

DRAFT SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

TOPICAL REPORT SL-TR-1, REVISION 20

"NUCLEAR QUALITY ASSURANCE PROGRAM"

SARGENT & LUNDY, LLC (S&L)

1 1.0 INTRODUCTION AND BACKGROUND
2

3 By letter dated September 21, 2007 (Reference 1), Sargent & Lundy, LLC (S&L) submitted the
4 updated, "Nuclear Quality Assurance Program," Topical Report (TR) SL-TR-1, Revision 20,
5 (hereafter referred to as the Quality Assurance Topical Report (QATR)) for U.S. Nuclear
6 Regulatory Commission (NRC) review and acceptance in accordance with the provisions of
7 Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.4(b)(7)(ii). S&L proposed that
8 the updated QATR would replace the current Quality Assurance (QA) program description for
9 S&L that had been accepted by the NRC as documented in the letter dated February 6, 2007
10 (Reference 2). The QATR was subsequently resubmitted on July 7, 2008 (Reference 3). S&L
11 concluded this was necessary for NRC to make a determination regarding acceptability of the
12 proposed Revision 20 to the S&L QATR.
13

14 2.0 REGULATORY EVALUATION
15

16 The NRC regulatory requirements related to QA programs for non-licensees are set forth in
17 10 CFR 50.4(b)(7)(ii). This regulation requires that a change to an NRC-accepted QATR from
18 non-licensees (i.e., architect/engineers, nuclear steam system supplier (NSSS) suppliers, fuel
19 suppliers, constructors, etc.) must be submitted to the NRC. When requested, the NRC will
20 review the proposed QATR for acceptability to ensure the applicable requirements of
21 Appendix B to 10 CFR Part 50 will be satisfied.
22

23 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing
24 Plants," to 10 CFR Part 50 establishes QA requirements for the design, construction and
25 operation of structures, systems, and components (SSCs) of the facility. The pertinent
26 requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related
27 functions of those SSCs and include designing, purchasing, fabricating, handling, shipping,
28 storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing,
29 refueling, and modifying.
30

31 3.0 TECHNICAL EVALUATION
32

33 3.1 Background
34

35 The proposed QATR is similar in many respects to previous submittals approved for licensees
36 for the purpose of meeting NUREG-0800, "Standard Review Plan for the Review of Safety

ENCLOSURE

1 Analysis Reports for Nuclear Power Plants,” Section 17.5, “Quality Assurance Program
2 Description – Design Certification, Early Site Permit and New License Applicants” (hereafter
3 referred to as SRP 17.5) and gain efficiencies from NRC-approved QA program alternatives.
4 The original QA program description was based largely on commitments to Appendix B to
5 10 CFR Part 50, Regulatory Guide (RG) 1.28, “Quality Assurance Program Requirements
6 (Design and Construction)” and RG 1.33, “Quality Assurance Program Requirements
7 (Operations).” The proposed QATR is based on American Society of Mechanical Engineers
8 (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, “Quality Assurance
9 Requirements for Nuclear Applications.” S&L considers the collective requirements of the
10 QATR and Standard NQA-1-1994 equivalent to the NRC staff guidance in SRP 17.5. SRP 17.5
11 outlines the review of a standardized QA program and is based on ASME Standard
12 NQA-1 (1994 Edition), RG 1.8, “Qualification and Training of Personnel for Nuclear Power
13 Plants,” RG 1.28, RG 1.33, and NRC Review Standard 002, “Processing Applications for Early
14 Site Permits.” The review approach of SRP 17.5 has previously been used by the NRC staff for
15 evaluating Standard NQA-1-1994 as the basis for a QA program by a non-licensee
16 (Reference 4).

17
18 Part I of Standard NQA-1-1994 sets forth programmatic requirements for the establishment and
19 execution of QA programs for the siting, design, construction, operation, and decommissioning
20 of nuclear facilities. Part II of the standard sets forth non-programmatic QA requirements for the
21 planning and execution of identified tasks during the fabrication, construction, modification,
22 repair, maintenance, and testing of SSCs for nuclear facilities. Standard NQA-1-1994 provides
23 guidance that is similar to that provided by the American National Standards
24 Institute (ANSI) N45.2 series of standards, which were developed in the 1970s and early 1980s.

25
26 The significant changes to the QA program in the S&L QATR are: 1) a commitment to
27 Standard NQA-1-1994 as the basis for the QA program and 2) incorporation of alternatives to
28 Standard NQA-1-1994 that have previously been reviewed and approved through the NRC
29 safety evaluation process.

30 31 3.2 Evaluation

32
33 The NRC staff evaluated the adequacy of the QATR in describing how the requirements of
34 Appendix B to 10 CFR Part 50 will be satisfied. The format and content of the QATR were
35 evaluated in accordance with the guidance of SRP 17.5, which provides a basis for the NRC
36 staff review of QA programs based on Standard NQA-1-1994. The acceptability of the level of
37 detail provided by the QATR is determined, in part, by its adequacy in addressing the
38 acceptance criteria of SRP 17.5. The NRC staff also reviewed alternatives from NQA-1-1994,
39 considered not to be reductions in QA program commitments, for conformance with the
40 provisions established in S&L’s previously accepted QATR dated February 2007 (Reference 2).

41 42 3.2.1 Format and Content of the QATR

43
44 The format used for the following evaluation follows the sequence of the 18 criteria of
45 Appendix B and corresponding provisions of Standard NQA-1-1994. The content of the QATR
46 provides guidance for establishing a top-level policy document that defines the quality
47 requirements and assigns major functional responsibilities. The S&L QATR can be used for
48 modifications and design analyses for activities associated with construction, operation, and
49 decommission affecting the quality and performance of safety-related SSCs. In addition, the

1 QATR applies a graded approach to the extent commensurate with the SSC's importance to
2 safety when delineated in procurement requirements. It is incumbent upon the client to identify
3 the specific QA requirements that must be met for the scope of activities.
4

5 3.2.1.1 Organization

6
7 The QATR is the top-level policy document that establishes S&L's overall methodology
8 regarding achievement and assurance of quality. Implementing documents provide more
9 detailed responsibilities and requirements and define the organizational interfaces involved in
10 conducting activities within the scope of the QATR. Compliance with the QATR and
11 implementing documents is mandatory for all personnel performing activities related to safety.
12

13 The QATR describes the organizational structure, functional responsibilities, and levels of
14 authority and interfaces for establishing, executing, and verifying QA program implementation.
15 Company services are organized into business groups and functional support groups. The
16 business groups are Nuclear Power Technologies and other business groups as determined by
17 the Chief Executive Officer (CEO). The functional support groups are Operations and Financial.
18 The CEO ensures that the size of the QA Division is commensurate with its duties and
19 responsibilities. Project instructions and governing company standards are established to
20 control quality-related activities. Specific implementing procedures are established to control
21 activities in compliance with the requirements of the program.
22

23 In establishing its organizational structure, S&L commits to compliance with Standard
24 NQA-1- 1994, Basic Requirement 1 and Supplement 1S-1.
25

26 3.2.1.2 QA Program

27
28 S&L has established the necessary measures and governing procedures to implement the
29 QA program described in the QATR. S&L policy makes compliance with the program
30 mandatory for all personnel performing quality-related activities. Safety-related SSCs for a
31 project are identified, and design and procurement activities are controlled by the program and
32 the implementing procedures. SSCs are required to prevent accidents that may cause undue
33 risk to the health and safety of the public or to mitigate the consequences of such accidents if
34 they were to occur. Senior management assesses the adequacy of this QA program's overall
35 implementation for a variety of projects and the reports of the assessments are approved by the
36 CEO and distributed to the responsible management for action.
37

38 Personnel working directly or indirectly for S&L are responsible for the achievement of
39 acceptable quality in the work covered by the QATR. Activities governed by the QA program
40 are performed as directed by documented instructions, procedures, and drawings that have a
41 level of detail appropriate for the activity's complexity and effect on safety. The CEO
42 establishes QA policy and objectives. The CEO has delegated to the QA Manager
43 responsibility for providing and maintaining the QA program policy and direction and for
44 coordinating and verifying its implementation on projects.
45

46 Personnel assigned to implement elements of the QA program shall be capable of performing
47 their assigned tasks. To this end, S&L establishes and maintains formal indoctrination and
48 training programs for personnel performing, verifying, or managing activities within the scope of
49 the QA program to assure that suitable proficiency is achieved and maintained.

1 If a client elects to qualify S&L personnel, such as those reporting directly to a plant manager in
2 accordance with the client's QA program, the personnel qualification requirements in the QATR
3 do not apply to these S&L personnel.
4

5 In establishing qualification and training programs, S&L commits to compliance with
6 Standard NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4, with
7 the proposed clarifications, exceptions or alternatives.
8

9 Evaluation of S&L's QA Program Proposed Clarifications, Exceptions or Alternatives

10
11 S&L proposed that a general grace period of 90 days may be applied to provisions that are
12 required to be performed on a periodic basis unless otherwise noted. Annual evaluations and
13 audits that must be performed on a triennial basis are examples where the 90-day general
14 grace period could be applied. The grace period does not allow the "clock" for a particular
15 activity to be reset forward. The "clock" for an activity is reset backwards by performing the
16 activity early.
17

18 The NRC staff determined that the wording was equivalent to the guidance in SRP 17.5,
19 Paragraph II.B.1. Therefore, the NRC staff finds the alternative equivalent to the NRC staff
20 guidance.
21

22 S&L proposed the following in lieu of the requirements for prospective lead auditors: "Lead
23 auditors shall have participated in a minimum of five QA audits within a period of time not to
24 exceed three years prior to the date of qualification, one audit of which is a nuclear QA audit
25 within the year prior to qualification or for individuals with related industry experience,
26 demonstrated ability to properly implement the audit process, to effectively organize and report
27 results, including participation in at least one nuclear audit within the year preceding the date of
28 qualification."
29

30 The NRC staff determined that the revised wording was equivalent to the guidance in SRP 17.5,
31 Paragraph II.S.4.c. Therefore, the NRC staff finds the alternative equivalent to the NRC staff
32 guidance.
33

34 S&L proposed that alternatives to the education and experience requirements, such as
35 experience other than at a nuclear-fueled electric power production plant, shall be evaluated
36 and documented by the CEO for the QA Manager, by the QA Manager for an individual
37 providing QA supervision and other members of the QA Division, and by the responsible
38 manager for other personnel in lieu of the applicable plant manager.
39

40 The NRC staff found the proposed alternative acceptable based on guidance in SRP 17.5,
41 Paragraph II.S.2.e. that states, "individuals who do not possess these formal education and
42 minimum experience requirements should not be eliminated automatically when other factors
43 provide sufficient demonstration of their abilities. These other factors are evaluated on a case-
44 by-case basis and approved and documented by senior management."
45

46 S&L proposed that management biennially assess the adequacy of its QA program's overall
47 implementation on projects which are in the operational or decommissioning phases.
48 Management will assess the adequacy of the QA program's overall implementation on projects

1 which are in the construction phase annually or at least once during the life of the activity,
2 whichever is shorter.

3
4 The NRC staff determined that the wording was essentially equivalent to the guidance in
5 SRP 17.5, Paragraph B.1. Therefore, the NRC staff finds the alternative equivalent to the NRC
6 staff guidance.

7 8 3.2.1.3 Design Control

9
10 S&L has established and implemented governing company standards and procedures, project
11 instructions, and standard operating procedures to control the design and design changes of
12 items that are subject to the provisions of the QATR. The design process includes provisions to
13 control design inputs, outputs, changes, interfaces, records, and organizational interfaces.
14 Design change control is equivalent to the original design. Procedures provide guidance and
15 specify methods for performing design verification. Design verification reviews are performed
16 by qualified personnel other than those who performed the original design. Design analyses are
17 required to be sufficiently detailed to permit design verification without recourse to the originator.
18 However, after design verification is complete, the originator and verifier can interact to resolve
19 any comments generated during the verification. During the system and structure design
20 reviews, design documents are reviewed against requirements of the applicable design criteria
21 and/or other supporting documents in accordance with procedures established by the
22 engineering department conducting the reviews. Responsibility to initiate and follow through on
23 any required changes is assigned to appropriate project personnel. The design change control
24 procedure requires documentation of the change and approval by the cognizant project
25 engineer.

26
27 In establishing its program for design control and verification, S&L commits to compliance with
28 Standard NQA-1-1994, Basic Requirement 3, and Supplement 3S-1.

29 30 3.2.1.4 Procurement Document Control

31
32 S&L has established the necessary procedures to verify that a statement of scope of the work to
33 be performed and other requirements necessary to assure quality are included or referenced in
34 S&L originated documents for procurement or equipment, materials, components, and services.
35 S&L procurement documents include information and requirements such as: 1) applicable
36 regulatory, standard and code requirements, drawings, and test and inspection requirements;
37 2) acceptance/rejection criteria; 3) identification of QA records to be controlled, maintained,
38 retained and/or delivered to the site prior to use or installation (retention times and disposition
39 requirements are specified for records to be retained); and 4) provisions for the supplier to
40 submit nonconformances together with their recommended disposition (use as is, rework or
41 repair) including the technical justification to S&L for review and approval and, if required,
42 recommendation of disposition to the client. Procurement documents are prepared, reviewed,
43 and approved by the appropriate disciplines and issued in a sequence of steps prescribed in
44 accordance with standard operating procedures prior to release for fabrication, construction, or
45 installation of items or performance of services. A change and/or revision to a procurement
46 document is subject to the same level of review and approval as the original document.

1 In establishing controls for procurement, S&L commits to compliance with Standard
2 NQA-1-1994, Basic Requirement 4 and Supplement 4S-1 with the proposed clarifications,
3 exceptions, or alternatives.

4
5 Evaluation of S&L's QA Program Proposed Clarifications, Exceptions, or Alternatives
6

7 S&L proposed that procedures will be established to verify that a statement of scope of the work
8 to be performed and applicable regulatory requirements, design bases, and other requirements
9 necessary to assure quality are included or referenced in S&L originated documents for
10 procurement of equipment, materials, components, and services.

11
12 The NRC staff determined that the wording was essentially equivalent to the guidance in
13 Paragraph II.D.1. of SRP 17.5. Therefore, the NRC staff finds the alternative equivalent to the
14 NRC staff guidance.

15
16 Section 2.3 of Supplement 4S-1 specifies that procurement documents require suppliers to have
17 a documented QA program that implements Standard NQA-1-1994, Part 1. S&L proposed that
18 in lieu of this requirement, the supplier's QA program identify the quality requirements including
19 reference as applicable to 10 CFR Part 50, Appendix B, ANSI/ASME N45.2,
20 ANSI/ASME NQA-1, ASME Section III, 10 CFR Part 21 and 10 CFR 50.55(e) that will be
21 required in procurement documents. S&L may allow suppliers to work directly under their
22 QATR, but will also provide oversight.

23
24 Paragraph II.D.2.d. of SRP 17.5 states in part that, the supplier's documented QA program will
25 be determined to meet the applicable requirements of Appendix B to 10 CFR Part 50, as
26 appropriate to the circumstances of procurement (or the supplier may work under the applicant's
27 approved QA program).

28
29 The NRC staff determined that the wording was essentially equivalent to the guidance in
30 Paragraph II.D.2.d. of SRP 17.5. Therefore, the NRC staff finds the alternative equivalent to the
31 NRC staff guidance.

32
33 3.2.1.5 Instructions, Procedures, and Drawings
34

35 S&L has established the necessary measures and governing procedures to ensure that
36 activities affecting quality are prescribed and performed in accordance with instructions,
37 procedures, or drawings of a type appropriate to the circumstances and include quantitative or
38 qualitative acceptance criteria to implement the QA program as described in the QATR. In
39 accordance with S&L standard operating procedures, project instructions are prepared to
40 provide for the following: 1) client requirements not addressed in a standard operating
41 procedure; 2) clarification and/or additional information for use with a standard operating
42 procedure; and 3) alternative methods, approved by the CEO or a Group Director, to standard
43 operating procedures for addressing programmatic requirements. A project instruction shall not
44 conflict with S&L's Nuclear QA Program.

45
46 In establishing procedural controls, S&L commits to compliance with Standard NQA-1-1994,
47 Basic Requirement 5.

1 3.2.1.6 Document Control

2
3 S&L has established the necessary measures and governing procedures to control the issuance
4 of design documents, instructions and procedures, including changes thereto, that prescribe
5 activities affecting quality. The program and implementing procedures include measures which
6 provide assurance that documents, including changes, are reviewed for adequacy and inclusion
7 of quality requirements, approved for release by authorized personnel and distributed for use at
8 the location where the prescribed activity is performed.

9
10 In establishing provisions for document control, S&L commits to compliance with Standard
11 NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

12
13 3.2.1.7 Control of Purchased Material, Equipment, and Services

14
15 S&L has established the necessary measures and procedures to assure that purchased items
16 and services are clearly and adequately specified in procurement documents and that suppliers
17 are capable of producing items and furnishing services, which conform to procurement
18 document requirements. Such control shall provide for the following as appropriate:
19 1) provisions for supplier evaluation, 2) review of procurement requirements, and 3) surveillance
20 of the supplier.

21
22 In establishing procurement verification controls, S&L commits to compliance with Standard
23 NQA-1-1994, Basic Requirement 7 and Supplement 7S-1 with the proposed clarifications,
24 exceptions, or alternatives.

25
26 Evaluation of S&L's QA Program Proposed Clarifications, Exceptions, or Alternatives

27
28 S&L proposed that if its supplier will be installing safety-related items in a nuclear plant or if
29 ownership is to be transferred, receipt inspection will be performed to ensure that specified
30 inspection, test and other records (such as certificates of conformance attesting that the
31 material, components and equipment conform to specified requirements), are available at the
32 nuclear plant prior to installation, use or ownership transfer.

33
34 The NRC staff found the proposed alternative acceptable based on guidance in SRP 17.5,
35 Paragraph II.G.5. that states, "the program is to include provisions for ensuring that
36 procurement, inspection, and test requirements have been satisfied before an item is placed in
37 service or used." Therefore, the NRC staff finds the alternative equivalent to the NRC staff
38 guidance.

39
40 3.2.1.8 Identification and Control of Materials, Parts, and Components

41
42 S&L does not normally engage in direct activities that require a QA program for identification
43 and control of materials, parts, and components. However, S&L may transfer ownership of a
44 safety-related item to a client prior to installation. In these cases of supplier installation or of
45 ownership transfer, procedures are established for the identification and control of materials,
46 parts and components, including partly fabricated assemblies. Identification is maintained on
47 the items or in documents traceable to the items. Controls are established to ensure that only
48 correct and accepted items are transferred to a client. Materials and parts important to the
49 function of safety-related SSCs are identified so that the identification can be traced to the

1 appropriate documentation such as drawings, specifications, purchase orders, manufacturing
2 and inspection documents, nonconformance reports, and physical and chemical mill test
3 reports. S&L procedures provide for identification of requirements during the generation of
4 drawings and procurement documents.

5
6 In establishing provisions for identification and control of items, S&L commits to compliance with
7 Standard NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

8 9 3.2.1.9 Control of Special Processes

10
11 S&L does not engage in direct activities that require a QA program for control of special
12 processes. However, when S&L is responsible for procurement or upon request by a client,
13 S&L provides for the review of procedures and surveillance of activities related to special
14 processes for suppliers engaged in fabricating and furnishing equipment, components, and
15 systems. S&L personnel that review and perform surveillance activities on special processes
16 are qualified as needed and certified in accordance with applicable codes, standards, and S&L
17 training programs. Requirements are established in procurement documents to assure that
18 special processes such as welding, heat treating, cleaning, and nondestructive examination are
19 performed under adequate controls and that procedures governing these processes are
20 established in accordance with applicable codes and specifications.

21
22 In establishing measures for the control of special processes, S&L commits to compliance with
23 Standard NQA-1-1994, Basic Requirement 9 and Supplement 9S-1.

24 25 3.2.1.10 Inspection

26
27 S&L inspects certain types of items and activities in conjunction with plant design, construction,
28 or modification, but is not responsible for overall inspection programs. Depending on project
29 requirements, S&L personnel are responsible for conducting inspections and for developing
30 inspection procedures. Procedures governing inspection are prepared in accordance with a
31 controlling standard operating procedure. Individuals performing inspections are other than
32 those who performed or directly supervised the activity being inspected and do not report
33 directly to the immediate supervisors responsible for the activity being inspected. Inspection
34 results are documented and distributed by means of inspection reports.

35
36 In addition to performing inspections, S&L reviews procedures submitted by clients/suppliers or
37 prepares procedures to be used by non-S&L organizations under their own QA programs.
38 Procedures submitted by clients/suppliers are reviewed for technical adequacy and
39 completeness and for conformance to procurement documents and other pertinent documents.

40
41 In establishing inspection requirements, S&L commits to compliance with Standard
42 NQA-1-1994, Basic Requirement 10, and Supplement 10S-1 with the proposed clarifications,
43 exceptions or alternatives.

44 45 Evaluation of S&L's QA Program Proposed Clarifications, Exceptions or Alternatives

46
47 S&L proposed that a program will establish the inspections to be performed (source, in-process,
48 final, receipt, maintenance, modification, inservice and operations). The inspection program
49 may be implemented by or for the organization performing the activity inspected.

1 The NRC staff determined that the wording was equivalent to the guidance in SRP 17.5,
2 Paragraph J.1. Therefore, the NRC staff finds the alternative equivalent to the NRC staff
3 guidance.

4 5 3.2.1.11 Test Control

6
7 S&L does not conduct tests other than those of their computer software. However, on request,
8 S&L suppliers may test safety-related items and S&L provides guidance to clients on
9 formulation of their test programs. If an S&L supplier will be installing safety-related items,
10 procedures provide criteria for determining the accuracy requirements of test equipment and
11 criteria for determining when a test is required or how or when testing activities are performed.
12 When post installation testing is used for acceptance of purchased items, post installation test
13 and acceptance documentation recommended by the supplier are required to be considered.
14 S&L may generate preoperational/startup test procedures for S&L or non-S&L designed
15 systems. Procedures are generated and reviewed by cognizant personnel in accordance with
16 governing S&L procedures. Procedures are consistent with design criteria, project requirements,
17 codes, standards, and regulatory documents.

18
19 In establishing provisions for testing, S&L commits to compliance with Standard NQA-1-1994,
20 Basic Requirement 11 and Supplement 11S-1.

21 22 3.2.1.12 Control of Measuring and Test Equipment

23
24 S&L engages in four general types of activities requiring calibration and control of measuring
25 equipment: 1) inspection activities at plant and construction sites and fabricators' facilities,
26 2) verification (via surveillance) by S&L that inspection or tests or other activities conducted by
27 non-S&L organizations have been performed with acceptably calibrated measuring or test
28 equipment, 3) acquisition of engineering design data at plant and construction sites by means
29 such as certain walkdowns and 4) in-house review of radiographic film. On client request S&L
30 also develops calibration procedures for use by non-S&L organizations or reviews calibration
31 procedures submitted by clients/suppliers. S&L performs no activities itself requiring
32 calibration/control of test equipment except for the QA Manager providing for control,
33 maintenance and use of calibrated step wedge film strips used with a densitometer in viewing
34 radiographic film. This activity is controlled by an approved procedure that requires adequate
35 documentation of calibration.

36
37 In establishing provisions for control of measuring and test equipment, S&L commits to
38 compliance with Standard NQA-1-1994, Basic Requirement 12 and Supplement 12S-1 with the
39 proposed clarifications, exceptions or alternatives.

40 41 Evaluation of S&L's QA Program Proposed Clarifications, Exceptions, or Alternatives

42
43 S&L proposed that procedures will establish requirements or specify activities, as applicable, to
44 labeling, tagging, or marking of equipment to indicate due date of next calibration. The
45 procedures will also establish specification of any other means of identification.

46
47 The NRC staff found the proposed alternative acceptable based on guidance in SRP 17.5,
48 Paragraph II.L.3. that states, "Measuring and test equipment is labeled, tagged or otherwise
49 controlled to indicate its calibration status and to ensure its traceability to calibration test data."

1 Therefore, the NRC staff finds the alternative equivalent to the NRC staff guidance.

2
3 S&L proposed that for procurement of commercial-grade calibration services for safety-related
4 applications, laboratory accreditation programs administered by the National Institute of
5 Standards and Technology and by the American Association for Laboratory Accreditation, as
6 recognized through the mutual recognition arrangement of the International Laboratory
7 Accreditation Program, are acceptable in lieu of a supplier audit, commercial-grade survey or
8 in-process surveillance provided that the guidance of SRP 17.5 is met.

9
10 The NRC staff determined that the wording was essentially equivalent to the guidance in
11 Paragraph II.L.8. of SRP 17.5. Therefore, the NRC staff finds the alternative equivalent
12 to the NRC staff guidance.

13 14 3.2.1.13 Handling, Storage, and Shipping

15
16 In general, S&L does not engage in direct activities which require a QA program for handling,
17 storage, and shipping. Storage is normally performed at the site by either the client or a
18 supplier. If S&L or its supplier elects to store the item, special handling, preservation, storage,
19 cleaning, and packaging requirements are established and accomplished by suitably trained
20 individuals in accordance with predetermined work and inspection instructions. When
21 requested by a client, S&L prepares instructions for packaging, handling, shipping, storage, and
22 preservation of items for inclusion in procurement documents. Likewise, S&L project
23 management ensures that test samples forwarded to S&L offices for shipment to a testing
24 laboratory are controlled in accordance with procedures and/or project instructions prior to
25 initiating the activity. Packaging, shipping, storage, and preservation of computer software
26 generated by or in custody of S&L, is performed per procedures.

27
28 In establishing provisions for handling, storage, and shipping, S&L commits to compliance with
29 Standard NQA-1-1994, Basic Requirement 13 and Supplement 13S-1 with the proposed
30 clarifications, exceptions, or alternatives.

31 32 Evaluation of S&L's QA Program Proposed Clarifications, Exceptions, or Alternatives

33
34 S&L proposed that the following controls apply during the operational and decommissioning
35 phases:

36
37 (a) Controls for the packaging, shipping, handling, and storage of items are required to
38 be established on a case-by-case basis with due regard for the item's complexity, use,
39 and sensitivity to damage. Prior to installation or use, the items are inspected and
40 serviced as necessary to ensure that no damage or deterioration exists which could
41 affect their function.

42
43 (b) Controls for hoisting, rigging, and transport activities are required to be established
44 that protect the integrity of the item involved as well as potentially affected nearby
45 structures and components. Applicable hoisting, rigging, and transportation regulations
46 and codes are followed.

1 (c) Cleanliness controls for work on safety related and risk-significant nonsafety related
2 equipment are required to be established that minimize the introduction of foreign
3 material and maintain system/component cleanliness throughout maintenance or
4 modification activities. Procedures require documented verification of absence of foreign
5 material prior to system closure.
6

7 The NRC staff determined that the wording was equivalent to the guidance in
8 Paragraphs II.M.6., II.M.7., and II.M.8. of SRP 17.5. Therefore, the NRC staff finds the
9 alternative equivalent to the NRC staff guidance.
10

11 3.2.1.14 Inspection, Test, and Operating Status

12
13 S&L does not normally engage in direct activities that require a QA program for identification of
14 the inspection, test and operating status of equipment. In cases where S&L supplies and
15 installs equipment or ownership is transferred to S&L, the items are identified whether they are
16 acceptable for installation. The client shall be consulted and written authorization from the
17 responsible design organization shall be obtained prior to altering the sequence of required
18 tests, inspections, and other operations performed at a nuclear plant site.
19

20 In establishing measures for control of inspection, test, and operating status, S&L commits to
21 compliance with Standard NQA-1-1994, Basic Requirement 14.
22

23 3.2.1.15 Nonconforming Materials, Parts, or Components

24
25 In general, S&L does not engage in direct activities which require a QA program for
26 nonconforming materials, parts, or components as this is the responsibility of suppliers. In the
27 cases of supplier installation or of ownership transfer, procedures are used to identify and
28 control items that do not conform to requirements. The affected client(s) are immediately
29 notified when an item is determined to be potentially inoperable, including identification of the
30 nonconforming condition. Nonconforming items are identified by marking, tagging, or other
31 methods which do not adversely affect the end use of the item. Procedures are used to review
32 and accept, reject, repair, or rework nonconforming items. Repaired or reworked items are
33 reexamined using procedures and the original acceptance criteria, unless the disposition has
34 established alternate acceptance criteria. Reports of S&L's nonconforming items are
35 periodically analyzed by the QA Division to identify trends, and significant results are reported to
36 upper management for review and assessment.
37

38 S&L ensures through procedures that nonconforming computer codes are not used in S&L
39 project work. On client request or as determined by S&L, S&L generates procurement
40 documents that require suppliers to furnish documentation of any nonconformance in
41 accordance with a QA program. S&L reviews supplier programs to assure that controls are
42 provided for nonconforming materials, parts, or components at supplier facilities.
43

44 In establishing measures for nonconforming materials, parts or components, S&L commits to
45 compliance with Standard NQA-1-1994, Basic Requirement 15, and Supplement 15S-1.

1 3.2.1.16 Corrective Action

2
3 S&L has established the necessary measures and governing procedures to promptly identify,
4 control, document, classify, and correct conditions adverse to quality. A standard operating
5 procedure assigns responsibilities for identifying and promptly correcting conditions adverse to
6 quality. This procedure requires any person who detects an apparent condition adverse to
7 quality to submit a Performance Improvement Process (PIP) form named after the acronym for
8 the Performance Improvement Process. The QA Manager or designee reviews the PIP form.
9 The purpose of this review is to identify conditions that require immediate management
10 attention, including that of the QA Manager.

11
12 In establishing provisions for corrective action, S&L commits to compliance with
13 Standard NQA-1-1994, Basic Requirement 16.

14
15 3.2.1.17 QA Records

16
17 S&L has established the necessary measures and implementing procedures for generation,
18 collection, compilation, storage, and retrieval of documentation necessary to provide records of
19 S&L quality-related activities.

20
21 Unless S&L is directed to forward all project-related QA records to the client, procedures require
22 retention of QA records such as, but not limited to design input documents, project design
23 documents (design criteria, drawings, calculations, specifications and standards), personnel
24 qualifications and certifications, personnel training records, audit and surveillance reports, and
25 replies thereto, inspection reports, calibration procedures/reports, nonconformance and
26 corrective action reports, change control documents, deviations, design review reports and
27 applicable correspondence, and meeting notes.

28
29 Procedures require that sufficient records be prepared as work is performed to provide evidence
30 of the quality of the activities performed, and that such records be consistent with applicable
31 codes, standards and specifications.

32
33 In establishing provisions for records, S&L commits to compliance with Standard NQA-1-1994,
34 Basic Requirement 17 and Supplement 17S-1.

35
36 3.2.1.18 Audits

37
38 S&L has established the necessary measures and governing procedures to implement audits to
39 verify that activities covered by the QATR are performed in conformance with established
40 requirements. S&L utilizes a system of planned audits and surveillances to verify compliance
41 with and to assess the effectiveness of all aspects of S&L's program and the implementing
42 procedures. Internal audit frequencies of well established activities may be extended one year
43 at a time beyond the two-year interval based on the results of an annual evaluation of the
44 applicable area and objective evidence that the area activities are being satisfactorily
45 accomplished. However, the internal audit frequency interval shall not exceed a maximum of
46 four years. If an adverse trend is identified in the applicable area, the extension of the interval
47 audit frequency interval shall be rescinded and an audit scheduled as soon as practicable.

1 Organizations subject to audit and surveillance by S&L include: 1) S&L business and functional
2 support groups, departments, divisions, and project groups; and 2) S&L suppliers or other
3 suppliers as requested by a client.
4

5 Audits and surveillances are conducted by S&L personnel who have no direct responsibility in
6 the areas they audit and review. Auditors are required to possess the educational training, and
7 experience qualifications for auditing and surveillance as specified in implementing procedures.
8

9 In establishing the independent audit program, S&L commits to compliance with
10 Standard NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.
11

12 4.0 CONCLUSION

13

14 The NRC staff evaluated S&L's QATR (Reference 3) submittal and the supplemental
15 correspondence. The NRC staff concludes that S&L's QA program description, including
16 alternatives, adequately addresses the requirements of Appendix B to 10 CFR Part 50 and is
17 therefore acceptable.
18

19 5.0 REFERENCES

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41 Date: December 11, 2008