



**HITACHI**

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U.S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Washington, D.C. 20555-0001

Subject: Reply to a Notice of Violation

References: 1) NRC Notice of Violation Docket Number 99900003/2009-201-01  
2) NRC Inspection Report 99900003/2009-201

GE-Hitachi Nuclear Energy Americas LLC (GEH) hereby responds to the Notice of Violation, Reference 1, dated March 13, 2009. The violation was identified during an NRC inspection, Reference 2, conducted from January 27 thru January 30, 2009 at our facility by inspectors V. Hall, Aaron Armstrong, and P. Prescott.

Our reply to Reference 1 is provided as an attachment to this letter.

The NRC inspection report comments and suggestions are helpful to us in our constant efforts to improve our programs, to ensure continued quality assurance of our products and processes, and to ensure our compliance with NRC regulations and license conditions.

Please contact me on (910) 819-6240 if you have any questions or would like to discuss this matter further.

Sincerely,

Richard Wittmeier

Attachment

cc: Jerry Head  
James Klapproth  
Peter Wells  
Harold Neems

IE09  
HRR

**Attachment**  
**Reply to NRC Notice of Violation**  
**Docket Number 99900003**  
**Inspection Report No. 99900003/2009-201**

This Attachment sets forth the reply of GE-Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Violation dated March 13, 2009 relative to NRC Inspection Report 99900003/2009-201 ("the Inspection Report"), Docket Number 99900003/2009-201-01 ("the Violation").

**The Violation**

The Notice of Violation provides the following description of the Violation:

"10 CFR Part 21, Section 21.21(a)(1), 'Notification of failure to comply or existence of a defect and its evaluation,' requires in part that, 'Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected."

"Contrary to the above, as of January 20, 2009:

GEH's 10 CFR Part 21 implementing procedure, Policies and Procedures (P&P) 70-42, 'Reporting of Defects and Nonconformance under 10 CFR Part 21,' dated January 22, 2009, was not an appropriate procedure to ensure evaluation of deviations and failures to comply associated with substantial safety hazards within 60 days of discovery. As a result, GEH failed to perform timely evaluations for the following deviations:

1. GEH Corrective Action Request (CAR) #45083 was initiated on April 4, 2008, regarding a configuration change affecting historical seismic qualifications of Robert Shaw safety-related pressure gauges for hydraulic control units. Completion of CAR #45083 on April 4, 2008, first identified the existence of a deviation. GEH completed its evaluation of this deviation in Potentially Reportable Condition (PRC) 08-12 on June 11, 2008, 68 days after discovery.
2. GEH CAR #45670 was initiated on June 25, 2008, regarding GEH's dedication of Model 86C temperature switches supplied by Ametek Panalarm. GEH discovered that the accuracy test data sheets for

the switches were not verified by a survey. Completion of CAR #45670 on July 15, 2008 first identified the existence of a deviation. GEH completed its evaluation of this deviation in PRC 08-24 on September 18, 2008, 85 days after discovery.”

“This issue has been identified as Violation 99900003/2009-201-01.”

“This is a Severity Level IV violation (Supplement VII).”

## **GEH’s Response to the Violation**

GEH is not contesting the violation and has taken steps to address the issues identified in the Inspection Report. While GEH believes these changes represent an improvement to its program, GEH further believes that its program met the requirements of 10 CFR Part 21 prior to these changes, as explained below.

### **I. Reason for the Violation**

#### **A. Background**

The Inspection Report notes that GEH’s Part 21 program is governed by Policy and Procedures (“P&P”) 70-42 and that the procedure provides for a two-step process, i.e., a Potential Safety Concern (PSC) and a Potentially Reportable Condition (PRC).

A PSC is defined by P&P 70-42 as “a condition that GEH or GNF personnel identify that may represent a deviation or failure to comply” (emphasis added). A PRC is defined as “a condition that raises a question regarding the possible existence of a deviation or failure to comply associated with a Substantial Safety Hazard.” Thus, the key difference between a PSC and a PRC involves whether a deviation or failure to comply is confirmed to exist. GEH’s procedure thus provides for the processing of situations where a person has identified a condition that may or may not represent a deviation or failure to comply. In this respect, P&P 70-42 addresses situations prior to “discovery” as defined in 10 CFR Part 21. GEH believes that this element of its program facilitates and encourages the raising and processing of concerns that may involve safety issues; a desirable feature it is preserving.

The Inspection Report notes that the definition of “discovery” in P&P 70-42 is consistent with the definition in 10 CFR §21.3, but concluded that the GEH’s procedures incorrectly describe the point of discovery because Section 3.3 of P&P 70-42 describes discovery as the point that a PSC becomes a PRC. The language in question reads as follows:

“3.3 Conversion to a PRC – Notify the SEP PM if the assessment performed concludes that a deviation or failure to comply has occurred. Upon receipt of this information by the SEP PM, or expiration of ten working days, the PSC becomes a PRC. It is at this point that discovery, per 10 CFR 21, has occurred.”

GEH agrees that the above language could introduce an undesirable ambiguity into P&P 70-42 with regard to “discovery” and, as explained below, GEH is taking steps to eliminate this potential ambiguity. GEH notes, however, that Section 3.3 of P&P 70-42 addresses only the conversion of a PSC to a PRC, and that discovery of a defect or failure to comply is not limited to this process. Section 4.1 of P&P 70-42 is clear that a PRC may be identified in a number of different ways, including identification by personnel without initiation of a PSC, and that any such identification constitutes “discovery”. Since Section 4.2 of P&P 70-42 requires in all cases that a PRC be processed within 60 days of discovery of a deviation or failure to comply, GEH believes that P&P 70-42 met the requirements of 10 CFR Part 21 prior to the steps described below.

GEH notes further that the NRC has reviewed GEH's P&P 70-42 on numerous occasions in earlier inspections, including most recently in November of 2008 in NRC Inspection Report 99901376/2008-201, which concluded that P&P 70-42 contained the appropriate timeliness controls per 10 CFR Part 21:

“The NRC inspectors verified that GNF P&P 70-42 contained the appropriate timeliness controls per 10 CFR Part 21, including (1) evaluating deviations and failures to comply within 60 days, (2) providing an interim report to the NRC if the evaluation cannot be completed within 60 days, (3) notifying the customer or affected licensees within 5 days of determining that GNF cannot perform the review, (4) informing the GNF responsible officer within 5 working days if notification of NRC is required, (5) notifying the NRC within 2 days if a defect or failure to comply exists, and (6) submitting a written report to the NRC within 30 days of initial notification that a defect or failure to comply exists.”

B. Analysis

10 CFR §21.21(a) provides as follows:

“(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to --

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2)

of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected” (emphasis added).

10 CFR §21.3 includes the following definition of discovery:

“Discovery means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in §21.21. (a).”

Thus, “discovery” involves the identification of the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedure discussed in §21.21 (a). As described below, GEH believes that the two examples cited in the Inspection Report were both processed within 60 days of discovery as defined in 10 CFR Part 21.

The Inspection Report includes a finding of two examples of the Violation. The first example involves GEH Corrective Action Request (CAR) #45083, which was initiated on April 4, 2008. The Inspection Report notes that GEH initiated a PSC on April 7, 2008; that the PSC was converted to a PRC on April 17, 2008; and that GEH closed the PRC on June 11, 2008, which is 68 days after initiation of the CAR. The Inspection Report states that no additional information was provided to initiate the PRC process and concludes that “discovery” occurred with the initiation of the CAR on April 4, 2008, with the result that closure of the PRC occurred 68 days after discovery in violation of 10 CFR Part 21.

GEH believes that discovery actually occurred on April 17, 2008, with the conversion of the PSC to a PRC since that is when the existence of the deviation was identified. The request for the PSC was made to the Safety Evaluation Program Manager (SEPM) pursuant to an email message dated April 4, 2008 that indicated Engineering was in the process of locating documentation evaluating/justifying the changes, but that thus far such documentation had neither been located nor a conclusion reached that the documentation did not exist.

Thus, when the initiation of a PSC was requested at the end of the workday on April 4, 2008 it was not known whether documentation existed to justify changes that had been made to the gauges. GEH submits that at that time the existence of a deviation had not been identified since the documentation issue was open. The PSC was initiated the next working day, April 7, 2008, with the direction from the SEPM that, “if the PSC does represent a deviation or failure to comply, inform me immediately so that a PRC evaluation can be initiated.” If a conclusion had not been reached within 10 working days, P&P 70-42 would have required that a PRC be initiated. On April 17, 2008, an email message advised the SEPM that it

had been concluded the documentation did not exist and that a PRC should be initiated, which the SEPM initiated the same day. Based on these facts, GEH believes discovery occurred on April 17, 2008 when it was determined that documentation did not exist, and in fact there was a deviation. Thus closure of the evaluation of the deviation on June 11, 2008 was timely as it occurred 56 days after initiation of the PRC.

The second example cited in the Violation involves CAR #45670 which was initiated on June 25, 2008. The Inspection Report notes that GEH initiated a PSC on July 15, 2008; that the PSC was converted to a PRC on July 29, 2008; and that GEH closed the PRC on September 18, 2008. The Inspection Report states that no additional information was provided to initiate the PRC process and concludes that "discovery" occurred with the initiation of the CAR on June 25, with the result that closure of the PRC occurred 85 days after discovery in violation of 10 CFR Part 21.

GEH believes that discovery actually occurred on July 29, 2008 when GEH initiated the PRC. As noted in the Inspection Report, GEH identified in an audit that accuracy test data sheets supplied by a vendor had not been verified by a timely survey of the vendor. As provided in 10 CFR §21.3, the existence of a deviation must be "potentially associated with a substantial safety hazard" for discovery to occur. As noted by the Inspection Report, CAR #45670 noted in the Problem Description that parts had been ordered from the supplier but that description did not indicate whether affected parts had actually been delivered to a purchaser for use in a facility or an activity subject to 10 CFR Part 21; a prerequisite for the existence of a defect. Corrective Action #2 of CAR #45670 which shows a completion date of July 15, 2008, documents that "Engineering will need to evaluate the impact of this situation for parts already delivered to customers and in use at the plant." On that date the SEPM was contacted and requested to open a PSC, which occurred on the same date. As noted above, under P&P 70-42, a PSC involves a situation where a deviation "may" exist, not where one has been identified, and in this case the SEPM did not conclude that a deviation existed when the request for a PSC was made. When the PSC was not closed within 10 working days, per P&P 70-42, it was converted to a PRC. The PRC was subsequently closed as non-reportable on September 18, 2008, which is 51 days after initiation of the PRC.

GEH is taking steps to commence the 60-day evaluation period upon initiation of a PSC or PRC, coincident with the initiation of a Corrective Action Request identifying a deviation or failure to comply, to minimize the risk of a failure to complete the evaluation within the required period based on uncertainties involving the date of discovery.

GEH acknowledges that clarifying the start of the 60-day evaluation period with respect to a PSC or PRC is an important improvement to its program, and as described below, P&P 70-42 is being changed such that the 60-day period commences on initiation of a Corrective Action Request prompting the further issuance of either a PSC or PRC, dependant on the detailed information provided.

## **II. Corrective Steps Taken and Results Achieved**

The following near-term steps were taken in response to the Violation while the corrective action process changes described in Section III, below, are being developed and implemented:

(a) The 60-day evaluation period was assessed for all active or new Part 21 evaluations. The SEPM utilized the earlier of the CAR initiation date (in the event a CAR had been initiated that identified a deviation or failure to comply) or the communication with the SEPM pursuant to P&P 70-42 to establish the start date of the 60-day evaluation period.

(b) The SEPM is screening all initiated CARs to determine if they might identify a deviation or failure to comply, but they had not been so annotated in the CAR description and had not been communicated to the SEPM by the initiator, process owner, or responsible person pursuant to P&P 70-42.

(c) Any CARs identified in step (b) above as potentially involving a deviation or failure to comply are discussed with appropriate engineering managers to determine if a deviation or failure to comply had been identified.

These interim steps will be continued until revisions to P&P 70-42 and CP-16-01 have been completed and issued for use.

## **III. Corrective Steps to Avoid Further Violations**

The following changes are being made to P&P 70-42 and Common Procedure ("CP") CP-16-01:

(a) The individual who identifies a condition adverse to quality is required to determine whether it involves a deviation or failure to comply potentially associated with a substantial safety hazard at the time the CAR is initiated. The CAR initiator shall document the determination in the CAR and immediately notify the SEPM to initiate the Part 21 process in P&P 70-42, referencing the CAR initiation date as the date of Discovery.

(b) If, during the subsequent steps of the corrective action process, additional information is discovered that identifies there is a deviation or failure to comply

potentially associated with a substantial safety hazard, a new CAR will be initiated and the Part 21 process in P&P 70-42 will be initiated on the same date as the new CAR is initiated.

(c) P&P 70-42 is being revised to address these actions and the following section is being added to avoid the ambiguity identified in the Inspection Report:

“4.4 Evaluation Period - Deviations and failures to comply associated with substantial safety hazards shall be evaluated as soon as practicable, and, except as provided in Section 4.5, within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected. To minimize the risk of failure to conduct a timely evaluation, the SEPM shall calculate the 60-day period beginning on the initiation date of any Corrective Action Request that initiated a PSC or PRC.”

#### **IV. Date Full Compliance Achieved**

As noted above, GEH is not contesting the violation but believes that its program met the requirements of 10 CFR Part 21 prior to these changes. The steps to improve P&P 70-42 identified in Sections II, above, have been implemented and will be administratively managed until procedural revisions are in place. The changes to procedures P&P 70-42 and CP-16-01 described in Section III above will be in-place no later than May 1, 2009.