

US Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555-0001

Date: February 12, 2016

SUBJECT: Reply to Notice of Nonconformance, resulting from Inspection report of Nova Machine Products No. 99901052/2015-201

U.S. Nuclear Regulatory Commission (NRC) inspection conducted at Nova Machine Products (Nova), November 30th through December 4th, 2015

The following provides the milestones and status associated with the Notice of Non-conformances stated in the report by the Nuclear Regulatory Commission noted above:

REPLY TO A NOTICE OF NONCONFORMANCE 99901052/2015-201-02

• REASON FOR NONCOMPLIANCE

At the time the accumulators were reverse engineered, it was Nova's understanding that implementing the Industry published guideline (EPRI TR-107372) would qualify the accumulators based on the construction of the item being in accordance with a published industry construction code and the Guideline. Criterion III "Design Control" was relegated as limited applicability since this is not considered a new "design" but rather a reverse engineered equivalent (duplicate or like-for-like) item. (Based on the Regulatory evaluation, the Nova procedure did not document the critical design and functional requirements resulting in an inadequate design verification during the RE process)

• CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED

- The corrective action associated with this verification testing has been entered into the Nova Corrective Action system as CAR # 279.
- Nova Machine has solicited additional information on design parameters that could be critical to the performance of the accumulators

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and has initiated Design Verification testing to be performed on the Reversed-Engineered HCU accumulators to assure that design input/output requirements have been met. This is being accomplished through a combination of an analysis, and qualification testing to demonstrate and establish design performance against design input requirements. Completion is targeted for April 30th, 2016.

- The accumulators have been shipped to various sites since 2005 and to date there has been no record of failure associated with the accumulators not performing their intended safety functions (i.e. SCRAM).
 - Nova is in the process of reviewing past safety related reversed engineered product over the past 10 years dating back to 2005. Thus far, the other Reverse-engineered products reviewed were single piece parts and not of the same classification as the HCU accumulator.
 - Review and revise as appropriate the Reverse Engineering Work Instruction (Nova W.I. 7.1.1 **Reverse Engineering**); specifically addressing adequate design control measures and adequate technical evaluations which identify and verify the *critical design attributes* associated with failure modes necessary to provide reasonable assurance that reverse engineered product could perform their intended safety function
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- CORRECTIVE STEPS THAT WILL BE TAKEN
 - No additional steps beyond those described above are anticipated
 - DATE FULL COMPLIANCE WILL BE ACHIEVED
 - Revision of our RE Procedure and subsequent training for affected individuals complete by April 30, 2016
 - Review of past Reverse Engineered products complete by March 31, 2016.
 - Engineering Analysis and Qualification testing of Nova accumulators complete by April 30, 2016

REPLY TO A NOTICE OF NONCONFORMANCE 99901052/2015-201-03

- **REASON FOR NONCOMPLIANCE**

Nova has always conducted Commercial Grade Surveys (Method 2) of its outside service suppliers. The critical characteristics chosen are critical to the control of Nova product that is being sent to and controlled at the supplier location. The critical characteristics included Material Control, Non-conforming Material Control, Test Control, Qualification of Personnel, etc.

In addition to Method 2, Nova was also performing a complete review and approval of the associated supplier certification, along with the Nova receiving inspection consisting of dimensional inspection and 100% visual inspection (as part of Method 1).

The actual surveys conducted at the supplier location do in fact include assessment of the above stated characteristics. The surveys conducted also included other quantifiable characteristics which may not have been clearly outlined in the Commercial Grade Dedication itself.

This method was thought to be acceptable based upon information from EPRI 3002002982 and as reviewed in prior audits of Nova Machine.

- **CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED**

- The corrective action associated with this nonconformance has been entered into the Nova Corrective Action system as CAR # 283.
- Method 2- In addition to the Critical characteristics currently identified (Material Control, Non-conforming Material Control, Test Control, Qualification of Personnel, etc.) for outside services such as plating and heat treat, Commercial Grade Dedication Plans will now include additional quantifiable characteristics as part of the Technical Evaluation process.

For example, the survey conducted of MT Heat Treat in 2015, included very specific review and assessment of quantifiable processes such as Age Hardening Temperature capabilities, Hardness range capabilities, etc. The Technical Evaluation, however, did not identify these. The Technical Evaluation will now capture this type of characteristic *before* the Survey is conducted so that the process will be closed loop.

- Method 1 - Dedication plans will now be focused on quantifiable critical characteristics (in addition to dimensional inspection and 100% visual inspection already in place) for these outside services (heat treat, plating) to supplement the Method 2 (Commercial Grade Surveys).

These quantifiable characteristics are defined by Engineering, consensus standards, and/or Work Instructions.

For Example, the hard chrome plating process will now have a Method 1 dedication plan created to measure quantifiable critical characteristics such as *Plating Type (Purity if applicable), Thickness, and Adhesion*. Nova will perform testing on these critical characteristics at in-coming inspection.

New Dedication plans CGD 2016-004 and CGD 2016-005 have been created in support of Method 1 enhanced process.

As pertains to product that has already been plated and accepted and in Nova inventory, Nova will perform supplementary Method I dedication, as described above, for the specific customer order at the time of sourcing.

- CORRECTIVE STEPS THAT WILL BE TAKEN
Finalize training in the use of the revised Method I dedication process.
- DATE FULL COMPLIANCE WILL BE ACHIEVED
March 31, 2016

REPLY TO A NOTICE OF NONCONFORMANCE 99901052/2015-201-04

- REASON FOR NONCOMPLIANCE
In 2015, Nova inadvertently permitted an individual to perform auditing activities in an area where the individual had responsibility; even though that individual was extremely careful not to evaluate any documents processed by him, the appearance of a lack of independence has been challenged.

Nova has always been diligent in this area to assure independency. Independence is always recognized as critical when performing audits. Nova has typically alternated external auditors year over year to guarantee this independence (not having the same auditor 2 years in a row) and Nova QA personnel are normally not involved as team members.

- CORRECTIVE ACTIONS TAKEN AND RESULTS ACHIEVED

- The corrective action associated with this nonconformance has been entered into the Nova Corrective Action system as CAR # 280.
- Nova has engaged in a re-audit (qualified external auditor) of the areas audited by the QA Manager in 2015. This would be re-audits of Sections 1C, 3.4, and 10.3 of the Nova Audit checklist. This re-audit was performed during the week of February 8th, 2016 by a qualified external Lead Auditor and independent of the areas audited.
- Reviewed internal audits from 2012, 2013, 2014. No other internal audits were found where a qualified auditor audited an area where they had direct responsibility. The audits in 2012 through 2014 were conducted by alternating Qualified Lead auditors (not performed by the same auditor 2 years in a row).
- Future audits will be performed by qualified auditors who are independent of the areas audited.

- CORRECTIVE STEPS THAT WILL BE TAKEN

No additional steps required.

- DATE FULL COMPLIANCE WILL BE ACHIEVED

With this letter dated February 12, 2016

If there are any questions regarding this communication, please contact Tad Gray, General Manager at 216-898-8374 or Frank Furfari, Quality Assurance Manager at 216-898-8394.

Sincerely,



Tad Gray
General Manager – Nova & AP Services