VELAN Inc.
2125 Ward Avenue, Montreal
Quebec, Canada H4M 1T6
Tel: (514) 748-7743 Fax: (514) 748-7641

February 19, 2008

U.S. Nuclear Regulatory Commission
Document Control Desk

Washington, D.C. 20555-0001

Attention: Document Control Desk
CC: Chief, Quality and Vendor Branch 1, Division of Construction Inspection and Operational Programs, Office of New Reactors

Subject: **REPLY TO A NOTICE OF VIOLATION**

Reference: Violation 99900061/2007-201-01

1) Reason for violation:

Instruction VEL-QCI-560, "Procedure for the Implementation of Regulations (U.S. NRC 10 CFR Part 21) for Reporting of Defects and Nonconformances" revision 3 dated September 8, 1997 does not provide clear guidance for interfacing with the processes governing the control of non-conforming material and corrective action.
The procedure relied heavily on the intimate knowledge of the quality system and experience of the Velan personnel dealing with the aforementioned processes, so much so that the references to some of these procedures have been inadvertently omitted. Nevertheless, the overall effectiveness of the Part 21 analysis and reporting processes was not affected.

2) Corrective Action / Results:

The instruction, VEL-QCI-560 was revised in order to incorporate suitable references to the procedures governing the control of non-conforming material and corrective action VEL-QCI-1316 and VEL-QCI-1317 respectively; to this effect sufficient detail has been provided in order to clarify the relationship among these system elements.

See below paragraphs 3.1. (a) to (c) from VEL-QCI-560 revision 4 dated February 11, 2008:

> 3.1 In House
>
> a) Internal nonconformities are documented on deviation reports in accordance with Velan procedures VEL-QCI-1316 and VEL-QCI-1317 and are reviewed by the Material Review Committee (MRC). Any such report issued for basic components shall be evaluated by the MRC whether or not the deviation could result in a substantial safety hazard.
> If material exhibiting these deviations has been shipped to a customer for use in a nuclear power plant in the U.S.A., it shall be reported to the Vice President, Quality Assurance or his delegate in writing on form 82-1-78 (Exhibit 2).

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b) Completed corrective actions shall be reviewed by the QA Manager in order to determine whether or not the root cause could create conditions resulting in a substantial safety hazard. If material exhibiting these deviations has been shipped to a customer for use in a nuclear power plant in the U.S.A., it shall be reported to the Vice President, Quality Assurance or his delegate in writing on form 82-1-78.

c) When deviations are discovered during internal audits which in the opinion of the the auditor could result in a substantial safety hazard, and materials which exhibit these deviations have been shipped to a customer for use in a Nuclear Power Plant in the U.S.A., it shall be reported to the Vice President, Quality Assurance or his delegate on form 82-1-78.

Paragraphs 3.2 and 3.3 have also been revised to reiterate that nonconformities identified by customers or suppliers are also to be documented on Velan deviation reports which will then follow the same path as described in 3.1(a) and 3.1(b).

The revision has no effect on the actual implementation of the instruction; it is our opinion that the procedure is now in compliance with the Regulation.

3) Corrective steps taken to avoid further violations:

The subject procedure was updated in accordance with the current version of the Part 21.
All other procedures interfacing with VEL-QCI-560, such as VEL-QCI-1316 and VEL-QCI-1317 for example, have been revised in a similar manner, closing the loop on this process.
All other elements of the instruction have been reviewed and found to be suitable and effective.

4) Date when full compliance will be achieved:

The document is currently in compliance.

We trust this meets with your acceptance. Should additional information be required please feel free to contact the undersigned.

Sincerely yours,

Velan Inc.

Victor Apostolescu, Eng.
Vice President Quality Assurance

cc: A.K. Velan, T.C. Velan, I.C. Velan, G. Perez, D. Bowers, B. Nilsson, Z. Palko, C. Correa