

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="" type="checkbox"/>	No <input type="checkbox"/>
Does the TR change maintain the original SE conclusions?	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>
Do the staff methods for establishing the original conclusions remain unaffected?	Yes	<input checked="" type="checkbox"/>	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>			
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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