



General Electric Company
175 Curtner Avenue, San Jose, CA 95125

December 17, 1993

MFN No. 230-93
Docket No. 52-004

Document Control Desk
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Attention: R. W. Borchardt, Director
Standardization Project Directorate
Associate Directorate for Advanced Reactors
and License Renewal
Office of Nuclear Reactor Regulation

Subject: **Reply to a Notice of Nonconformance,
NRC Inspection Report No. 99900403/93-01**

This letter addresses the NRC staff findings documented in the subject report dated November 18, 1993. In accordance with Enclosure 1 of the subject report, a copy of this letter is also being sent to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation. Further, in the transmittal letter of the subject report, the staff asked that GE's response specifically address (1) a description of the steps that have been or will be taken to correct these items, (2) a description of the steps that have been or will be taken to prevent recurrence, (3) the dates by which corrective actions and preventive measures were or will be completed.

Items (1), (2) and (3) are addressed as part of the attachment to this letter. In the attachment, NONCONFORMANCES, each nonconformance has the following provided: i) a description of the steps that have or will be taken to correct these items, or alternatively, an explanation of GE's practice with supporting justification as to how it complies with 10 CFR Part 50, Appendix B, GE Nuclear Energy's QA Program Topical Report, NEDO-11209-04A, and GE Nuclear Energy's Engineering Operating Procedures, NEDE-21109; (ii) a description of the steps that have been or will be taken to prevent recurrence for each case, where appropriate; and (iii) the dates when corrective actions and preventive measures were, or will be, completed, where appropriate.

Since the August 9 through 13, 1993 NRC inspection, GE met with the NRC on October 4, 1993, wherein GE received further clarification of the NRC concerns, and then met with the NRC again on November 16, 1993, wherein GE presented responses to NRC concerns.

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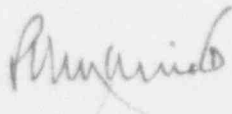
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GE believes this response fully addresses all issues and concerns raised by the staff in the subject inspection report. GE remains committed to quality leadership and to high quality in products and services through timely and effective compliance with all its quality requirements. This policy, which includes the SBWR Program, continues to have the unqualified endorsement and full support of GE-NE management.

Sincerely,



P. W. Marriott, Manager
Advanced Plant Technologies

Attachment

cc: D. M. Crutchfield-NRC
M. Malloy-NRC
S. M. Franks-DOE
J. E. Leatherman-GE
L. S. Gifford-GE
Chief, Vendor Inspection Branch, Division of Reactor
Inspection and Licensee Performance, Office of Nuclear
Reactor Regulation (USNRC)

NONCONFORMANCES

Nonconformance 93-01-01

Criterion III of Appendix B to 10 CFR Part 50, "Design Control," requires that the design control measures shall provide for verifying or checking the adequacy of design.

Engineering Operating Procedure (EOP) 40-3.00, "Engineering Computer Programs" (ECPs), states in Section 4.4.1 that "GE-NE components that apply approved ECPs to design and development activities are responsible for documenting both verification of inputs and confirmation that the utilization is within the application range of the ECP."

Contrary to the above, (1) the TRACG input decks used to model the GIST facility were not independently verified to be correct, and (2) the GE-NE Code Qualification Document (CQD), Licensing Topical Report NEDE-32177P, "TRACG Qualification," dated February 1993, which provides a description of the qualification of TRACG against various activities including the GDSCS integrated systems test, was submitted to the NRC for review and approval for referencing in licensing actions for the SBWR without receiving independent design verification or design review as required for a level 1 code used to support design basis analyses. (93-01-01)

GE Response

- i. The following is a description of the steps that have or will be taken to correct these items, or alternatively, an explanation of GE's practice with supporting justification as to how it complies with 10 CFR 50, Appendix B, GE Nuclear Energy's QA Program Topical Report, NEDO-11209-04A, and GE Nuclear Energy's Engineering Practices and Procedures.

The TRACG ECP that was examined by the inspection team was a traceable version that had been extensively tested, but independent verification for Level 2 had not yet been completed. It has since been subjected to a Level 2 design review for independent verification per Engineering Operating Procedure (EOP) 40-3.00. In the Level 2 design review, a single responsible Design Review Team is charged with the entire verification scope. This Design Review included a review of the encoded technology and the qualification as described in NEDE-32176P, "TRACG Model Description" and NEDE-32177P, "TRACG Qualification." The Design Review is documented in the Design Record File for the TRACG ECP (DRF A00-04147).

In addition, as agreed to with the inspection team, the GIST input decks have been subjected to an additional independent verification.

- ii. The following is a description of the steps that have or will be taken to prevent recurrence for each case.
 1. In the January 1994 monthly "In Pursuit of Quality" bulletin sent to all GENE employees, a notice will be published to re-emphasize that all licensing submittals require either verification prior to submittal or formal verification deferral with clear notice in the licensing submittal documentation.
 2. GENE currently has requirements that all employees provide confirmation of familiarity with EOPs that are related to their job requirements. In addition, an augmented training program, with verification of competence via examination, is currently being prepared and implemented. A specific course of training on EOP 42-6.00, including verification deferral requirements, is in preparation and is scheduled for availability by February 15, 1994.
 3. Specific employees involved in SBWR design will be identified by February 15, 1994 and will be given priority in this training process. These employees will be trained by June 1, 1994.
- iii. The following are the dates when corrective actions and preventive measures were, or will be, completed.

All corrective actions and preventive measures have been completed or scheduled as described above.

Nonconformance 93-01-02

Criterion XVII of Appendix B to 10 CFR Part 50, "Quality Assurance Records," states, in part, "that sufficient records shall be maintained to furnish evidence of activities affecting quality and that the records shall include operating logs and the results of reviews, inspections, tests, and that records shall be identifiable and retrievable."

Engineering Operating Procedure (EOP) 42-10.00, "Design Record Files" (DRF), requires, in part, that the DRF contain or reference (as applicable) design and evaluation records, test reports, controlled documents, and documentation and pertinent references that support the design. EOP 35-3.00, "Engineering Tests," further defines evaluation records as including instrument calibration records.

The GIST Program Test Plan and Procedure (TP&P) 521.1322, Revision 2, dated November 29, 1988, specifies documents to be included in the DRF, including "all test records."

Contrary to the above, certain documentation required to be contained or referenced in the DRF was not included therein. Specific documents that should have been contained or referenced in the DRF were: the Final Test Report (NEDO-31680) for the GIST Program; instrument calibration records, which were located in a desk drawer in another building; and final design drawings for the facility. Some drawings were found in a cabinet at the facility itself. This set of drawings did not include final numbered, approved, as-built design drawings, which are required by the QA Plan to be retained for the lifetime of the item. Also, data tapes for the GIST tests, which are part of the test records specified for inclusion in the DRF by TP&P 521.1322, were not referenced therein. (93-01-02)

GE Response

- i. The following is a description of the steps that have or will be taken to correct these items, or alternatively, an explanation of GE's practice with supporting justification as to how it complies with 10 CFR 50, Appendix B, GE Nuclear Energy's QA Program Topical Report, NEDO-11209-04A, and GE Nuclear Energy's Engineering Practices and Procedures.

GE has opened Design Record File (DRF) A00-02917-1, a supplement to the DRF applicable to the GIST program, to file the missing records. The missing records, as cited by the NRC, have either been included in the DRF or reference is made to those documents which are retrievable in GE's document control system. Specifically, the Final Test Report (NEDO-31680), which did reference the original DRF, is now also referenced in the DRF. All of the instrument calibration records are included in the DRF. The DRF includes the facility design drawings. The drawings for the vessel components (e.g., reactor model, drywell, etc.) are individually stored in the permanent GE document reference system, and the DRF gives the reference numbers for them. The location of the data tapes is documented in the DRF.

- ii. The following is a description of the steps that have or will be taken to prevent recurrence for each case.

The GIST test was performed in accordance with EOP 35-3.00, "Engineering Tests". As a result of this inspection, GE has concluded that several changes to this EOP are appropriate, to increase its clarity, and to better define specific test requirements. One specific change to be implemented is a listing of appropriate documentation to be included in the DRF for Engineering Tests. GE has developed a draft generic test DRF table of contents (attached), which is currently under review, including an informal review by NRC personnel. Once this document has been finalized, it will be formally added to testing requirements as documented in EOP 35-3.00.

- iii. The following are the dates when corrective actions and preventive measures were, or will be, completed.

Revision 10 of EOP 35-3.00 will be issued by April 1, 1994.

PRELIMINARY DRAFT

GENERIC SBWR TESTING

DESIGN RECORD FILE TABLE OF CONTENTS

1. Test Requirements
 - 1.1 Test Specification
 - 1.2 Backup Analyses
 - 1.3 Quality Assurance Requirements

2. Test Facility/Article Design
 - 2.1 Design Specifications
 - 2.2 Facility Design Drawings
 - 2.3 Backup Analyses
 - 2.4 Verification and/or Design Reviews

3. Test Planning
 - 3.1 Quality Assurance Plan
 - 3.2 Instrumentation Plan
 - 3.2.1 Instrument List and Basis
 - 3.2.2 Measurement Uncertainty Analysis
 - 3.2.3 Instrument Calibration Plan
 - 3.2.3 Pre-Test Instrumentation Acceptability Criteria
(zero shift, out of service, etc.)
 - 3.3 Data Acquisition Plan
 - 3.3.1 DAS hardware Description/Requirements
 - 3.3.2 Wire/Cable lists - DAS hookup
 - 3.3.3 Data Acquisition Software
 - 3.3.4 Verifications
 - 3.4 Facility Safety Plan
 - 3.4.1 Significant Hazards Summary
 - 3.4.2 Accident Response Plan
 - 3.5 Test Plan and Procedures Document
 - 3.5.1 Test Matrix
 - 3.5.2 Initial Conditions Acceptance Criteria
 - 3.5.3 Test Instructions
 - 3.6 Expected Test Results
 - 3.6.1 Test Acceptance Criteria
 - 3.7 Verifications and/or Design Reviews

4. Facility Checkout and Shakedown
 - 4.1 Facility As-Built Drawings
 - 4.1.1 Geometry Verifications
 - 4.2 Shakedown Test Requirements
 - 4.2.1 Shakedown Plans/Extent/Requirements
 - 4.2.2 Shakedown Matrix

- 4.2.3 Expected Performance and Acceptance Criteria
- 4.3 Corrected Items Punchlist
 - 4.3.1 Correction Dispositions
- 4.4 Ready to Test Certification
 - 4.4.1 Verification Statements
- 5. Test Performance Documentation
 - 5.1 Instrument Calibration Records
 - 5.2 DAS Wirelist Verification
 - 5.3 Pre-test Checklists
 - 5.3.1 Test Instructions Checklists
 - 5.3.2 Initial Condition Acceptance
 - 5.3.3 DAS/Instrumentation Acceptance
 - 5.4 Post-test Checklists
 - 5.4.1 Test Logs
 - 5.4.2 Facility Shutdown Checklists
 - 5.4.3 Test or Instrumentation Nonconformances
 - 5.5 Raw Data Printouts
 - 5.5.1 Engineering Units Printout
 - 5.5.2 Electronic Data Storage Information
- 6. Data Reduction
 - 6.1 Data Reduction Software
 - 6.1.1 Analytical Basis
 - 6.1.2 Computer Software
 - 6.1.3 Software Validation
 - 6.1.4 Software Verification
 - 6.2 Reduced Data Records
 - 6.2.1 Data Reduction Inputs
 - 6.2.2 Reduced Data Printouts
 - 6.2.3 Electronic Data Storage Information
- 7. Data Analysis and Reports
 - 7.1 Apparent Test Results Reports
 - 7.1.1 Analytical Basis
 - 7.1.2 Comment Resolution
 - 7.1.3 Verifications
 - 7.2 Final Test Reports
 - 7.2.1 Analytical Basis
 - 7.2.2 Comment Resolution
 - 7.2.3 Verifications
- 8. Test Article Dispositions

Nonconformance 93-01-03

Criterion III of Appendix B to 10 CFR Part 50, "Design Control," requires that design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

GE-NE QA Program topical report, NEDO-11209-04A, under Section 3.11, "Design Change Control," states, in part, "The control procedure requires that every change must be documented, design verified, approved by the responsible engineer, and reviewed by the appropriate interfacing components."

Contrary to the above, there was no documentation or independent verification of changes made to the TRACG code as a result of the GIST Program. The changes include changes to the interfacial shear and heat transfer when a two-phase level is present, changes to the model for condensation on cold walls when air is present, and the implementation of a horizontally stratified flow map. (93-01-03)

CF Response

- i. The following is a description of the steps that have or will be taken to correct these items, or alternatively, an explanation of GE's practice with supporting justification as to how it complies with 10 CFR 50, Appendix B, GE Nuclear Energy's QA Program Topical Report, NEDO-11209-04A, and GE Nuclear Energy's Engineering Practices and Procedures.

EOP 40-3.00, "Engineering Computer Programs," provides for both changes to software versions and new versions of software. Changes to software are documented and verified on an individual basis. Such changed versions then replace the original version of the software in the control system. However, the creation of new versions of software are treated and controlled as totally independent new developments. All of the documentation and verification requirements for new software are applied to each new version. The prior version can remain available, unchanged, with a different control system label to indicate that a later version exists (i.e., control is changed from Level 2 to Level 3). The new version software can make use of as much or as little of the coding from prior versions as is appropriate. However, in all cases the control, documentation and verification must meet the full standards for new software. These standards and requirements are documented in EOP 40-3.00 and include software management plans, multiple design reviews, specifications, test plans, and independent verification.

The TRACG Engineering Computer Program (ECP) that was examined by the inspection team is controlled as a new version in the GE control system, not as a changed prior version. Only the sections of EOP 40-3.00 controlling new versions of ECPs apply to this version. That is, the cases noted in this nonconformance finding were not changes to existing versions but rather

creation of a new version. As such, the documentation and verification were appropriately addressed to the entire new software system, rather than being narrowly focused on differences.

The version of the TRACG ECP that was examined by the inspection team has all the documentation which is required for a new version of an ECP. Complete documentation of the models, including the interfacial shear and heat transfer when a two-phase level is present, the condensation on cold walls when air is present, and the horizontally stratified flow models and the testing, were included in Licensing Topical Reports, NEDE-32176P, "TRACG Model Description" and NEDE-32177P, "TRACG Qualification." Independent verification, as noted in Nonconformance 93-01-01, had not been done at the time of report submittal but has since been done through a Level 2 Design Review and filed in DRF A00-04147.

GE continues to believe that a single responsible Design Review Team chartered with the entire verification scope is the best way to assure that all verification objectives are met. This control system for ECPs has been successfully used by GE-NE for nearly 20 years.

- ii. The following is a description of the steps that have or will be taken to prevent recurrence for each case.

The preventive action for this item is covered by that for Nonconformance 93-01-01.

- iii. The following are the dates when corrective actions and preventive measures were, or will be, completed.

All corrective and preventive actions have been or will be completed as described above and in the response to Nonconformance 93-01-01.

Nonconformance 93-01-04

Criterion XII of Appendix B to 10 CFR Part 50, "Control of Measuring and Test Equipment," states that, "measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

Section 2.2 of EOP 35-3.20, "Calibration Control," Revision 2, dated September 2, 1988, states that maintenance and test equipment calibrations were to be performed using controls which assured traceability to certified equipment having known valid relationships to nationally recognized standards. In addition, EOP 35-3.20 states that calibration services should be classified as safety-related services unless justified and documented otherwise.

GIST Program TP&P 521.1322, Section 4.1.2, requires test equipment be calibrated against auditable standards traceable to the National Bureau of Standards.

Contrary to the above, GE-NE purchased flow meters used in the GIST tests from a commercial grade supplier who was not on GE-NE's approved supplier list, and accepted and used the instruments as calibrated by the supplier without further verification of the quality or traceability of those calibrations. (93-01-04)

GE Response

- i. The following is a description of the steps that have or will be taken to correct these items, or alternatively, an explanation of GE's practice with supporting justification as to how it complies with 10 CFR 50, Appendix B, GE Nuclear Energy's QA Program Topical Report, NEDO-11209-04A, and GE Nuclear Energy's Engineering Practices and Procedures.

GE has obtained certificates of calibration of the flow meters from the original supplier. These certificates trace the calibration of the instruments to the National Institute of Standards and Technology. These records are filed in the supplement to the original DRF for the GIST program (DRF A00-02917-1), as discussed in the response to Nonconformance 93-01-02. Since the equipment supplier is not on the list of approved equipment suppliers for GE, the measurements made by these instruments are being verified against other measurements made during the GIST tests whose data were collected by instruments calibrated at GE. Specifically, the GDOS flowrates can and will be derived by performing a mass balance on the RPV water inventory during the period of time when the GDOS is injecting to the vessel.

- ii. The following is a description of the steps that have or will be taken to prevent recurrence for each case.

Failure to independently verify the flow meter calibration was an oversight. Nevertheless, review of EOP 35-3.20 has determined that a deficiency exists in

this EOP, in that while it does establish the requirements for calibration of measurement and test equipment (M&TE), it does not include a definition of such equipment. Therefore, GE will issue a revision to EOP 35-3.20 which defines M&TE to include all active and passive devices which can affect the accuracy of test measurements.

- iii. The following are the dates when corrective actions and preventive measures were, or will be, completed.

EOP 35-3.20 will be revised and issued by April 1, 1994. Verification of the GDCS flow meter data against other test data will be completed and verified by February 28, 1994.

Nonconformance 93-01-05

Criterion XI of Appendix B to 10 CFR Part 50, "Test Control," states, in part, "Test results shall be documented and evaluated to assure that test requirements have been satisfied."

EOP 35-3.00, "Engineering Tests," requires, in part, that all test anomalies be reviewed and dispositioned. Documented evidence of the review and disposition must be traceable and consistent with EOP 42-10.00, "Design Record File."

EOP 42-10.00, "Design Record Files," requires that supporting information must conform to requirements of EOPs or other authorizations governing the work activity.

GIST Program TP&P 521.1322, Section 4.2.4, requires that nonconformance reports (NCRs) are to be prepared for tests that do not meet acceptance criteria and that copies of the completed, approved NCRs are to be included in the DRF.

Contrary to the above, GE-NE failed to document in the DRF the review and disposition of anomalies in three tests, C01, D01, and D03. These tests were considered to be "invalid" as a result of incorrect valve alignment (C01) or incorrect power input to the test section (D01 and D03). For one of the tests (C01), a note was found on the folder in the DRF in which hard-copy data plots were stored, indicating that a problem existed for the tests; however, the problem indicated on the folder (incorrect power input) was not consistent with the actual reason given in NEDO-31680 for the test's invalidation (incorrect valve alignment). (93-01-05)

GE Response

- i. The following is a description of the steps that have or will be taken to correct these items, or alternatively, an explanation of GE's practice with supporting justification as to how it complies with 10 CFR 50, Appendix B, GE Nuclear Energy's QA Program Topical Report, NEDO-11209-04A, and GE Nuclear Energy's Engineering Practices and Procedures.

As discussed in the response to Nonconformance 93-01-02, GE has opened a supplement to the original DRF (DRF A00-02917-1) and filed in it all missing documentation. This includes nonconformance reports for the three tests (C01, D01, and D03) which failed to satisfy the test requirements for their test conditions.* The reasons for the nonconformances and the dispositions are given. These reasons were previously documented in both the Final Test Report

* For Test C01, the note, on the DRF folder for the repeated test (C01A) data, incorrectly implied that the problem was an error in the decay heat controller, which was the case for the other two nonconforming tests. That was not the case for C01. The reason for the nonconformance is correctly stated in the nonconformance report for each test.

(NEDO-31680) and the Final Program Report (GEFR-00850) for GIST. In each case, the test was completed successfully on the next try. None of the nonconforming tests were used by GE in any subsequent design activity for the SBWR.

- ii. The following is a description of the steps that have or will be taken to prevent recurrence for each case.

As discussed in the response to Nonconformance 93-01-02, GE has prepared a generic DRF Table of Contents for SBWR Testing. The Table of Contents includes a section on nonconformance reports.

- iii. The following are the dates when corrective actions and preventive measures were, or will be, completed.

All corrective and preventive actions have been or will be completed as described above and in the response to Nonconformance 93-01-02.