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Proposed 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
Attention: Ms. S. Black, Mail Stop 10A19

Gentlemen:

On June 18, 1997, Messrs. K. Heck and L. Campbell (NRC) called Patrick Sheppard and me to discuss comments on proposed Revision 12 to our Topical Report SL-TR-1A, S&L QA Program, which I submitted to you on April 18, 1997. Based on this conversation, we have made the attached changes to the proposal and have provided additional justification.

Please call me at (312) 269-6562 if you have any questions.

Yours very truly,

Randall L. Kurtz

Randall L. Kurtz
Quality Assurance Manager

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Enclosure
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Proposed Revision to S&L Topical Report SL-TR-1A (QA Program)

1. (Page 02-3, line 23 to page 02-4, line 1) A requirement was added for test requirements and acceptance criteria to be provided or approved by the organization responsible for the design or use of a computer program. Mr. Heck inquired about the controls which are imposed when an organization other than the program user provides test requirements.

   User Manuals are issued for each computer program which has been approved for use by S&L personnel. These manuals identify the portion of the program which has been verified and validated and state any assumptions and limitations. Our calculation procedures require the calculation preparer to determine whether the software is appropriate for the work and that the program has been verified and validated. The preparer's work is then independently verified by the reviewer.

2. (Page 03-1, paragraph a) This has been clarified. Applicable design inputs are identified, documented and their selection is reviewed and approved. Additionally, separate design criteria documents are prepared for new structures and systems.

3. (Page 03-4) This has been reworded to state that, 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. This is based on Section 6.3 of ANSI N45.2.13-1976.

4. (Page 04-4) This has been reworded to make it clear that suppliers of basic components are always evaluated in accordance with quality assurance procedures, whereas suppliers of commercial grade items and services are evaluated in accordance with these procedures when necessary.

5. (page 16-1, line 5) This has been changed to state that the Quality Assurance Manager is notified of apparent nonconformances "in writing," rather than "by memorandum." This is to allow notification via electronic means, as well as via hard copy memorandum.

   This does not violate the definition of "discovery" in 10 CFR 21.3. Discovery is defined as "the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in 10 CFR 21.21(a)."

   This definition was published in July 31, 1991. In the Statements of Consideration which was published with the new regulation, it states: "The time limit for evaluation of deviations and failures to comply begins on the date a deviation or failure to comply is discovered. Thus, in order to complete the documentation, some evaluation must take place to identify a deviation or failure to comply. Further, the discovery process is intended to be included in the procedures necessary to comply with part 21 or § 50.55(e)." At the moment, we do not have any contracts which require us to follow 10 CFR 50.55(e).

   A responsible engineer who discovers an apparent defect or noncompliance is required by S&L procedures to immediately notify the QA Manager. If the QA Manager:

   - finds that the item or activity is used or to be used at a facility or activity subject to 10 CFR 21

- finds that the facility, activity, or component, in the case of S&L work, is within S&L's scope of responsibility
- finds that the design has been offered for acceptance
- finds that the possibility of the existence of a substantial safety hazard cannot be immediately eliminated , and
- does not have actual knowledge that the client or supplier has already reported the defect or noncompliance to the NRC in accordance with 10 CFR 21, 10 CFR 50.55(e), 10 CFR 50.72, 10 CFR 50.73 or 10 CFR 73.71,

the manager signs a form and the 60-day clock per 10 CFR 21.21(a)(1) begins. In the case of deviations or failures to comply discovered by S&L's suppliers, the 60-day clock begins upon receipt of notification per 10 CFR 21.21(b).

6. (Page 16-2) We have decided to restore 10 CFR 50.55(e) to this corrective action section. Conceivably, a major modification to an existing or a new research reactor or U.S. Department of Energy facility, or major modifications to a utilization facility, could require us to follow this regulation.

7. (Page 17-2) This has been reworded to state that a record facility or facilities minimizes the risk of damage or destruction from fire, flood, tornadoes, condensation, vermin and decay and satisfies Regulatory Guide 1.88, except for the minimum four hour fire rating for a single facility.

8. (Page 18-5, lines 19 and 20, and page 18-6) Details have been added about reauditing of corrective action resulting from an audit or surveillance. Criteria have been given for when only verification of implementation of corrective action is performed and for when more general reauditing is required.

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 Quality Assurance Program and comply with the General Quality Assurance Procedures, the Director of Engineering, ~~and~~ 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 ~~CEO~~, makes compliance with the S&L Quality Assurance Manual mandatory for all S&L personnel performing quality-related activities.

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

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

02.03 S&L s~~S~~tandards and p~~P~~rocedures 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 level of management generates standards

and/or procedures covering its areas of responsibility unless standards and/or procedures issued by another level of management adequately specify requirements. 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 the personnel 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, standards, and regulatory agencies.

02.05 The development and use of computer programs for quality-related activities are controlled by the Quality Assurance Program. Computer programs and other software are developed in defined sequential phases as part of a software life cycle. Engineering application programs are verified for correctness and feasibility of program functions and for achievement of requirements for each phase within the assumptions and limitations stated in the program documentation. Prior to use, programs are validated by documented testing to demonstrate proper performance. Test requirements and acceptance criteria are provided or approved by the organization responsible for the design or use of the

program to be tested, unless otherwise designated. A variety of typical problems is used in the validation process. Results are checked against known solutions, solutions obtained from other verified and validated computer programs, and/or hand calculations.

Procedures require computer programs used for engineering design or analysis applications to be uniquely identified., ~~validated and~~ These programs, which will not be individually verified and validated for each application, are ~~and~~listed in the S&L online configuration management database. ~~After they are so validated and listed, the program files are placed under controls that will not permit them to be changed without authorization. Only this set of controlled program files may be accessed for computer processing.~~ To the extent appropriate, controls are established to prevent unauthorized changes to verified and validated program files. Temporary changes to listed programs 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, ~~category~~ position descriptions and experience records have been prepared. The ~~category~~ position descriptions include minimum educational and experience requirements for each position. Experience records are used to verify qualification of persons in quality-related positions ~~within their respective disciplines~~.

03.00 DESIGN CONTROL

03.01 The design of structures, systems and components is planned and controlled by cCompany standards and procedures, project instructions, and General Quality Assurance Procedures. Design processes are prescribed, accomplished and documented in accordance with procedures which establish the responsibilities and interfaces of each organizational unit that has an assigned design function. Organization responsibilities are described for preparing, reviewing and approving design documents such as design criteria, drawings, calculations, computer programs, procurement documents and procedures. Included are measures to assure that:

a. ~~design criteria for new structures and new systems are prepared fc: these structures, and systems and components therein, which identify the applicable design bases, commitments of the SAR, regulatory requirements, codes and standards.~~ 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 quality assurance procedures

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 thermal, stress, radiation, hydraulic and accident analysis; compatibility of materials; accessibility for in-service inspection and testing; maintenance and repair; and specifying functional criteria in accordance with design and quality assurance procedures. When

appropriate, acceptance/rejection criteria are included in design documents.

03.04 Verification of design is accomplished by performing design reviews, alternate calculations, or a qualification testing program. When a test program is used to verify the adequacy of a design feature by suitable qualification testing of a prototype, the conditions, when possible, will extend to the most adverse design conditions. 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 division responsible for the review assures that:

a. design characteristics can be controlled, inspected and tested

b. inspection and test criteria are identified.

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.

Technical inadequacies in S&L design documents detected during review or when distributed for interface comment are controlled and corrected through resolution of comments in accordance with procedures.

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, a status list identifying design documents submitted by suppliers for which an S&L review is required is prepared and maintained.~~ 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

division in accordance with quality assurance procedures, 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 participating project team members within S&L are identified and controlled by means of quality assurance procedures. These procedures provide for the preparation of design documents by qualified individuals and design verification by individuals who are independent of the preparer within the appropriate engineering division. 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

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

16.00 CORRECTIVE ACTION

16.01 Procedures assigning responsibilities for identifying and promptly correcting nonconformances are included in the Quality Assurance Manual. These procedures require any person who detects an apparent nonconformance to notify the Quality Assurance Manager in writing ~~by memorandum~~. The Quality Assurance Manager reviews the apparent nonconformance and, if necessary, initiates an investigation. If a nonconformance does not exist, the initiator is so notified. If a nonconformance does exist, a corrective action report is initiated. Nonconformances may be detected during audits or surveillances, or during the design process. The Project Manager and applicable Group Director and Department Manager are provided with reports of nonconformances in S&L work. The Quality Assurance Manager monitors reports of nonconformances and classifies them. The procedures assign responsibility for verifying that a reported nonconformance 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 nonconformance is determined to be a significant condition adverse to quality, the Quality Assurance Manager reports the occurrence to the Chief Executive Officer ~~Chief Operations & Finance Officer~~ and the affected Group Director(s). The Quality Assurance Manager may stop or otherwise control further processing of such deficiency or nonconformance 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)~~and 10 CFR 50.55(e)~~ as part of its corrective action program.

17.03 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 provides controlled access, minimizes the risk of damage or destruction from ~~and protection against~~ fire, flood, tornadoes, condensation, vermin and decay and satisfy the requirements described in Regulatory Guide 1.88, except for the minimum fire rating requirement for a single record facility. Instead, S&L provides for a:

(a) 2 hour fire rated vault meeting NFPA 232-1975, or

(b) 2 hour fire rated class B file containers meeting the requirements of NFPA 232-1975, or

(c) 2 hour fire rated file room meeting the requirements of NFPA 232-1975 with the following additional provisions:

(1) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station;

(2) records storage in fully enclosed metal cabinets;

(3) adequate access and aisle ways;

(4) prohibition in the room of work not directly associated with record storage or retrieval;

b. identification of the auditors and lead auditor

c. identification of persons and/or areas audited

d. description of each nonconformance 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 nonconformances is required in accordance with procedures. Nonconforming areas 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 nonconformance report, indicating corrective action to be taken and the schedule for completion. Extension of the 30 day requirement for responding to nonconformances may be granted by the Quality Assurance Manager when justifiable. Reaudits, when necessary, are conducted on a timely basis, commensurate with the~~but initiated no later than 60 days after~~ 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, it shall be more general. Audit and surveillance reports are filed and available for audit.