

September 8, 2017

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

SUBJECT: VELAN INC.'S RESPONSE TO THE U.S. NUCLEAR REGULATORY  
COMMISSION INSPECTION REPORT NO. 99900061/2017-201, NOTICE OF  
VIOLATION, AND NOTICE OF NONCONFORMANCE

Dear Mr. Apostolescu:

Thank you for your June 29, 2017 letter in response to the Notice of Violation (NOV) and Notice of Nonconformances (NONs) that were discussed in the subject U.S. Nuclear Regulatory Commission (NRC) inspection report (IR).

We have reviewed your letter and found that it is not fully responsive to NOV 99900061/2017-201-01 and to NONs 99900061/2017-201-02 and 99900061/2017-201-03. Specifically:

1. Your response to NOV 99900061/2017-201-01 failed to address several areas of concern to the NRC staff. Clarify your response as follows:
  - a. The response states that all materials received from suppliers (based on NCA-3800 or NX-2610) will be dedicated prior to assembly, and that these activities will be done in addition to any tests and examinations required by Section III of the ASME Code. The response also states that for Material Organizations who decline to implement "said regulations," (assuming the regulations being referred to are Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 and 10 CFR Part 21), then the NCA-3800 audit of the supplier will also serve as a commercial-grade survey with respect to critical characteristics. The NRC staff notes that Section III of the ASME Code does not include or allow a process for commercial-grade dedication of ASME Code pressure boundary material. The ASME Code includes a process for the utilization of unqualified source material in NCA 3855.5, but not for performing commercial-grade dedication of material as defined in 10 CFR Part 21. In addition, a commercial-grade survey is used to verify that a supplier of commercial-grade items controls, through quality activities, some or all of the critical characteristics of the designated commercial-grade items that were identified in the technical evaluation. An audit to verify the implementation of a supplier's NCA-3800 quality program cannot be used in lieu of performing a commercial-grade survey.

Clarify your response to indicate what type of actions Velan will perform to evaluate the *material* (including material that meets the requirements of NX-2610) *and services* that were procured from suppliers that did not have a 10 CFR Part 21 program. Your response should also address how Velan plans to address this issue for any future procurement of both *material and services*.

2. Your response to NONs 99900061/2017-201-02 and 99900061/2017-201-03 failed to address several areas of concern to the NRC staff. Clarify your response as follows:
  - a. The response states that quality surveys of suppliers whose quality systems do not implement Appendix B or Part 21 will also double as commercial-grade surveys. It is not clear what "quality surveys" is Velan referring to. As noted in question 1a above, commercial-grade surveys are used to verify that a supplier of commercial-grade items controls the critical characteristics that were identified in the technical evaluation.
  - b. The response states that audit reports not containing adequate objective evidence of the pass down of technical and regulatory requirements is because the audits checklist did not ask sufficient questions and that the audit checklist is under revision. The answer also refers to Attachment No. 4 which includes a sample of the additional questions. Clarify your response to explain whether Velan is (1) planning in adding these questions to all their audit checklists; (2) planning on training their lead auditors and auditors on the changes to the checklist, and more importantly, (3) retrain their lead auditors and auditors on how to complete the checklists to demonstrate that the audit criteria was adequately verified.
3. The responses to the NOV and the NONs did not address the extent of condition for items that had already been delivered. Your response should include an appropriate extent of condition for components that had been already been delivered to the U.S. nuclear power plants.
4. As discussed during a phone call on August 16, 2017, when responding to this letter, Velan should clarify whether it intends to buy basic components from suppliers with quality programs that meet the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, or whether it plans, as the organization with the design requirements and information, to control the basic components 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.

In accordance with 10 CFR 2.390 "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information 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, 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 is 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 will 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 safeguards information 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."

Please contact Mr. Yamir Diaz-Castillo at 301-415-2228, or via electronic mail at Yamir.Diaz-Castillo@nrc.gov, if you have any questions or need assistance regarding this matter.

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

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DATED: September 8, 2017

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