



Velan Inc.

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June 29, 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

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

Please see below our response to the aforementioned issues.

Violation 99900061/2017-201-01

1) Reason for violation:

Velan has not invoked 10CFR50 App. B and 10CFR Part 21 on Material Organization (defined in ASME III NCA-3800) established outside US as they do not understand these regulations and therefore do not accept the terms. Velan has reviewed, surveyed and accepted the quality programs implemented by these suppliers, and has invoked requirements for notifying Velan in case of deficiencies or defects identified after delivery.

2) Corrective Actions that are currently implemented:

Beginning with May 12, as instructed in the attachment (Attachment #1), all material received from suppliers qualified by Velan in accordance with ASME III requirements, whether based on NCA-3800 or NX-2610, are now dedicated prior to being assembled into a valve or delivered as a spare part; these activities are in addition to any tests and examinations required by ASME III. Please see enclosed Attachment # 2 for a sample evidence of implementation. This action will continue until the revision of the manual (described below in 3) is deployed and its requirements are gradually implemented. Therefore we consider all such material to be in full compliance with the Regulation as of May 12.

3) Additional Corrective Action that will be taken:

The Velan QA program for 10CFR50 App. B applications, VEL-QC-155, is being currently revised to address the situation. Deadline for revision: September 30, 2017.

Note that suppliers can always write their programs in compliance with and implement 10CFR50 App. B and 10CFR Part 21; this option already exists in the manual. The revision will identify only alternate options.

IED9
NRD



The aforementioned revision will cover the following elements:

- Material Organizations which implement NCA-3800 quality programs and are qualified by Velan to supply ASME III pressure boundary parts on the basis of an audit to NCA-3800:
 - o If the Organization declines to implement said regulations then the Velan audit of the Supplier's NCA-3800 program will also serve as a Commercial Grade Survey with respect to critical characteristics (activities as well as specific properties) that take place during material manufacturing such as marking, testing, certification, and traceability, based on the fact that the NCA-3800 covers these activities in ample details. Upon receipt of material Velan will complete the dedication activities by reviewing and accepting the material certification issued by the manufacturer. No specific material testing will be necessary for this purpose. This dedication will be performed in addition to any tests and examinations required by ASME III, and never in lieu of.
- Material Organizations which implement parts of NCA-3800, as permitted by the ASME III NX-2610 exclusions; two options will be provided, as follows:
 - o Velan will perform an on-site Commercial Grade Survey with respect to material manufacture, testing, certification, and traceability to such. Upon receipt of material Velan will complete the dedication activities by reviewing and accepting the material certification issued by the manufacturer. No specific material testing will be necessary for this purpose.
 - o If the Organization delivers material on infrequent basis, and no Commercial Grade Survey is performed then Velan will perform dedication of material on 100% basis. This dedication will be performed in addition to any tests and examinations required by ASME III, and never in lieu of.

When applied, Commercial Grade Surveys will implement the guidance provided in TR-3002002982.

4) Full compliance is already achieved, as provided in 2 above; the additional corrective actions in 3) describe programmatic actions that will strengthen the Velan App. B program and eventually reduce the amount of dedication work done as a result of (2) on the basis of suppliers implementing full blown App. B programs or programs or procedures in support of Method 2 of TR-3002002982.

Nonconformance 99900061/2017-201-02 and 99900061/2017-201-03

1) Reason for nonconformance:

- A) Velan has not invoked 10CFR50 App. B and 10CFR Part 21 on local (Canadian) or international material and service suppliers as they do not understand these regulations and therefore do not accept the terms. Velan has reviewed, surveyed and accepted the quality programs implemented by these suppliers, and has invoked requirements for notifying Velan in case of deficiencies or defects identified after delivery; in this category there are suppliers of heat treatment, calibration, NDE and laboratory services.
- B1) Velan has not invoked or verified all the quality assurance requirements on suppliers of services (heat treatment, calibration, NDE and laboratory) in a manner consistent with NCA-3800. We feel the NRC assessment is rather subjective on this issue. NCA-3800 does not require suppliers of services to have full blown NCA-3800 programs. NCA-3811 and NCA-3855.3(b)(1) and NCA-3855.3(b)(2) essentially allow the Certificate Holder to accept supplier's quality programs that implement requirements that are consistent with those contained in NCA-3800 or have the supplier work to controls established by the Certificate Holder, as it is the case with NDE contractors for example.



- B2) Velan has not invoked 10CFR50 App. B and 10CFR Part 21 on Material Organization (defined in ASME III NCA-3800) established outside US and approved by Velan approved on the basis of NX-2610 as they do not understand these regulations and therefore do not accept the terms. Velan has reviewed, surveyed and accepted the quality programs implemented by these suppliers, and has invoked requirements for notifying Velan in case of deficiencies or defects identified after delivery. Velan performs additional tests and examinations (check analysis and hardness tests) however, because the manufacturers are not in full compliance with App. B, Velan comes short in meeting its obligation as "dedicating entity" considering the reduced sampling rate implemented during the aforementioned tests and examinations.
- B3) 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:

- A) Quality surveys of suppliers whose quality systems do not implement the applicable criteria of App. B or Part 21 will also double as Commercial Grade Surveys. See Attachment #3 for a sample Commercial Grade Survey evaluation form for NDE. Deadline: September 30, 2017.
- B1) We believe that for the most part the quality programs implemented by our service suppliers and accepted by us answer the intent of NCA-3800. Suppliers of NDE services work to controls imposed by us, as permitted by NCA-3855.3(b)(2). We are, nevertheless, in the process of performing a gap analysis the result of which (i.e. necessary system or procedure upgrades) will be documented and communicated to suppliers. Deadline: September 30, 2017.
- B2) The immediate and additional corrective action are covered in the response to NOV.
- B3) Audit checklist are under revision; most will be completed before September 30, 2017, the balance will be completed on as-needed basis. See Attachment #4 for a sample revision to introduce additional questions.

3) Additional Corrective Action that will be taken:

- A) As stated in the response to the NOV, we are in the process of revising the program; it is expected that most of these suppliers will decline implementing the Regulation, therefore, the program will strengthen the application of commercial grade surveys coupled with dedication of the service upon receipt at Velan. Deadline September 30, 2017.
- B1) Same as in 2.B1 above.
- B2) The immediate and additional corrective action are covered in the response to NOV.
- B3) Same as in 2.B3 above.

4) Full compliance for these two NONs will be achieved progressively by September 30, 2017.

We recognize the fact that these deficiencies point to an incomplete implementation of the App. B and Part 21 requirements with respect to the control of non-US suppliers of material and services.

Except for the aforementioned issues, Velan has implemented adequate technical and quality controls over its suppliers, and at no time was material of nonconforming material grade or heat treat condition shipped to customers. There are no OPEX records of valve nonconformities related to these issues.

Sincerely,

Victor Apostolescu, Eng.
Vice-president, Quality Assurance

Victor Apostolescu, Eng.

From: Victor Apostolescu, Eng.
Sent: May-12-17 7:27 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: Pressure boundary parts for ASME Valves - Supplemental dedication

This instruction is effective immediately; the manuals and procedures will be updated accordingly in the upcoming weeks and months. Until such time you are to follow the steps indicated below.

It applies to all pressure retaining parts for ASME III valves, N or K, for US customers, irrespective of the Supplier's method of approval (NCA-3800 audit, or QSC, or NX-2610).

1. Work on the floor (shop orders already issued)
 - a. For part shop order, add by hand at the final inspection stage PMI and hardness per QCI-1123
 - b. If the part shop orders are closed and the parts are already in assembly, then add the PMI and hardness requirements at the release stage of the NARS
 - c. If the valve is already assembled, do PMI and hardness on the accessible parts; for those parts that are not accessible do PMI and hardness on an equal number of parts from stock of the same heat
2. Work in planning, shop orders not released yet, discuss with and instruct planners to place the PMI and hardness at the release to production stage.

Note that this PMI and hardness applies in addition to all testing and examination required by ASME III and never in lieu of or as an alternative to material upgrade via NCA-3855.5.

You are to document this memo in your training files as well as the files of any staff (planner for example) or inspector you will so train.

All lead auditors and auditors shall also record this instruction in their files and verify implementation during fabrication and 1123 audits.

Please let me know if you have any questions or need any clarifications.

DIMENSIONAL, HARDNESS, VISUAL & PMI VERIFICATION RECORD

CUSTOMER: AREVA
 ORDER NO.: SO0004442
 ITEM NO.: 20
 QUANTITY: 12
 PROJ. ENG. DWG.: P1-76800-N03 rev. K
 M.O. #: A10002754

VEL-QCI-1123 Rev. 19
 VEL-QCI-1713 Rev. 9
 VEL-QC-155 Rev. 24
 VEL-QCI-884 Rev. 15
 VEL-QC-730 Rev.
 VEL-QC-742 Rev.
 VEL-QC-743 Rev.
 PMI UNIT ASSET NOS.: G21-13492
 HARDNESS TESTER ASSET NOS.: G17-10101, G17-4114

PART DESCRIPTION and HEAT/TREAT CODE	MATERIAL SPEC/GRADE	DRAWING NO. & REV.	GAUGE ASSET NO.		DIMENSIONAL INSPECTION INSPECTOR/DATE	HARDNESS RC/HB INSPECTOR/DATE	PMI INSPECTOR/DATE	VISUAL INSPECTION INSPECTOR/DATE
Body	SA10S A10SN	3513-163/V	G22-13181 G04-11103 G03-0072-B G03-7198	G22-11212 G21-9075 G03-8092	See S/o: 107788 VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 78-80 RB	VEL INSP. 81 JUN 12 2017	See S/o: 107788 VEL INSP. 81 JUN 12 2017
Bonnet	SA10S A10SN	3524-157/B	G22-10481 G13-7964 G4-9133 G11-10666	G22-11936 G22-12973 G3-8428	See S/o: 107789 VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 78-82 RB	VEL INSP. 81 JUN 12 2017	See S/o: 107789 VEL INSP. 81 JUN 12 2017
Body-bonnet studs	SAR3 B7	VEL-OPI-001/17	G22-13714 G05-8519		VEL INSP. 81 JUN 12 2017	N/A	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017
Body-bonnet nuts	SAR4 2H	VEL-OPI-001/17	G22-13714 G04-11103		VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 30 RC	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017
Disc & hardfacing (if applicable)	SA479 816 HF:ALLOY 40	3542-061/B	G22-13181 G22-12973 G17-0877		See S/o: 107719 VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 36 RB Disc	VEL INSP. 81 JUN 12 2017	See S/o: 107719 VEL INSP. 81 JUN 12 2017
Stem	A276 316B	3534-074/H	G22-13714 G05-8547 G21-6757 G21-7170	G22-12640 G11-7713 G05-8518 G21-2393	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 30-32 RC	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017
Seat	SFAS.21 N09644	1593-034/D	G22-13181 G17-0877		See S/o: 206456 VEL INSP. 81 JUN 12 2017	See S/o: 206456 VEL INSP. 81 JUN 12 2017 50-52 RC	See S/o: 206456 VEL INSP. 81 JUN 12 2017	See S/o: 206456 VEL INSP. 81 JUN 12 2017



DIMENSIONAL, HARDNESS, VISUAL & PMI VERIFICATION RECORD

CUSTOMER: AREVA
ORDER NO.: SO0004442
ITEM NO.: 20
QUANTITY: 12
PROJ. ENG. DWG.: P1-76800-N03 rev. K
M.O. #: A10002754

VEL-QCI-1123 Rev. 19
VEL-QCI-1713 Rev. 9
VEL-QC-155 Rev. 24
VEL-QCI-884 Rev. 15
PMI UNIT ASSET NOS.: G21-13492
HARDNESS TESTER ASSET NOS.: G17-10101, G17-4114

PART DESCRIPTION and HEAT/TRACE CODE	MATERIAL SPEC/GRADE	DRAWING NO. & REV.	GAUGE ASSET NO.	DIMENSIONAL INSPECTION INSPECTOR/DATE	HARDNESS RC/HB INSPECTOR/DATE	PMI INSPECTOR/DATE	VISUAL INSPECTION INSPECTOR/DATE
Packing flange	CS A105	2534-010/A	G22-13714	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 80-85 RB	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017
Gland studs	A193 B8M2	VEL-OPI-001/17	G22-13714 G05-9400	VEL INSP. 81 JUN 12 2017	N/A	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017
Gland nuts	A193 8m	VEL-OPI-001/17	G22-13714 G04-9211	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 25 RC	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017
Belleville bushing	A532 416	3606-113/D	G22-13714 G04-9211	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 15 RC	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017
Yoke Bushing	A532 416	3613-000/H	G22-13714 G04-7914 G05-7481	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017 15 RC	VEL INSP. 81 JUN 12 2017	VEL INSP. 81 JUN 12 2017

VALVE WEIGHT : _____ Complete form in EI-110



COMMERCIAL SERVICE SUPPLIER - VENDOR DEDICATION CHECKLIST

VENDOR NAME & ADDRESS:

TYPES OF SERVICE PROVIDED :

NOTE: THIS CHECKLIST DOCUMENTS CRITICAL CHARACTERISTICS VERIFIED DURING THE COMMERCIAL GRADE SURVEY AND ADDITIONAL CHECKS PERFORMED WHEN SERVICES ARE PROVIDED

1.0 TECHNICAL AND QUALITY REQUIREMENTS

NOTE: Verification that the purchase order conveys the appropriate technical and quality requirements will provide reasonable assurance that the purchase order meets the Customer's order and specification. The Velan purchase order to contractor is reviewed by the QA Manager.

REQUIREMENT	COMPLIANCE		EVIDENCE EXAMINED/REMARKS
	YES	NO	
a. Does the Velan purchase order incorporate appropriate technical requirements?	()	()	
b. Is the work performed in accordance with Velan NDE procedure?	()	()	
c. Was the Suppliers NDE written practice as reviewed and approved by Velan NDE Level III against SNT-TC-1A (2011 Ed) and NB-5520?	()	()	
d. Does the Velan purchase order invoke the appropriate quality assurance requirements, such as:			
1. Revision and date of Vendor's QA Manual approved by Velan	()	()	
2. Appropriate standards	()	()	
3. Certification requirements	()	()	
4. The Velan procedure applicable to work	()	()	
5. Hold/witness points	()	()	



COMMERCIAL SERVICE SUPPLIER - VENDOR DEDICATION CHECKLIST

2.0 VALIDATION AND VERIFICATION OF TEST RESULTS

NOTE: Verification that the Test Report and RT film meets the purchase order and procedure will provide reasonable assurance that the service meets the Customer's order and specification.

REQUIREMENT	COMPLIANCE		EVIDENCE EXAMINED/REMARKS
	YES	NO	
a. Have all RT Film and Reports been reviewed and approved by Velan NDE Level III for compliance and reporting of the following? 1) Source to film distance; 2) Source size; Isotope used or X-Ray equipment, manufacturer, including strength (Ci or KV); 3) Number of films per cassette; 4) Material and thickness range of material; 5) Screens used and thickness; 6) Description of object including identification; 7) IQI (block and shims used); 8) Time and number of exposures; 9) Shooting sketch; 10) Single or double wall exposure; 11) Single or double wall viewing; 12) Distance between film and object when film /cassette is not in contact with object; 13) Orientation of location markers; 14) Blocking or masking technique, if used; 15) Identification and evaluation of indications.	()	()	
b. Has a qualified sub-contractor NDE Inspector performed the examination and certification?	()	()	
c. Has the Supplier performed the test in compliance with a Velan procedure?	()	()	

Based on the results of this verification and the commercial grade survey on file this vendor is dedicated; the service provided by them meets the requirements of 10CFR50 App. B and 10CFR Part 21.

By:

Name/Signature

Title

Date



VENDOR SURVEY CHECKLIST CALIBRATION SERVICES

CALIBRATION PROGRAM:

	YES	NO	N/A	<u>REMARKS</u>
1. Are reference standards calibrated to a higher level of accuracy than the level being certified by the vendor?	()	()	()	
2. Do the contractor's procedures provide control for supporting records to show that established schedules and procedures are applied to maintain the accuracy of measurement standards?	()	()	()	
3. Does the Vendor have an adequate written system for the retention of calibration certificates or reports (until recalibrated)?	()	()	()	
4. Do documents for procurement of materials or services include requirements to assure compliance with:				
a) Velan Purchase Order?	()	()	()	
b) Technical Requirements?	()	()	()	
c) Quality and Regulatory Requirements?	()	()	()	

NOTES: