



Velan Inc.

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October 16, 2017

U.S. Nuclear Regulatory Commission
Document Control Desk

Washington, D.C. 20555-0001

Attention: Document Control Desk
CC: Chief, Quality Assurance Vendor Inspection Branch-2, Division of Construction Inspection and Operational Programs, Office of New Reactors

Subject: **REPLY TO A NOTICE OF VIOLATION
REPLY TO A NOTICE OF NONCONFORMANCE
NRC Letter dated September 8, 2017 in response to Velan letter date June 29, 2017**

Reference: Violation 99900061/2017-201-01
Nonconformance 99900061/2017-201-02, 99900061/2017-201-03

General remark:

Velan controls all the activities involved in the design and manufacturing of our valve assemblies and can therefore ensure compliance with all technical and quality requirements conveyed in the nuclear facilities' purchase orders.

It is our intention to control safety-related items under Velan's Appendix B to 10 CFR Part 50 to ensure that the basic component meets the design requirements necessary for it to perform safety functions. Nevertheless, whenever possible, we will procure basic components from suppliers whose quality programs comply with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, as determined by on-site audits.

Velan is in compliance with the technical and quality requirements invoked on us by utilities; the actions described in the following pages will clarify and strengthen our program.

Please see below our revised responses to the subject issues.

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NRD



Violation 99900061/2017-201-01

Requirement: 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."

Finding: 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.

Response:

1) Reason for violation:

Assumption that transposing the requirements of the Regulation into a Velan contractual document is equivalent with specifying the actual Regulation by name.

2) Corrective Actions that are currently implemented:

The violation does not have a technical or quality impact on goods or services received from suppliers and does not affect Code compliance. No additional activities are necessary during receiving inspection; the reviews and verification of certification material and services from suppliers qualified based on NCA-3800 requirements are adequate to meet the Code (ASME Section III) requirements; the traceability requirements inherent to our purchasing documents allow Velan to fulfill our 10CFR Part 21 obligations in the event we are notified by the Supplier of conditions adverse to quality or when we become aware of such.

The Velan 10CFR50 App. B quality Manual, VEL-QC-155, is currently under revision to clarify the requirements for invoking 10CFR Part 21 on our suppliers, according to the type of control we deem necessary; in addition, the manual will be updated to provide adequate guidance on all options available to us for procurement of commercial grade or safety-related items that are subsequently incorporated into basic components for the nuclear industry, under the controls established in our program for design, assembly, test, etc. VEL-QCI-561 will be cancelled.

3) Additional Corrective Action that will be taken:

Personnel whose roles and functions are affected by the manual revision will be trained accordingly.

4) The date when full compliance will be achieved.

The revision is planned for completion on or before November 30, 2017. Personnel affected by the revision will be trained within three weeks from the distribution of the manual.



Nonconformance 99900061/2017-201-02

Requirement: 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."

Finding: 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.

Response:

1) Reason for nonconformance:

Refer to the NOV.

Additional clarification: Velan requires all suppliers of materials and services approved in accordance with NCA-3800 to perform the work in accordance with controls described in the Supplier's quality program approved by us and include a statement in their certification attesting to such; this comes from NCA-3862.2(b) and (c). The quality programs of these suppliers are adequate for the purpose, however, the goods or services are not safety-related since 10CFR Part 21 was invoked via a surrogate document, VEL-QCI-561.

2) Corrective Actions that are currently implemented:

The non-conformity does not have a technical or quality impact on goods or services received from suppliers; it does not affect Code compliance.

The Velan 10CFR50 App. B quality Manual, VEL-QC-155, is currently under revision to rectify the situation; in addition, the manual will be updated to provide adequate guidance on all options available to us for procurement of commercial grade or safety-related items that are subsequently incorporated into basic components for the nuclear industry, under the controls established in our program for design, assembly, test, etc.

VEL-QCI-561 will be cancelled.

3) Additional Corrective Action that will be taken:

Personnel whose roles and functions are affected by the manual revision will be trained accordingly.

4) The date when full compliance will be achieved.

The revision is planned for completion on or before November 30, 2017. Personnel affected by the revision will be trained within three weeks from the distribution of the manual.



Nonconformance 99900061/2017-201-03

Requirement:

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."

Finding: 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."
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.



Response:

1) Reason for nonconformance:

- 1) The NRC finding is somewhat incorrect; NCA-3842.2 refers strictly to Material Organizations and is not intended to cover approved suppliers (such as calibration, heat treatment, laboratory, or NDE services). Approved suppliers are addressed in NCA-3811(b) and NCA-4255.3(b); these allow the Certificate Holder to accept supplier's quality programs consistent with the scope of supply or have the supplier work to controls established by the Certificate Holder, as it is the case with NDE contractors for example. Controls established by Velan have been found adequate by ASME during their surveys. We do not view this as a non-conformity, but as an opportunity for improvement; consequently, we have instructed our Lead Auditors to ensure that audit checklist are completed to the extent necessary to support the audit recommendations.
- 2) Refer to the NOV.
Additional clarification: Velan requires all suppliers of materials approved in accordance with NX-2610 to perform the work in accordance with controls described in the Supplier's quality program approved by us and include a statement in their certification attesting to such. The quality programs of these suppliers are adequate for the purpose, however, the goods or services are not safety-related since 10CFR Part 21 was invoked via a surrogate document, VEL-QCI-561. Note that brazing material is allowed to be purchased by this method but not welding filler, and we do not use NX-2610 for the latter.
- 3) Audit reports do not contain adequate objective evidence to conclude that Velan has verified that the suppliers had passed down the applicable technical and regulatory requirements from the POs to their sub-suppliers; this is the result of the audit checklist not asking sufficient questions on this subject.

2) Corrective Actions that are currently implemented:

The non-conformity does not have a technical or quality impact on goods or services received from suppliers; it does not affect Code compliance.

- 1) We have instructed our Lead Auditors to ensure that audit checklist are completed to the extent necessary to support the audit recommendations.
- 2) Velan has implemented additional tests and examinations (check analysis and hardness tests) of at least one piece from each heat of material, starting May 12, 2017.
- 3) Audit checklists have been revised to add sufficient questions on this subject, as documented in the first response.

3) Additional Corrective Action that will be taken:

- 1) None
- 2) These materials will not be purchased as basic components; Velan shall exercise the controls in our App. B program to ensure that the material incorporated in a basic component will allow it to perform its safety-related function. Our quality program will be revised to reflect this position as well as the supplementary checks described above. Also, where possible, we will work with our traditional suppliers to upgrade their programs from NX-2610 to NCA-4200. The latter is a long term action and it will take more than a year to complete.
- 3) Document training in the auditors' files.

4) The date when full compliance will be achieved.

The revision is planned for completion on or before November 30, 2017. Personnel affected by the revision will be trained within three weeks from the distribution of the manual.



Extent of Condition:

Since 2006, 19048 parts (of which 1355 are ASME III, balance non-Code) and 4703 valves (of which 4258 are ASME III, balance non-Code) have been delivered to various utilities located in the United States under our 10CFR 50 App. B and ASME III programs.

The issues identified by the above NOV and NON do not affect the technical or quality requirements attached by the governing Code (ASME III or ASME B16.34 or earlier versions of same); instead the departures from 10CFR50 App. B and 10CFR Part 21 are essentially the result of invoking the reportability requirements of the latter via substitute documents.

As a minimum, Velan has implemented all the technical and quality requirements stemming from the governing Code and the design or technical specifications imposed in contractual documents.

In addition, Velan performs hundreds of chemical and mechanical checks and tests every year required during the course of our commercial business, on material received from the same suppliers, without any significant findings.

Finally, there are no OPEX records of valve nonconformities that can be attributed to nonconforming material with respect to chemical/mechanical properties.

Sincerely,

A handwritten signature in black ink, appearing to read "Victor Apostolescu".

Victor Apostolescu, Eng.
Vice-president, Quality Assurance