

June 5, 2017

Mr. Victor Apostolescu
Vice President of Quality Assurance
Velan Inc.
550 McArthur St.
Montreal, QC H4T 1X8, Canada

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
NO. 99900061/2017-201 OF VELAN INC., NOTICE OF VIOLATION AND
NOTICE OF NONCONFORMANCE

Dear Mr. Apostolescu:

On May 8-11, 2017, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Velan Inc.'s (hereafter referred to as Velan) facilities in Montreal, Canada. The purpose of this limited-scope routine inspection was to assess Velan'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 Velan's implementation of the quality activities associated with the design, fabrication, and testing of safety-related valves and valve replacement parts being supplied to the domestic operating reactors. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The NRC evaluated the violation in accordance with the agency's Enforcement Policy, which is available on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The enclosed Notice of Violation (NOV) cites the violation, and the subject inspection report details the circumstances surrounding it. The NOV cites Velan for failing to specify in procurement documents for suppliers of safety-related material and services that the provisions of 10 CFR Part 21 apply.

You are required to respond to this letter and to follow the instructions specified in the enclosed NOV when preparing your response. In your response to the enclosed NOV, Velan should document the results of the extent of condition review for this finding and determine if there are any effects on other safety-related components. If you have additional information that you believe the NRC should consider, you may provide it in your response to the NOV. The NRC's review of your response to the NOV also will determine if further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, during 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 Velan was not fully implementing its QA program in the areas of procurement document control and control of purchased material, equipment, and services. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter. In response to the enclosed notice of nonconformance (NON), Velan should document the results of the extent of condition review for these findings 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 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,

/RA/

John P. Burke, Chief
Quality Assurance Vendor Inspection Branch-2
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99900061

Enclosures:

1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99900061/2017-201
and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
NO. 99900061/2017-201 OF VELAN INC., NOTICE OF VIOLATION AND
NOTICE OF NONCONFORMANCE

Dated: June 5, 2017

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OFFICE	NRO/DCIP/QVIB-2	NRO/DCIP/QVIB-2	NRO/DCIP/QVIB-2
NAME	YDiaz-Castillo	JOrtega-Luciano	RPatel
DATE	06/01/2017	06/01/2017	06/01/2017
OFFICE	NRO/DCIP/QVIB-3	NRO/DCIP/QVIB-1	NRO/DCIP/QVIB-2
NAME	AFerguson	SSmith (CWeber for)	JBurke
DATE	06/01/2017	06/01/2017	06/05/2017

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NOTICE OF VIOLATION

Velan Inc.
550 McArthur St.
Montreal, QC H4T 1X8
Canada

Docket No. 99900061
Report No. 2017-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Velan Inc.'s (hereafter referred to as Velan) facilities in Montreal, Canada, from May 8, 2017, through May 11, 2017, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Section 21.31, "Procurement documents," of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, requires that "Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply."

Contrary to the above, as of May 11, 2017, Velan failed to specify in procurement documents for suppliers of safety-related materials and services to be procured as basic components that the provisions of 10 CFR Part 21 apply. Specifically, Velan imposed in the purchase orders (POs) that suppliers meet procedure VEL-QCI-561, "The Application of U.S. NRC Regulations 10 CFR Part 21 as Applicable to Non U.S.A Suppliers," Revision 0, dated January 3, 1978, rather than imposing the applicable requirements of 10 CFR Part 21. Velan developed this procedure to address the fact that Velan's international suppliers do not implement a program that meets the requirements of 10 CFR Part 21 and therefore will not accept POs that impose 10 CFR Part 21. This procedure relieves Velan's suppliers from their responsibilities under 10 CFR Part 21 and requires the suppliers to notify Velan of any deviations identified in the materials or services supplied to Velan. Examples of materials and services procured include but are not limited to bars, fittings, flanges, plates, tubing, castings, fasteners, forgings, heat treating, calibration, chemical and mechanical testing, and non-destructive examination.

This issue has been identified as Violation 99900061/2017-201-01.

This is a Severity Level IV violation (Section 6.9.d of the NRC Enforcement Policy).

Under the provisions of 10 CFR 2.201, "Notice of Violation," Velan is hereby required to submit 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 Vendor Inspection Branch-2, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this notice of violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include (1) the reason for the violation or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence if the correspondence adequately addresses the required response. Where good cause is shown, the NRC will consider extending the response time.

If you contest this enforcement action, provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible it 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 the 5th day of June 2017.

NOTICE OF NONCONFORMANCE

Velan Inc.
550 McArthur St.
Montreal, QC H4T 1X8
Canada

Docket No. 99900061
Report No. 2017-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Velan Inc.'s (hereafter referred to as Velan) facilities in Montreal, Canada, from May 8, 2017 through May 11, 2017, Velan did not conduct certain activities in accordance with NRC requirements that were contractually imposed upon Velan by its customers or NRC licensees:

- A. Criterion IV "Procurement Document Control," 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, in part, that "Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether by the applicant or by its contractors or subcontractors."

Contrary to the above, as of May 11, 2017, Velan failed to include the applicable regulatory requirements in its safety-related procurement documents for materials and services procured as basic components that are necessary to ensure that adequate quality is suitably included or referenced. Specifically, Velan did not impose the requirements of Appendix B to 10 CFR Part 50 in its safety-related purchase orders (POs) for materials and services procured as basic components. Rather than imposing Appendix B to 10 CFR Part 50, Velan states in the POs that the work must be performed in accordance with the suppliers' quality assurance manual approved by Velan. Examples of materials and services procured without the imposition of Appendix B to 10 CFR Part 50 in the POs include but are not limited to bars, fittings, flanges, plates, tubing, castings, fasteners, forgings, heat treating, calibration, chemical and mechanical testing, and non-destructive examination. POs shall specify compliance with the requirements of Appendix B to 10 CFR Part 50 to ensure that adequate quality assurance is applied and to ensure that Appendix B to 10 CFR Part 50 is adequately passed down to the sub-suppliers.

This issue has been identified as Nonconformance 99900061/2017-201-02.

- B. Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50, states, in part, that "Measures shall be established to assure 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. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Subsection NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," of Section III, "Rules for Construction of Nuclear Facility Components," of the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel (B&PV) Code, states, in part, that "Evaluation of a Material Organization's Quality System Program by parties other than the Society, as provided by NCA-3820(b), shall be performed in accordance with the requirements of (a) through (i) below. [...] (a) The Quality System Program shall be surveyed, accepted, and audited by the party performing the evaluation on the basis of its compliance with the applicable material requirements of this Section and the requirements of NCA-3850."

Contrary to the above, as of May 11, 2017, Velan failed to establish adequate measures for source evaluation and selection of contractors and subcontractors and failed to establish adequate measures to obtain objective evidence of quality furnished by the contractors or subcontractors. Specifically, the NRC inspection team determined that:

1. Velan failed to adequately qualify material organizations as approved suppliers in accordance with the requirements of NCA-3842.2. Specifically, Velan inadequately qualified these suppliers as Qualified Material Organizations based on the suppliers' International Organization for Standardization (ISO) 9001:2008, "Quality Management System (QMS) - Requirements," and ISO/International Electrotechnical Commission (IEC) 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories," Quality Systems Manuals. The NRC inspection team identified several instances in which the audit checklists did not provide sufficient objective evidence to support the conclusion that the suppliers had met the applicable requirements of Subsection NCA-3850, "Quality System Program Requirements." For example, the NRC inspection team noted that the checklist requirements were identified as being met, however, there was no additional information provided within the checklist to support the auditor's conclusion that the applicable NCA-3850 requirement was met. The NRC inspection team also noted that the checklists did not provide a clear connection to the applicable requirements of NCA-3850. In addition, the NRC staff noted that the auditor's findings were often cited against the requirements of ISO 9001:2008 and ISO/IEC 17025:2005 and not against the applicable requirement of NCA-3850. Furthermore, the NRC inspection team reviewed the quality manuals of several of these suppliers to independently verify whether they met the applicable requirements of NCA-3800, however, the quality manuals did not contain additional attachments or appendices that would address the gap between a Quality Systems Program based on ISO 9001:2008 and ISO/IEC 17025:2005 and an ASME B&PV NCA-3800 Quality Systems Program.
2. For material that meets the requirements of Subsections NB/NC/ND-2610, "Documentation and Maintenance of Quality Systems Programs," of Section III of the ASME B&PV Code, i.e. material for components of 2-inches or less of nominal pipe size, Velan has been procuring these materials as basic components from commercial suppliers. Since this material is exempted from the applicable requirements of Section III of the ASME B&PV Code, Velan has not been conducting a supplier audit to verify and document the effectiveness of the suppliers' quality program to meet the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, "Reporting of Defects and Noncompliance," or conducting any additional verification or acceptance activities to ensure that the components would perform

their intended safety related function. Examples of the type of materials include castings, fasteners, forgings, welding, and brazing.

3. The NRC inspection team determined that the external audits performed by Velan on their Appendix B to 10 CFR Part 50 safety-related suppliers did not contain sufficient objective evidence to conclude that Velan had verified that the suppliers had passed down the applicable technical and regulatory requirements from the POs to their sub-suppliers. For example, for the audit of a supplier of safety-related heat treating services, the audit report discusses the fact that all the calibration is sub-contracted, however, the audit report failed to discuss what controls and applicable technical and quality requirements the supplier imposes on its sub-suppliers. Examples of the suppliers reviewed include suppliers of material (bars, fittings, flanges, plates, tubing, castings, fasteners, forgings, welding, and brazing) and services (heat treating, calibration, chemical and mechanical testing, and non-destructive examination).

This issue has been identified as Nonconformance 99900061/2017-201-03.

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 Vendor Inspection Branch-2, Division of Construction Inspection and Operational Programs, Office of New Reactors, 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 and the results achieved; (3) the corrective steps that will be to avoid further noncompliance; and (4) the date when the corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that the NRC 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 the 5th day of June 2017.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT**

Docket No.: 99900061

Report No.: 99900061/2017-201

Vendor: Velan Inc.
550 McArthur St.
Montreal, QC H4T 1X8
Canada

Vendor Contact: Mr. Victor Apostolescu
Vice President of Quality Assurance
Email: victor.apostolescu@velan.com
Phone: 1-514-748-7748

Nuclear Industry Activity: Velan Inc. is under contract with several domestic operating reactors to provide safety-related valves and valve replacement parts. Velan Inc.'s scope of supply includes safety-related and American Society of Mechanical Engineers Boiler and Pressure Vessel Code Class 1, 2, and 3 valves and valve replacement parts.

Inspection Dates: May 8-11, 2017

Inspectors: Yamir Diaz-Castillo NRO/DCIP/QVIB-2
Jonathan Ortega-Luciano NRO/DCIP/QVIB-2
Raju Patel NRO/DCIP/QVIB-2
Ashley D. Ferguson NRO/DCIP/QVIB-3

Approved by: John P. Burke, Chief
Quality Assurance Vendor Inspection Branch-2
Division of Construction Inspection
and Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

Velan Inc.
99900061/2017-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a vendor inspection at the Velan Inc. (hereafter referred to as Velan) facilities in Montreal, Canada, 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." In addition, the NRC inspection team also verified that Velan implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that met the NRC's regulatory requirements. The NRC inspection team conducted the inspection on May 8-11, 2017.

This technically-focused inspection specifically evaluated Velan's implementation of quality activities associated with the design, fabrication, and testing of safety-related valves and valve replacement parts for the domestic operating reactors. Specific activities observed by the NRC inspection team included:

- Conduct of a Material Review Board meeting to discuss the status of deviation reports
- Calibration of an inside micrometer, a thread plug, and a pressure gage
- Hydrostatic testing of a 3-inch 1525 class bolted bonnet (BB) gate valve for Duke Energy Carolinas
- Dimensional inspection as part of the commercial-grade dedication process for a valve body and 0.75-inch BB gate bonnet for AREVA
- Hardness testing and material verification using Positive Material Identification (PMI) as part of the commercial-grade dedication process for a wedge seal for Duke Energy Carolinas
- Set-up and performance of corrosion resistance gas tungsten arc welding (GTAW) for the weld procedure qualification of an 0.25-inch Inconel inlay on a 1-inch thick carbon steel plate
- Set-up and performance of a visible-dye liquid penetrant examination of a wedge on an valve component
- Contract Review of AREVA purchase order (PO) No. 1016058468 into Velan sales order No. S000004535/P011-896337-N for 1-inch 800 class BB globe valve
- Conduct of Engineering Change Order No. 816720 of a body for a 4-inch 150 Class BB gate valve part No. P012 895047-N01 for Exelon Nine Mile Point

In addition to observing these activities, the NRC inspection team verified that measuring and test equipment (M&TE) was properly identified, marked, calibrated, and used within its calibrated range.

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 Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017, IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017, and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 13, 2012.

This was the second NRC inspection of Velan's facility in Montreal, Canada. The last NRC inspection was conducted in September 2007 and the results are documented in Inspection Report No. 99900061/2007-201, dated December 18, 2007. The report identified one violation of NRC requirements and four nonconformances to NRC requirements that were contractually imposed on Velan by its customers. This inspection report documents the NRC's review of Velan's implementation of corrective actions for these issues.

With the exception of the notice of violation and nonconformances described below, the NRC inspection team concluded that Velan's QA policies and procedures comply with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, and that Velan's personnel are implementing these policies and procedures effectively. The results of this inspection are summarized below.

10 CFR Part 21 Program

The NRC inspection team issued Violation 99900061/2017-201-01 in association with Velan's failure to implement the regulatory requirements of 10 CFR Part 21. Violation 99900061/2017-201-01 cites Velan for failing to specify in procurement documents for suppliers of safety-related materials and services to be procured as basic components that the provisions of 10 CFR Part 21 apply. Specifically, Velan imposed in the POs that suppliers meet procedure VEL-QCI-561, "The Application of U.S. NRC Regulations 10 CFR Part 21 as Applicable to Non U.S.A Suppliers," Revision 0, dated January 3, 1978, rather than imposing the applicable requirements of 10 CFR Part 21. Velan developed this procedure to address the fact that Velan's international suppliers do not implement a program that meets the requirements of 10 CFR Part 21 and therefore will not accept POs that impose 10 CFR Part 21. This procedure relieves Velan's suppliers from their responsibilities under 10 CFR Part 21 and requires the suppliers to notify Velan of any deviations identified in the materials or services supplied to Velan.

Procurement Document Control

The NRC inspection team issued Nonconformance 99900061/2017-201-02 in association with Velan's failure to implement the regulatory requirements of Criterion IV, "Procurement Document Control" of Appendix B to 10 CFR Part 50. Nonconformance 99900061/2017-201-02 cites Velan for failing to include the applicable regulatory requirements in its safety-related procurement documents for materials and services procured as basic components that are necessary to ensure that adequate quality is suitably included or referenced. Specifically, Velan did not impose the requirements of Appendix B to 10 CFR Part 50 in its safety-related POs for materials and services procured as basic components. Rather than imposing Appendix B to 10 CFR Part 50, Velan states in the POs that the work must be performed in accordance with the suppliers' quality assurance manual approved by Velan.

Supplier Oversight

The NRC inspection team also issued Nonconformance 99900061/2017-201-03 in association with Velan's failure to implement the regulatory requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Nonconformance 99900061/2017-201-03 cites Velan for failing to establish adequate measures for source evaluation and selection of contractors and subcontractors and for failing to establish adequate measures to obtain objective evidence of quality furnished by the contractors or subcontractors. Specifically, the NRC inspection team determined that Velan failed to adequately qualify material organizations as approved suppliers in accordance with the requirements of Subsection NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," of Section III, "Rules for Construction of Nuclear Facility Components," of the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel (B&PV) Code. Velan inadequately qualified these suppliers as Qualified Material Organizations based on the suppliers' International Organization for Standardization (ISO) 9001:2008, "Quality Management System (QMS) - Requirements," and ISO/International Electrotechnical Commission 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories," Quality Systems Manuals.

In addition, for material that meets the requirements of Subsection NB/NC/ND-2610, "Documentation and Maintenance of Quality Systems Programs," of Section III of the ASME B&PV Code, i.e. material for components of 2-inches or less of nominal pipe size, Velan has been procuring these materials as basic components from commercial suppliers. Since this material is exempted from the applicable requirements of Section III of the ASME B&PV Code, Velan has not been conducting a supplier audit to verify and document the effectiveness of the suppliers' quality program to meet the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 or conducting any additional verification or acceptance activities to ensure that the components would perform their intended safety related function. Furthermore, the external audits performed by Velan on their Appendix B to 10 CFR Part 50 safety-related suppliers did not contain sufficient objective evidence to conclude that Velan had verified that the suppliers had passed down the applicable technical and regulatory requirements from the POs to their sub-suppliers.

Other Inspection Areas

The NRC inspection team determined that Velan is implementing its programs for design control, commercial-grade dedication, material traceability, manufacturing control, test control, control of M&TE, nonconforming materials, parts or components, corrective actions, and internal audits in accordance with the applicable regulatory requirements of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and activities observed, the NRC inspection team also determined that Velan is implementing its policies and procedures associated with these programs. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed Velan Inc.'s (hereafter referred to as Velan) policies and implementing procedures that govern Velan's 10 CFR Part 21, "Reporting of Defects and Noncompliance," program to verify compliance with the regulatory requirements. In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of Velan's purchase orders (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." The NRC inspection team also verified that Velan's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program.

For a sample of 10 CFR Part 21 evaluations performed by Velan, the NRC inspection team verified that Velan had effectively implemented the requirements for evaluating deviations and failures to comply. The NRC inspection team verified that the notifications were performed in accordance with the requirements of 10 CFR 21.21, as applicable.

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

b. Observations and Findings

During the review of a sample of safety-related POs for materials and services to verify Velan's compliance with the requirements of 10 CFR 21.31, the NRC inspection team noted that the POs for Velan's international suppliers did not specify that the provisions of 10 CFR Part 21 apply. Rather than imposing that the requirements of 10 CFR Part 21 apply, Velan imposes in the POs procedure VEL-QCI-561, "The Application of U.S. NRC Regulations 10 CFR Part 21 as Applicable to Non U.S.A Suppliers," Revision 0, dated January 3, 1978. Velan developed this procedure to address the fact that Velan's international suppliers do not implement a program that meets the requirements of 10 CFR Part 21 and therefore do not accept POs that impose 10 CFR Part 21. This procedure relieves Velan's suppliers from their responsibilities under 10 CFR Part 21 and requires the suppliers to notify Velan of any deviations identified in the materials or services supplied to Velan. The regulations in 10 CFR Part 21 do not allow for suppliers of basic components to relieve their sub-suppliers of the responsibilities under 10 CFR Part 21 when procuring materials or services as basic components.

The NRC inspection team identified this issue as an example of Violation 99900061/2017-201-01 for Velan's failure to specify in procurement documents for suppliers of safety-related materials and services to be procured as basic components that the provisions of 10 CFR Part 21 apply. At the time of the inspection Velan had not initiated a corrective action report (CAR) to address this issue. Examples of materials and services procured include but are not limited to bars, fittings, flanges, plates, tubing, castings, fasteners, forgings, heat treating, calibration, chemical and mechanical testing, and non-destructive examination. Velan should document the

results of the extent of condition review for this Violation and determine the effect on any previously delivered safety-related components.

c. Conclusion

The NRC inspection team issued Violation 99900061/2017-201-01 in association with Velan's failure to implement the regulatory requirements of 10 CFR Part 21. Violation 99900061/2017-201-01 cites Velan for failing to specify in procurement documents for suppliers of safety-related materials and services to be procured as basic components that the provisions of 10 CFR Part 21 apply. Specifically, Velan imposed in the POs that suppliers meet procedure VEL-QCI-561 rather than imposing the applicable requirements of 10 CFR Part 21. Velan developed this procedure to address the fact that Velan's international suppliers do not implement a program that meets the requirements of 10 CFR Part 21 and therefore will not accept POs that impose 10 CFR Part 21. This procedure relieves Velan's suppliers from their responsibilities under 10 CFR Part 21 and requires the suppliers to notify Velan of any deviations identified in the materials or services supplied to Velan.

2. Procurement Document Control, Supplier Oversight, and Internal Audits

a. Inspection Scope

The NRC inspection team reviewed Velan's policies and implementing procedures that govern the implementation of its oversight of contracted activities and internal audits programs to verify compliance with the requirements of Criterion IV, "Procurement Document Control," Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The NRC inspection team reviewed a sample of POs, external and internal audits, and receipt inspection records to evaluate compliance with the applicable regulatory and technical requirements. The NRC inspection team also reviewed the disposition of audit findings to resolve for adequacy and timeliness.

The NRC inspection team confirmed that the internal audit reports contained objective evidence of the review of the relevant quality assurance criteria of Appendix B to 10 CFR Part 50. The NRC inspection team also verified that external and internal audits were performed by qualified lead auditors and auditors. In addition, the NRC inspection team also reviewed a sample of training and qualification records of Velan's lead auditors and auditors and confirmed that auditing personnel had completed all the required training and had maintained qualification and certification in accordance with Velan's policies and procedures.

The NRC inspection team also discussed the procurement document control and supplier oversight programs with Velan's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

b.1 Procurement Document Control

During the review of a sample of safety-related POs, the NRC inspection team noted that Velan did not impose the requirements of Appendix B to 10 CFR Part 50 for safety-related materials and services procured as basic components. Rather than imposing Appendix B to 10 CFR Part 50 as a requirement in the PO, Velan imposes in the POs that the work must be performed in accordance with the suppliers' quality assurance manual approved by Velan. Velan's list of suppliers include Quality System Certificate Holders and Certificate Holders that implement quality programs in accordance with the requirements of Subsection NCA-3800, "Metallic Material Organization's Quality System Program," and Article NCA-4000, "Quality Assurance," respectively, of Subsection NCA, "General Requirements for Division 1 and Division 2," of Section III, "Rules for Construction of Nuclear Facility Components," of the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel (B&PV) Code. In addition, Velan has suppliers whose quality programs are based on the International Organization for Standardization (ISO) 9001:2008, "Quality Management System (QMS) - Requirements," and ISO/International Electrotechnical Commission (IEC) 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories," Quality Systems Manuals. Velan qualifies these suppliers as Material Organizations (MOs) with a quality program that meets the applicable requirements of NCA-3800 in accordance with the requirements of Subsection NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders" (refer to Section b.2 below for a Nonconformance on Velan's qualification of these suppliers).

In order to ensure that parts with safety functions have adequate quality assurance (QA) applied, POs shall specify compliance with the requirements of Appendix B to 10 CFR Part 50. In addition, imposing Appendix B to 10 CFR Part 50 in the POs ensures that it is passed down to the sub-suppliers. The NRC inspection team identified this issue as an example of Nonconformance 99900061/2017-201-02 for Velan's failure to impose the requirements of Appendix B to 10 CFR Part 50 in its safety-related POs for materials and services procured as basic components. At the time of the inspection Velan had not initiated a CAR to address this issue. Examples of materials and services procured without the imposition of Appendix B to 10 CFR Part 50 in the POs include but are not limited to bars, fittings, flanges, plates, tubing, castings, fasteners, forgings, heat treating, calibration, chemical and mechanical testing, and non-destructive examination. Velan should document the results of the extent of condition review for this Nonconformance and determine the effect on any previously delivered safety-related components.

b.2 Supplier Oversight

During the review of a sample of external audit reports, the NRC inspection team noted that most of Velan's suppliers have quality programs that are based on ISO 9001:2008 and ISO/IEC 17025:2005 and that the audit was performed using a custom made checklist by Velan. During further discussions with Velan's staff, the NRC inspection team learned that Velan had qualified most of their suppliers of safety-related materials and services as approved suppliers in accordance with the

requirements of Subsection NCA-3842.2 of Section III of the ASME B&PV Code. Although the ASME B&PV Code allows for the qualification of MOs by Certificate Holders, such as Velan, the MOs' quality systems program must meet the applicable requirements of NCA-3800.

In order to qualify these suppliers as MOs, Velan must ensure that the suppliers' quality systems program meets the requirements of Section NCA-3850, "Quality System Program Requirements," of Section III of the ASME B&PV Code, as required by Subsection NCA 3842.2 (a). Specifically, Subsection NCA-3442.2 (a) states: "The Quality System Program shall be surveyed, accepted, and audited by the party performing the evaluation on the basis of its compliance with the applicable material requirements of this Section and the requirements of NCA-3850." The NRC inspection team identified several instances in which the audit checklists did not provide sufficient objective evidence to support the conclusion that the suppliers had met the applicable requirements of NCA-3850. For example, the NRC inspection team noted several instances where certain checklist requirements were identified as being met, however, there was no additional information provided within the checklist to support the Velan auditor's conclusion that the NCA-3850 requirement was met. The NRC inspection team also noted that the checklists do not provide a clear connection to the applicable requirements of NCA-3850. In addition, the NRC staff noted that the auditor's findings were often cited against the requirements of ISO 9001:2008 and ISO/IEC 17025:2005 and not against the applicable requirement of NCA-3850. Furthermore, the NRC inspection team reviewed the quality manuals of several of these suppliers to independently verify whether they met the applicable requirements of NCA-3800, however, the quality manuals did not contain additional attachments or appendices that would address the gap between a Quality Systems Program based on ISO 9001:2008 and ISO/IEC 17025:2005 and an ASME B&PV NCA-3800 Quality Systems Program.

The NRC inspection team identified this issue as an example of Nonconformance 99900061/2017-201-03 for Velan's failure to establish adequate measures for source evaluation and selection of contractors and subcontractors and failed to establish adequate measures to obtain objective evidence of quality furnished by the contractors or subcontractors. At the time of the inspection Velan had not initiated a CAR to address this issue. The suppliers identified by the NRC inspection team include but are not limited to suppliers of bars, fittings, flanges, plates, tubing, castings, fasteners, forgings, heat treating, calibration, chemical and mechanical testing, and non-destructive examination. Velan should document the results of the extent of condition review for this Nonconformance and determine the effect on any previously delivered safety-related components.

In addition, the NRC inspection team identified that for material that meets the requirements of Subsection NB/NC/ND-2610, "Documentation and Maintenance of Quality Systems Programs of Section III of the ASME B&PV Code, i.e. material for components of 2 inches or less of nominal pipe size, Velan has been procuring these materials as basic components from commercial suppliers. Since this material is exempted from the applicable requirements of Section III of the ASME B&PV Code, Velan has not been conducting a supplier audit to verify and document the effectiveness of the suppliers' quality program to meet the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, or conducting any additional verification or acceptance activities to ensure that the components would perform

their intended safety related function. While these materials may be exempted from the applicable ASME B&PV Code requirements, safety-related materials procured as basic components are to be manufactured under a QA program that meets the requirements of Appendix B to 10 CFR Part 50 and a program that meets the requirements of 10 CFR Part 21.

The NRC inspection team identified this issue as another example of Nonconformance 99900061/2017-201-03 for Velan's failure to establish adequate measures for source evaluation and selection of contractors and subcontractors and failed to establish adequate measures to obtain objective evidence of quality furnished by the contractors or subcontractors. At the time of the inspection Velan had not initiated a CAR to address this issue. The suppliers identified by the NRC inspection team include suppliers of castings, fasteners, forgings, welding, and brazing. Velan should document the results of the extent of condition review for this Nonconformance and determine the effect on any previously delivered safety-related components.

Furthermore, for all the external audits of suppliers reviewed, the NRC inspection team noted that Velan did not verify that these suppliers had imposed and verified the necessary controls, including the applicable regulatory and technical requirements, on their sub-suppliers. The NRC inspection team determined that the external audits did not contain any information to conclude if the suppliers had passed down the applicable technical and regulatory requirements from the PO to their sub-suppliers. For example, for the audit of a supplier of safety-related heat treating services, the audit discusses the fact that all the calibration is sub-contracted, however, the audit failed to discuss what controls and applicable technical and quality requirements the supplier imposes on its sub-suppliers. The external audit also stated that the supplier performs self-qualification of suppliers based on their Quality Management Systems, however, there is no further information that describes what this self-qualification consists of, what requirements are verified during the audits, etc.

The NRC inspection team identified this issue as another example of Nonconformance 99900061/2017-201-03 for Velan's failure to establish adequate measures for source evaluation and selection of contractors and subcontractors and failed to establish adequate measures to obtain objective evidence of quality furnished by the contractors or subcontractors. At the time of the inspection Velan had not initiated a CAR to address this issue. Velan should document the results of the extent of condition review for this Nonconformance and determine the effect on any previously delivered safety-related components.

c. Conclusion

The NRC inspection team also issued Nonconformance 99900061/2017-201-03 in association with Velan's failure to implement the regulatory requirements of Criterion VII, of Appendix B to 10 CFR Part 50. Nonconformance 99900061/2017-201-03 cites Velan for failing to establish adequate measures for source evaluation and selection of contractors and subcontractors and for failing to establish adequate measures to obtain objective evidence of quality furnished by the contractors or subcontractors. Specifically, the NRC inspection team determined that Velan failed to adequately qualify MOs as approved suppliers in accordance with the requirements of Subsection NCA-3842.2 of

Section III of the ASME B&PV Code. Velan inadequately qualified these suppliers as Qualified MOs based on the suppliers' ISO 9001:2008 and ISO/IEC 17025:2005 Quality Systems Manuals.

In addition, for material that meets the requirements of Subsection NB/NC/ND-2610 of Section III of the ASME B&PV Code, i.e. material for components of 2-inches or less of nominal pipe size, Velan has been procuring these materials as basic components from commercial suppliers. Since this material is exempted from the applicable requirements of Section III of the ASME B&PV Code, Velan has not been conducting a supplier audit to verify and document the effectiveness of the suppliers' quality program to meet the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 or conducting any additional verification or acceptance activities to ensure that the components would perform their intended safety related function. Furthermore, the external audits performed by Velan on their Appendix B to 10 CFR Part 50 safety-related suppliers did not contain sufficient objective evidence to conclude that Velan had verified that the suppliers had passed down the applicable technical and regulatory requirements from the POs to their sub-suppliers.

3. Design Control and Commercial-Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed Velan's policies and implementing procedures that govern the design-control program to verify their compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50," and the applicable requirements of Section III of the ASME B&PV Code.

The NRC inspection team reviewed a sample of design reports, design specifications, engineering drawings, shop travelers, and ASME B&PV Code data reports and verified that these documents contained the required information in accordance with Velan's procedures and the ASME B&PV Code requirements.

Specifically, the NRC inspection team reviewed a design package for a 16x12x16-inch, 1525 Class, Section III ASME B&PV Code Class 1 pressure sealed gate valve for Palo Verde Nuclear Generating Station (PNVGS) and for a 4-inch 1500 Class, ASME B&PV Code Section III Class 1 special class bolted bonnet gate valve with Limatorque actuator for Catawba Nuclear Station. Each design package consisted of a design/seismic weak link report, design file, static load test report, technical calculation, engineering change order and change notice, drawing data sheets, bill of materials, and deviation reports (DRs). The NRC inspection team confirmed that the design reports, engineering calculations, and associated test reports include the correct technical and regulatory requirements as required by customer specifications, Velan's procedures, and the applicable ASME B&PV Code requirements. The NRC inspection team also reviewed 12 technical calculation reports for Section III ASME B&PV Code valve components to verify their accuracy, consistency, and that they were reviewed and approved independently by different engineers.

The NRC inspection team also reviewed Velan's customer order specification issue notice No. P012-890485-N, Revision 0, dated October 15, 2015, issued for PNVGS and confirmed that the customer requirements were adequately translated into the applicable Velan's drawings, instructions, procedures and specifications.

In addition, the NRC inspection team reviewed Velan's software validation and verification of ANSYS software version 15.0 used for the design and technical calculations of safety-related valves and valve components. The NRC inspection team also discussed with Velan's engineering staff the evaluation of software errors submitted by ANSYS to verify that they have no significant impact on current and past design and technical calculations. The NRC inspection team confirmed that Velan had performed an evaluation of software errors on several modules and versions of ANSYS to verify that the errors reported do not represent a significant condition adverse to quality to current and past design calculations. The NRC inspection team also reviewed qualification records for three Registered Professional Engineers to verify they were qualified in accordance with the Velan's procedures and Appendix XXIII, "Certified Professional Engineer," of Section III of the ASME B&PV Code.

Furthermore, the NRC inspection team reviewed Velan's program for the dedication of commercial-grade items for use in safety-related applications to verify its compliance with the applicable technical and regulatory requirements. This assessment included a review of the policies and procedures governing the implementation of commercial-grade dedication (CGD) activities, interviews with Velan's personnel, observation of dedication activities, and review of related documentation. Specifically, the NRC inspection team reviewed dedication packages to assess the different elements of the CGD program, including the technical evaluation process, design drawings, work package instructions, and inspection reports. The NRC inspection team evaluated the criteria for the identification of item functions, credible failure mechanisms/modes, selection of critical characteristics and acceptance criteria, and the identification of verification methods to verify effective implementation of Velan's dedication process.

The NRC inspection team also discussed the design control and commercial-grade dedication programs with Velan's management and technical 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 Velan is implementing its design control and commercial-grade dedication programs 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 also determined that Velan is implementing its policies and procedures associated with the design control and commercial-grade dedication programs. No findings of significance were identified.

4. Material Traceability

a. Inspection Scope

The NRC inspection team reviewed Velan's policies and implementing procedures that govern material traceability to verify compliance with the regulatory requirements of Criterion VIII, "Identification and Control of Material, Parts, and Components," of Appendix B to 10 CFR Part 50.

The NRC inspection team verified that the identification markings used on the materials provided a clear and legible identification and do not adversely affect its function or the service life of the item. The NRC inspection team verified that the part number or trace code number was maintained on the item and in documents traceable to the item. The NRC inspection team also reviewed a sample of Certified Material Test Reports and Certificates of Conformance reports to verify compliance with the procurements document requirements for chemical composition, mechanical properties and/or dimension.

The NRC inspection team also discussed the material traceability program with Velan's management and technical 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. Conclusions

The NRC inspection team concluded that Velan is implementing its material traceability program in accordance with the regulatory requirements of Criterion VIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Velan is implementing its policies and procedures associated with the material traceability program. No findings of significance were identified.

5. Manufacturing Control

a. Inspection Scope

The NRC inspection team reviewed Velan's policies and implementing procedures that govern the control of special processes to verify compliance with the regulatory requirements of Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50 and with the applicable requirements of Subsection NCA, Subsection NB, "Class 1 Components," Subsection NC, "Class 2 Components," and Subsection ND, "Class 3 Components," of Section III, Section V, "Nondestructive Examination," and Section IX, "Welding and Brazing Qualification," of the ASME B&PV Code.

Specifically, the NRC inspection team reviewed a sample of Velan's welding and brazing procedures and their associated procedure qualification record (PQR) to verify they were qualified in accordance with the requirements of Section IX of the ASME B&PV Code. The NRC inspection team also reviewed several nuclear travelers for in-process

domestic nuclear orders and completed U.S. operating fleet data packages where travelers indicated the welder had stamped and dated the welding operation performed in accordance with specified welding procedure and documented the weld wire used on the traveler.

The NRC inspection team performed a walk-down of the weld storage area to verify weld materials were controlled to prevent degradation, inadvertent use, or loss of traceability in accordance with the applicable Velan's procedures. The NRC inspection team also reviewed several examples of weld issuance tickets that links the weld material issuance to the shop traveler and the welder. The NRC inspection team noted that the weld area was kept clean and protected from wind and moisture. In addition, the NRC inspection team noted the weld machines were calibrated within the range of use, using known traceable standards and that the calibration frequency was maintained.

The NRC inspection team witnessed the liquid penetrant examination of a wedge for a Section III ASME B&PV Code Class 1 bolted bonnet gate valve for Duke Energy using visible dye penetrant method with a non-aqueous developer. The NRC inspection team confirmed that Velan performed the examination in accordance with the applicable procedures and the requirements of Section V of the ASME B&PV Code. The NRC inspection team verified that the non-destructive examination (NDE) inspector was adequately qualified, and used calibrated equipment that was within the applicable inspection range. The NDE inspector documented the NDE results in the NDE log book, with the NDE operation stamped on the traveler. The NRC inspection team also reviewed a sample of NDE reports from three completed valve data packages and confirmed that the NDE reports contained the required information in accordance with Velan's NDE procedures and Section V of the ASME B&PV Code.

The NRC inspection team also reviewed the associated welder qualification records and confirmed that the welders had completed the required training and had maintained their qualifications in accordance with Velan's procedures and the applicable requirements of Sections III and IX of the ASME B&PV Code. In addition, the NRC inspection team reviewed Velan's NDE personnel training and qualification records and confirmed that the NDE personnel had completed the required training and had maintained their qualifications in accordance with Velan's procedures and the applicable requirements of ASNT SNT-TC-1A, "American Society for Nondestructive Testing Recommended Practice," Revision 11, and Sections III and V of the ASME B&PV Code.

The NRC inspection team also discussed the manufacturing control program with Velan'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 Velan is implementing its manufacturing control program in accordance with the regulatory requirements of Criterion IX of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Velan is implementing its policies and procedures associated with the control of special processes program. No findings of significance were identified.

6. Test Control

a. Inspection Scope

The NRC inspection team reviewed Velan's policies and implementing procedures that govern the test control program to verify compliance with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50.

The NRC inspection team observed and verified that the hydrostatic testing for 3-inch 1525 class bolted bonnet gate valve for Duke Energy Carolinas was performed in accordance with Velan's procedures. The NRC inspection team verified that the test was performed within the required parameters using calibrated gauges and demineralized water and that the results were within the acceptance criteria. The NRC inspection team also assessed indoctrination and training of inspection and test personnel, and reviewed a sample of completed documentation from various portions of the manufacturing process to verify adherence to established procedures.

The NRC inspection team also discussed the test control program with Velan's management and technical 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 Velan is implementing its test control program in accordance with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Velan is implementing its policies and procedures associated with the test control program. No findings of significance were identified.

7. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed Velan's policies and implementing procedures that govern the measuring and testing equipment (M&TE) program to verify compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The NRC inspection team also observed the calibration of an inside micrometer, a thread plug, and a pressure gage.

For a sample of M&TE, the NRC inspection team determined that the M&TE had the appropriate calibration stickers and current calibration dates, including the calibration due date. The NRC inspection team also verified that the M&TE had been calibrated, adjusted, and maintained at prescribed intervals prior to use. In addition, the calibration records reviewed by the NRC inspection team indicated the as-found or as-left conditions, accuracy required, calibration results, calibration dates, and the due date for recalibration. The NRC inspection team also verified that the selected M&TE was calibrated using procedures traceable to known industry standards.

The NRC inspection team also verified that when M&TE equipment is received from the calibration service supplier and the calibration certificate states that it was found to be out of calibration, Velan generates a nonconformance report to identify items that have been accepted using this equipment since the last valid calibration date and to perform an extent of condition review.

The NRC inspection team also discussed the M&TE program with Velan's management and technical 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 Velan is implementing its M&TE program in accordance with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Velan is implementing its policies and procedures associated with the M&TE program. No findings of significance were identified.

8. Nonconforming Materials, Parts, or Components and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed Velan's policies and implementing procedures that govern the control of nonconformances 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.

The NRC inspection team observed a Material Review Board (MRB) meeting held by Velan staff from the Quality, Engineering, and Production departments. The purpose of the MRB is to discuss the dispositioning of nonconforming items submitted in deviation reports (DRs) by the shop staff.

The NRC inspection team reviewed a sample of DRs to verify that Velan: (1) dispositioned nonconforming items in accordance with procedures, (2) documented an appropriate technical justification for various dispositions, (3) took adequate corrective action with regard to the nonconforming items, and (4) identified nonconforming items, as appropriate, for 10 CFR Part 21 applicability. For DRs that were dispositioned as "use as is," the NRC inspection team confirmed that the technical

justifications were documented to verify the acceptability of the nonconforming item. The NRC inspection team also verified that Velan processed customer-returned items under its nonconformance program by initiating a Return Goods Authorization and a DR.

Furthermore, the NRC inspection team performed a walk down of the nonconformance segregation areas for Plants 1 and 2 to verify that nonconforming materials were properly identified, marked, and segregated, when practical, to ensure that they were not reintroduced into the production processes.

The NRC inspection team reviewed a sample of CARs to ensure that conditions adverse to quality were promptly identified and corrected. In addition, the NRC inspection team verified that the CARs provide: (1) adequate documentation and description of conditions adverse to quality; (2) an appropriate analysis of the cause of these conditions and the corrective actions taken to prevent recurrence; (3) direction for review and approval by the responsible authority; (4) a description of the current status of the corrective actions; and (5) the follow-up actions taken to verify timely and effective implementation of the corrective actions. Furthermore, the NRC inspection team verified that the Velan's corrective action process provides a link to the 10 CFR Part 21 program.

The NRC inspection team also discussed the nonconforming materials, parts, or components and corrective action programs with Velan's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

b.1 Corrective Action Associated with Violation 99900061/2007-201-01

Following the September 2007 inspection of Velan, the NRC issued Violation 99900061/2007-201-01 for Velan's failure to provide procedural guidance for the interface of the corrective action and nonconformance reporting processes with the 10 CFR Part 21 program to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard.

In its response to the NRC dated February 19, 2008, Velan stated that VEL-QCI-560, "Procedures for the Implementation of Regulations (US NRC 10 CFR Part 21) For Reporting of Defects and Noncompliance," Revision 7, dated August 10, 2015, was revised to incorporate the following suitable references to the procedures governing the control of non-conforming material and corrective action: VEL-QCI-1316, "Deviation Reports," Revision 11, dated January 20, 2016 and VEL-QCI-1317, "Deviation Report Analysis Root Cause and Corrective Action Revision 12, dated April 13, 2016, respectively. In addition, Velan's response stated that VEL-QCI-1316 and VEL-QCI-1317 would also be revised to include a reference to the 10 CFR Part 21 evaluation process.

The NRC inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions. The NRC inspection team verified that procedure VEL-QCI-560 was revised to ensure that internal nonconformities and corrective actions were evaluated for 10 CFR Part 21 applicability. The NRC inspection team also verified that VEL-QCI-1316 and

VEL-QCI-1317 were revised to include a link between the 10 CFR Part 21 evaluation process and the corrective action and nonconformance processes. Based on its review, the NRC inspection team closed Violation 99900061/2007-201-01.

b.2 Corrective Action Associated with Nonconformance 99900061/2007-201-01

The NRC also issued Nonconformance 99900061/2007-201-01 for Velan's failure to assure the applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services. Specifically, Velan assembled a safety-related valve using a non-safety-related limit switch due to the limit switch being improperly identified on the assembly drawing.

In its response to the NRC dated March 19, 2008, Velan stated that it had requested and received written confirmation from the customer that the limit switch performs a non-safety-related function, and therefore was acceptable. In addition, Velan stated that VEL-QCI-474, "Quality Control Program for Actuators and Accessories," Revision 6, dated February 21, 2007, would be revised to indicate that: 1) Velan shall not provide non-safety-related components performing a safety-related function under any circumstances; and 2) Velan may provide non-safety components on valves upon customer request via written communication that the component will not perform a safety-related function. Furthermore, VEL-QCI-474 would be revised to include a checklist for safety-related components as required for nuclear valves.

The NRC inspection team reviewed the communication between Velan and the customer and confirmed that the limit switch was not used in a safety-related application. The NRC inspection team noted that although VEL-QCI-474 was not revised, Velan performed an evaluation of the safety function for each valve component and the classification of all components in accordance with EWI-0500, "Critical Component Evaluation Procedure." This evaluation ensured that all valve components are properly classified based on their potential failure method and safety function. Through discussion with Velan engineering staff, the NRC inspection team learned that the procurement function had been reorganized so that each procurement specialist is responsible for specific components; thus reducing errors caused by the lack of knowledge of the requirements associated with a component. The NRC inspection team reviewed a sample of POs to verify that safety related components were procured as such. Based on its review, the NRC inspection team closed Nonconformance 99900061-2007-201-01.

b.3 Corrective Action Associated with Nonconformance 99900061/2007-201-02

The NRC also issued Nonconformance 99900061/2007-201-02 for Velan's failure to adhere to procedure VEL-QCI-560 which required Form No. 82-1-78 to be used to document the evaluation and the decisions as to whether or not a deviation is a defect or noncompliance.

In its response to the NRC dated February 20, 2008, Velan stated that key staff responsible for enforcing the procedure were retrained. The NRC inspection team reviewed the training log of personal responsible for the implementation of the 10 CFR Part 21 program. The NRC inspection team also verified that Form No. 82-1-78 has been used to document the results of five 10 CFR Part 21 deviation

evaluations completed since the 2007 NRC inspection. Based on its review, the NRC inspection team closed Nonconformance 99900061/2007-201-02.

b.4 Corrective Action Associated with Nonconformance 99900061/2007-201-03

The NRC also issued Nonconformance 99900061/2007-201-03 for Velan's failure to provide objective evidence of quality furnished by contractors or subcontractors. Specifically, Velan's vendor survey reports sampled by the NRC inspectors did not include sufficient objective evidence to support Velan auditor's conclusions with respect to the areas reviewed.

In its response to the NRC dated February 20, 2008, Velan stated that the Quality Manager interviewed the Lead Auditors and determined that despite the lack of documentation in the report, the information verified during the audit was sufficient to justify the approval of Velan's suppliers and that no corrective action would be taken. However, as a preventive measure, Velan instructed its Lead Auditors to capture more of the information reviewed in the report or to collect and attach to the report, objective evidence of the areas reviewed.

The NRC inspection team reviewed a sample of supplier audits conducted since the 2007 NRC inspection. The NRC inspection team noted that for the sample of audits reviewed, Velan attached supplemental information to the audit checklists. However, based on its review, the NRC inspection team determined that the supplemental information did not provide adequate objective evidence of the areas reviewed during the supplier audits. Specifically, for the sample of audits reviewed, Velan did not include objective evidence to conclude that Velan had verified that their suppliers passed down the applicable technical and regulatory requirements from the PO to their sub-suppliers. The NRC inspection team identified this issue as part of Nonconformance 99900061/2017-201-03 and has, therefore, closed Nonconformance 99900061/2007-201-03.

b.5 Corrective Action Associated with Nonconformance 99900061/2007-201-04

The NRC also issued Nonconformance 99900061/2007-201-04 for Velan's failure to establish measure to assure conditions adverse to quality are promptly identified and corrected. Specifically, VEL-QCI-1317 did not include provisions to address corrective action for issues or findings identified as a result of audits or inspections performed by outside organizations such as the Nuclear Procurement issues Committee (NUPIC), ASME, or the NRC. In addition, the actions taken to evaluate the root cause and extent of condition of the deviations evaluated under the 10 CFR Part 21 program were not performed in accordance with the corrective action or deficiency reporting procedures.

In its response to the NRC dated February 20, 2008, Velan stated that VEL-QCI-1317 was revised to include provisions for addressing issues identified as a result of audits, inspections, and complaints from third-party agencies or customers. Velan also stated that the use of the CAR form was mandated in all instances where corrective action is sought outside of the DR process. In addition, Velan stated that VEL-QCI-560 was revised to mandate the use of the DR form to document all instances of 10 CFR Part 21 deviations from customers or suppliers.

The NRC inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions. The NRC inspection team verified that VEL-QCI-560 and VEL-QCI-1317 were revised to include provisions for addressing issues identified as a result of audits, inspections, and complaints from third-party agencies or customers. The NRC inspection team also verified that Velan initiated CARs, in accordance with VEL-QCI-1317, for findings identified as a result of the last third-party audit (NUPIC) conducted in December 2015. The NRC inspection team observed that at the time of the inspection, there were no instances in which corrective actions, required to be reported in the CAR form, were generated outside of the DR process, other than for issues identified during third-party audits. In addition, the NRC inspection team reviewed a sample of 10 CFR Part 21 evaluations completed since to the 2007 NRC inspection to verify the use of the deviation report form. Based on its review, the NRC inspection team closed Nonconformance 99900061/2007-201-04.

c. Conclusion

The NRC inspection team concluded that Velan is implementing its nonconforming materials, parts, or components and corrective action programs in accordance with the regulatory requirements of Criterion XV and Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Velan is implementing its policies and procedures associated with the control of nonconforming materials, parts, or components and corrective action. No findings of significance were identified.

9. Entrance and Exit Meetings

On May 8, 2017, the NRC inspection team discussed the scope of the inspection with Martin Allen, Velan's Vice President of Operations, and other members of Velan's management and technical staff. On May 11, 2017, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Allen and other members of Velan'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

Name	Title	Affiliation	Entrance	Exit	Interviewed
Martin Allen	Vice President of Operations	Velan Inc.	X	X	
Victor Apostolescu	Vice President of Quality Assurance (QA)	Velan Inc.	X	X	X
Pierre Lamarre	General Manager Plants 1-5	Velan Inc.	X	X	
J. Yvon Plouffe	Director of Operations Plant 2	Velan Inc.	X		
Cristina Minescu	Quality Manager Plants 1 & 2	Velan Inc.	X	X	
Carl Correa	Quality Audit Manager	Velan Inc.	X	X	X
Mihaela Panazan	QA Administrator	Velan Inc.	X		
Eric Zaidi	System Administrator	Velan Inc.			X
Oswaldo Rodrigues	Quality Control (QC) Manager Plant 1	Velan Inc.	X	X	X
Laurent Delord	QC Manager Plant 2	Velan Inc.	X		X
Yves Lauzé	Design Director	Velan Inc.	X		
Paul Major	Design Manager	Velan Inc.	X	X	X
Marc Bouchard	Project Engineering Director	Velan Inc.	X		
Dipa Patel	Project Engineering Manager	Velan Inc.	X		
Madeleine Murphy	Analytical Engineering Manager	Velan Inc.	X	X	X
Christian Schweiger	Nuclear Program Manager	Velan Inc.		X	
Nicole Asselin	Project Leader	Velan Inc.	X	X	
Sorin Simniceann	Nondestructive Examination (NDE) Manager	Velan Inc.		X	X
Daniel Fafarb	NDE Level II Inspector	Velan Inc.			X
Parveen Kumar	NDE Level II Inspector	Velan Inc.			X

Name	Title	Affiliation	Entrance	Exit	Interviewed
Pankaj Patel	Welding Supervisor	Velan Inc.			X
Matthew Bellanger	QA Specialist	Velan Inc.	X	X	
Nasos Bramos	QA Specialist	Velan Inc.	X		
Kazimierz Mekarski	QC Inspector	Velan Inc.			X
Ramon Losloso	QC Inspector	Velan Inc.			X
Jimmy Georgousis	QC Inspector	Velan Inc.			X
Corneliu Pop	Calibration Technician	Velan Inc.			X
Mohammed Ishtiaq	Receipt Inspector	Velan Inc.			X
Alexandru Ciupe	Hydrostatic Testing Inspector	Velan Inc.			X
Anh Vo Nguyen	Production Planner	Velan Inc.			X
Oscar A. Lazarte	Liaison Engineer	Velan Inc.			X
Yamir Diaz-Castillo	Inspection Team Leader	NRC	X	X	
Jonathan Ortega-Luciano	Inspector	NRC	X	X	
Raju Patel	Inspector	NRC	X	X	
Ashley Ferguson	Inspector	NRC	X	X	

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 13, 2012.

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
99900061/2007-201-01	Closed	NOV	10 CFR Part 21
99900061/2007-201-01	Closed	NON	Criterion IV
99900061/2007-201-02	Closed	NON	Criterion V
99900061/2007-201-03	Closed	NON	Criterion VII
99900061/2007-201-04	Closed	NON	Criterion XVI
99900061/2017-201-01	Opened	NOV	10 CFR Part 21
99900061/2017-201-02	Opened	NON	Criterion IV
99900061/2017-201-03	Opened	NON	Criterion VII

4. DOCUMENTS REVIEWED

Policies and Procedures

- Velan Inc. Corporate Quality Assurance Manual for Nuclear Line Valves, Valve Parts, and As a Material Organization, Class 1, 2, and 3 of the ASME Section III, Division I, Boiler and Pressure Vessel Code, Revision 19, dated August 9, 2016
- EWI-0010, "Engineering Change Request," Revision 0, dated July 22, 2009
- EWI-0011, "Engineering Change Order," Revision 0, dated November 6, 2009
- EWI-0012, "Engineering Change Notice," Revision 0, dated July 21, 2009
- EWI-0226, "Qualification of Engineering Personnel: Approval, Independent Review and Certification," Revision 0, dated November 27, 2009
- EWI-4001, "Design Reports," Revision A, June 18, 2010

- EWI-4002, "Reconciliation of Design Documents with As-Built Drawings and Data," Revision A, dated February 19, 2013
- EWI-4100, "Technical Calculations," Revision D, dated September 25, 2014
- EWI-500, "Critical Component Evaluation Procedure," dated April 19, 2013
- VEL-NDT-537B - "Liquid Penetrant Examination for Nuclear Valves, Nuclear Valve Components, Welds, Hard facings and Claddings," Revision 5, dated March 9, 2016
- VEL-NDT-543B, "Magnetic Particle Examination For ASME Boiler and Pressure Vessel Code Section III, Nuclear Power Plant Components, Fluorescent Magnetic Particles in Oil or Water Suspension," Revision 14, dated February 29, 2016
- VEL-NDT-640B, "Hydrostatic Testing of Nuclear Gate, Globe and Check Valves," Revision 7, dated December 16, 2002
- VEL-P-881, "Marking Requirements," Revision 3, dated January 14, 2015
- VEL-PS-059, "Procurement of Calibration Services," Revision 10, dated August 12, 2015
- VEL-PS-086, "Purchase Specification Procurement of Laboratory Services," Revision 0, dated December 22, 2005
- VEL-PS-099, "Purchase of Filler Metal for ASME Section III Valves," Revision 1, dated June 17, 2013
- VEL-PS-101, "High Quality Water Verification," Revision 3, dated March 15, 2017
- VEL-QC-155, "Quality Control of Parts Used for Nuclear Valves," Revision 24, dated August 14, 2015
- VEL-QC-700, "Calibration Procedure Manual," Revision 20, dated August 4, 2015
- VEL-QC-704, "Procedure for Monitoring High Quality Water," Revision 1, dated June 9, 1995
- VEL-QC-705, "Training and Indoctrination Program of Quality Related Personnel (QAM)," Revision 2, dated August 8, 2014
- VEL-QC-737, "Valve Sketches," Revision 2, May 23, 2014
- VEL-QC-900, "Quality Assurance Manual for Valves and Parts Manufactured in Accordance with ASME B16.34, API-6D, API 600, ISO 9001, API Q1, P.E.D., and C.S.A B51," Revision 17, dated February 28, 2014
- VEL-QCI-3074, "Contract Instructions," Revision 11 date March 31, 2017
- VEL-QCI-474, "Quality Control Program for Actuators and Accessories," Revision 6, dated February 21, 2007

- VEL-QCI-560, "Procedures for the Implementation of Regulations (US NRC 10 CFR Part 21) For Reporting of Defects and Noncompliance," Revision 7, dated August 10, 2015
- VEL-QCI-561, "The Application of U.S. NRC Regulations 10 CFR Part 21 As Applicable to Non U.S.A Suppliers," Revision 0, dated January 3, 1978
- VEL-QCI-884, "Positive Material Identification," Revision 15, dated March 2, 2016
- VEL-QCI-902, "Control of Material Traceability," Revision 1, dated January 28, 2015
- VEL-QCI-926, "Attachment of Nameplates," Revision 1 dated July 28, 1993
- VEL-QCI-953, "Receiving Inspection, Revision 11, dated September 14, 2016
- VEL-QCI-992, "Training, Indoctrination, and Qualification Program Audit Personnel," Revision 6, dated October 19, 2012
- VEL-QCI-999, "Training, Indoctrination, and Qualification Program Personnel," Revision 12, dated March 16, 2016
- VEL-QCI-1123, "Commercial Grade Dedication Procedure," Revision 19 dated September 15, 2015
- VEL-QCI-1138, "Trace Code Markings for Bar Stocks and Pipes," Revision 2, dated July 7, 2011
- VEL-QCI-1192, "Serial Number Assignment and Monogram Name Plate Stamping," Revision 4, dated May 15, 2000
- VEL-QCI-1299, "Supplier Approval ISO 9001," Revision 7, dated October 20, 2011
- VEL-QCI-1316, "Deviation Reports," Revision 11, dated January 20, 2016
- VEL-QCI-1317, "Deviation Report Analysis Root Cause and Corrective Action," Revision 12, dated April 13, 2016
- VEL-QCI-1713, "Testing by Material Specification for VEL-QCI-1123," Revision 9, dated June 21, 2016
- VEL-QCI-2345, "Contract Instruction," for Velan Nuclear Standardized Program for gate, globe, piston, and check valve ≤ 2 National Pipe Size, Revision 16, dated August 19, 2009
- VEL-QCI-3074, "Contract Instruction," for Duke Power Company - Oconee Nuclear Station, 2.5-inch and larger gate, globe and check valves, Revision 11, dated March 31, 2017
- VEL-QCI-3554, "Contract Instruction," Revision 14, dated March 31, 2017

- VEL-QCI-6450, "Contract Instruction," for Constellation Energy-Nine Mile Point Nuclear Station, Valves Carbon Steel 2, Revision 0, dated August 21, 2011
- VEL-QCI-6835, "Inspection and Test Plan for CAT ID 9230004959," Revision 1, dated August 24, 2016
- VEL-QCI-6881, "Inspection and Test Plan for Catalogue. ID. 0001646817 1," for Exelon - Nine Mile Point, Revision 0, dated July 14, 2016
- VEL-SPS-001, "Velan Standard Purchase Order Notes and Certification Requirements," Revision 18, dated October 28, 2016
- Quality Assurance Requirements Sheet 748, Revision 12, dated June 10, 2013
- SW-ANS-1010, "External Software Specifications," for ANSYS Mechanical/CFX-15.0, Revision C, dated October 19, 2016

Design Documents

- Drawing No. P12-873577-N01, Revision G
- Drawing No. 8954-090, "Wedge Opercule," Version 2
- Drawing No. 8954-200, "Wedge M/C (With Equalizer)," Version 1
- Drawing No. P0120893164-No1, "Bolted Bonnet Gate Valve (Forged)," Revision A
- Drawing No. P012-895047-N01, "Bolted Bonnet Gate Valve (Forged)," Revision 0, dated September 15, 2016
- Drawing No. P012-894653-N01, "Pressure Seal Gate Valve (Forged) c/w Bare Stem," Revision D, dated December 2, 2012
- Design File No. P-177, "4-inch, 900 class Conventional Port Gate Valve, Assembly No. 8850-077" Revision 0, dated August 10, 2016
- Design/Seismic/Weak Link Report No. 3334, "4-inch 900 Class Pressure Seal Gate Valve, Nuclear Class 1," Revision A, dated February 20, 2017
- Design Report No.3535, "2.5-inch 1725 Class Bolted Bonnet Gate Valve with Limitorque SMB-00-25 Actuator, Nuclear Class 1, Duke Class A," Revision 0, dated April 20, 2017
- Technical Calculation No. 0007, "Body Minimum Wall Thickness ASME B16.34-2009," Revision 0, dated October 17, 2012
- Technical Calculation No. 0008, "Backseal Analysis," Revision 0, dated November 29, 2016
- Technical Calculation No. 0009, "Body Flange Calculation ASME Section III," Revision B, dated June 20, 2014

- Engineering Change Order No. 806229 to change gasket roughness dimensions for a 2-inch forged bolted bennet gate valve
- Engineering Change Order No. 809187 to revise drawing No. 8943-127 for surface finish on gasket contact area only
- Engineering Change Order No. 816720 for a body pressure relief pipe and cap and new body machine and configuration drawing,

American Society of Mechanical Engineers (ASME) Code Data Reports, and Shop Travelers Welding Records

- ASME B&PV Code Valve Data Package for Georgia Power Company (Vogtle 1 & 2 Electric Generating Plant) for an 8.00-inch 150 class Torque Seal Triple Offset Butterfly Valve, dated February 17, 2016
- ASME B&PV Code Valve Data Package for Duke Energy Carolinas, LLC (Catawba Nuclear Station) for 4-inch 1500 class Spl. Cl. Bolted Bonnet Gate Valve c/w Electric Actuator, dated March 23, 2016
- ASME B&PV Code data report NPV-1, "Nuclear Pump or Valves," for a 4-inch 900 class Gate valve, model No. B12 7054P-13RSN, fabricated and tested in accordance with ASME Section III Class 1, 2007 Edition 2008 addenda, reviewed and approved by ANI and Velan on February 28, 2017
- ASME Code data report NPV-1, "Nuclear Pump or Valves," for a 16-inch 1525 class Pressure Seal Gate valve, model No. B20 X054P13RSN, fabricated and tested in accordance with ASME Section III Class 1, 1974 Edition 1975 winter addenda, reviewed and approved by ANI and Velan on March 1, 2016,
- ASME Code data report NPV-1, "Nuclear Pump or Valves," for a 4-inch 150 class Bolted Bonnet gate valve, model No. B12 0054b-02PSN, fabricated and tested in accordance with ASME Section III Class 3, 1971 Edition, 1972 winter addenda, reviewed and approved by ANI and Velan on February 3, 2016
- Welding Procedure Specification (WPS) GT-0168, "Hard Facing Overlay," Revision 1, dated April 24, 2007
- WPS GT-8860, "GTAW Manual Groove and filled Welds," Revision 11, dated July 26, 2013
- WPS GT-1166, "GTAW Groove and Fillet Welds," Revision 9, dated June 25, 2015
- Brazing Procedure Specification (BPS) No. FBP-101-06-107.0, "Vacuum Furnace Brazing of Stellite Seat Rings of Material AMS 5387A to Body of P-101 Materials," Revision 0, dated September 19, 1998

Calibration, Heat Treatment, Non-Destructive Examination, Inspection and Test Records

- Certificate of Conformance (CFC) No. 20455-01 for SST 410 A479 Stem from Liard Industries, dated February 22, 2016
- Certificate of Compliance associated with purchase order (PO) No. 229501 dated February 6, 2015
- Inspection Certificate No. 403897 for 2 body from Ulma Lazkao Forging, dated March 20, 2017
- Certificate of Calibration No. 3565016 from David L. Ellis Company for the calibration of a brinell test block (no date available)
- Certificate of Calibration No. 187523 from Primo Instrument for the calibration of a thermometer, dated April 28, 2016
- Certificate of Calibration No. 192441 from Primo Instrument for the calibration of a thermocouple, dated July 21, 2016
- Certificate of Calibration No. 207030 from Trescal for the calibration of a super micrometer, dated March 16, 2017
- Certificate of Calibration No. 208187 from Trescal for the calibration of a pressure module, dated March 21, 2017
- Certificate of Calibration No.463799 from Ulrich Metrology for the calibration of a thread wire, dated April 1, 2015
- Certificate of Calibration No. 481621 from Ulrich Metrology for the calibration of a cylindrical ring, dated July 13, 2015
- Calibration Reports of Defective/Lost Measuring and Test Equipment for the following equipment:
 - Light-radio meter, asset No. G21-12718, dated January 27, 2017
 - Weigh scale, asset No. G14-11299, dated January 28, 2017
 - Position transducer, asset No. G21-13428, dated February 2, 2017
 - Dial indicator, asset No. G11-13461, dated February 27, 2017
 - Pressure gauge, asset No. G16-13673, dated March 9, 2017
 - Pressure transducer, asset No. G21-10974, dated April 6, 2017
- Liquid Penetrant (LP) test report No.172006, dated February 27, 2017
- LP report No. 162018 dated April 29, 2016

Purchase Orders, Audit Reports, and Commercial-Grade Dedication

- Purchase Order (PO) Nos. 03014410 and 03016303 from Duke Energy Carolinas, LLC (Oconee Nuclear Station) to Velan for 3-inch gate valves, dated January 27, 2016, and dated December 1, 2016, respectively
- PO No. 099-257108 to Stoncor Group for Carbozinc 11SG, dated October 21, 2016
- PO No. 099-256487 to Stoncor Group for Carbozinc 11SG, dated June 6, 2016
- PO No. 099-255990 to Stoncor Group for Carboguard 890 and Thinner, dated March 1, 2016
- PO No. 280635 to Liard Industries for a stem, dated January 18, 2017
- PO No. 280445 to PDK for a stem, dated October 18, 2016
- PO No. 119464 to Industrial Tectonics for balls, Revision 3, dated October 24, 2012
- PO No. 233472 to Ulma Lazkao Forging for forgings, dated November 2, 2016
- PO No. 233529 to Ulma Lazkao Forging for body forgings, dated November 9, 2016
- PO No. 230799 to Cowan Dynamics for O-rings, dated April 17, 2015
- PO No. 25391-10232 to Simutech Group for ANSYS software, dated March 27, 2017
- PO No. 190295 to B&G Manufacturing for studs, dated September 29, 2011
- PO No. 233934 to Trust Manufacturing for studs and hex nuts, dated February 3, 2017
- PO No. 233605 to Flowserve for actuators, Revision 1, dated December 21, 2016
- PO No. 233468 to Rotork for actuators, dated November 1, 2016
- PO No. P20000538 to Amsteel Castings for castings, Revision 2, dated April 20, 2017
- PO No. 233518 to Ampo S. Coop for castings, dated November 8, 2016
- PO No. 229945 to Magnum Forge & Machine Works for forgings, dated October 17, 2014
- PO No. 164399 to M.M. Forgings Limited for forgings, Revision 1, dated February 10, 2017
- PO No. 280044 to Groupe Mequaltch Inc. for nondestructive testing services, dated March 15, 2016
- PO No. 231304 to Kennametal for casting, Revision 2, dated October 5, 2016

- PO No. 230834 to Metaltek International for studs, dated April 27, 2015
- PO No. BP0000999 to Wall Colmonoy Inc. for brazing paste, dated February 24, 2017
- PO No. 233946 to Energy & Process for studs, dated February 6, 2017
- PO No. 2333346 to Dubose National Energy Services for bars, dated October 11, 2016
- PO No. BP0000963 to Ulrich Metrologie Inc. for calibration services, dated March 13, 2017
- PO No. BP0000903 to Primo Instruments for calibration services, dated March 14, 2017
- Customer PO No.12-894563-N from Limerick for several valves, Revision 5, dated September 14, 2016
- Customer PO No. 012-888151-N from Xcel Energy for a disc valve, dated May 3, 2016
- Approved Vendors List (AVL) - 1, "Current Status of Approved Suppliers of Materials and Services for Pressure Containing Parts for ASME Section III, Division 1 Valves, Revision 79, dated April 26, 2017
- AVL-2, "Current Status of Approved Suppliers of Calibration Services," Revision 45, dated December 1, 2016
- AVL-3, "Current Status of Approved Suppliers of Operators, Switches, and Solenoids for Safety Related Functions," Revision 51, dated June 20, 2016
- AVL-4, "Current Status of Approved Suppliers of Qualification Testing Services," Revision 6, dated May 28, 2015
- AVL-6, "Current Status of Approved Suppliers of Software," Revision 2, dated October 20, 2016
- Audit Report of Ampo S. Coop., dated May 2016
- Audit Report of Amsteel Castings (materials), dated December 7, 2016
- Audit Report of Amsteel Castings (non-destructive examination services), dated December 7, 2016
- Audit Reports of Cowan Dynamics, dated January 31, 2013 and March 2, 2016, respectively
- Audit Report of Exova Canada (Burlington), dated August 5, 2015

- Audit Report of Exova Canada (Quebec), dated May 26, 2016
- Audit Report of Exova Canada (Pointe-Claire), dated November 25, 2014
- Audit Report of Liard Industries, dated February 12, 2016
- Audit Report of Magnum Forge & Machine Works, dated December 9, 2016
- Audit Report of Mequaltech (laboratory), dated October 16, 2014
- Audit Report of Mequaltech (non-destructive examination services), dated October 16, 2014
- Audit Report of Metcor, dated August 14, 2015
- Audit Report of Mistras-Optimus, dated August 19, 2015
- Audit Report of PDK, dated October 17, 2014
- Audit Report of Primo Instrument, dated November 1, 2016
- Audit Report of ULMA Lazkao forging S.L, dated May 12, 2016
- Audit Report of Ulrich Metrology, dated May 13, 2014
- Audit Report of Wyman Gordon, dated September 25, 2015
- Internal Audit Report No. 16-04-P2, Purchasing and Receiving, dated December 1, 2016
- Internal Audit Report No. 16-02-P2, Preparation and Distribution of Quality documents, dated January 18, 2016
- Internal Audit Report No. 16-08-P2, control of Non-conforming material and Corrective Action, dated January 18, 2016
- Internal Audit Report No. 16-16-P2 Audit of the Audit Function dated February 20, 2017
- Internal Audit Report No. 16-09-P1 Welding Quality Control dated January 3, 2017
- Internal Audit Report No. 16-04-P1 Purchasing Receiving dated January 15, 2016
- Internal Audit Report No. 16-08-P1 control of Non-conforming material and Corrective Action dated January 26, 2016
- Nuclear Industry Assessment Committee (NIAC) Audit Report No. 20074 of ANSYS, Inc., dated May 29, 2015
- NIAC Audit Report No. 21017 of Limitorque, dated November 16, 2016

- NIAC Audit Report No. 21043 of Rotork Controls, dated September 15, 2016
- NIAC Commercial-Grade Survey No. 20122 of Utah Water Research Laboratory, dated May 21, 2015

10 CFR Part 21 Evaluations

- Evaluation No. P012-763780-N-EVAL, dated June 14, 2010
- Evaluation No. P014-878249-D-EVAL, dated July 5, 2010
- Limitorque Gear Switch, dated September 23, 2010
- Global Valve, dated June 2, 2011

Nonconformance Reports

- Deviation Report (DR) No. 2000017 dated May 1, 2017
- DR No. 2000125 dated January 20, 2017
- DR No. 2000125 dated January 20, 2017
- DR No. 2000120 dated February 2, 2017
- DR No. 2000091 dated February 17, 2017
- DR No. 2000089 dated February 10, 2017
- DR No. 1000115, dated March 3, 2017
- DR No. 84368 dated August 22, 2016

Corrective Action Reports

- CAR No. PQA 15-024 F-01 dated August 14, 2015
- CAR No. PQA 15-024 F-02 dated August 14, 2015
- CAR No. PQA 15-024 F-03 dated August 14, 2015
- CAR No. 16-QCI-1123-P4-1 dated April 11, 2016

Corrective Action Reports Opened During the NRC Inspection

- US-NRC-2017-01 dated May 10, 2017
- US-NRC-2017-02 dated May 9, 2017
- US-NRC-2017-03 dated May 9, 2017
- US-NRC-2017-4 dated May 10, 201
- US-NRC-2017-05 dated May 10, 2017
- US-NRC-2017-06 dated May 10, 2017

Training and Qualification Records

- Lead Auditor records for Victor Apostolescu, Cristina Minescu, Carl Correa, and Matthew Bellanger
- Hydrostatic Testing records for Alexandru Ciupe
- Nondestructive examination records for Sorin Simniceann (Level III), Daniel Fafard (Level II), Ruel Macarine, (Level II), R. Losioso (PMI Inspector)
- Registered Professional Engineers records for Yves Lauze, Madeleine Murphy, Paul Major, and Stanley Isbitsky
- Welder Performance Qualification records for D. Aounrasy, M. Bernier, A. Patel, R. Charrou, and H. Patel
- Brazing Operator Performance Qualification records for D. Aounrasy, A. Patel, M. Bernier, and D. Vachon

Miscellaneous

Memorandum from Carl Correa to Victor Apostolescu, "NRC Nonconformance 9990061/2007-201-03," dated February 18, 2008