



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 30, 2021

Ms. Melanie Dirks,
Quality Manager
SOR Inc.
14685 West 105th Street
Lenexa, KS 66215

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF
SOR INC. NO. 99900824/2021-201, AND NOTICE OF NONCONFORMANCE

Dear Ms. Dirks:

From May 17 through May 21, 2020, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at SOR Inc. (hereafter referred to as SOR) facility in Lenexa, KS. The purpose of this limited-scope routine inspection was to assess SOR's compliance with provisions of Title 10 of the Code of Federal Regulations (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

This technically-focused inspection specifically evaluated SOR's quality assurance (QA) program activities including the design, fabrication, testing, and dedication of nuclear qualified pressure, differential pressure, vacuum, and temperature switches being supplied to the U.S. operating nuclear power plants. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of SOR's overall quality assurance (QA) or 10 CFR Part 21 programs. Further, the inspection assessed SOR's corrective actions to close the previous Notice of Nonconformance (NON) 99900824/2017-201-01 and NON 99900824/2017-201-02 documented in the NRC's Inspection Report No. 99900824/2017-201, dated December 1, 2017 (Agencywide Documents Access and Management System Accession (ADAMS) Accession No. ML17324B317).

Based on the results of this inspection, the NRC inspection team found that the implementation of your QA program did not meet certain regulatory requirements imposed on you by your customers or NRC licensees. Specifically, the NRC inspection team determined that SOR was not fully implementing its QA program in the area of corrective action. The specific finding and references to the pertinent requirements are identified in the enclosures to this letter. In response to the enclosed Notice of Nonconformance (NON), SOR should document the results of the extent of condition review for the finding and determine if there are any effects on other safety-related components. Please provide a written statement or explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NON. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," the NRC will make available electronically for public inspection a copy of this letter, its enclosure, and your response through the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is

accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information would create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation



Signed by Kavanagh, Kerri
on 06/30/21

Docket No.: 99900824

EPID No.: I-2021-201-0040

Enclosure: Inspection Report No. 99900824/2021-201
and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF SOR INC. NO. 99900824/2021-201, AND NOTICE OF NONCONFORMANCE
Dated: June 30, 2021

accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information would create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

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NRR-106

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DATE	6/28/2021	6/30/2021	

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NOTICE OF NONCONFORMANCE

SOR Inc
14685 West 105th Street
Lenexa, KS 66215

Docket No. 99900824
Report No. 2021-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the SOR Inc. (hereafter referred to as SOR) facilities located in Lenexa, KS, from May 17 through May 21, 2020, SOR did not conduct certain activities in accordance with NRC requirements that were contractually imposed upon SOR by its customers:

- A. Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."

SOR Procedure 094-152, "Corrective Action Report," Revision 8 provides for the case of a significant condition adverse to quality, the cause of the condition shall be determined, and corrective action taken to preclude recurrence. Adverse conditions include failures, malfunctions, deficiencies, defective items, out-of-control processes, and nonconformances.

Contrary to the above, as of May 21, 2021, SOR failed to assure that conditions adverse to quality were promptly identified and corrected. Specifically, SOR closed its corrective action reports (CARs) No. 972, 974, 975, and 976 without adequately implementing the corrective actions to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected:

1. In response to Nonconformance 99900824-217-201-01, SOR initiated CAR No. 972 and 976, to address the finding related to failure to include suitable qualification testing of prototype units under the most adverse design conditions to verify the adequacy of the design of safety-related switches. SOR addressed the technical issues related to this finding by modifying the qualification report to provide bounding conditions for the qualified life of the safety-related switches. However, SOR failed to adequately implement the corrective actions identified in CAR No. 972 and 976 to prevent future reoccurrence of the root cause identified in these CARs related to third-party qualification report reviews. As a result, a third-party generated qualification report did not follow the required corrective actions identified in CAR No. 972 and 976 for two SOR engineers to review this qualification report for completeness and compliance to relative technical requirement as imposed by Ameren Missouri (Callaway) procurement document. In addition, SOR failed to document the record of review for this third-party qualification report, as required by the corrective actions in CAR No. 972 and 976.
2. In response to Nonconformance 99900824-217-201-02, SOR initiated CAR No. 975, to address the finding related to conflicting switch configurations in SOR's qualification report. SOR supplied a non-standard pressure switch model to Exelon (LaSalle) that was not addressed in SOR's qualification analysis. The non-standard model qualification was bounded to half of the levels for radiation (15Mrad), cycle

aging (15,000), and qualified life (10-years) of the standard model (30Mrad, 30,000 cycles, 20-years). SOR addressed the lower qualification level for the O-ring configuration of the pressure switch. However, SOR failed to provide an engineering justification to support the 20-years qualified life of the pressure switch with O-ring configuration as required by CAR No. 975.

3. CAR No. 974, which was created to address SOR's failure to define by procedure several disposition codes used for nuclear related nonconformance reports, known as material review reports (MRRs). SOR failed to adequately implement the corrective actions identified in CAR No. 974 to prevent future recurrence of assigning disposition codes to MRRs not directly defined by procedure. As a result, SOR generated 8 MRRs and assigned dispositions codes not defined by SOR's implementing procedures.

This issue has been identified as Nonconformance 99900824/2021-201-01.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, Quality Assurance and Vendor Inspection Branch, Division of Reactor Oversight, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further noncompliance; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made electronically available for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC's Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that the Agency can make it available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information would create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Dated this 30th day of June 2021.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR OVERSIGHT
VENDOR INSPECTION REPORT**

Docket No.: 99900824

Report No.: 99900824/2021-201

Vendor: SOR Inc.
14685 West 105th Street
Lenexa, KS, 66215

Vendor Contact: Melanie Dirks
Quality Manager
Email: MDirks@sorinc.com

Nuclear Industry Activity: SOR provides pressure, differential pressure, vacuum and temperature switches for safety-related applications to U.S. nuclear power plants.

Inspection Dates: May 17 - 21, 2021

Inspection Team Leader Jonathan Ortega-Luciano NRR/DRO/IQVB

Inspectors: Deanna Zhang NRR/DRO/IQVB
Nicholas Savvoir NRR/DRO/IQVB

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

SOR, Inc.
99900824/2021-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a vendor inspection at the SOR Inc. (hereafter referred to as SOR) facility located in Lenexa, KS, to verify that it had implemented an adequate quality assurance (QA) program that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." In addition, the NRC inspection team verified SOR's corrective actions initiated to address the Notice of Nonconformances (NONs) identified during the October 2017 NRC Inspection.

This technically-focused inspection evaluated SOR's design, fabrication, testing, and dedication of nuclear qualified pressure, differential pressure, vacuum and temperature switches supplied to U.S. nuclear power plants. Additionally, this inspection evaluated the implementation of select portions of SOR's QA program activities of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

These regulations served as the bases for the NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

During the course of this inspection, the NRC inspection team implemented portions of Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019; IP 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017; and IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017.

The results of this inspection are summarized below.

Nonconforming Materials, Parts, or Components and Corrective Action

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the Nonconforming Materials, Parts, or Components and Corrective Action programs to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

Additionally, the NRC inspection team reviewed the implementation and closure of the corrective actions taken by SOR in response to NON 99900824/2017-201-01 and NON 99900824/2017-201-02 documented in the NRC's Inspection Report No. 99900824/2017-201, dated December 1, 2017 (Agencywide Documents Access and Management System Accession (ADAMS) Accession No. ML17324B317). Based on the review of the corrective actions, the NRC inspection team closed NON 99900824/2017-201-01 and NON 99900824/2017-201-02 and issued NON 99900824/2021-201-01, in association with SOR's failure to implement the regulatory requirements of Criterion XVI. NON 99900824/2021-201-01 cites SOR for failing to ensure conditions adverse to quality were promptly identified and corrected. Specifically, SOR closed its corrective actions reports (CARs) 972, 974, 975, and 976 without fully implementing

the previous committed corrective actions to address NON 99900824/2017-201-01, NON 99900824/2017-201-02, and other issues identified during the October 2017 NRC inspection.

10 CFR Part 21

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program. The NRC inspection team: (1) reviewed the 10 CFR Part 21 postings, (2) reviewed a sample of purchase orders (POs), and (3) verified that SOR's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program. No findings of significance were identified.

Design Control

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the implementation of its design control program to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of qualification reports, and the calculations and analyses in support of the conclusions in these qualification reports. No findings of significance were identified.

Commercial-Grade Dedication and Oversight of Contracted Activities

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) program to verify compliance with the requirements of Criterion III, "Design Control," Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspection team reviewed dedication packages to assess the different elements of the CGD program, including the technical evaluation process, work package instructions, and inspection reports. The NRC inspection team evaluated the criteria for the identification of item safety functions, credible failure mechanisms/modes, selection of critical characteristics and acceptance criteria, and the identification of verification methods to verify effective implementation of SOR's CGD process. No findings of significance were identified.

The NRC inspection team reviewed SOR's supplier qualification process, procurement process, and control of suppliers by focusing on control of key elements of the design, manufacturing, assembly, and testing, as applicable, for a sample of parts, components and services being procured. The NRC inspection team reviewed a sample of external audits performed by SOR to verify that SOR provides adequate oversight of its suppliers. The NRC inspection team verified that the scheduled audits were performed by qualified individuals using checklists and/or procedures and that these checklists and/or procedures include an audit plan, documented objective evidence, audit results, and a review of audit results by responsible management. The NRC inspection team verified that the audits were performed at the minimum frequency as specified in the SOR's requirements. No findings of significance were identified.

Internal Audits

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the implementation of its internal audit program to verify compliance with the regulatory requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed the frequency of the internal audits, the audit reports' objective evidence, and

verified findings were captured in the corrective action program. No findings of significance were identified.

REPORT DETAILS

1. Corrective Action

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed SOR Inc. (hereafter referred to as SOR) policies and implementing procedures that govern the control of nonconformances and corrective actions to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing Production and Utilization Facilities."

The NRC inspection team performed a walk-down of SOR's fabrication and receiving storage areas to verify that nonconforming items were properly identified, marked, and segregated, when practical, to ensure that they were not re-introduced into the production processes. Additionally, the NRC inspection team reviewed a sample of SOR's material review reports (MRRs) formerly referred to as nonconformance reports and corrective action reports (CARs) to verify that: (1) nonconforming items were dispositioned in accordance with procedures; (2) technical justifications were documented as appropriate for dispositions; and (3) nonconforming items were evaluated for 10 CFR Part 21 applicability, as appropriate. Furthermore, the NRC inspection team reviewed the implementation and closure of the corrective actions taken in response to Notice of Nonconformance (NON) 99900824/2017-201-01 and 99900824/2017-201-02, documented in NRC inspection report No. 99900824/2017-201, dated December 1, 2017, (Agencywide Documents Access and Management System Accession (ADAMS) No. ML17324B317).

The NRC inspection team discussed the nonconformance and corrective action programs with SOR's management and technical staff. The references and attendance lists in the attachment to this inspection report identify the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observation and Findings

b.1 Corrective Action Associated with Nonconformance No. 99900824/2017-201-01

In the October 2017 inspection report for SOR, the NRC issued NON 99900824/2017-201-01 for SOR's failure to include suitable qualification testing of prototype units under the most adverse design conditions to verify the adequacy of the design of safety-related switches. Specifically, SOR failed to meet the technical requirements imposed by licensees' purchase orders (POs). SOR responded to the NRC's inspection report by letter dated February 23, 2018, (ADAMS Accession No. ML18054B540). SOR stated it has issued qualification report 9085-102, Revision 3 to adjust the qualified life based on re-performed calculations using bounding conditions, include technical evaluation for activation energies used, address how test anomalies affected the qualification of switches. In addition, SOR issued Corrective Action Reports (CARs) 972 and 976 which include the following steps: suspending orders and quotes; performing an extent of

condition; documenting permanent corrective actions; and identifying how the effectiveness of the corrective actions will be assessed.

The NRC inspection team reviewed the documentation that provided the objective evidence for the completion and implementation of the corrective actions, including review of the qualification report 9085-102, Revision 3. The NRC inspection team found that SOR failed to adequately implement the corrective actions identified in CARs 972 and 976 to address the extent of condition related to third-party qualification report reviews identified in these CARs. As a result, a third-party generated qualification report did not follow the required corrective actions identified in CARs 972 and 976 for two SOR engineers to review this qualification report for completeness and compliance to technical requirements imposed in PO 888230, Revision 0 from Ameren Missouri for the procurement of temperature switches for the Callaway Nuclear Generating Station. In addition, SOR failed to document the record of review for this third-party qualification report, as required by the corrective actions in CARs 972 and 976. Further, SOR failed to correctly translate the technical requirements from PO 888230 in the PO to the third-party performing the qualification. Based on the corrective actions being inadequate, the NRC inspection team documented this as the first example of ineffective corrective actions. The NRC inspection team issued NON 99900824/2021-201-01 and closed NON 99900824-2017-201-01.

b.2 Corrective Action Associated with NON 99900824/2017-201-02

In the October 2017 inspection report for SOR, the NRC issued NON 99900824/2017-201-02 for conflicting switch configurations in SOR's qualification report. Specifically, SOR supplied a non-standard pressure switch model to Exelon (LaSalle) that was not addressed in SOR's qualification analysis. The report summary states that the switch is qualified to 20-years and 30 Mrad, however Table 1 of Appendix A, of the qualification report, states its qualified for 10-years and 15 Mrad. SOR responded to the NRC's inspection report by letter, dated December 21, 2017 (ADAMS Accession No. ML17355A519). In its response, SOR stated that it can demonstrate by combination of test and analysis that the O-ring configuration of the pressure switch provided to Exelon is suitable for 20-years at 120 degrees F, and will revised Test Report 9058-112 to add the justification supporting the qualified life. In addition, SOR issued CAR 975 which include the following steps: revision of Test Report 9058-112 to include the lower qualification levels for the O-ring configuration, add the justification for the 20-year qualified life, and perform extent of condition review.

The NRC inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions, including review of Test Report 9058-112. The NRC inspection team identified that SOR failed to revise Test Report 9058-112 Revision 6 to demonstrate that the O-ring pressure switch configuration is suitable for a 20-year qualified life as required by CAR-975. Based on the corrective actions being inadequate, the NRC inspection team documented this as the second example of ineffective corrective actions. The NRC inspection team issued NON 99900824/2021-201-01 and closed NON 99900824-2017-201-02.

b.3 Corrective Action Associated with an issue identified during the October 2017 NRC Inspection

The NRC inspection team identified several issues that were screened as minor in accordance with Inspection Manual Chapter 0617, "Vendor and Quality Assurance Implementation Inspection Reports," during the October 2017 inspection of SOR. As a result of that, SOR issued CAR 974 for using several disposition codes not directly defined in Procedure 094-043, "Non-Conformance Report," Revision 42. SOR closed out CAR 974 by revising Procedure 094-043 to Revision 46. Revision 46 of the procedure included definitions of undefined disposition codes and generated a 'Note' stating that when an entire lot of parts are to be sorted, enter the disposition code that corresponds to the actions to take on the nonconforming parts found. The NRC inspection team reviewed a sample of SOR's nuclear related MRRs and identified that several MRRs contained the disposition code ACC and one MRR was dispositioned with a DIT code. ACC and DIT disposition codes are not defined in Procedure 094-043 as one of the codes available for SOR to assign as part of the disposition process. The NRC inspection team concluded that Procedure 094-043 does not define disposition codes ACC and DIT nor the action to be followed when MRRs are dispositioned with these codes. The NRC inspection team identified this as a third example of ineffective corrective actions. The NRC inspection team issued NON 99900824/2021-201-01.

c. Conclusion

The NRC inspection team issued Nonconformance 99900824/2021-201-01 in association with SOR's failure to implement the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Nonconformance 99900824/2021-201-01 cites SOR's failure to effectively implement corrective actions and to prevent recurrence of similar issues related to (1) third-party qualification reports reviews and approval; (2) justification for qualified life in the test report; and (3) use of undefined MRR dispositions codes.

The NRC inspection team closed NON 99900824/2017-201-01 because SOR revised the qualification test reports to address the technical issues identified in this NON. The NRC inspection team closed 99900824/2017-201-02 because SOR revised procedures and revised test reports to include lower qualification level configuration.

2. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the implementation of its Title 10 of the Code of Federal Regulations (10 CFR) Part 21, "Reporting of Defects and Noncompliance," program to verify compliance with the regulatory requirements. The NRC inspection team also evaluated the 10 CFR Part 21 postings and a sample of SOR's POs for compliance with the requirements of 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," and 10 CFR 21.31, "Procurement Documents." In addition, the NRC inspection team also verified that SOR's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program. Furthermore, for a sample of 10 CFR Part 21 evaluations performed by SOR, the NRC inspection team verified that SOR had effectively implemented the requirements for evaluating deviations and failures to comply.

The NRC inspection team also discussed the 10 CFR Part 21 program with SOR's management staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that SOR is implementing its 10 CFR Part 21 program in accordance with the regulatory requirements of 10 CFR Part 21. Based on the limited sample of documents reviewed, the NRC inspection team also determined that SOR is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

3. Design Control

a. Inspection Scope

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the implementation of its design control program to verify compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspection team evaluated the implementation of SOR's design control process associated with the performance of qualification analysis for temperature and pressure switches. The NRC inspection team verified that the calculations and analysis performed for temperature and pressure switches for the expected bounding conditions in revised qualification reports for these switches were conducted in accordance with SOR's design process. The NRC inspection team also verified that the SOR qualification reports reviewed received appropriate review and approval.

The NRC inspection team also discussed the design control program with SOR's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observation and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that SOR is implementing its design control in accordance with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team determined that SOR is effectively implementing its policies and procedures associated with the design control. No findings of significance were identified.

4. Commercial-Grade Dedication and Oversight of Contracted Activities

a. Inspection Scope

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) and oversight of suppliers programs to verify compliance with the requirements of Criterion III, "Design Control," Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

SOR is a member of Nuclear Industry Assessment Committee (NIAC), which consists of companies who supply components and services to the nuclear industry based on a quality assurance (QA) program that meets the requirements of Appendix B to 10 CFR Part 50 and accept 10 CFR Part 21. The NRC inspection team confirmed that once a NIAC audit or commercial-grade survey is received, SOR's QA Manager reviews them for completeness and adequacy. These documents are evaluated in accordance with SOR's QA program and if found to be acceptable, the QA Manager will document and use these evaluations as the basis for including these suppliers on SOR's Approved Suppliers List (ASL).

The NRC inspection team reviewed a sample of CGD plans, checklists, reports, associated POs, and commercial-grade surveys of several vendors on SOR's ASL. The NRC inspection team evaluated a sample of technical evaluations and concluded that the technical evaluations in the dedication plans appropriately identify the critical characteristics and technical attributes necessary to provide reasonable assurance that the item or services would perform their intended safety function.

The NRC inspection team reviewed a sample of external audits to verify the implementation of SOR's supplier oversight program. The NRC inspection team verified that SOR had prepared and approved plans that identify the audit scope and applicable checklist criteria before the initiation of the audit activity. The NRC inspection team confirmed that the audit reports contained objective evidence of the review of the relevant QA criteria of Appendix B to 10 CFR Part 50. For audits that resulted in findings, the NRC inspection team verified that the supplier had established a plan for corrective action and that SOR had reviewed and approved the corrective action and verified its satisfactory completion and proper documentation. The NRC inspection team verified that the POs included, as appropriate: the scope of work, right of access to facilities, and extension of contractual requirements to subcontractors. In addition, the NRC inspection team confirmed that the reviewed safety-related POs invoked the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

The NRC inspection team also reviewed a sample of training and qualification records of lead auditors and verified that auditing personnel had completed the required training and maintained qualification and certification in accordance with SOR's policies and procedures.

The NRC inspection team also discussed the oversight of suppliers with SOR's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observation and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that SOR is implementing its CGD program and oversight of contracted activities in accordance with the regulatory requirements of Criterion III, Criterion IV, and Criterion VII, respectively, of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team determined that SOR is implementing its policies and procedures associated with CGD program and oversight of contracted activities. No findings of significance were identified.

5. Internal Audits

a. Inspection Scope

The NRC inspection team reviewed SOR's policies and implementing procedures that govern the implementation of internal audits programs to verify compliance with the requirements of Criterion XVIII, "Internal Audits," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed a sample of internal audit reports and verified that for this limited sample, SOR had prepared and approved audit plans that identify the scope and criteria to be audited. The NRC inspection team confirmed that the audit reports contained objective evidence of the areas reviewed. The NRC inspection team verified that the internal audits were performed by qualified auditors and that these audits were performed by personnel not having direct responsibilities in the areas being audited. Furthermore, the NRC inspection team reviewed a sample of training and qualification records of SOR's lead auditors and confirmed that auditing personnel had completed all the required training and had maintained the applicable qualification and certification in accordance with SOR's policies and procedures.

The NRC inspection team also discussed the internal audits programs with SOR's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observation and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that SOR was implementing its internal audits program in accordance with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team determined that SOR was implementing its policies and procedures associated with the internal audit program. No findings of significance were identified.

6. Entrance and Exit Meetings

On May 17,2021, the NRC inspection team discussed the scope of the inspection with Ms. Melanie Dirks, Quality Manager, and other members of SOR's management and technical staff. On May 21, 2021, the NRC inspection team presented the inspection results and observations during an exit meeting with Ms. Melanie Dirks, Quality Manager, and other members of SOR's management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. Entrance/Exit Meeting Attendees and Persons Interviewed

Name	Title	Affiliation	Entrance	Exit	Interviewed
Jonathan Ortega-Luciano	Inspector - Team Leader	NRC	X	X	
Deanna Zhang	Inspector	NRC	X	X	
Nicholas Savvoir	Inspector	NRC	X	X	
Kerri Kavanagh*	Branch Chief	NRC		X	
Melanie Dirks	Director of Quality	SOR	X	X	X
Sara Roo	Senior Mechanical Engineer	SOR	X	X	X
Kyle Pfautsch	Buyer	SOR	X	X	
Linda Coutts	Technical Project Support	SOR	X	X	
Chris Poskin	Supply Chain Director	SOR	X	X	
Mike Bequette	Vice President of Engineering	SOR	X	X	X
Bert Benton	Chief Operating Officer	SOR		X	

*Teleconference call

2. INSPECTION PROCEDURES USED

- Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019
- IP 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017
- IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99900824/2017-201-01	CLOSED	NON	Criterion III
99900824/2017-201-02	CLOSED	NON	Criterion IV
99900824/2021-201-01	OPEN	NON	Criterion XVI

4. DOCUMENTS REVIEWED

Policies and Procedures

- 002-035, "Purchase Order Specification," Revision 23, dated December 9, 2016
- 094-043, "Non-conformance Report," Revision 46, dated February 25, 2021
- 094-052, "Commercial Vendor Assessment," Revision 4, dated October 13, 2020
- 095-041, "Engineering Test Report," Revision 10, dated May 23, 2018
- 7701-128, "Internal Audit Work Instructions," Revision 23, dated January 4, 2021
- 8301-117, "Quality Review Board," Revision 17, dated February 16, 2021
- 8303-100, "Quality Assurance for SOR Nuclear-Qualified Products," Revision 16, dated May 19, 2020
- 8303-109, "Qualifications of Inspection, Testing and Audit Personnel," Revision 16, dated February 16, 2021
- 8303-110, "Reporting of Potential Deviation for Defect per NRC CFR Part 21," Revision 14, dated June 22, 2015
- 8303-112, "Vendor Audit / Commercial Grade Survey Procedure," Revision 14, dated February 16, 2021
- 8520-017, "Commercial Grade Dedication Procedure," Revision 11, dated March 16, 2020
- 8923-307, "Final Calibration Procedure," Revision 6, dated February 11, 2021

Procurement Documents (PO)

- PO 888230 SR, Revision 0, dated August 15, 2019
- PO KP00281023, dated September 17, 2019

Qualification Reports

- 9058-102, "Nuclear Qualification Test Report – Pressure, Vacuum, and Temperature Switches," Revision 3, dated March 20, 2018
- K-115823-REP-0001, "Qualification of SOR Temperature Switches, model 20XRX-WX125-U-C7A-TTNQX," Revision 1, dated July 3, 2020
- 9058-112, "Nuclear Qualification Test Report – 131 and 141 Series Differential Pressure Switches," Revision 6, dated January 4, 2018

Material Review Report (MRR)

- | | | |
|-----------|-----------|------------|
| • MRR 103 | • MRR 354 | • MRR 913 |
| • MRR 211 | • MRR 356 | • MRR 928 |
| • MRR 237 | • MRR 695 | • MRR 1144 |
| • MRR 322 | • MRR 707 | |
| • MRR 324 | • MRR 720 | |

Corrective Action Report (CAR)

- | | | |
|-----------|------------|------------|
| • CAR 974 | • CAR 976 | • CAR 1017 |
| • CAR 975 | • CAR 1003 | |

Corrective Actions Reports Generated During This Inspection

- CAR 1030 dated May 20, 2021 – Revise Sampling Plan Justification note in Form 1643 (01.19)
- CAR 1031 dated May 20, 2021 – Revise procedure to align with NRC SER [safety evaluation report] on NEI 14-05A Revision 1
- CAR 1032 dated May 20, 2021 – Define QA roles and responsibilities for Procurement Document Control
- CAR 1033 dated May 20, 2021 – Revision 6 of Test Report 9058-112 did not include detail in determining suitability of the qualified life, pertaining the Arrhenius equation
- CAR 1034 dated May 20, 2021 – Procedure 094-043 Rev. 46 does not define codes ACC and DIT

Commercial-Grade Surveys/Audit Reports

- Commercial-Grade Survey for Stamping Services dated August 24, 2020
- Quality Assurance Internal Audit Plan, dated November 13, 2018
- Quality Assurance Internal Audit Plan, dated November 13, 2019
- Quality Assurance Internal Audit Plan, dated November 22, 2019
- Quality Assurance Internal Audit Plan, dated October 28, 2020
- Quality Assurance Internal Audit Report, dated December 18, 2018
- Quality Assurance Internal Audit Report, dated December 3, 2019
- Quality Assurance Internal Audit Report, dated December 4, 2019
- Quality Assurance Internal Audit Report, dated December 3, 2020

10 CFR Part 21 Documents

- Evaluation of Potential Deviation for Defect Report for Potential Issues Related to SOR Nuclear Qualification Test Report 9058-102, Revisions 1 and 2, dated February 2, 2018
- Evaluation of Potential Deviation for Defect Report for Issues Related to the Configuration of the Switch in SOR Nuclear Qualification Test Report 9058-112, Revision 3, dated December 13, 2017

Miscellaneous

- SOR Commercial-Grade Dedication Plan – Casting Housing, Revision 1
- Job # NK00000263-0000 casting
- Customer Special Request (CSR) Form 1501 date April 2018
- CSR 001-514, Revision 13 dated May 3, 2019