

April 7, 2008

United States Nuclear Regulatory Commission
Washington, DC 20555

Attn: Document Control Desk

Subject: Reply to a Notice of Violation

Reference: U.S. Nuclear Regulatory Commission (NRC) Inspection Report No. 72-1015/2007-201 and
Notice of Violation

In response to the referenced report, we hereby provide our response to the Notice of Violation (NOV) included therein. The inspection report was received by us on March 5, 2008 and addressed the inspection conducted from October 29 to November 2, 2007 and January 14 to 17, 2008 at the GE-Hitachi (GEH) Custom Fabrication facility in Canonsburg, PA. Attached to this letter please find our reply (Enclosure 1), that addresses each of the requested attributes related to the two identified violations described in the NOV resultant from that inspection. As discussed in the report we understand that the NRC has placed the GEH facility on an increased inspection frequency and will conduct an additional inspection there after GEH has effected the prescribed QA program improvements. Therefore, we have included no objective evidence to substantiate completed actions and will instead have appropriate documentation compiled and available for review at such time as the inspection team chooses to return.

In addition to the specific issues identified in the NOV, the accompanying inspection report also identified several other QA programmatic areas where enhancement is appropriate. Identified areas included inadequate procedure development and implementation and the observance of typographical errors in records. Although a reply for those areas was not requested, GEH and NAC have reviewed the inspection report to identify each of these areas and are implementing appropriate QA program enhancement actions to address them. Accordingly, in addition to the NOV related response, we are also identifying activities being implemented or planned to improve the overall effectiveness of the QA program at GEH. Enclosure 2 describes those activities.

After review of our submittal, should there be any remaining question or concern, please feel free to contact me at (678) 328-1311 or Howard Smith at (678) 328-1276 and we will be happy to address such issue(s) to your satisfaction.

Sincerely,



Kent S. Cole
President

cc: David W. Pastrak
Chief, Rules, Inspections and Operations Branch,
Division of Spent Fuel Storage and Transportation,
Office of Nuclear Material Safety and Safeguards

ENCLOSURES: 1) Reply to NRC Notice of Violation
2) GE-Hitachi (Custom Fabrication) QA Program Enhancement Activities

QA20080026

ENCLOSURE 1

Reply to NRC Notice of Violation

ENCLOSURE 1
Reply to NRC Notice of Violation

Violation

- A. 10 CFR 72.150, "Instructions, procedures and drawings," states, in part, that the certificate holder shall prescribe activities affecting quality by documented procedures and shall require that these procedures be followed.

Contrary to the above, the following instances were identified by the NRC where activities affecting quality were not prescribed in documented procedures, or where procedures for activities affecting quality were not followed:

- 1) GEH Commercial Nuclear Quality Assurance Manual, Section 7.0, Revision 9, "Control of Purchased Material, Items, and Services," step 7.4.C.1, states, in part, that auditing services may be performed by approved third party auditing organizations provided the auditing organization has been audited and approved by GEH and is identified on the GEH Approved Suppliers List (ASL) as an auditing organization. The NRC identified that NIAC, a third party auditor, was not listed on GEH's ASL as an approved auditing organization.
- 2) The NRC identified that Quality Assurance Procedure 960, Revision 5, did not provide proper procedural controls to maintain the computer data base welder continuity program. Specifically, the procedure did not adequately prescribe how to input data and maintain procedural control of the new computer data base welder continuity program.
- 3) The NRC identified that the GEH process used to "upgrade" material under American Society of Mechanical Engineers (ASME) guidelines was not prescribed in an approved Quality Assurance Procedure.

- B. 10 CFR 72.158, "Control of special processes," states, in part, that the certificate holder shall establish measures to ensure that special processes, including welding, are accomplished by qualified personnel.

Contrary to the above, the NRC identified that a welder was shown as qualified to perform two separate welding processes, yet his qualification to do so had actually lapsed.

Reason for Violation:

The reasons for each of the above components of this NOV differ:

- A1) Recognizing that Nuclear Industry Assessment Committee (NIAC) is not a company and that GEH does not issue quality-related purchase orders to NIAC, GEH personnel failed to appreciate the specific wording in the cited paragraph of their QA Manual that is being interpreted to apply to NIAC. GEH believed that since any audits received from NIAC members were reviewed in accordance with GEH procedure QAP-1820, *Procedure for*

ENCLOSURE 1
Reply to NRC Notice of Violation

Evaluation of Third Party Audit Reports before acceptance, they were compliant with the applicable provisions of their QA Program.

- A2) GEH was in the process of upgrading their welding tracking system by implementing a computer based program for tracking welding consumable material issuance and welder qualifications. However, as the program upgrade had not yet been fully implemented, shop supervisors were required to manually record issuance of consumable material for subsequent manual entry into the database. As noted by the NOV, this combination of actions was not adequately described in the applicable procedure or completely successful in controlling the process.
- A3) While it is accurate to note that a GEH procedure had not been developed for controlling "upgrading" of material, the controls described in the GEH QA Manual (Section 8.5) for this process were considered by GEH to be adequately detailed for performance of the activities. GEH personnel incorrectly assumed that a separate implementation procedure was not required so long as they adhered to the sufficiently detailed direction in the QA Manual.
- B. The combination of control mechanisms described in the Reason A2 above, were cumbersome for the Welding Engineer to accurately maintain and prone to human error. Even though the Welding Engineer was conscientious in implementing the prescribed controls, the unwieldy manual system significantly contributed to cause his errors that resulted in this nonconforming condition.

Corrective Steps Taken and Results Achieved:

- A1) 1. QAP-1820, *Procedure for Evaluation of Third Party Audit Reports* was revised to clearly identify that NIAC is considered to be a third party provider of audit services.
2. Following the direction of the newly revised QAP-1820, an evaluation was conducted by GEH to accept the audit of NIAC that had been performed by another NIAC member (Precision Custom Components) during the most recent NIAC annual meeting. Member attendance at annual NIAC meetings is mandatory so that these audits of the members by other members can be accomplished.
3. A supplier evaluation was performed and documented in accordance with GEH QA-700, *Supplier Qualification and Oversight* as prerequisite for adding NIAC to the GEH Approved Supplier Listing (ASL).
4. NIAC was added to the GEH ASL.
5. The actions above are documented in accordance with GEH Request for Corrective Action (RCA) 2007-053.
- A2) 1. QAP-960, *Welding Process Control* was critiqued and revised to account for and provide adequate direction for the use of both manual and computerized database tracking of welder continuity.
2. GEH developed RCA 2007-055 to document the cause and resolution of this issue. Additionally, the computer database was critiqued and restored by correcting all noted errors (including typographical errors).

ENCLOSURE 1
Reply to NRC Notice of Violation

3. Responsible personnel were trained to the requirements of the revised QAP.
- A3) 1. GEH has developed Corrective Action Report (CAR) 44853 to control the resolution of this issue. The reply to that CAR, received April 3rd, includes actions to develop an adequately detailed implementing procedure (QAP) and training of appropriate personnel on: 1) the appropriate level of proceduralization that is required to implement the QA Manual requirements, and 2) the requirements of the newly issued QAP for material upgrading.
- B. 1. Developed RCA 2007-055 to control the assessment, documentation and resolution of this issue.
2. Performed an extent of condition assessment to ascertain whether any other welders were similarly affected. Three years of welder qualification data were reviewed. There were two other welders (one was a fitter) with a lapse in qualification. In the first instance, fitter #856 performed tack welds on projects that were not NAC related and which were consumed by the production welds; therefore posing no potential impact to the product. There were no other welding applications to deliverable product by this individual so there is no impact to product quality.

In the second instance (for welder #630), he welded on several projects (only one of which was NAC related) during the interval when his qualifications for that particular welding process (SAW) had lapsed. Upon discovery, GEH developed Nonconformance Report (NCR) 2008-502 that documented his continued involvement in other welding processes during the interval when his SAW qualification was not current. GEH NCR 2008-502 was submitted to NAC (who, in turn, submitted it to their customer, Arizona Public Service) for review and approval. The 'use-as-is' nonconformance report was subsequently approved by all concerned parties.

Shortly after discovery, both of these individuals were subjected to weld requalification testing in the appropriate method and both passed the qualification on their initial efforts. Coupled with their continued performance of welding with other processes, the successful completion of requalification tests establishes the proficiency of both welders to produce acceptable welds during their period of lapsed qualification. RCA 2007-055 documents this conclusion along with the conclusion basis.

Corrective Steps Taken to Avoid Further Violations:

To specifically address the issue identified on the NOV:

- A1) GEH has decided to not continue their participation in NIAC, effective January, 2008. GEH has conducted a thorough review of their Approved Supplier Listing as part of their corrective actions associated with CAR 44282 (inadequate supplier control) and determined that the NIAC situation was unique. There are no other currently approved third party providers of auditing services who are not listed on the ASL.

ENCLOSURE 1
Reply to NRC Notice of Violation

Additionally, among the preventative actions identified in the foregoing CAR, GEH has revised applicable implementation procedures to clarify their requirements (*Procurement Document Control*, QAP-400 and *Supplier Qualification and Oversight*, QAP-700), conducted additional training of the applicable personnel and committed to the use of a Purchase Order review checklist by QA personnel. The completed checklists provide a record that confirms the scope to be procured is consistent with the supplier's listing on the ASL.

Finally, for an indefinite period, GEH has implemented a monthly management check to confirm that GEH procurement activities are consistent with the applicable programmatic commitments.

- A2) In addition to the procedural enhancement and personnel training discussed under the **Corrective Steps Taken and Results Achieved** section, GEH has implemented periodic evaluations of the welder database to confirm accuracy and completeness of database information and reports resultant from its use. These evaluations are in addition to formal audits of the process and will continue until routine compliance is achieved and maintained. Further, GEH expanded training of responsible personnel beyond QAP-960 (see **Corrective Steps Taken and Results Achieved**, Action A2) to also include QAP-510, *Development and Revision of QAPs*, and QAP-540, *Work Instructions*, emphasizing the need to include sufficient information in procedures and instructions to assure that the task(s) to be completed can be performed in a consistent manner.
- A3) Resolution of GEH CAR 44853 will result in proceduralization of the process that is described in the GEH QA Manual and routinely employed to upgrade any material. All controls described in the GEH QA program (QA Manual and QA Procedures) are subjected to comprehensive internal audits to assure continued compliance.
- B. GEH has evaluated the process described in their QAP for database development and use (QAP-960, *Welding Process Control*) and has modified (revised) it to result in an enhanced process that describes both the manual and computer based systems. The procedural enhancements included the method to track weld wire issuance and welder qualifications as well as the generation of accurate reports. Subsequent to revision and controlled distribution of this QAP, training sessions were conducted with the applicable personnel to assure that a common understanding exists among those persons who are charged with implementing and monitoring the process. As an additional measure of assurance, the automated GEH Compliance Calendar has been employed to result in a documented quarterly review of the weld continuity database for accuracy and content.

Date to Achieve Full Compliance:

With the exception of the actions described in **Corrective Steps Taken and Results Achieved**, item A3), each of the corrective and preventative actions discussed in the foregoing have been completed. When the specified actions are ongoing, such as periodic checks and reviews,

ENCLOSURE 1
Reply to NRC Notice of Violation

completion of the first check/review is considered to be complete, recognizing that additional future checks/reviews will occur.

Regarding the A3) actions, each of the specified corrective/preventive actions (QAP development and issuance as well as training of the applicable personnel) should be complete by **June 30, 2008**.

ENCLOSURE 2

GE-Hitachi (Custom Fabrication) QA Program Enhancement Activities

ENCLOSURE 2

GE-Hitachi (Custom Fabrication) QA Program Enhancement Activities

In addition to addressing the specific NOV described issues, there were several comments dispersed throughout the NRC Inspection Report indicating QA programmatic weakness in those areas. Although a reply was not requested for those comments, the NAC and GEH team concur that additional QA programmatic enhancement is warranted and have specified several initiatives and actions to accomplish that enhancement.

These are ongoing tasks that were mostly initiated after the initial NAC surveillance of GEH in April, 2007 as a precursor to release of GEH to resume fabrication on NAC related spent fuel systems. Recognizing that these actions address QA programmatic enhancement areas versus resolution of any specifically identified deficiencies, complete implementation and assessment is spread over a longer period than the NOV related issues. However, when completed, these activities will provide enhanced methods for GEH and NAC to monitor achievement of a level of quality consistent with NAC's, our customers and the NCR's expectations. Full implementation and confirmation by NAC/GEH (including completion of an effectiveness assessment by NAC) is anticipated to be achieved by **September 30, 2008**. Accordingly, we are pleased to provide the following listing of programmatic enhancement activities:

Corrective Action and Commitment Tracking

- GEH has extensively revised the Quality Assurance Procedure (QAP) that governs their corrective action program (QAP-1600). This procedure revision includes detailed guidance for use of the Commitment Tracking System (CTS), a system for capturing and responding to conditions adverse to quality as well as process-enhancement actions. The procedure and system requires entry of trend codes, effects and extent of condition, and improves timely completion performance through e-mail notification and reporting. Corrective Action Requests (CARs) are now prioritized depending on severity (A1-A3 for conditions adverse to quality, and B for process enhancements) and all CARs require initiator approval of both responses and closure after completion of action items. Guidance on completion of the extent of condition has also been added to the procedure. The new system provides significantly improved management visibility of any overdue commitments such as CAR responses, corrective and preventive actions, and effectiveness reviews as well as aging of CARs. These performance metrics are frequently reviewed by the local GEH management team, and included on monthly Quality Council reviews with GEH headquarters' management, including the President and CEO. Through the combined efforts of an enhanced QAP, a more robust tracking system provided by CTS, and management oversight and accountability, GEH self-monitoring of and adherence to committed actions will be much improved.

Attention to Detail of Records

- GEH is continuing to address minor typographical and factual errors (attention-to-detail issues) as identified by the NRC, NAC and NAC customers. The GEH goal is to produce error-free products and documentation and the method to achieve that goal is by devising and driving continuous-improvement efforts. These efforts include launching of the INPO-based Human Performance improvement program, increased management oversight and internal QA surveillance. Each of these activities are tracked for performance in the software based GEH Compliance Calendar and through the

ENCLOSURE 2

GE-Hitachi (Custom Fabrication) QA Program Enhancement Activities

Commitment Tracking System to ensure timely completion. Issues are communicated weekly in informal (but mandatory) Toolbox Talks conducted with applicable shop and office personnel. Additionally, periodic management quality assessments are performed to identify developing trends based on defect rates (through nonconformance reports and surveillance data).

Approved Supplier Listing Enhancement and Use

- In order to ensure that quality-related products and services are procured from currently approved vendors on the GEH Approved Supplier List (ASL), consistent with their approved scope of supply, the formal rigor prescribed by QAP-400, *Procurement Document Control*, for review of procurement documents has been enhanced. The QAP was revised to require that GEH Quality Analysts perform a detailed and documented evaluation of electronic ASL records prior to approving purchase orders. The completed checklists provide a record of the reviewed attributes including:
 - Supplier is listed on the ASL
 - Supplier address as listed on the PO matches the supplier address on the ASL
 - Supplier status on the ASL is satisfactory
 - Intended scope of procurement meets the qualification of the supplier as listed on the ASL
 - Intended scope of procurement meets the quality systems for which the supplier has been evaluated
 - Applicable supplier restrictions as listed on the ASL have been incorporated on the procurement document.
- Additional efforts to strengthen the interface between the GEH resource planning system and the ASL are underway, such as linking the purchasing system and ASL to prevent purchase of safety-related products and services from non-ASL providers.
- QAP-700, *Supplier Qualification and Oversight*, was revised to require the GEH ASL to be electronically controlled by the Quality Manager so that only the current version is available for use by the QA Analysts.

Audit (Internal and Supplier) Criteria and Depth

- GEH has revised the QAP pertaining to the internal audit program (QAP-1810). Changes included frequent monitoring of in-process operations such as welding, assembly, and testing. These operations are scheduled and monitored through the GEH Compliance Calendar. Other actions include revision of QAP-400 on procurement document control and QAP-700 on supplier qualification and oversight to clarify and provide more specific details on PO preparation and use/maintenance of the GEH ASL.
- GEH QAPs QAP-700 and QAP-400 were also reviewed and revised to provide enhanced direction for identification, application and documentation of the appropriate audit criteria as applicable to the supplier to be audited. To assure that the identified audit criteria is accurately listed on the GEH ASL, a common database was established that will automatically transfer the information from the supplier qualification evaluation report to the ASL, thereby precluding the possibility of transposition errors. As a minimum, this information will include:

ENCLOSURE 2

GE-Hitachi (Custom Fabrication) QA Program Enhancement Activities

- Supplier name and location. Also, identify if the supplier has an order entry point different from the approved location or uses a Post Office box
- Scope of supply
- Applicable QA requirements including identification of the basis for the supplier's quality program (such as 10 CFR 50, 71 and/or 72, etc.) and the basis used for assessment of the supplier
- Supplier approval status
- Any restrictions that apply
- Next scheduled audit date.