine conformance with specified requirements;
- b. receiving inspections as described in Chapter 07.00 of this program;
- c. review of development of inspection requirements, specifications, and acceptance criteria in design and procurement documents per Chapters 03.00 and 04.00 of this program.

Inspections are governed by procedures that provide criteria for determining accuracy requirements of inspection equipment, as applicable. Inspection procedures are approved by Quality Assurance and the cognizant inspector. Inspections are performed by qualified S&L personnel or its suppliers.

- 10.02 Depending on project requirements, personnel from S&L are responsible for conducting inspections and for development of governing inspection procedures. Individuals performing inspections are other than those who performed or directly supervised the activity being inspected and do not report directly to the immediate supervisors who are responsible for the activity being inspected.

If the individuals performing inspection are not part of a QA organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule shall be reviewed and found acceptable by S&L's Quality Assurance Division prior to the initiation of the activity. Personnel qualification criteria for inspections are established by responsible persons in accordance with a certification procedure, reviewed and approved by Quality Assurance prior to the start of inspection activities.

- 10.03 Inspectors are qualified and certified in accordance with a documented qualification, training, and testing program. The program is described in a certification procedure that conforms to applicable codes, standards, client requirements, and regulatory documents and that ensures that qualifications and certifications are maintained current.
- 10.04 Procedures governing inspections are prepared in accordance with a controlling standard operating procedure and provide for the following, as applicable:
- a. identification of characteristics and/or activities to be inspected;

- b. a description of the method of inspection;
 - c. identification of the individuals or groups responsible for performing the inspection in accordance with Section 10.02, above;
 - d. acceptance and rejection criteria;
 - e. identification of required procedures, drawings and specifications and revisions thereof;
 - f. recording of inspector or data recorder and the results of the inspection operation;
 - g. specification of necessary measuring equipment including accuracy requirements;
 - h. mandatory hold points;
 - i. inspection reports (records) as indicated in Section 17.03;
 - j. explanation of any deviations from inspection requirements and approval of any deviation by responsible persons and, as necessary, by design persons.
- 10.05 When mandatory inspection hold points are required in inspection of suppliers' items/activities, they are specified and documented with procedures that implement Chapter 07.00 of this program. Any hold points for other types of inspections are specified and documented in accordance with the inspection procedures of Section 10.04, above.
- 10.06 Inspection results are documented and distributed by means of inspection reports. Format, detailed content, and certification requirements of inspection reports are addressed by procedures approved by Quality Assurance. These procedures require the inspector to determine if an item/activity meets

specifications and also ensure that inspection results are evaluated for acceptability of the item/activity by an S&L responsible individual. The procedure also ensures that inspection results and evaluations are acted upon, as needed, by the client or by S&L.

- 10.07 In addition to performing inspections, S&L reviews procedures submitted by clients/suppliers or prepares procedures to be used by non-S&L organizations under their own quality assurance programs. Procedures developed by S&L are generated similarly and are equivalent in content to procedures used by S&L, except as modified by client or by project requirements. Personnel who review inspection procedures or evaluate the adequacy of such procedures to accomplish the inspection objectives are certified inspectors in accordance with ASME NQA-1-1994, Supplement 2S-1, as delineated in Chapter 00.00, Introduction. Procedures submitted by clients/suppliers are reviewed for technical adequacy and completeness, and for conformance to procurement documents and other pertinent documents.

11.00 TEST CONTROL

11.01 S&L does not conduct tests other than of software. However, on request, S&L suppliers may test safety-related items and S&L provides guidance to clients on formulation of their test programs. S&L provides the following services in connection with test activities performed by non-S&L organizations:

- a. surveillance of tests in progress;
- b. inclusion of test requirements, parameters and acceptance criteria in design and procurement documents in accordance with applicable codes, standards, and regulatory documents;
- c. development of preoperational, startup, and other test procedures; review of test procedures submitted by clients or suppliers. When post-installation testing is used for acceptance of purchased items, post-installation test and acceptance documentation recommended by the supplier are required to be considered. Personnel who prepare or review test procedures or evaluate the adequacy of such procedures to accomplish the test objectives are certified as testers in accordance with ASME NQA-1-1994, Supplement 2S-1, as delineated in Chapter 00.00, Introduction, or as Preoperational Test Engineers or Startup Test Engineers in accordance with Regulatory Guide 1.8 (Section 00.00 of this program), as appropriate;
- d. review of test reports, evaluation of test results.

11.02 If an S&L supplier will be installing safety-related items, procedures provide criteria for determining the accuracy requirements of test equipment and criteria for determining when a test is required or how or when testing activities are performed.

Test procedures or instructions provide as required for the following:

- a. The requirements and acceptance limits contained in applicable design and procurement documents;
- b. Instructions for performing the test;
- c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation including their accuracy requirements, completeness of the item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage;
- d. Mandatory inspection hold points for witness by a client, S&L or an inspector (as required);
- e. Acceptance and rejection criteria;
- f. Methods of documentation or recording test data and results;
- g. Provisions for assuring test prerequisites have been met.

Test results are documented, evaluated, and their acceptability determined by a responsible individual or group.

- 11.03 Inspections and surveillances of supplier tests at witness points and other stages are conducted and reported per Chapters 07.00 and 10.00 of the program and implementing procedures. Inspections and surveillances are performed by qualified S&L persons certified under an S&L procedure.

Supplier's compliance with procedural reporting and other procurement requirements is verified.

- 11.04 Inclusion of test criteria, instructions, and specifications in design and procurement documents is governed by Chapters 03.00 and 04.00 of the program and implementing procedures. Procurement documents specify witness points, acceptance limits, test environments, personnel certification, and other requirements to be included in procedures submitted by the supplier.
- 11.05 S&L may generate preoperational/startup test procedures for S&L or non-S&L designed systems. Procedures are generated and reviewed by cognizant personnel in accordance with governing S&L procedures. Preparers, reviewers, and approvers of preoperational/startup test procedures meet the qualifications of Regulatory Guide 1.8 (Section 00.00 of this program). Preoperational/startup test procedures include test instructions, acceptance/rejection criteria, test prerequisites, mandatory witness points, documentation of data and results, and related items. Procedures are consistent with design criteria and project requirements, and with codes, standards, and regulatory documents.

Vendor and client test procedures submitted to S&L are reviewed for compliance with procurement documents and inclusion of the above items. Reviews are performed and documented by qualified persons.

12.00 CONTROL OF MEASURING AND TEST EQUIPMENT

12.01 S&L engages in four general types of activities requiring calibration and control of measuring equipment: (1) inspection activities at plant and construction sites, fabricators' facilities, and elsewhere as described in Chapter 10.00 of the program, (2) verification (via surveillance) by S&L that inspection or tests or other activities conducted by non-S&L organizations have been performed with acceptably calibrated measuring or test equipment (see Chapter 07.00), (3) acquisition of engineering design data at plant and construction sites by means such as certain walkdowns, and (4) in-house review of radiographic film or images. On client request S&L also develops calibration procedures for use by non-S&L organizations, or reviews calibration procedures submitted by clients/suppliers. S&L performs no activities itself requiring calibration/control of test equipment.

For procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC), are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance provided that all of the following conditions are met:

- a. Accreditation is to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
- b. Use of the alternative method is limited to the National Voluntary Laboratory Accreditation Program and the American Association for Laboratory Accreditation, as recognized by ILAC signatories.
- c. The scope of the accreditation covers the contracted services.

- d. Purchase documents impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements.
- e. Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
- f. Purchase documents require identification of the laboratory equipment/standards used.
- g. The alternative method is limited to the domestic calibration service suppliers.
- h. The alternative method is applicable to subsuppliers of calibration service suppliers, provided the above conditions are met.

12.02 S&L organizations performing inspection or surveillance activities are responsible for establishing and implementing a calibration program and for documenting the program by calibration procedures. The procedures are developed by qualified, certified persons in accordance with a controlling procedure that provides a quality assurance framework for the calibration program and in accordance with applicable codes, standards, and regulatory documents.

Quality Assurance generates the controlling procedure, reviews the calibration procedures, and performs an audit or surveillance to ensure the effectiveness of the calibration program. Audit or surveillance of a calibration service shall include evaluating the qualifications of the personnel responsible for calibration and, where applicable, traceability of the calibration to national standards. On client request, or as determined by S&L, supplier calibration procedures are reviewed and audits or surveillances of supplier calibration activities are

conducted to assure conformance to procurement documents and supplier quality assurance programs.

12.03 Calibration, maintenance, and control of measuring equipment used in inspections, surveillances, or other activities is controlled by procedures. These procedures are developed by qualified and, as necessary, certified persons from the organizations performing the inspections or surveillances, and approved by Quality Assurance. Procedures are issued separately or as part of the inspection or surveillance procedures to which they apply. The procedures establish requirements for or specify the following activities or functions as applicable:

- a. scope of calibration, maintenance, and control program including identification of affected equipment;
- b. identification of persons/organizations responsible for carrying out required activities;
- c. calibration techniques per applicable codes, standards, regulatory documents, or manufacturers' instructions;
- d. maintenance and control of equipment;
- e. identification of measuring and test equipment for traceability to calibration data;
- f. labeling, tagging, or marking of equipment to indicate due date of next calibration; specification of any other means of identification;
- g. intervals between calibrations (based on the required accuracy, purpose, degree of usage, stability characteristics, and other considerations affecting the measurement);

- h. accuracy of calibration standards;
 - (1) calibration of equipment against standards having an accuracy of at least four times the required accuracy of the equipment being calibrated; or
 - (2) calibration against standards more accurate than equipment being calibrated to assure that calibrated equipment is within the required tolerances; or
 - (3) calibration against standards with the same accuracy as the equipment being calibrated if adequate for particular requirements;
 - (4) for the second and third options, written justification and authorizations is documented by the responsible engineer;
- i. identification and documented traceability of reference and transfer calibration standards or calibration instruments to nationally recognized standards or the basis for calibration when nationally recognized standards do not exist;
- j. when measuring or test equipment is found to be out of calibration, an evaluation of the validity of inspection or surveillance results since the last calibration and an evaluation of the acceptance of the items measured, as applicable is documented; inspections/surveillances of suspect items, as needed is repeated; out-of-calibration equipment is identified to prevent its use; and, inaccurate results are reported to the S&L Quality Assurance Manager when they are used as input for approved design documents.

12.04 In cases where measuring equipment must be calibrated by a supplier, such as with certain sealed units, controlling procedures require adequate documented qualification equivalent to applicable requirements of Section 12.03, above.

- 12.05 With reference to in-house calibration activities performed in S&L's offices, the Quality Assurance Manager provides for control, maintenance, and use of calibrated step wedge film strips used with a densitometer in viewing radiographic film. This activity is controlled by an approved procedure that requires adequate documentation of calibration.
- 12.06 Upon client request or as determined by S&L, S&L reviews calibration procedures submitted by clients/suppliers or prepares procedures to be used by non-S&L organizations. Procedures developed by S&L are generated similarly and are equivalent in content to procedures used by S&L except as modified by clients or project requirements. Procedures submitted by clients/suppliers are reviewed by personnel with the appropriate process qualifications for technical adequacy and completeness and for conformance to procurement documents, supplier quality assurance program, and other pertinent documents.

13.00 HANDLING, STORAGE, AND SHIPPING

- 13.01 In general, S&L does not engage in direct activities which require a quality assurance program for handling, storage, and shipping. However, as discussed in Chapter 07.00, S&L suppliers may install safety-related items or S&L may transfer ownership of a safety-related item to a client prior to installation.

Even in these cases, storage is normally performed at the site by either the client or a supplier. If S&L or its supplier elects to store the item, special handling, preservation, storage, cleaning and packaging requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

Procedures are established and described to control the cleaning, handling, storage and packaging of materials, components and systems in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

Handling, storage and shipping are normally the responsibility of various client suppliers, and storage at the site is the responsibility of the client. However, when requested by a client, S&L prepares instructions for packaging, handling, shipping, storage, and preservation of items for inclusion in procurement documents.

Likewise, S&L project management ensures that test samples forwarded to S&L offices for shipment to a testing laboratory are controlled in accordance with procedures and/or project instructions prior to initiating the activity.

On client request or as determined by S&L, surveillance of handling, storage, and shipping activities is provided in the facilities of suppliers fabricating or furnishing items for the project. Verification of proper shipping is also included as part of receiving inspections per Chapters 07.00 and 10.00 of this program. Surveillances and inspections are conducted by qualified personnel whose work is assigned, performed, reported, and reviewed in accordance with documented procedures.

Aside from the above activities, packaging, shipping, storage, and preservation of software, generated by or in custody of S&L, is performed per procedures.

The following controls apply during the operational and decommissioning phases:

- (a) Controls for the packaging, shipping, handling and storage of items are required to be established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to ensure that no damage or deterioration exists which could affect their function.
- (b) Controls for hoisting, rigging, and transport activities are required to be established that protect the integrity of the item involved as well as potentially affected nearby structures and components. Applicable hoisting, rigging, and transportation regulations and codes are followed.
- (c) Cleanliness controls for work on safety related and risk-significant nonsafety related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Procedures require documented verification of absence of foreign material prior to system closure.

14.00 INSPECTION, TEST, AND OPERATING STATUS

- 14.01 S&L does not normally engage in direct activities which require a quality assurance program for identification of the inspection, test, and operating status. In the cases of S&L supplier installation or of ownership transfer, items are identified whether they are acceptable for installation. The date the items were placed in the acceptable or unacceptable status is indicated.

Only an inspector qualified in accordance with ASME NQA-1-1994, Supplement 2S-1 may remove or alter an inspection status indicator.

The client shall be consulted and written authorization from the responsible design organization shall be obtained prior to altering the sequence of required tests, inspections and other operations performed at a nuclear plant site. Such actions, whether performed at a nuclear plant site or not, shall be subject to the same controls as the original review and approval.

15.00 NONCONFORMING MATERIALS, PARTS OR COMPONENTS

15.01 In general, S&L does not engage in direct activities which require a quality assurance program for nonconforming materials, parts, or components as this is the responsibility of suppliers. In the cases of supplier installation or of ownership transfer, procedures are used to identify and control items that do not conform to requirements. These procedures address:

- a. Identification of nonconforming items;
- b. Documentation of identified nonconformances;
- c. Segregation of nonconforming items;
- d. Disposition of nonconforming items;
- e. Notification of affected organizations.

Affected client(s) are immediately notified when an item is determined to be potentially inoperable, including identification of the nonconforming condition.

Nonconforming items are identified by marking, tagging or other methods which do not adversely affect the end use of the item.

When practical, nonconforming items are segregated by placing them in a hold area until properly dispositioned. When segregation is impractical or impossible, other precautions are employed to preclude inadvertent use of a nonconforming item.

Procedures are used to review and accept, reject, repair or rework nonconforming items. The processing of a nonconforming item is controlled pending an evaluation and an approved disposition by authorized personnel. Nonconformances are corrected or resolved prior to the initiation of the

preoperational test program on the item. The ultimate disposition of nonconforming items is documented.

Each disposition is traceable to each item.

Dispositions designated “use-as-is” ensure that the final condition of any nonconforming item will not adversely affect the safety, operability or maintainability of the item, or of the component or system in which it is installed. The as-built records, if such records are required, reflect the accepted deviation.

Repaired or reworked items are reexamined using procedures and the original acceptance criteria unless the disposition has established alternate acceptance criteria.

Reports of S&L owned nonconforming items are periodically analyzed by the QA Division to show quality trends, and the significant results are reported to upper management for review and assessment.

S&L reports any nonconforming items that are discovered and, on client request, recommends disposition thereof (see Chapters 07.00 and 10.00 of the program). Likewise, S&L assures through procedures that nonconforming computer codes are not used in S&L project work.

On client request or as determined by S&L, S&L generates procurement documents that require suppliers to furnish documentation of any nonconformance in accordance with a QA program. S&L reviews supplier programs to assure that controls are provided for nonconforming materials, parts or components at the supplier facilities.

S&L reviews documented instances of nonconforming parts and components where such nonconformances affect the design, and provides the client with a written evaluation of such effects. Recommendations are made in accordance with specification and design requirements.

16.00 CORRECTIVE ACTION

- 16.01 A standard operating procedure assigns responsibilities for identifying and promptly correcting conditions adverse to quality. This procedure requires any person who detects an apparent condition adverse to quality to submit a “PIP,” named after the acronym for the Performance Improvement Process. Management, at all levels, is to foster a “no-fault” attitude toward the identification of conditions that are adverse to quality.

The Quality Assurance Manager or designee reviews the PIP. The purpose of this review is to identify conditions that require immediate management attention, including that of the Quality Assurance Manager. PIPs are assigned to a Dispositioner. The Engineering Oversight Team (EOT), headed by the Director of Engineering and consisting of executives, managers, and other senior personnel, meets regularly, typically weekly, to review the results of various stages of the program, e.g., PIP initiation, disposition, and closure.

The Quality Assurance Manager, a member of the EOT, monitors reports of conditions adverse to quality and classifies them. The procedures assign responsibility for verifying that a reported condition adverse to quality has been corrected. The implementation and effectiveness of the corrective action is verified. This is performed by follow-up audits when appropriate. The corrective action documentation is then completed.

- 16.02 If a condition adverse to quality is determined to be a significant condition adverse to quality, the Quality Assurance Manager reports the occurrence to the Chief Executive Officer and the affected Group Director(s). The Quality Assurance Manager may stop or otherwise control further processing of such a condition adverse to quality until disposition of the unsatisfactory condition has been accomplished. The appropriate Group Director assures that the cause and its impact on completed or related items or activities are identified and the

action necessary to correct the condition and to preclude its recurrence is taken. This is verified and the corrective action documented.

- 16.03 S&L complies with 10 CFR 21 and 10 CFR 50.55(e) as part of its corrective action program, including the control of nonconforming items in accordance with Chapter 15.00 of this program.

17.00 QUALITY ASSURANCE RECORDS

- 17.01 Requirements are established in this program and implementing procedures for generation, collection, compilation, storage, and retrieval of documentation necessary to provide records of quality for S&L quality-related activities.

Unless S&L is directed to forward all project-related quality assurance records to the client, procedures require retention of quality assurance records such as, but not limited to design input documents, project design documents (design criteria, drawings, calculations, specifications, and standards), personnel qualifications and certifications, personnel training records, audit and surveillance reports and replies thereto, inspection reports, calibration procedures/reports, nonconformances and corrective action reports, change control documents, deviations, design review reports, applicable correspondence and meeting notes.

- 17.02 Procedures require that sufficient records be prepared as work is performed to provide assurance of the quality of the activities performed, and that such records be consistent with applicable codes, standards, and specifications. The quality assurance records are identified and filed in a timely and orderly manner to allow for access and retrievability. They are carefully handled to maintain legibility and preserve the original quality of the records to the maximum extent.

- 17.03 Inspection and test records, other than for software, contain the following in addition to those referenced in Section 10.06 where applicable:

- a. A description of the type of observation;
- b. The date and results of the inspection and test;
- c. Information related to conditions adverse to quality;

- d. Inspector or data recorder identification;
- e. Evidence as to the acceptability of the results;
- f. Any other information needed to describe the essentials of the inspection or test and the results.

Action taken to resolve any discrepancies noted, if such action is requested by the client, is addressed and recorded in accordance with corrective action procedures.

- 17.04 Procedures, consistent with regulatory requirements, have been prepared and include the requisites for transmittal, retention, maintenance and retrieval of records. Records are stored in a facility or in separate remote locations that provide controlled access, minimize the risk of damage or destruction from fire, flood, tornadoes, condensation, vermin and decay and satisfy the requirements described in ASME NQA-1-1994, Supplement 17S-1, Section 4 titled "Storage, Preservation, and Safekeeping".
- 17.05 Quality assurance records are maintained by S&L until a project is complete unless otherwise directed by the client. At completion of the project, the quality assurance records are dispositioned in accordance with procedures.
- 17.06 Records associated with radwaste packaging shall include the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities and shall include closely related specifications such as required qualifications of personnel, procedures, and equipment. Records shall be retained for 3 years beyond the date when S&L or its suppliers last engages in the related activity. If any portion of the written procedures or instructions is superceded, S&L or its suppliers shall retain the superceded material for 3 years after it is superceded.

- 17.07 Records associated with ISFSIs must include the following: design records, records of use and the results of reviews, inspections, tests, audits, monitoring of work performance, and material analysis.

Records pertaining to the design, fabrication, erection, testing, maintenance, and use of ISFSI structures, systems, and components important to safety shall be maintained under the control of, and as directed by, the licensee until the NRC terminates the ISFSI license.

- 17.08 Electronic records may be authenticated in accordance with the guidance given in Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 11, 2011, entitled “Authentication of Records and Media.” This authentication shall be made in one of three ways: a hard copy authorization from the authentication authority to add the authority’s electronic signature to the document; an electronic signature controlled by a user ID/password combination; or a digital signature. When authentication authority is transferred to a designee, measures are identified and documented to ensure that only those designees properly authorized do authenticate records/media. Documentation of authentication delegation shall be maintained whether E-mail, fax or documentation of telephone calls or text messages.

The Computer Services Division establishes rules for passwords to be used for electronic signatures.

- 17.09 Records, whether generated electronically or otherwise, shall be formatted in accordance with a standard that minimizes susceptibility to obsolescence, e.g., Adobe’s Portable Document Format (PDF). These electronically formatted records shall be managed in accordance with the guidance given in NIRMA TG15-2011, titled, “Management of Electronic Records,” except as this guidance becomes technically obsolete. Typically, there shall be two tape cartridge or magnetic disk backups, each with a copy of electronic records.

One copy of each electronic record shall be stored in a record storage facility or in separate remote locations as described in Section 17.04. The choice of storage media may change as technology changes. The applicable regulations in Appendix B to 10 CFR 50, 10 CFR 71.135, 10 CFR 72.174, and 10 CFR 76.93 shall be followed.

- 17.10 Software associated with electronic records are controlled in accordance with Sections 02.05 and 06.03. Personal computers and appropriate servers are periodically and automatically scanned for viruses.
- 17.11 A disaster plan for the protection and restoration of quality records retained in an electronic format and following the guidance of NIRMA TG21-2011 titled, "Required Records Protection, Disaster Recovery and Business Continuation," is in place except as this guidance becomes technically obsolete.

18.0 AUDITS

18.01 S&L utilizes a system of planned audits and surveillances to verify compliance with and to assess the effectiveness of all aspects of the S&L Nuclear Quality Assurance Program and the implementing procedures. Organizations subject to audit and surveillance by S&L include:

- a. S&L business and functional support groups, departments, divisions and project groups;
- b. S&L suppliers, or other suppliers as requested by a client.

Audits and surveillances include evaluation of quality system practices and/or procedures and the effectiveness of their implementation, monitoring of work areas and activities, and review of pertinent documents and their control and maintenance.

18.02 Audits and surveillances within S&L are carried out by Quality Assurance in accordance with the requirements of standard operating procedures. The objectives of these audits and surveillances are:

- a. to verify that the policies, procedures, and instructions necessary for implementation of this program are established in a timely manner;
- b. to determine the degree of compliance with this program and its implementing procedures by personnel performing quality-related functions;
- c. to determine the degree of compliance on each project with project instructions, standards, procedures and other applicable documents, such as codes and national standards which provide guidance for the project;

- d. to assess the effectiveness of this program and its implementing procedures.

Audits and surveillances are conducted by S&L personnel who have no direct responsibility in the areas they audit and review. Auditors are required to possess the educational, training, and experience qualifications for auditing and surveillance as specified in implementing procedures.

The Nuclear Quality Assurance Program requires that the work of support divisions and nuclear project teams be audited on applicable elements of this program, implementing quality assurance procedures, project instructions, standards and procedures on the basis of the safety importance of the activity being performed, but at least biennially for nuclear facility projects or projects supporting gaseous diffusion plants which are in the operating or decommissioning phase, and annually or once during the life of the activity, whichever is shorter, for projects in the construction phase. Projects supporting radioactive material packaging or ISFSIs are audited at least annually.

Internal audit frequencies of well established activities, conducted of projects supporting facilities in the operating or decommissioning phase, may be extended one year at a time beyond the two-year interval based on the results of an annual evaluation of the applicable area and objective evidence that the area activities are being satisfactorily accomplished. The evaluation shall include a detailed performance analysis of the area based upon applicable internal and external source data and due consideration of the impact of any changes in responsibility, resources or management. However, the internal audit frequency interval shall not exceed a maximum of four years. If an adverse trend is identified in the applicable area, the extension of the interval audit frequency interval shall be rescinded and an audit scheduled as soon as practicable.

An audit schedule is prepared each year identifying the audits to be performed and their scheduled dates. Scheduling is dynamic and resources are supplemented when QA program effectiveness is in doubt.

Surveillances led by qualified lead auditors may be substituted for portions or all of an audit, if a lead auditor evaluates the surveillance(s) as examining the same activity to be audited and the surveillance(s) is performed within the same biennial or annual audit period.

Under special circumstances, the Quality Assurance Manager may grant postponements of audits as specified in standard operating procedures.

Audits and surveillances are initiated early in the design and procurement phase. The following areas fall within the scope of the S&L audit program:

- a. preparation, review, approval, and control of early procurements;
- b. indoctrination and training programs;
- c. interface control among the client, S&L, and other organizations.

Audit and surveillance reports are approved by the Quality Assurance Manager or Chief Executive Officer, or their designees, and distributed to the persons directly responsible for the areas or functions audited: Chief Executive Officer, the appropriate Business Group Director, the Project Director and Project Manager, the Director of Engineering, the appropriate Operations Group Managers, and to others designated by the Quality Assurance Manager.

- 18.03 External audits and surveillances, as required, of suppliers are performed by Quality Assurance with assistance, as required, of personnel from appropriate projects or divisions acting as technical specialists.

18.04 Procedures for both internal and external audits provide for audit planning, execution, evaluation of results, postaudit conference with management in the audited area, and reporting. An audit plan is developed for each audit, indicating the audit scope, the activities to be audited, the applicable documents and requirements, the schedule, and the audit team. Audits are performed in accordance with written procedures or checklists. The audit checklist, when required, is intended for use as a guide and may be altered or departed from during an audit in order to achieve the audit's objectives. Such changes must be documented and become part of the audit record.

A written report is required for each audit and surveillance. The report includes:

- a. a statement of the audit scope;
- b. identification of the auditors and lead auditor;
- c. identification of persons and/or areas audited;
- d. description of each condition adverse to quality identified;
- e. request to responsible personnel for reply on corrective action within a stated period;
- f. an evaluation statement regarding the effectiveness of the program elements that were audited, if appropriate;
- g. recommendations for improvement of the Program, as appropriate.

Follow-up of deficient areas as described in reports of conditions adverse to quality is required in accordance with procedures. Areas with conditions adverse to quality are reaudited and/or appropriate corrective action documentation is examined as necessary to assure that effective corrective action has been taken by the responsible management.

The management of the area audited responds within 30 days of receipt of the conditions adverse to quality report, indicating corrective action to be taken and the schedule for completion. Extension of the 30-day requirement for responding to conditions adverse to quality may be granted by the Quality Assurance Manager when justifiable. Reaudits, when necessary, are conducted on a timely basis, commensurate with the scheduled completion of corrective action in accordance with quality assurance procedures. These reaudits may either be limited to verification of implementation of required corrective actions or, when corrective action results in significant reorganization or procedure revisions, when the quality of an item is suspected to be in jeopardy due to deficiencies in this quality assurance program identified during the nonconformance evaluation, or when a systematic, independent assessment of program effectiveness is considered necessary, they shall be more general. Audit and surveillance reports are filed and available for audit.

Errors reported in PIPs, including audit data, are analyzed by the QA organization and the resulting reports indicating any quality problems and the effectiveness of the QA program, including the need for reaudit of deficient areas, are reported to management for review and assessment.