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Licensee Contractor and Vendor Inspection Status Report

Quarterly Report
January - March 1994

U.S. Nuclear Regulatory Commission

Office of Nuclear Reactor Regulation

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**Division of Reactor Inspection and Licensee Performance
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001**

ABSTRACT

This periodical covers the results of inspections performed by the NRC's Vendor Inspection Branch that have been distributed to the inspected organizations during the period from January 1994 through March 1994. A list of selected bulletins and information notices involving vendor issues and copies of pertinent correspondence involving vendor issues are also included in this periodical.

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PREFACE

A fundamental premise of the Nuclear Regulatory Commission (NRC) licensing and inspection program is that licensees are responsible for the proper construction and safe and efficient operation of their nuclear power plants. The total government-industry system for the inspection of commercial nuclear facilities has been designed to provide for multiple levels of inspection and verification. Licensees, contractors, and vendors each participate in a quality verification process in compliance with requirements prescribed by the NRC's rules and regulations (Title 10 Code of Federal Regulations). The NRC performs an overview of the commercial nuclear industry by inspection to determine whether its requirements are being met by licensees and their contractors, while the major inspection effort is performed by the industry within the framework of ongoing quality verification programs.

The licensee is responsible for developing and maintaining a detailed quality assurance (QA) plan with implementing procedures pursuant to 10 CFR 50. Through a system of planned and periodic audits and inspections, the licensee is responsible for assuring that suppliers, contractors and vendors also have suitable and appropriate quality programs that meet NRC requirements, guides, codes and standards.

The Vendor Inspection Branch (VIB) reviews and inspects nuclear steam system suppliers (NSSSs), architect engineering (AE) firms, suppliers of products and services, independent testing laboratories performing equipment qualification tests, and holders of NRC licenses (construction permit holders and operating licenses) in vendor-related areas. These inspections are performed to assure that the root causes of reported vendor-related problems are determined and appropriate corrective actions are developed. The inspections also review the vendors' conformance with applicable NRC and industry quality requirements, the adequacy of licensees' oversight of their vendors, and that adequate interfaces exist between licensees and vendors.

The VIB inspection emphasis is placed on the quality and suitability of vendor products, licensee-vendor interface, environmental qualification of equipment, and review of equipment problems found during operation and their corrective action. When nonconformances with NRC requirements and regulations are found, the inspected organization is required to take appropriate corrective action and to institute preventive measures to preclude recurrence. When generic implications are identified, NRC assures that affected licensees are informed through vendor reporting or by NRC generic correspondence such as information notices and bulletins.

This periodical (White Book) is published quarterly and contains copies of all vendor inspection reports issued during the calendar quarter for which it is published. Each vendor inspection report lists the nuclear facilities to which the results are applicable thereby informing licensees and vendors of potential problems. In addition, the affected Regional Offices are notified of any significant problem areas that may require special attention.

The White Book also contains a list of selected bulletins and information notices involving vendor issues. Copies of other pertinent correspondence involving vendor issues are also included in this White Book issue.

Correspondence with contractors and vendors relative to inspection data contained in the White Book is placed in the USNRC Public Document Room, located in Washington, D.C.

INSPECTION REPORTS

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 14, 1994

Docket No. 99900030

Mr. Peter C. Valli, President and
Chief Executive Officer
BW/IP International, Inc.
Suite 900
Long Beach, California 90802

Dear Mr. Valli:

SUBJECT: NOTICE OF NONCONFORMANCE
(NRC INSPECTION REPORT No. 99900030/93-01)

This refers to the inspection conducted by Messrs. R.L. Pettis, Jr. and R.P. McIntyre of this office on December 6-9, 1993. At the conclusion of the inspection, the findings were discussed with those members of your staff identified in the enclosed report.

The inspection was conducted to review documentation related to reports submitted to the NRC pursuant to Title 10 of the Code of Federal Regulations, Part 21 (10 CFR Part 21), which involve equipment supplied by BW/IP, and to review the implementation of BW/IP corrective actions which resulted from our previous inspection performed in 1989. Areas examined during the inspection and our findings are discussed in the enclosed report. This inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations by the inspectors.

Based on the results of this inspection, it was found that the implementation of your quality assurance program failed to meet certain NRC requirements. Specifically, the NRC inspection team identified instances in which BW/IP failed to notify its customers of defects in equipment for those cases in which BW/IP reported the defect to the NRC pursuant to 10 CFR Part 21. BW/IP procedures implementing 10 CFR Part 21 require such customer notification. The NRC inspectors also identified instances in which BW/IP accepted material from suppliers which did not conform to purchase order requirements.

The specific findings and references to the pertinent requirements are identified in the enclosed Notice of Nonconformance and inspection report. Please provide us within 30 days from the date of this letter a written statement in accordance with the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses requested by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosures:
1. Notice of Nonconformance
2. Inspection Report No. 99900030/93-01

Enclosure 1

NOTICE OF NONCONFORMANCE

BW/IP International, Inc.
Vernon, California

Docket No.: 99900030/93-01

Based on the results of an NRC inspection conducted on December 6-9, 1993, it appears that certain of your activities were not conducted in accordance with NRC requirements.

A. Criterion V of Appendix B to 10 CFR Part 50, "Instructions. Procedures, and Drawings," states, in part, that activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.

BW/IP Procedure L-A-16, "Product Defect Reporting In Compliance with 10 CFR Part 21 Requirements," dated March 9, 1990, states in "General," that a defect report must be sent to both the NRC and any affected purchaser. Item 21 of "Procedure," also states that the Cognizant Project Manager advises purchasers or licensees with like equipment which may be subject to the reported defect.

Contrary to the above, BW/IP could not produce documentation to support notification to 5 of 15 licensees of the results of BW/IP's 10 CFR Part 21 Evaluation Board for Deviation CFR 91-004. The Deviation related to cast components supplied by ACME Castings, Incorporated (ACME), who failed to pass down the requirements of 10 CFR Part 21 to its subvendors providing heat treatment services, and had an unacceptable 10 CFR Part 50, Appendix B, quality assurance program. BW/IP reported the defect to the NRC on October 2, 1989.

A review of the BW/IP Deviation Evaluation Summary Sheet indicated closure of the evaluation on October 2, 1991, and also requested program managers to notify 15 pump and valve customers of the Board's results. The notification stated that in the absence of supporting documentation, the potential exists for improper heat treatment of items produced by ACME and recommended that inspections be performed to assure that the parts will perform their intended safety function. (93-01-01)

B. Criterion V of Appendix B to 10 CFR Part 50, "Instructions, Procedures, and Drawings," states, in part, that activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.

BW/IP Policy and Procedure L-A-16, "Reporting of Defects and Failures to Comply in Nuclear Products and Services," dated July 29, 1992, (which supersedes L-A-16, dated March 9, 1990), states, in Item 23 of "Procedure," that the Cognizant Project Manager advises purchasers or licensees with like equipment which may be subject to the defect.

Contrary to the above, the inspectors identified two instances (NRC 93-055 and 93-057, and NRC 93-071) in which BW/IP notified the NRC of known check valve defects (CFRN-9301, dated February 12, 1993, and CFRN-9302, dated February 18,1993), yet did not notify its customers of the defect until November 30, 1993, after the NRC contacted BW/IP concerning the scope of the December 6, 1993, inspection.
(93-01-02)

C. Criterion VII of Appendix B to 10 CFR Part 50, "Control of Purchased Material, Equipment and Services," requires, in part, that measures shall be established to assure that purchased material, equipment, and services conform to the procurement documents.

BW/IP Specification PS-1535, paragraph 3.3.3, which is referenced as a procurement document in Purchase Order (PO) V 407811, dated April 28, 1992, to Delta Centrifugal Corporation for ASTM A-743 castings, limits the maximum hardness level of Type 420 castings to 255 Brinell hardness number (BHN).

Contrary to the above, on June 17, 1992, BW/IP quality control accepted a Type 420 casting procured under this PO having a hardness of 262 BHN as indicated on the Certified Material Test Report (CMTR). (93-01-03)

D. Criterion VII of Appendix B to 10 CFR Part 50, "Control of Purchased Material, Equipment, and Services," requires, in part, that measures shall be established to assure that purchased material, equipment, and services conform to the procurement documents.

Paragraph B of BW/IP PO V 413444, dated January 11, 1993, to Nova Machine Products Corporation (NOVA) for eight ASME SA-193 Grade B6 studs, requires that if subtier suppliers not holding ASME Quality System Certificates are used, their quality system program revision and date and the name of the approving organization to whom the material is being supplied must appear on the subtier CMTR. Paragraph K of the same PO requires the identification of the mill supplying the material.

Contrary to the above, the material certification provided by NOVA for this material did not identify the supplying mill or identify the mill's quality system program or the approving organization. (93-01-04)

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each nonconformance: (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; and (3) the dates your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 14th day of March, 1994

Enclosure 2

U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR INSPECTION AND LICENSEE PERFORMANCE

ORGANIZATION:	BW/IP INTERNATIONAL, INC. VERNON, CALIFORNIA
REPORT NO.:	99900030/93-01
CORRESPONDENCE ADDRESS:	BW/IP International, Inc. 2300 East Vernon Avenue Vernon, California 90058
ORGANIZATIONAL CONTACT:	R. D. Ham Manager of Quality (213) 587-6171
NUCLEAR INDUSTRY ACTIVITY:	Manufacturer of valves and pumps used in nuclear safety-related applications
INSPECTION CONDUCTED:	December 6-9, 1993
TEAM LEADER:	Robert L. Pettis Jr. 2/24/94 Robert L. Pettis, Jr., P.E. Date Reactive Inspection Section No. 1 Vendor Inspection Branch (VIB)
OTHER INSPECTORS:	R.P. McIntyre, Senior Reactor Engineer, VIB
APPROVED:	Robert L. Pettis Jr. 2/24/94 for Uldis Potapovs, Chief Date Reactive Inspection Section No. 1 Vendor Inspection Branch
INSPECTION BASES:	10 CFR Part 21 and 10 CFR Part 50, Appendix B
INSPECTION SCOPE:	Review selected 10 CFR Part 21 reports submitted to the NRC and corrective actions which resulted from the previous NRC inspection.
PLANT SITE APPLICABILITY:	Numerous

1 INSPECTION SUMMARY

1.1 Violations

No violations were identified during the inspection.

1.2 Nonconformances

1.2.1 Contrary to Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 (Appendix B), and BW/IP International, Incorporated (BW/IP), Procedure L-A-16, "Product Defect Reporting In Compliance with 10 CFR Part 21 Requirements," dated March 9, 1990, BW/IP could not produce documentation to support notification to 5 of 15 licensees of the results of its 10 CFR Part 21 Evaluation Board for Deviation CFR 91-004. The Deviation related to cast components supplied by ACME Castings, Incorporated (ACME), who failed to pass down 10 CFR Part 21 requirements to its subvendors providing heat treatment services. Additionally, ACME's Appendix B quality assurance (QA) program was identified as unacceptable by BW/IP. BW/IP reported the defect to the NRC on October 2, 1989. (93-01-01)

1.2.2 Contrary to Criterion V, "Instructions, Procedures, and Drawings," of Appendix B, and BW/IP Procedure L-A-16, "Reporting of Defects and Failures to Comply in Nuclear Products and Services," dated July 29, 1992, (which supersedes L-A-16, dated March 9, 1990), BW/IP notified the NRC of known defects with check valves (CFRN-9301, dated February 12, 1993, and CFRN-9302, dated February 18,1993), yet did not notify their customers of the defect until November 30, 1993, after the NRC contacted BW/IP concerning the scope of the December 6, 1993, inspection. Two separate examples of this nonconformance have been identified and are referred to as Part A and B. (93-01-02)

1.2.3 Contrary to Criterion VII of Appendix B, "Control of Purchased Material, Equipment and Services," and BW/IP Specification PS-1535, paragraph 3.3.3, which is referenced as a procurement document in Purchase Order (PO) V 407811, dated April 28, 1992, to Delta Centrifugal Corporation for American Society for Testing and Materials (ASTM) ASTM A-743 castings, BW/IP quality control accepted, on June 17, 1992, a Type 420 casting procured under this PO having a hardness of 262 Brinell hardness number (BHN) as indicated on the Certified Material Test Report (CMTR), which exceeded the specification limit of 255 BHN. (93-01-03)

1.2.4 Contrary to Criterion VII of Appendix B, "Control of Purchased Material, Equipment, and Services," and Paragraph B of BW/IP PO V 413444, dated January 11, 1993, to Nova Machine Products Corporation (NOVA) for eight ASME SA-193 Grade B6 studs, BW/IP accepted a material certification provided by NOVA which did not identify the supplying mill or identify the mill's quality system program or the approving organization. (93-01-04)

2 STATUS OF PREVIOUS INSPECTION FINDINGS

2.1 <u>(Closed) Violation 89-01-01</u>

Contrary to Section 21.21, "Notification of failure to comply or existence of a defect," of 10 CFR Part 21, BW/IP could not provide documentation to support their basis for informing TU Electric, in a letter dated June 22, 1989, that a previous deficiency related to the adjustment height of the swing arm did not constitute a reportable condition pursuant to the provisions of 10 CFR Part 21. This condition led to excessive backleakage through 13 safety-related swing check valves. In addition, BW/IP also failed to notify all of its nuclear customers of the deviation. A 10 CFR Part 21 report would have resulted if BW/IP had evaluated the deviation. Also, BW/IP had not initiated an evaluation of a broken cast swing arm which was metallurgically tested and determined to have material flaws (hot cracks).

With respect to the adjustment height issue, BW/IP notified all of its customers on September 22, 1989, of the deviation and the steps necessary to prevent improper valve operation pursuant to BW/IP Tech Alert No. 8909-77-001. With respect to the broken cast swing arm issue, BW/IP reported the deviation to the NRC on October 2, 1989. The NRC issued Information Notice 90-03 on the subject on January 23, 1990.

2.2 <u>(Closed) Nonconformance 89-01-02</u>

Contrary to Criterion III, "Design Control," of Appendix B, BW/IP failed to adequately review for suitability, eight replacement swing arms supplied to the Comanche Peak Steam Electric Station (CPSES). The swing arm, classified by BW/IP as a critical nonpressure boundary item, is essential to the operation of the swing check valve used in various safety-related applications at the CPSES and other nuclear facilities.

BW/IP stated that it fabricated the swing arms as safety-related in accordance with its Appendix B QA program, however, BW/IP acknowledges the NRC position concerning its dedication program. Since the inspection, BW/IP has participated in various industry sponsored meetings and seminars to improve its dedication practices. These included participating in a dedication seminar for commercial grade items, presented by General Electric on June 15, 1990; the Valve Manufacturers Association Quality Conference held in Houston, Texas, in 1991, which 16 other companies attended; Nuclear Procurement Issues Committee (NUPIC) Supplier Meetings in 1991, 1992 and 1993, in which the Electric Power Research Institute's (EPRI's) "Supplemental Guidance for EPRI Report NP-5652," dated June 4, 1993, was presented (1993 meeting); and several others. In July 1990, BW/IP developed Engineering Procedure B3-6, "Utilizing Commercial Items in Safety-Related Components," which references EPRI NP-5652 and NP-6405, in addition to other Los Angeles Operations (LAO) procedures. According to BW/IP, the procedure has had limited use since its inception. The NRC inspection team did not review the adequacy of the procedure during the inspection.

2.3 <u>(Closed) Nonconformance 89-01-03</u>

BW/IP failed to audit 17 suppliers of nuclear safety-related items due to their status as holders of an American Society of Mechanical Engineers (ASME) Quality System Certificate (QSC).

BW/IP acknowledged the NRC position on auditing ASME QSC holders, pursuant to NRC Information Notice 86-21, and on June 1, 1990, revised Section 7-3.3(7) of its Nuclear Program Quality Manual (NPQM) to require an implementation audit of QSC and Certificate of Authorization holders prior to use of the material. The procedure also states that a follow-up audit will be performed every three years thereafter for maintenance on BW/IP's approved vendor list (AVL). Since implementation of this policy, over 15 QSC holders currently on the AVL have been audited.

2.4 <u>(Closed) Nonconformance 89-01-04</u>

BW/IP failed to qualify ACME as a supplier of safety-related quality level (QL) QL-3 (safety-related) and QL-4 (military) items. ACME's quality program, based on Military Specification MIL-I-45208A, was disapproved by BW/IP on November 11, 1985. On June 8, 1987, ACME's vendor status was changed to that of a QL-3 and QL-4 supplier based solely on ACME's certification that they comply with the provisions of 10 CFR Part 21.

On September 28, 1989, BW/IP, together with TU Electric, audited ACME and identified several deficiencies within the implementation of ACME's quality program which included, for example, improper identification, segregation and control of nonconforming material, and inadequate documentation of inspection and testing personnel training and qualification records. The audit results were documented on Request for Corrective Action (RCA) 89-17. Based on these results, the NRC requested that BW/IP review POs placed with ACME to identify where potential nonconforming material may have been used, notify affected customers, and evaluate such deviations pursuant to the requirements of 10 CFR Part 21.

BW/IP evaluated all POs placed with ACME since 1978 and referred the issue to its 10 CFR Part 21 Evaluation Board for disposition. The Board concluded that for Deviation CFR 91-004 there was no impact, however notification of the Board's results was requested to be sent to all BW/IP pump and valve customers as noted in an October 2, 1991 letter. Notification was intended for 15 utilities and stated that implementation of the recommended inspections described in the letter is sufficient to assure the identified parts will perform their intended safety function. However, there was no documentation in the file to support notification to Commonwealth Edison, Tennessee Valley Authority (TVA), TU Electric, Southern California Edison and Carolina Power and Light. The corrective actions mainly addressed the potential for improper heat treatment by ACME since they had insufficient documentation to identify the provider of the heat treatment.

ACME furnished BW/IP with pump impellers, reactor coolant pump case wear rings, valve swing arms and gate guides, valve seats and clevises. After a follow-up audit of ACME by BW/IP on September 18, 1990, identified open and unresolved deficiencies, previously identified in RCA 89-17 almost one year earlier, BW/IP issued Instruction Notice 90-19, dated September 20, 1990, to formally remove ACME from the AVL as a QL-3 supplier. Nonconformance 93-01-01 was identified during this part of the inspection.

2.5 (Closed) Nonconformance 89-01-05

BW/IP failed to survey initially and audit triennially 43 suppliers of safety-related QL-1, 3 and 4 items currently on the BW/IP AVL.

BW/IP revised its AVL to delete the 43 vendors. This was reviewed during the inspection.

2.6 (Closed) Nonconformance 89-01-06

Quality Survey/Audit Reports and Quality Audit Checklists for vendors/suppliers evaluated by BW/IP are incomplete and/or inadequate to determine that the supplier's quality program had been effectively implemented.

BW/IP deleted Eagle Pattern & Manufacturing Company from its AVL on September 29, 1989, and placed limitations on two other suppliers (GMC Precision Tool and Toolex) which are now limited to only providing machining services for LAO provided material. These limitations were documented in a BW/IP Vendor Status Memo (VSM) dated February 12, 1990. BW/IP also performed a computer search of POs placed with M&N Metals, Incorporated (M&N), to determine any impact on material purchased. Although the results of BW/IP's review were not documented, BW/IP stated that the material supplied to them on the five POs identified was not affected. However, BW/IP deleted M&N from its AVL per a VSM dated February 12, 1990.

2.7 (Closed) Nonconformance 89-01-07

Contrary to Criterion XVI of Appendix B and Section 16, "Corrective Action," of the BW/IP NPQM, RCAs are not issued for conditions detrimental to quality for nonpressure boundary, non-ASME Code, safety-related items.

BW/IP revised Section 16-1 of its NPQM to clarify that RCAs are applicable to document deficiencies in non-ASME Code, safety-related items. Revision 1, to Section 16-1.2, now states that conditions adverse to quality shall be documented and corrected using RCAs.

2.8 (Closed) Nonconformance 89-01-08

Contrary to Criterion XVII, "Quality Assurance Records," of Appendix B and Section 17, "Control and Maintenance of Quality Records," of the BW/IP NPQM, an adequate system for quality record retention and retrieval did not exist.

BW/IP stated that although design calculations exist for all ASME Code pressure boundary parts, design calculations for other than pressure boundary parts were not required to be retained by Section 17 of BW/IP's NPQM in effect at the time. These calculations would have been performed by BW/IP at its Van

Nuys, California, plant prior to the transfer in 1985 of the valve product lines to the Vernon, California, plant. BW/IP's interpretation of Criterion XVII of Appendix B is that retention of design calculations is not a mandatory requirement since they are not specifically mentioned in the list of the types of records to be retained.

2.9 (Closed) Nonconformance 89-01-09

Contrary to Criterion XVIII, "Quality Assurance Records," of Appendix B, Engineering Change Notices and supporting engineering analyses were unavailable to support field changes of bolt torque specifications implemented as a result of two deficiency reports submitted by the TVA to the NRC, for a 6-inch and 12-inch motor operated gate valve installed at the Bellefonte and Watts Bar nuclear power plants.

BW/IP provided documentation of corrective actions which included a systematic review of other drawings which were generated in the same manner as the nonconformance, and a meeting held with designers, checkers and project engineers. As a result of the inspection team's review of this issue, this item is considered closed.

2.10 (Closed) Unresolved Item 89-01-10

Section 21.51, "Maintenance of Records," of 10 CFR Part 21 requires that records be maintained to assure compliance with the regulation. However, BW/IP was unable to produce records that documented evaluations for three occurrences that were reported to the NRC by licensees in 1981 and 1984. BW/IP stated that these records may be in storage.

BW/IP could not locate such records. Corrective action included revisions to its record keeping and retrieval system to prevent this problem from occurring in the future.

2.11 (Closed) Unresolved Item 89-01-11

BW/IP could not produce the Acceptance Test Procedure (ATP) results for the 3-inch and 4-inch check valves supplied to the CPSES which failed during hot functional testing. BW/IP stated that these records may be in storage.

BW/IP stated that records containing the relevant ATP results were available for review during the inspection. However, time did not permit the NRC inspection team to review such test results. Based on the statement from BW/IP that the documentation exists, this issue is considered closed.

2.12 (Closed) Unresolved Item 89-01-12

Documentation was not available during the 1989 inspection to support the procurement, qualification of suppliers, and the overall nuclear QA program in place at the Van Nuys plant, prior to 1986 for the swing check valve product line. BW/IP stated that these records may be in storage.

BW/IP could not produce the documentation and stated that based upon a number of pre-1986 NRC inspections of the Van Nuys plant records for its valve product line, it concluded that the Van Nuys plant was in compliance with NRC regulations in effect at the time.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

During the entrance meeting in Vernon, California, on December 6, 1993, the NRC inspection team met with members of the BW/IP staff and discussed the scope of the inspection, and established working interfaces. The inspection team observed activities, held discussions with BW/IP's staff, and reviewed records and procedures. The specific areas, documentation reviewed, and the team's findings are described in this report. The persons who participated in and who were contacted during the inspection are listed in Section 4 of this report. During the exit meeting on December 9, 1993, the inspection team summarized the inspection findings with BW/IP's management and staff.

3.2 Review of 10 CFR Part 21 Reports

To facilitate the review of actions performed by BW/IP in support of 10 CFR Part 21 notifications reported to the NRC, the NRC inspection team reviewed BW/IP Procedures L-A-16, "Product Defect Reporting In Compliance with 10 CFR Part 21 Requirements," dated March 9, 1990, and Policy and Procedure L-A-16, "Reporting of Defects and Failures to Comply in Nuclear Products and Services," dated July 29, 1992, (supersedes L-A-16, dated March 9, 1990), which implements 10 CFR Part 21. The procedures appeared adequate and if properly implemented should provide an effective means of complying with the regulation.

The following notifications, submitted to the NRC pursuant to 10 CFR Part 21, were reviewed during the inspection. The NRC inspection team's review consisted of a review of documentation contained in BW/IP's 10 CFR Part 21 Evaluation Board's files for each item, interviews with personnel, and an examination of representative records and procedures.

3.2.1 (Closed) NRC 92-008 and 92-096

On June 30, 1992, BW/IP notified the NRC of a reportable defect concerning the interchangeability of a swing arm (BW/IP Part Number 72543) for a 3-inch, 900 pound, swing check valve (BW/IP Model 75510). The incident was initially reported to BW/IP by TU Electric on January 16, 1992. The report stated that the swing arm was not completely interchangeable with the original part. An inspection of the part by BW/IP identified critical dimensions to be the same as the original part, except for the elongated stud hole provided for improved seating. BW/IP's evaluation also identified that under the most adverse tolerance stack-up conditions, the part demonstrated no interference with other valve internals. BW/IP concluded that the part was considered equivalent in form, fit, and function to the original part, and that no corrective action is necessary. The report stated that BW/IP would inform its customers of the potential interference by issuing a Technical Service Bulletin. In July 1992, BW/IP Tech Alert No. 9304-77-003 was issued to eight nuclear utilities potentially affected by this issue.

The Tech Alert stated that no immediate corrective actions are necessary based on the results of an interference study and on field experience of swing check valves of similar design. However, valves in systems subject to rapid flow reversal transients should be identified and evaluated on a case-by-case basis.

3.2.2 (Closed) NRC 92-112

On July 7, 1992, TU Electric submitted an interim report regarding backleakage discovered through auxiliary feedwater (AFW) system check valves at Unit 1 of the CPSES which was previously reported to the NRC on May 19, 1989. On December 21, 1989, TU Electric submitted Final Report (TXX-89849, SDAR CP-89-015) to the NRC for CPSES Unit 1. NRC 92-112 is an interim report which provides corrective action for commitments identified in TXX-89849 concerning Unit 2. Based on the actions taken in response to Unit 1 issues in 1989, including a 10 CFR Part 21 report and the issuance of a BW/IP Technical Service Alert, this issue is considered closed.

3.2.3 (Closed) NRC 93-025

On October 13, 1993, TU Electric notified the NRC of a reportable defect in an Interim Report pursuant to 10 CFR 50.55(e), concerning two manually operated 3-inch gate valves supplied by BW/IP in which the stems had separated from the disks and the disks remained tightly wedged in the seats. It was stated by TU Electric that the cause of the condition appeared to be a design error (oversized handwheels) combined with excessive force being applied during valve operation.

BW/IP stated that they were never notified by TU Electric of this potential design error. On December 11, 1993, TU Electric submitted a Final Report on the defect stating that it was determined that additional administrative controls will be implemented to prevent inadvertent damage during valve operation and additional operator awareness training would be conducted. No further mention was made of a design error by BW/IP.

3.2.4 (Closed) NRC 93-055 and 93-057

On February 12, 1993, BW/IP submitted a 10 CFR Part 21 Notification (CFRN-9301) to the NRC identifying a defect in a basic component which led to the failure of a BW/IP 4-inch, 150 pound, bolted bonnet swing check valve to fully close during pre-operational testing at the CPSES. The top of the disk was found to be lodged under the seat lip, thus preventing full closure. Another valve also located in the component cooling water return line subsequently failed testing in a similar manner. The root cause of the failures to close was due to the configuration of the attachment weld between the disk and the stud. Prior to 1977, this weld was placed on the back surface of the stud and extended into the bushing. In disks manufactured after 1977, the weld was recessed into the back surface of the disk and a final machine cut was made to assure a flush surface.

BW/IP stated that the notification applied to all BW/IP 4-inch, 150 pound, bolted bonnet swing check valves which have a raised disk-stud retention weld on the back surface of the disk and affected valves would require a new disk component or refurbishment of the existing disk.

BW/IP Policy and Procedure L-A-16, "Reporting of Defects and Failures to Comply in Nuclear Products and Services," effective date July 29, 1992, requires that BW/IP advise purchasers and licensees with like equipment which may be subject to the defect. Contrary to the above, BW/IP did not notify its other customers of this defect until November 30, 1993, almost 10 months after notifying the NRC. As a result, Part A of Nonconformance 93-01-02 was identified during this part of the inspection.

3.2.5 (Closed) NRC 93-071

On February 18, 1993, BW/IP submitted a 10 CFR Part 21 Notification (CFRN-9302) to the NRC identifying a defect in a basic component which led to the failure of a BW/IP 4-inch, 150 pound, bolted bonnet swing check valve to fully close during pre-operational testing at the CPSES. The valve was radiographed and the disk was found to be lodged in the full open position. Subsequent disassembly revealed four points of contact between the disk-swing arm assembly and the body. Failure to close is attributable to the internal body wall protrusions which result from the contact of the two machined bores perpendicular to the flow direction. BW/IP stated that the notification applied to all BW/IP 4, 6, 8, and 10-inch, 150 and 300 pound, bolted bonnet swing check valves which have a two piece forged body construction.

BW/IP further stated that installed valves should be inspected for evidence of disk-body contact at the protrusions and if contact is observed, protrusions should be removed and blended to the internal body contour. Design modifications will be implemented to assure proper operating clearances between the disk and the valve body for new valve applications.

As identified previously in NRC 93-055 and 93-057, BW/IP did not notify their other customers of this defect until November 30, 1993, almost 10 months after notifying the NRC. As a result, Part B of Nonconformance 93-01-02 was identified during this part of the inspection.

3.2.6 (Closed) NRC 93-111

On May 21, 1991, TU Electric submitted to the NRC a voluntary report (the event did not meet the reporting criteria of 10 CFR 50.73) due to interest resulting from previous experience with check valves in the AFW system at the CPSES. The report identified the failure of one of eight 4-inch, 900 pound pressure seal check valves in the AFW to meet acceptance criteria during reverse flow testing on April 18, 1991. TU Electric identified the root cause of the failure as a manufacturing error in the machining process of the valve body casting that allowed excess casting material to remain on the inside surface of the valve body. The affected check valve stuck open due to interference between the disk counterweight and a lip of the excess casting material on the valve body, allowing reverse flow in one branch of the AFW.

However, the counterweight was added in April 1990 as a design modification to the eight check valves. The TU report also stated under root cause that in an unmodified condition the valve would not have stuck open, and thus, the condition described should not be considered a generic problem for this model check valve in other applications. This is not considered a generic issue.

3.3 Raw Water Pump Impeller Liner Issue

During receiving inspection in June 1993 at the Fort Calhoun Station, Omaha Public Power District (OPPD) identified that the carbon content of impeller liners (castings) purchased from BW/IP were outside of the allowable range permitted by the material specification for ASTM A-487 Grade CA6NM Class A material. BW/IP Deviation Evaluation Summary Sheet CFR 93-009 documented that the impeller liners were supplied to BW/IP by Atlas Foundry (ATLAS) with a material certification that showed all four liners were from the same material heats and to be within specification for carbon content. Both an OPPD material analysis performed by an independent laboratory and an analysis performed by ATLAS confirmed an out-of-specification condition for the carbon content.

ATLAS' review of the situation determined that the out-of-specification condition was an isolated case and was caused by errors by both the furnace operator, who added five pounds of carbon to the melt instead of one-half pound, and the chemistry laboratory operator who misread the 0.29 carbon content as 0.029, as would be expected for CA6NM material.

In order to provide additional assurance that the above condition does not occur again, BW/IP revised the Procurement Specification for Safety Related CA6NM and WCB Castings, PS-1585, Revision A, on December 8, 1993, to include the requirement that hardness shall be reported on the CMTR for all castings. As a result, this issue is considered closed.

3.4 Undersized Fillet Weld Issue

On February 5, 1992, TU Electric informed the NRC that, while disassembling BW/IP check valves on Unit 2 of the CPSES, the clevis on each of two valves was inadvertently broken. The TU Electric engineering review conducted as part of the repair work package identified that the fillet weld holding the clevis to the valve bonnet was approximately one eighth-inch in width, in accordance with BW/IP fabrication drawings.

However, the BW/IP seismic qualification report (Stress Report NSR 454KA1-1), which is generic for all BW/IP swing check valves, analyzed a one quarter-inch clevis-to-bonnet fillet weld attachment, with no credit taken for the capscrew connection. BW/IP stated that the clevis is attached to the bonnet by the capscrew, which is the main load path. In addition, a one eighth-inch fillet weld is placed around the clevis base. BW/IP fabrication drawings and shop practice is to use a one eighth-inch attachment weld. In January 1993, BW/IP reanalyzed the seismic analysis with a one eighth-inch weld as part of

Deviation Evaluation CFR 92-002, which was opened to evaluate the problem for customer notification and potential 10 CFR Part 21 reportability. The new analysis determined that the stresses for a one eighth-inch weld were within the allowable design stress limits without taking credit for the capscrew. The analysis also determined that, without the weld, the bolted connection alone was fully capable of supporting the entire load.

BW/IP valve engineering identified approximately 145 similar check valve installations that still exist that were analyzed with the one quarter-inch fillet weld and no credit for the bolt. Following the inspection, BW/IP provided to the NRC a Deviation Evaluation Summary Sheet (DESS), dated January 6, 1994, which closed the issue. The DESS stated that the weld is classified as a non-structural, non-pressure boundary attachment weld. The calculations show that the bolt (which was not considered in the original seismic analysis) is the primary load carrying component. Further calculations were performed of the bolt stresses under seismic loads ignoring the clevis to bonnet weld for different valve and bolt sizes. All results were well within the allowable stress limits by a significant margin. BW/IP corrective actions included notification to all customers by January 31, 1994. As a result, this issue is considered closed.

3.5 Material Procurement

BW/IP's AVL was reviewed and recent procurement documents from selected vendors on this list were examined to assess the effectiveness of quality assurance implementation in this area. As a result of this review, two nonconformances were identified.

1. On April 28, 1992, BW/IP issued PO V 407811 to Delta Centrifugal (DELTA) for a QL 3 ASTM A-743, CA 40F, TP 420 casting, 6.625-inch outside diameter, 2.250-inch inside diameter, 102-inch long for stock. The material was to be supplied in accordance with the BW/IP approved quality program description dated March 8, 1989. The PO also invoked BW/IP Specification PS 1535, Revision B, paragraphs 2.0, 3.3.3, and 3.3.4. BW/IP Quality Control accepted this material as meeting the PO requirements on June 17, 1992.

   The NRC inspection team's review of DELTA's CMTR indicated measured hardness level of 262 BHN. This value exceeds the maximum hardness limit of 255 BHN specified in paragraph 3.3.3 of the referenced BW/IP material specification. The acceptance of nonconforming material without adequate justification was identified as Nonconformance 93-01-03. Before the completion of this inspection, BW/IP executed a Nonconformance Report which provided an acceptable technical basis for acceptance of the nonconforming material.

2. On January 11, 1993, BW/IP issued PO V 413444 to Nova Machine Products Corporation (NOVA) for eight 0.750 inch-10 UNC studs meeting the requirements of ASME SA-193 Grade B6 and BW/IP Specification 1T-5461, paragraphs 3.3, 4.4, and 5. Paragraph 3.3 of this specification states that a certification of material is required for this part. It also states that this certification is normally a mill certificate reporting

the actual test values of chemical analysis and mechanical properties and certificate of heat treatment per the material specification.

Paragraph B of the PO requires that, if subtier suppliers not holding ASME QSCs are used, their quality system program revision and date and the name of the approving organization to whom the material is being supplied must appear on the subtier CMTR. Paragraph K of the PO requires the identification of the mill supplying the material.

A review of BW\IP's files for this material contained a certification from NOVA stating that the material was purchased from a qualified source and manufactured in accordance with NOVA's QSC. Although the NOVA certificate reported the material heat number and provided chemical analysis of the material, it did not identify the producing mill or provide information concerning the producing mill's quality system as required by the purchase documents. Acceptance of this material without adequate verification of conformance to the PO requirements was identified as Nonconformance 93-01-04.

Before the completion of this inspection, BW/IP contacted NOVA by telephone and obtained information showing that the material was obtained from H&D Steel Service Center (H&D) as SA-479, Type 410 steel. H&D, in turn, purchased the material from Slater Steel. Although this information indicated that H&D had been qualified by NOVA, there was no statement on the Slater Steel certification that their quality system program had been reviewed by H&D or by NOVA.

4 PERSONNEL CONTACTED

4.1 BW/IP, International, Inc.

*+ F. Costanzo, Manager of Engineering, Nuclear Products Operations (NPO)
*+ D. Gibson, Manager, NPO
* D. Koo, Manager, Valve Engineering
*+ D. McCourt, Manager, Manufacturing, NPO
*+ L. Fettis, Manager, Valve Operations
*+ D. Ham, Manager of Quality
*+ K. Probst, Supervisor, Quality Assurance Audits
J. Mieding, Manager of Engineering, Commercial Products Operations
*+ D. Lattimore, Supervisor, Quality Engineering
*+ K. Huber, Section Head, Special Projects
W. Klenner, Nuclear Valve Product Manager

U.S. Nuclear Regulatory Commission

* U. Potapovs, Chief, Reactive Inspection Section No. 1, Vendor Inspection Branch

+ Attended the entrance meeting
* Attended the exit meeting

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 10, 1994

Docket No. 99901263

Mr. Mark Mathias, General Manager
Consolidated Power Supply
3556 Mary Taylor Road
Birmingham, Alabama 35235

Dear Mr. Mathias:

SUBJECT: NOTICE OF NONCONFORMANCE
(NRC INSPECTION REPORT NO. 99901263/93-01)

This letter addresses the U. S. Nuclear Regulatory Commission (NRC) inspection of your facility at Birmingham, Alabama, conducted by Messrs. L. L. Campbell, D. H. Brewer, and D. G. Naujock of this office December 6 through 10, 1993, and the discussions of their findings with you and members of your staff at the conclusion of the inspection. The inspection was conducted to evaluate Consolidated Power Supply's (CPS's) quality program and its implementation in selected areas such as (1) control of purchased material and services, (2) material and traceability control, (3) training and inspection, and (4) commercial grade item dedication.

Areas examined during the NRC inspection and our findings are discussed in the enclosed inspection report. This inspection consisted of an examination of procedures and representative records, discussion and interviews with personnel, and observations by the inspectors.

Although no violations of Section 21.21, "Notification," of Title 10 of the Code of Federal Regulations (10 CFR) were identified during the inspection, the NRC inspectors found an error in CPS's notification to its customers for an out of calibration pressure gauge used for hydrostatic testing pressure boundary items. This error is identified as an open item and is discussed in detail in the enclosed inspection report. Please provide us a discussion on the actions taken by CPS to correct this error.

In addition, during the inspection it was found that the implementation of your quality assurance (QA) program failed to meet certain NRC requirements. Although CPS has prepared a procedure which addresses the essential elements of the commercial grade item dedication process, CPS failed to properly identify the necessary critical characteristics for ensuring that certain carbon steel fittings met specification requirements. The inspection also identified instances in which CPS failed to implement its QA manual requirements for the maintenance of calibration records and identifying acceptance criteria for calibration activities. The specific findings and reference to the pertinent requirements are identified in the enclosures of this letter.

Please provide us within 30 days from the date of this letter a written statement in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you can show good cause for us to do so.

The responses requested by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511. In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosed inspection report will be placed in the NRC Public Document Room.

If there are any questions concerning this inspection we will be pleased to discuss them with you.

Sincerely,

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 999001263/93-01

ENCLOSURE 1

NOTICE OF NONCONFORMANCE

Consolidated Power Supply
Birmingham, Alabama

Docket No.: 99901263/93-01

Based on the results of an NRC inspection conducted on December 6 through 10, 1993, it appears that certain of your activities were not conducted in accordance with NRC requirements.

A. Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, requires, in part, that measures shall be established to assure that purchased material conforms to procurement documents.

   Paragraph 3.6 of Section 3, "Order Processing," of the Consolidated Power Supply (CPS) Quality Assurance (QA) Manual, Third Edition, Revision 1, dated March 31, 1993, requires, in part, that applicable requirements necessary to meet the customer's purchase order shall be documented on appropriate documents.

   Contrary to the above, neither the Material Critical Characteristics Form No. 701/FIT-14-A216, Revision 0, dated January 22, 1993, for A-216 steel castings nor the sales order for Bechtel Constructors Purchase Order (PO) No. CEF-5658, dated January 29, 1993, for various A-216, Grade WCB, 2½ inch to 3 inch, steel cast flanges and reducers, identified adequate critical characteristics and verifications to ensure that the flanges and reducers being supplied met the customer's procurement document requirements (Nonconformance 99901263/93-01-01).

B. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 requires, in part, that activities affecting quality shall be accomplished in accordance with instructions, procedures, or drawings.

   Section 12, "Control of Measuring and Test Equipment," of the CPS QA Manual requires, in part, that calibration records will be maintained on file and will include information such as the procedure and its revision used and the signature of personnel performing the calibrations.

   Section 17, "Quality Assurance Records," of the CPS QA Manual requires, in part, that all records shall be reviewed for completeness and accuracy by the QA Department and be legible, reproducible, identifiable, and easily retrievable.

Contrary to the above, past calibration records for the CPS spectrometer were being stored on a computer diskette and were not easily retrievable due to the spectrometer's software program. Also, there was no documented evidence that these past calibrations had been reviewed and accepted by the QA Department (Nonconformance 99901263/93-01-02).

C. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 requires, in part, that activities affecting quality shall be accomplished in accordance with instructions, procedures, or drawings, and that these documents shall include appropriate acceptance criteria for determining that important activities have been satisfactorily accomplished.

Section 5, "Instructions, Procedures, and Drawings," of the CPS QA manual requires, in part, that all activities affecting quality are to be accomplished in accordance with written procedures and/or instructions that contain appropriate acceptance criteria when applicable.

Contrary to the above, CPS Procedure No. SP-202, Revision 6, dated October 6, 1993, failed to contain an acceptance criterion for the daily spectrometer standardization and limits on the analysis range for each element affected by the one point standardization method (Nonconformance 99901263/93-01-03).

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each nonconformance: (1) a description of steps that have been or will be taken to correct these items; (2) a description of steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 10th day of February, 1994.

ENCLOSURE 2

ORGANIZATION:	Consolidated Power Supply Birmingham, Alabama
REPORT NO.:	999001263/93-01
CORRESPONDENCE ADDRESS:	Mr. Mark Mathias General Manager Consolidated Power Supply 3556 Mary Taylor Road Birmingham, Alabama 35235
NUCLEAR INDUSTRY ACTIVITY:	Supplies pipe and steel products for use at commercial facilities and nuclear power plants
INSPECTION CONDUCTED:	December 6 through 10, 1993
INSPECTOR:	Larry L Campbell 1/31/94 Larry L. Campbell Date Reactive Inspection Section No. 1 Vendor Inspection Branch
OTHER INSPECTORS:	David H. Brewer, Reactor Engineer Donald G. Naujock, Materials Engineer
APPROVED:	Uldis Potapovs 2-1-94 Uldis Potapovs, Chief Date Reactive Inspection Section No. 1 Vendor Inspection Branch
INSPECTION BASIS:	10 CFR Part 21 and Appendix B to 10 CFR Part 50
INSPECTION SCOPE:	To review and evaluate the Consolidated Power Supply (CPS) quality assurance program and its implementation in selected areas such as (1) control of purchased material and services, (2) material and traceability control, (3) training and inspection, and (4) commercial grade item dedication.
PLANT SITE APPLICABILITY:	Browns Ferry (50-259, 50-260, 50-296) Brunswick (50-324, 50-325) Farley (50-348, 50-364) Indian Point, Unit 2 (50-247) Pilgrim (50-293) South Texas Project (50-498, 50-499) Turkey Point (50-250, 50-251) Other plants using CPS products

1. INSPECTION SUMMARY

1.1 Nonconformances

Contrary to Criterion VII of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50 and Section 3 of the Consolidated Power Supply (CPS) Quality Assurance (QA) Manual, the Material Critical Characteristics Form No. 701/FIT-14-216, Revision 0, dated January 23, 1993, and the Sales Order Form No. 6534424 for the supply of flanges and reducers in accordance with Bechtel Constructors Purchase Order (PO) No. CEF-5658, dated January 28, 1993, did not contain adequate measures to ensure that the material being supplied met the customer procurement document requirements (Nonconformance 99901263/93-01-01, see Section 3.4.1.1 of this report).

Contrary to Criterion V of Appendix B to 10 CFR Part 50 and Sections 12 and 17 of the CPS QA Manual, calibration records for the CPS spectrometer were being stored on computer diskettes, were not easily retrievable due to the software program, and offered no documented objective evidence that these calibrations had been reviewed and accepted by the CPS QA Department (Nonconformance 99901263/93-01-02, see Section 3.5.2.1 of this report).

Contrary to Criterion V of Appendix B to 10 CFR Part 50 and Section V of the CPS QA Manual. CPS Procedure No. SP-202 did not contain an acceptance criterion for the daily spectrometer standardization and set no limits on the analysis range for each element affected by the one-point standardization method (Nonconformance 99901263/93-01-03, see Section 3.5.2.2 of this report).

1.2 Open Item

CPS performed an incorrect analysis of the calibration results for a pressure gauge found to be out of calibration. This incorrect analysis resulted in an error in CPS's notification to its customers. The inaccuracy of the notification to CPS customers is considered an open item pending corrective action by CPS (Open Item 99901263/93-01-04, see Section 3.2.1.1 of this report).

2 STATUS OF PREVIOUS INSPECTION FINDINGS

This was the first inspection at CPS.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

In the entrance meeting on December 6, 1993, the NRC inspectors discussed the scope of the inspection and established interfaces with CPS management. During the exit meeting on December 10, 1993, the NRC inspectors discussed their findings and concerns with CPS management and other staff.

3.2 10 CFR Part 21

The NRC inspectors observed that CPS maintained the required 10 CFR Part 21 postings in three locations: the inspection area of the shop, the break room, and the testing laboratory. In the inspection area of the shop and the break room, Section 206 of the Energy Reorganization Act of 1974 was posted behind 10 CFR Part 21, so that it was not readily visible. When the NRC inspectors informed CPS of this, they immediately repositioned the Section 206 material so that it became readily visible.

CPS Procedure No. SP-601, "Identification, Evaluation and Reporting of Defects and Failure to Comply," Revision 4, dated October 6, 1993, was written to implement the provisions of 10 CFR Part 21. The NRC inspectors reviewed the procedure for compliance with the January 1, 1993, version of 10 CFR Part 21 and found no discrepancies.

3.2.1 Implementation of the CPS 10 CFR Part 21 Procedure

CPS Procedure No. SP-405, "Nonconformances," Revision 2, dated October 14, 1992, provides instructions for processing defects and failures to comply. The quality assurance manager is responsible for implementing the procedure and receiving reports. All nonconforming material is described in a nonconformance report (NCR) that is assigned a unique number. An NCR Log is maintained to track nonconforming material. A space on the NCR form is used for stating whether or not the nonconformance is reportable under the provisions of 10 CFR Part 21.

Within the last two years, CPS has filed the following Part 21 reports with the NRC:

(1) calibration of a pressure gauge used to pressure test pipe and fittings which showed the gauge was beyond acceptable limits for indicating accurate pressure,

(2) square steel pipe obtained from a supplier which showed inadequate closure in the welded seam, and

(3) inadequate traceability for material obtained from a supplier for upgrade to ASME Code, Section III, NCA-3867.4(e).

3.2.1.1 Pressure Gauge

The NRC inspectors reviewed documentation for the nonconforming gauge and observed that this gauge and other gauges were being calibrated in a timely manner and that a use log had been maintained identifying products that had been accepted using the gauge. The Gauge Use Record showed that the products of six customers had been accepted by the nonconforming gauge since the last calibration. The six customers were notified of the discrepancy identified by the calibration activity. Responses were received from all U.S. customers noting plans for resolving the situation. One customer, Comision Federal de

Electricidad, of Mexico, did not respond. CPS stated that the nonconforming gauge had been removed from service.

The nonconforming gauge had a range of 0 to 5000 pounds per square inch (psi). Calibration was performed at 1000-psi intervals from 0 to 5000 psi. The official calibration record showed that at 0 psi the gauge showed below 0 psi and at each of the pressures checked, the gauge showed from 150 to 200 psi lower than the standard. For example, when the standard was set to 2000 psi, the gauge indicated 1850 psi. The NRC inspectors observed that CPS had notified its customers that pressure testing of pipe and fittings was lower than the required pressure. The NRC inspectors noted that this was an incorrect analysis of the calibration report. If the gauge read 1850 psi when the actual pressure was 2000 psi, and the gauge was pressurized to 2000 psi, actual pressure would be 2150 psi. This means that the pressure used to test products was higher than indicated rather than lower. The inaccuracy of the notification to CPS customers is considered an open item pending corrective action by CPS (Open Item 99901263/93-01-04).

3.2.1.2 Steel Tubing

CPS obtained the defective 4 inch by 4 inch by 1/2 inch wall, A-500, Grade B, square structural steel tubing from the material manufacturer, UNR-Leavitt, Chicago, Illinois, and supplied the steel tubing to Bechtel Constructors for use at the Tennessee Valley Authority (TVA) Browns Ferry Nuclear Plant. During fabrication activity at Browns Ferry, a defective seam weld was observed in two pieces of tubing cut from the same length. CPS stated that UNR-Leavitt had performed root-cause analysis and taken corrective action. The NRC inspectors reviewed the CPS Part 21 file and found it contained a copy of the UNR-Leavitt root cause analysis and corrective action report. The NRC inspectors considered the corrective action adequate.

3.2.1.3 Improperly Upgraded Code Material

The NRC inspectors evaluated CPS's actions for the improperly upgraded American Society of Mechanical Engineers (ASME) Section III Code material. CPS procured one 24 inch flange, SA-182, Type 316L, from Texas Metal Works (TMW) and one test bar from TMW invoking the TMW quality program for traceability of the material within the TMW facility. The material was "upgraded" by CPS in accordance with the requirements of NCA-3867.4(e) and delivered to Connex Pipe Systems (Connex), Marietta, Ohio.

The initial concern for traceability was identified during a survey conducted by the ASME at CPS, October 12-14, 1992. The ASME auditor questioned the CPS upgrade process because the TMW certification stated that tests had been performed on material from the same heat but not from the same piece from which the flange had been produced. CPS performed a source surveillance at TMW on October 16-17, 1992, and verified that the material supplied to Connex had not come from a piece of material that had been tested by either TMW or CPS. Therefore, the flange supplied to Connex by CPS could not be properly upgraded according to the requirements of ASME Code, Section III, NCA-3867.4(e).

CPS initiated an evaluation to determine what other materials may have been supplied from TMW through CPS without acceptable ASME Code upgrade. Eleven orders were identified for review. CPS determined that two had used the same starting piece for testing and the production of parts, however nine orders had been improperly upgraded. CPS notified the customers affected by the nine orders that ASME Code certification for the affected materials had been withdrawn. CPS has determined that TMW is unwilling to perform the activities necessary to provide adequate traceability for ASME Code, Section III, NCA-3867.4(e), upgrade. CPS personnel stated that TMW has been removed from the CPS Approved Vendors List.

3.2.2 CPS Procurement Documents

The NRC inspectors examined the CPS Approved Vendor List for companies that provided calibration and nondestructive evaluation services. Seven companies provided these services to CPS. Three of these companies were selected for review to determine that purchase orders placed by CPS incorporated the requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B. In each case, the NRC inspectors found the requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B, had been incorporated in the purchase order, either directly in the PO's text or by reference to the company's QA manual.

Among the POs reviewed were those to SATEC Materials Testing Equipment for the calibration of the tensile testing machine; Laboratory Testing, Inc. for nondestructive examination (NDE) services (ultrasonic testing on the specific order reviewed); and Gage Lab Corp. for calibration services. The Approved Vendor List itemized the revision and date of the quality assurance manual to which each company was audited, the date of the most recent audit, and the expiration date of approval. The NRC inspectors observed that all audits were current.

3.3 <u>CPS Commercial Grade Dedication Program</u>

3.3.1 Methodology

The requirements for CPS's dedication process are prescribed in Procedure No. SP-701, Revision 3, dated January 9, 1992. The NRC inspectors reviewed Procedure No. SP-701 and several other procedures controlling CPS's dedication activities such as (1) processing incoming orders, (2) receiving inspection, (3) laboratory testing, (4) audits and surveys, and (5) quality control inspector training and certification. The implementation of CPS's dedication process was also reviewed and is discussed in Section 3.4 of this report.

Incoming customer purchase orders (POs) are initially reviewed by the Sales Department and a sales order is generated. The sales order includes a description of the material to be supplied, instructions for processing the material, and the appropriate quality level (QL) for the material being supplied. If a customer's PO is for several items having different QLs, a separate sales order is used for each QL.

CPS has assigned the QL-3 designation for items purchased as commercial grade that are to be dedicated for safety-related applications. Procedure

No. SP-701 requires that critical characteristics for an item to be dedicated be determined by a person who holds an engineering degree and who is familiar with the item, and be documented on CPS Form No. 701. A Form No. 701 is not prepared for each sales order, but is prepared for specific types and, in some instances, specific sizes of material (e.g., 4 inch and smaller A-105 carbon steel socket weld fittings or A-36 carbon steel angle). The completed Form No. 701 is reviewed by the QA Manager.

Before releasing the sales order for processing, the QA department reviews it to ensure that adequate instructions have been given, including the verification of critical characteristics identified on the applicable Form No. 701. Also, when a supplier is being used to control and verify a quality-related activity, the QA review ensures that the supplier has been audited or surveyed and approved for performing the activity.

3.3.2 Dedication Program Weaknesses

The NRC inspectors reviewed CPS's QA Manual, Third Edition, Revision 1, dated March 31, 1993, and determined that it failed to identify responsibilities and controls for the commercial grade dedication process. Although the title of Section 9, "Upgrade of Stock Material and Dedication of Commercial Grade Items," implies that its scope includes the dedication process, this section only requires that a procedure be developed to describe the dedication process. CPS informed the NRC inspectors that a revision to its QA manual, effective January 2, 1994, identifies a new position in CPS's organizational structure, a quality engineer, responsible for evaluating and documenting critical characteristics of material for the CPS commercial grade dedication program.

The NRC inspectors concluded that Procedure No. SP-701 addresses the essential elements of the dedication process and that sufficient guidance for performing activities such as inspection and testing are given in other procedures and instructions. Although the NRC inspectors determined that, in general, the CPS dedication process was adequate, the following program weaknesses appear to have contributed to the one unacceptable dedication package reviewed by the NRC inspectors (see Nonconformance 99901263/93-01-01 in Section 3.4.1 of this report):

(1) Procedure No. SP-701 does not contain requirements or guidance for selecting critical characteristics.

(2) The bases for not verifying certain material specification requirements (considered to be critical characteristics) are not required to be documented on the Material Critical Characteristics Form No. 701.

(3) Laboratory test results are accepted as meeting the material specification requirements without questioning what effects these results have on other material specification requirements not verified during the dedication process. This is of concern when the other material requirements, not verified, are considered critical characteristics or when there are questionable differences between the CPS test results and the test results provided by the material supplier.

(4) The NRC inspectors questioned CPS's practice of including unvalidated supplier material certifications (stamped "QA Accepted" during the initial screening of incoming commercial grade items) in documentation packages supplied to customers when confirmatory material property overchecks clearly show that the supplier certification was questionable (see Section 3.4.1.1 of this report).

(5) The NRC inspectors expressed a concern that CPS does not appear to be documenting abnormal laboratory conditions that could potentially impact test laboratory results (see Section 3.5.4 of this report).

CPS informed the NRC inspectors that in response to a November 18, 1993, letter to CPS (Mr. Steven W. Andrews, Quality Assurance Manager) from NRC (Leif J. Norrholm, Chief, Vendor Inspection Branch), "Request for Interpretation on Commercial Grade Dedication Practices," in which the NRC responded to several dedication questions, CPS will be revising its dedication program.

3.3.3 Dedication Program Strengths

The NRC inspectors considered the following to be strengths in CPS's dedication program:

(1) Strong management support and involvement in establishing a commercial grade dedication program consistent with recent NRC correspondence to CPS.

(2) CPS test laboratory capabilities for verifying material critical characteristics includes equipment such as the Baird spectrometer, a nitrogen analyzer, a Baldwin tensile machine, and various types of hardness testers. The CPS lab is outfitted with rebuilt equipment that utilizes computer enhancements and new equipment that utilizes the latest improvements associated with proven technology. CPS management is responsive to the needs of the lab. The lab technician has received special training from the suppliers of the lab equipment. The lab is involved in round-robin chemical testing programs which helps CPS evaluate its lab's performance.

(3) CPS personnel performing testing, inspection, and document review activities were knowledgeable about their work and had a positive attitude.

(4) Limited-scope audits and surveys were used to support dedications.

(5) Initial screening of commercial grade material using material test reports submitted by the commercial suppliers (these test reports were not considered to be valid and were not used to verify critical characteristics; however these reports, along with receiving inspections, were used to screen potentially unacceptable material before subjecting the material to laboratory testing).

(6) CPS performed some type of test(s) on each QL-3 piece of material being dedicated.

3.4 CPS Commercial Grade Dedication Program Implementation

The NRC inspectors reviewed several in-process and completed QL-3 commercial grade material dedication sales order packages to determine if the critical characteristics for materials had been properly identified and verified, and if adequate procedural controls were in place. The NRC inspectors also observed in-process inspection and testing activities, test equipment calibrations, and processing of sales orders for QL-3 materials.

3.4.1 QL-3 Sales Order Packages

The NRC inspectors reviewed the following completed QL-3 sales orders.

3.4.1.1 1993 Completed Order Packages

1. Sales Order No. 6537637 for the supply of one piece of 48-inch-wide by 96-inch-long by 1/2-inch-thick, A-240, Type 316L, plate in accordance with Carolina Power & Light PO No. 7J2390CH, dated August 8, 1993, to the Brunswick Nuclear Plant. CPS tested a sample and confirmed that the following material critical characteristics met specification requirements: (1) yield and ultimate strength, (2) chemistry (including nitrogen), (3) elongation, and (4) hardness.

2. Sales Order No. 6535197 for the supply of 2 1/2 inch diameter by 11 to 13 foot, A-479, Type 316, round bar in accordance with Florida Power & Light Company PO No. C93677-90332, dated March 31, 1993, to the Turkey Point Nuclear Plant. CPS tested a sample and confirmed that the following material critical characteristics met specification requirements: (1) yield and ultimate strength, (2) chemistry (including nitrogen), (3) elongation, and (4) reduction of area.

3. Sales Order No. 6535751 for the supply of one piece of 1 inch by 4 foot by 8 foot, A-36 carbon steel plate in accordance with Boston Edison Company PO No. STR129269, dated June 2, 1993, to the Pilgrim Nuclear Station. CPS tested a sample and confirmed that the following material critical characteristics met specification requirements: (1) yield and ultimate strength, (2) chemistry, (3) elongation, and (4) reduction of area.

4. Sales Order No.6534424 for the supply of several 2 1/2 inch and 3 inch, A-216, Grade WCB, flanged fittings in accordance with Bechtel Constructors PO No. CEF 5658, dated January 13, 1993, to the Consolidated Edison Company's Indian Point Nuclear Plant, Unit No. 2. CPS purchased these fittings, with flange bolt holes undrilled, from Glover Machine Works (Glover), an unapproved vendor. The fittings were sent to Jordan Machine Company (Jordan), an approved supplier for machining and traceability of material for machining services. Jordan machined the bolt holes for each flanged fitting and bagged the machined

filings, identified each bag so that it was traceable to the machined fitting, and sent the machined flanged fitting and bags of machined filings to CPS.

For each bag of machined filings received, CPS cleaned the machined filings, melted them into a test specimen, and tested the chemistry of each specimen to confirm that the chemistry requirements of Material Specification A-216 were met. CPS did not perform hardness checks or other tests to confirm the physical properties of the fittings.

The NRC inspectors discussed the dedication of the fittings with CPS, and determined that the Material Critical Characteristics Form No. 701/FIT-14-A216, "Carbon Steel Castings, Suitable for Fusion Welding-High Temperature Service, Specification A-216," did not identify adequate critical characteristics to ensure that the fittings met the requirements of Specification A-216. The NRC inspectors also expressed a concern to CPS on the use of chemistry testing to accept the physical properties of the fittings.

The following is a listing of certain chemical elements for selected A-216 fittings (supplied in accordance with Bechtel Constructors PO No. CEF-5658) obtained by the CPS test laboratory and compared to Glover's test report and the A-216 specification requirements:

Element	A-216 Specification Requirement (w/o)*	Glover Material Test Report (w/o)*	CPS Material Test Report (w/o)*
Carbon (C)	0.30 maximum	0.23 to 0.27	0.069, 0.095 0.101, 0.130 0.199, etc.
Manganese (Mn)	1.0 maximum	0.62 to 0.68	0.554, 0.633 0.561, 0.655 0.698, etc.
Silicon (Si)	0.60 maximum	0.27 to 0.58	0.208, 0.277 0.435, 0.288 0.315, etc.
Phosphorus (P)	0.04 maximum	0.007 to 0.011	0.0186, 0.0193 0.0174, 0.0185 0.0202, etc.
Sulfur (S)	0.045 maximum	0.016 to 0.021	0.0277, 0.0258 0.0192, 0.0262 0.0275, etc.

* Weight percent

The NRC inspectors also discussed the acceptance of the CPS chemistry test results with CPS QA personnel and determined that acceptance of the results was based on <u>not exceeding the maximum percent of the element identified in Specification A-216</u>. The NRC inspectors were informed by the CPS QA manager that neither an evaluation to assess the impact of the reported chemistry on the materials physical properties nor a comparison of the CPS test results to the supplied vendor test report was required. The NRC inspectors discussed the results of the chemistry analysis with CPS including the acceptance of the material physical properties based only on verifying the material chemistry. The NRC inspectors identified several material specifications, other than A-216, having chemistry requirements enveloping the CPS identified chemistry. The NRC inspectors further identified that several of these specifications permitted the material to have less tensile strength than that required by the A-216 specification.

Although CPS did not take credit for the Glover Certified Material Test Report (CMTR), based o significant descrepancies between the chemical compositions stated in the Glover CMTR and those obtained by CPS (e. g., carbon), it appears that the CMTR supplied by Glover was not for the A-216 fittings received by CPS. This is based on the assumption that Jordan, an approved supplier, maintained traceability of the machined filings. The certification from Glover, used for the initial screening of the incoming commercial grade material, was reviewed and accepted by CPS QA. The certification from Glover and CPS test laboratory results were both included in the documentation package supplied to CPS's customer.

The NRC inspectors determined that there are no requirements in CPS's dedication program for comparing and evaluating CPS's test results to the vendor-supplied test reports, and for identifying questionable vendor test reports when they are being supplied to a customer. The NRC inspectors reviewed several documentation packages for dedicated material forwarded by CPS to its customers and determined that the certification used for the initial screening was included in these packages. The NRC inspectors questioned CPS's practice of including the unvalidated supplier certification (stamped "QA Accepted" during the initial commercial grade material screening process) in the documentation packages supplied to customers when confirmatory material property overchecks by CPS clearly show that the supplier certification was questionable. The NRC inspectors considered this an area needing improvement. When documentation provided by a supplier is questionable, such documentation should be identified as questionable when it is being supplied to a customer.

The NRC inspectors considered the dedication of these fittings to be a nonconformance because the critical characteristics identified and the verification methods did not provide reasonable assurance that the flanges and reducers supplied met the customer's procurement document requirements (Nonconformance 99901263/93-01-01).

3.4.1.2 In-process Sales Order Packages

1. Sales Order No. 6538718 for the supply of 12-inch-wide by 20-foot-long by 1/4-inch-thick, A-36 flat bar in accordance with Houston Power & Light PO No. QS003624, dated December 1, 1993, to the South Texas Project Electric Generating Station. CPS tested a sample and confirmed that the following material critical characteristics met specification requirements: (1) yield and ultimate strength, (2) chemistry, (3) elongation, and (4) reduction of area. CPS then shipped the material to Metalplate Galvanizing Inc., a CPS-qualified source, for galvanizing in accordance with CPS PO No. Z65-38314, Revision 0, dated December 2, 1993. The NRC inspectors observed the tensile and chemical testing of this material (see Section 3.5.3 of this report).

2. Sales Order No. 6538800 for the supply of Number 22-gage, 4-foot-wide by 10-foot-long, A-527 galvanized sheet steel in accordance with Alabama Power Company PO No. QP931738, dated November 23, 1993, to the Farley Nuclear Plant. The NRC inspectors observed the processing of this sales order and the QA review before its release for work. In addition to identifying the need for chemical and physical testing, the sales order identified a requirement for CPS source inspection to witness the cutting of the test sample and for establishing material traceability.

3.5 <u>Testing Laboratory</u>

CPS has the capabilities of performing in-house dimensional checks, mechanical tests, and chemical analysis. Tests not performed in-house are performed by qualified testing facilities.

3.5.1 Calibration

The NRC inspectors reviewed current and historical calibration records for: (1) a Baldwin universal tensile testing machine and extensiometers, (2) two Wilson hardness testers, (3) a Clark portable hardness tester, and (4) a Baird DV-4 spectrometer. The calibration records were reviewed for frequency of calibration and for compliance to the requirements of CPS Procedure No. SP-202, "Calibration and Maintenance of Measuring and Test Equipment," Revision 6, dated October 6, 1993.

3.5.2 Spectrometer Calibration

The Baird DV-4 spectrometer, CPS QA Identification (ID) No. 55, Serial Number (S/N) 1487, was calibrated annually in accordance with CPS Procedure No. SP-703, "Chemistry Testing," Revision 5, dated October 6, 1993, and consisted of two steps. The first step is the creation of a curve-set by developing curves for each element (a curve-set is a family of individual curves). The curve is a plot of light intensity emitted from a spark and the certified chemical concentration from purchased standards. The plot starts at zero and rises steadily up and to the right with increasing chemical concentrations. The second step is the standardization of the curve-set.

3.5.2.1 Curve-Set Calibration

The NRC inspectors reviewed the current carbon (C) and manganese (Mn) calibration curves and found that the Mn curve was not traceable to the National Institute of Standards and Technology (NIST) standards as required by Section 12.3 of the CPS QA manual. Further investigation by the NRC inspectors revealed that the NIST standards were part of the data base used to generate the original curve, but their relationships to the curves were not documented and traceable to NIST. CPS demonstrated to the NRC inspectors that the Mn curve was traceable to NIST standards by reconstructing the exact curve, which included the relative locations of selected NIST standards with respect to the curve. The Mn curve was printed, dated, and filed for future reference.

CPS informed the NRC inspectors that it assigns each curve-set a unique name, and that the computer software program requires changing the curve-set name when a change is made in the curve-set. Hard copies of curve-sets and changes to the curve-sets were not readily available for review by the NRC inspectors. CPS reviewed historical data that was stored on computer floppy diskettes in order to determine the date that a curve-set was installed in the computer. Each entry reviewed listed the curve-set name along with the average chemical analysis. By reviewing all entries stored on the diskettes, CPS was able to identify when the curve-sets were changed for the "low carbon and alloy steel" systems. CPS determined that changes were made to the curve-sets on February 7, 1991; April 17, 1992; and October 12, 1993, and recreated the curve-sets. The NRC inspectors considered the calibration records to be a nonconformance because calibration records for the CPS spectrometer were being stored on computer diskettes, were not easily retrievable due to the software program, and offered no documented objective evidence that these calibrations had been reviewed and accepted by the CPS QA Department (Nonconformance 99901263/93-01-02).

CPS informed the NRC inspectors that it would review the historical data, make copies of the curve-sets used with the different alloy systems, and date each curve in the curve-sets. During the conduct of the inspection, CPS prepared Nonconformance Report No. 93-212 and Corrective Action Request No. I93-33, both dated December 10, 1993, to document the unavailable spectrometer calibration records.

3.5.2.2 Curve-Set Standardization

The NRC inspectors and CPS discussed the standardization of curve-sets. The stored curve-sets are sensitive to atmospheric effects, equipment wear, and equipment cleanliness. In order to maintain a high level of accuracy, repeatability, and reproducibility, CPS repositions the curve-sets each day before their use or more frequently if necessary.

The repositioning of a curve-set is called "standardization" (STDZ). The most common type of STDZ is two-point STDZ. Two-point STDZ is accomplished by sparking standards that contain high and low chemical values of each element and locking the curves on these values. When the approximate chemical analysis of a test sample is known, a standard of similar chemical composition can be used to lock the curve-set at that point. Locking the curve-set on a chemical composition is called one-point STDZ.

CPS uses a checklist in the STDZ procedure and files the checklist along with the proof of accuracy as a QA record. The proof of accuracy consists of sparking a NIST standard on the spectrometer and comparing the chemical analysis with the standard deviations printed on the certified material test report (CMTR) for that NIST standard. CPS informed the NRC inspectors that although its acceptance criterion is not proceduralized, the acceptance criterion for elements, which routinely exceed the standard deviations for a particular NIST standard, would be a 2-percent maximum deviation. The NRC inspectors reviewed selected files back to July 7, 1992, and found that the verbally stated acceptance criterion for STDZ was followed. The absence of this acceptance criterion and its potential effect on test results is further discussed in Section 3.5.3 of this report. The NRC inspectors considered the absence of an acceptance criterion to be a nonconformance because CPS Procedure No. SP-202 did not contain an acceptance criterion for the daily spectrometer standardization and set no limits on the analysis range for each element affected by the one-point standardization method (Nonconformance 99901263/93-01-03).

3.5.3 Tensile and Chemical Testing

The NRC inspector observed the tensile and chemical testing of a sample taken from a 12-inch-wide by 20-foot-long by 1/4 inch thick, A-36 flat bar (see Item 2, Section 3.4.1.2 of this report). From the test sample, CPS machined a longitudinal tensile test and cut a chemical test. Both tests were assigned Lab No 93-1893. The tensile test was pulled on the Baldwin tensile machine, QA ID No. 21, in accordance with CPS Procedure No. SP-706, "Tensile Testing," Revision 2, dated October 6, 1993. The results were calculated with the aid of the M-TEST software package from Advance Machine Technology, Inc.

Before running the chemical test, the spectrometer was STDZ using two-point STDZ and checked against NIST Standard No. 1763 for proof of accuracy. The Mn result was 1.44 percent, which was below the certified value of 1.58 percent. CPS moved the Mn curve to the certified value using one-point STDZ. A recheck with NIST Standard No. 1763 verified that the curve was reading correctly with a Mn value of 1.589 percent. Lab Sample No. 93-1893 was tested and recorded a Mn value of 0.65 percent. Because the value for Lab Sample No. 93-1893 was well below the one-point STDZ value, the Mn curve was checked using NIST Standard 1761. NIST Standard No. 1761 produced a Mn value of 0.80 percent, well above the certified Mn value of 0.678 percent.

The NRC inspectors observed that the CPS lab technician recognized that a problem existed with the Mn curve, but did not have procedures or training to resolve it. The lab technician consulted with technical representatives from Baird Company and discovered that the STDZ Mn curve was approximately 0.10 percent above the certified Mn value for NIST Standard No.1763. CPS determined that using the one-point STDZ, the entered Mn curve was shifted proportionally to the certified value of 1.58 percent. The shifted Mn curve gave correct values at 1.58 percent, but gave higher values for Mn with lower chemical concentrations, and that the further from the one-point STDZ value of 1.589 percent, the greater the error. The large error detected between Lab Sample No. 93-1893 and NIST Standard No. 1761 illustrates the importance of having an acceptance criterion for chemical ranges when using one-point STDZ. The absence of this acceptance criterion is addressed in Section 3.5.2.2 of this report (Nonconformance 99901263/93-01-03).

After restandardization of the spectrometer, CPS retested Lab Sample No. 93-1893 and determined that it met the requirements of A-36 and certified by CPS to the values in the following table. A comparison sample was sent to an independent lab, NIMS Company, for chemical analysis. The chemical analysis from NIMS Company, a qualified source for CPS, verified the results obtained by CPS. The results of the various chemistry testing follow.

Mid-America Steel's CMTR Data, CPS Test and Comparison Test

C w/o*	Mn w/o*	P w/o*	S w/o*	Tensile ksi	Yield ksi	Elongation (percent)	Remarks
0.25	0.70	0.009	0.004	70.4	51.9	27.5	From Mid America CMTR
0.17	0.52	0.013	0.012	64.0	45.0	29.0	CPS verification tests (elongation in 2-inches Lab No. 93-1893)
0.16	0.49	0.010	0.009				NIMS verification analysis

* Weight Percent

CPS used the test report results from Mid America for the initial screening of the commercial grade purchased plate. CPS's test results showed that the plate met the requirements of A-36.

3.5.3.1 CPS Material Test Report

The NRC inspectors reviewed the CPS test report for the Lab Sample No. 93-1893 chemical and physical tests, and determined that the test equipment was not identified on the test report as is required by Paragraph 11.7 of Section 11, "Test Control," of the CPS QA Manual. CPS informed the NRC inspectors that it had revised the test report form on October 10, 1993, and eliminated the requirement to enter the test equipment ID number on the form. CPS informed the inspectors that its QA manual had been revised and, effective January 2, 1994, Section 11 of the QA Manual would not require that test equipment be identified on the test report, but that all test reports shall identify and/or be traceable to the equipment used. Although this statement resolves the NRC inspectors' concern that the test equipment is not identified on the CPS test report, the NRC inspectors found that the hardness test reports are not easily traceable to the hardness testing equipment. After hardness readings are taken, they are recorded on Form No. 709B, "Rockwell Hardness Sample Result Log." Form No. 709B, at present, does not identify which of the three hardness testers were used for a particular entry. CPS was able to demonstrate to the NRC inspectors a method for matching the entries with the associated hardness testers. CPS informed the NRC inspectors that a column would be added to Form No. 709B for entering the test equipment ID number.

3.5.4 Abnormal Laboratory Conditions

The NRC inspectors determined that CPS does not maintain historical data on abnormal laboratory conditions that can have an effect on test results. For example, when the NRC inspection team arrived at CPS on December 6, 1993, one phase of electricity was not connected to the facility. Of the two remaining phases, one phase was supplying power to the spectrometer, but not to the lab computers. The effect of the power outage was a temporary loss of color to the cathode-ray tubes attached to the lab computer. The NRC inspectors, through discussions with CPS, identified another example when the CPS test laboratory experienced difficulties standardizing the spectrometer. The cause for the difficulties was identified as contaminated argon. By replacing the argon with a higher purity argon, the difficulties were resolved. Since the problem occurred suddenly and was detected during STDZ, CPS surmised that the contaminated argon did not affect test results. The NRC inspectors expressed a concern that, in the future, either of the conditions discussed could potentially impact test laboratory results, and CPS should document and evaluate the abnormal conditions. The NRC inspectors and CPS discussed that one method available for documenting and evaluating the effects of abnormal laboratory conditions is the use of the CPS nonconformance process, however the NRC inspectors agreed that this is not the only acceptable method to evaluate abnormal laboratory conditions.

3.6 CPS Inspector Certification Process

The NRC inspectors reviewed the CPS QA program for inspector training. CPS maintains three procedures relating to training, qualification, and certification of inspection and audit personnel: Procedure No. SP-501, "Qualification and Certification of Lead Audit Personnel," Revision 1, dated January 9, 1992; Procedure No. SP-502, "Indoctrination and Training," Revision 1, dated January 9, 1992; and Procedure No. SP-503, "Qualification and Certification of Inspection Personnel," Revision 1, dated January 9, 1992. In all cases, the QA Manager was responsible for establishing qualification requirements and documenting the completion of those requirements.

Procedure No. SP-503 defined four levels of inspection personnel: (1) Inspector in Training and (2) Level I, (3) Level II, and (4) Level III. General requirements for qualification at each level were well defined, but the NRC inspectors observed that requirements for inspection personnel to demonstrate their capabilities during the certification process (e.g., performance demonstration and/or written examination) were not well defined. The NRC inspectors reviewed documentation in the inspector training files indicating that the inspectors were adequately trained to perform their duties. However, the procedure could be strengthened by being more prescriptive in performance based requirements for the inspector certification process. The NRC inspectors considered this a weakness in the CPS inspector certification process.

4 PERSONNEL CONTACTED

Consolidated Power Supply Division (Consolidated Pipe and Supply Company, Inc.)

* * + Howard Kerr, President
* * + Mark Mathias, General Manager
* * + Steven Andrews, Quality Assurance Manager
* * + Carl Marr, Sales Manager
* Jeff Shaw, Regional Manager
* * Connie Zeitvagel, Sales Services/Operations Manager
* * + Charles Hayes, Quality Control Manager
* * Gary Parsons, Warehouse Manager
* * + Mark Woodard, Laboratory Supervisor
* * + Robert Stockton, Assistant Quality Assurance Manager
* * + Linda Hollon, Quality Assurance Representative
* * + Joe Robbins, Quality Assurance Representative
* * + Rachel Woods, Quality Assurance Representative
* * + Keith Kennedy, Quality Assurance Representative
* * Sandra Robbins, Quality Assurance Clerk
* * + Bryan Parnell, Quality Control Inspector
* * + Jeremy Smith, Quality Control Inspector

* Attended the Entrance Meeting
\+ Attended the Exit Meeting

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 21, 1994

Docket No. 99900786

Mr. R. Sheen, Manager
Distribution Components
GE Electrical Distribution and Control
41 Woodford Avenue
Plainville, Connecticut 06062

Dear Mr. Sheen:

SUBJECT: NRC INSPECTION REPORT NO. 99900786/93-01

This letter addresses the inspection at your facility in Plainville, Connecticut, conducted by Mssrs. K.R. Naidu and S.D. Alexander of this office on August 26-27, 1993, and the discussions of their findings with you and other members of your staff at the conclusion of the inspection.

The principal purpose of the inspection was to examine certain areas in the design, operation, manufacture, testing, and maintenance of electrical distribution components, specifically, RMS-9 type overcurrent trip devices, and certain molded case circuit breakers used in direct current applications. Areas examined during the inspection and our findings are discussed in the enclosed report. This inspection consisted of an examination of technical documentation, discussions with and presentations by GE personnel, and observations by the inspectors.

We recognize that the scope of your activities is limited to the manufacture and supply of commercial grade items as defined in Part 21 of Title 10 of the Code of Federal Regulations; although, insofar as your products are used in safety-related applications in NRC-licensed facilities, we have an interest in their suitability and reliability under the Atomic Energy Act of 1954, as amended, as well as the Energy Reorganization Act of 1974. Therefore, we appreciated your cooperation, and within the scope of this inspection, we found no instance in which NRC requirements had not been met.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosed inspection report will be placed in the NRC's Public Document Room. Should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosure: Inspection Report 9900786/93-01

Enclosure 1

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR INSPECTION AND LICENSEE PERFORMANCE

ORGANIZATION:	GE Electrical Distribution and Control (GE-ED&C) Plainville, Connecticut
REPORT NO.:	99900786/93-01
CORRESPONDENCE ADDRESS:	Electrical Distribution and Control 41 Woodford Avenue Plainville, Connecticut 06062
NUCLEAR INDUSTRY ACTIVITY:	Manufacturer and Supplier of Commercial Grade, Low-Voltage Distribution Equipment
INSPECTION CONDUCTED:	August 26-27, 1993 at GE-ED&C August 30-31, 1993 at Maine Yankee
ASSIGNED INSPECTOR:	for Gregory C Cwalina 1/11/94 Stephen D. Alexander, Date Reactive Inspection Section-2 (RIS-2) Vendor Inspection Branch (VIB)
OTHER INSPECTORS:	Kamalakar R. Naidu, RIS-2, VIB
APPROVED BY:	Gregory C Cwalina 1/11/94 Gregory C. Cwalina, Section Chief Date RIS-2, VIB
INSPECTION BASES	10 CFR Part 21, 10 CFR Part 50, Appendix B
INSPECTION SCOPE:	Obtain information on RMS-9 overcurrent trip devices, THMK, THJK, and TJJ molded-case circuit breakers, CR124 overload relays, and certain other issues
PLANT SITE APPLICABILITY:	Maine Yankee, Browns Ferry, Oconee, Point Beach, and all other plants utilizing RMS-9 trip devices, GE molded-case circuit breakers, CR124s, etc.

1 INSPECTION SUMMARY

1.1 Violations

No violations were identified during this inspection.

1.2 Nonconformances

No nonconformances were identified during this inspection.

1.3 Unresolved Items

No unresolved items were identified during this inspection.

1.4 Inspector Followup Items

1.4.1 (93-01-01) RMS-9 Tripping (see Section 2.1)
1.4.2 (93-01-02) RMS-9 Flux Shifter (see Section 2.2)
1.4.3 (93-01-03) THKM Molded-Case Circuit Breakers (see Section 2.3)
1.4.4 (93-01-04) CR124 Overload Relays (see Section 2.4)
1.4.5 (93-01-05) THJK and TJJ Molded-Case Circuit Breakers (see Section 2.5)

2 INSPECTION FINDINGS AND OTHER COMMENTS

The principal purpose of this inspection was to obtain information regarding the incidents of unwanted tripping of GE AK-type circuit breakers equipped with RMS-9 digital trip units at the Browns Ferry Nuclear Plant (Browns Ferry) and the Maine Yankee Atomic Power Station (Maine Yankee). Also discussed during this inspection were problems with resetting of RMS-9 flux shifter trip mechanisms, out-of-tolerance tripping of THMK-type molded case circuit breakers at Oconee, CR-124 relay problems, and THJK-type breaker problems at Point Beach. In addition, the inspectors learned of planned testing on a nonsafety-related 480-volt bus at Maine Yankee, with the assistance of GE Nuclear Energy (GE NE), intended to attempt to reproduce and analyze the transients that appear to have caused the RMS-9 trips. Immediately following the visit to GE-ED&C, the inspectors went to Maine Yankee to review the test plan, examine the test setup and observe the testing.

2.1 Undesirable Trips With RMS-9 Units

2.1.1 Background Licensees of several nuclear power plants have installed RMS-9 overcurrent trip units manufactured and distributed by GE Electrical Distribution and Control (ED&C). In many cases, the trip units were part of conversion kits to replace the electro-mechanical EC-type series overload trip units that were previously used in GE AK-type, low-voltage circuit breakers. Problems with unwanted tripping of these units include the following:

2.1.1.1 On August 4, 1993, the NRC was informed that Maine Yankee had experienced a condition that the licensee described as sympathetic tripping of two safety-related, RMS-9-equipped breakers on July 30, 1993, one of which was a load breaker (with longtime and instantaneous trip functions) and the other a motor control center (MCC) feeder breaker (with longtime-shorttime trips).

Both of the affected breakers were fed from the plant's delta-connected, 480-volt, engineered safeguards buses which are of an ungrounded design like those at Browns Ferry. The trips may have been initiated by current spikes caused by an intermittent ground fault on the boric acid makeup tank startup heaters, a nonsafety-related load on that bus; although the heater breaker did not trip. Also, the trips occurred during the process of ground isolation which may have created or contributed to transients on the buses. However, the transients were not sufficient to trip other RMS-9-equipped breakers, some of which, acting as Class 1E isolation devices, are meant to protect the safety-related buses from faults and overloads on nonsafety-related circuits. Because of the concern with common-mode fault initiators, the fact that many of these circuits are also not environmentally qualified is significant.

2.1.1.2 In October 1992, the Tennessee Valley Authority (TVA) reported to the NRC pursuant to Part 21 of Title 10 of the Code of Federal Regulations (10 CFR Part 21) (Log. No. 93-258) that the ungrounded, delta-connected, 480-volt distribution system at Browns Ferry had experienced short-duration, high-amplitude current transients (possibly high-frequency electrical noise spikes) that caused unwanted tripping of some GE AK-type circuit breakers fitted with GE RMS-9 solid-state digital trip units. These units have a low-pass filter (described by some as a "holdoff circuit") that is supposed to attenuate (and effectively exclude) most transients of this sort. However, TVA reported that testing of the trip units revealed that the instantaneous trip function of the trip unit would respond to current transients as short as 100 microseconds and trip the breaker when the peak amplitude of the current pulse or spike was sufficiently above the instantaneous trip setpoint of the RMS-9 unit. When a ground fault occurs intermittently, e.g., by means of insulation breakdown or flash over, in an ungrounded system, it can cause spikes of a type to which the RMS-9 can respond. TVA has also postulated that this disturbance may have caused the Browns Ferry breakers to trip. TVA also reported that it has been investigating with GE NE development of RMS-9 trip units that are less sensitive to such transients, but may be backfitting some AK breakers with EC-type series overload trip units in the interim.

The NRC is concerned that a common-mode initiator of ground faults such as a loss-of-coolant accident or high-energy line break could conceivably cause propagation of short-duration, high-current transients to multiple portions of an electrical distribution system which could result in spurious tripping of RMS-9-equipped breakers and the attendant loss of vital loads, possibly in more than one train.

2.1.2 Results of the inspection During the inspection, cognizant personnel representing GE ED&C and GE NE Power Delivery Services of King of Prussia, Pennsylvania, shared with the NRC inspectors the information that they had been able to obtain thus far from Maine Yankee and Browns Ferry. However, the cause of the unwanted tripping was not yet fully understood. GE NE personnel had agreed to assist Maine Yankee in performing tests on a nonsafety-related, 480-vac bus that was ungrounded and delta-connected, similar to the one on which the trips had occurred, to try to reproduce them and capture the characteristics of the transients to which some of the RMS-9 trip units had responded. On August 30-31, 1993, VIB inspectors observed Maine Yankee personnel perform electrical switching operations on a nonsafety-related 480-

volt bus after introducing a ground. These tests were intended to reproduce electrical transients that may have caused unwanted tripping of GE AK-type circuit breakers equipped with RMS-9 type digital overcurrent trip units. Unfortunately, the transients to which the RMS-9s had responded were not able to be reproduced, so the results were inconclusive. GE NE, ED&C, and TVA are considering conducting similar tests at Browns Ferry in the near future.

The tripping events at Maine Yankee also had some other unexplained aspects that suggest that the transients may not merely be interpreted by the RMS-9s as so-called "trippable events," but may also somehow affect the operation of the RMS-9s. Some of the units that tripped at Maine Yankee did not exhibit the popped-out "targets" or trip mode indicators that would have been expected under the circumstances. Certain proprietary features of the circuit design would be consistent with an instantaneous trip without its target popping out. However, ED&C was not able to explain why this occurred in a unit without an instantaneous trip function that tripped instead on its short-time function. This issue is designated Inspector Followup Item 93-01-01.

2.2 Problems RMS-9 Flux Shifters

On January 29, 1993, GE NE informed the NRC pursuant to the requirements of 10 CFR Part 21 (LOG No. 93-058) that the flux shifters (trip actuators) triggered by RMS-9 devices mounted on electrically-operated AK-25 and AKR-30S breakers were not resetting after tripping the breakers so that the breakers can be reclosed. During the refurbishing of two electrically-operated AK-25 type circuit breakers at GE's switchgear service shop in Hammond, Indiana, the technician observed that following a trip, the flux shifter did not reset. However, with a heavier spring, the flux shifter did reset following a trip. GE procured several heavier springs and distributed them to their service facilities but had not used them so far. A GE NE representative associated with the GE switchgear service shop in Philadelphia stated that in his experience, all the instances of flux shifters not resetting could be attributed to worn, dirty, and/or misaligned parts. ED&C also stated that this problem could occur (although it had not yet to their knowledge) on manually operated breakers of this type as well. However, they had not tested the heavier flux shifter springs on manually operated breakers. Breaker factory personnel in Bloomington, Illinois, were concerned that the heavier spring may detract excessively from the opening force margin. This is less than that of the electrically operated breakers because the manual breakers have slightly weaker operating springs. GE NE and ED&C advised that licensees who either have experienced problems with flux shifter resetting (or who are concerned that they might) should contact their GE NE field service representative to help address the problem. This issue is designated Inspector Followup Item 93-01-02.

2.3 Problems With Trip Units on THKM type Molded Case Circuit Breakers

On June 1, 1993, Duke Power Company (Duke) personnel informed the NRC that they had observed GE THKM-type molded-case circuit breakers at their Oconee Nuclear Station (Oconee) tripping below the manufacturer's published values. ED&C manufactures and distributes THKM type breakers and their accessories such as shunt or undervoltage trip units. According to Duke's information, Duke, Farwell and Hendricks (an organization in Cincinnati, Ohio, that performs dedication and qualification testing services), and the GE NE test facility in San Jose, California, tested the breakers and obtained results which were outside the tolerances published in GE's literature. Some of the breakers even tripped outside the field tolerances given in National Electrical Manufacturers Association (NEMA) Publication AB 4-1991.

The following breakers were tested:

Specimen 1: THKM 826 F000 equipped with M6 magnetic-only instantaneous trip adjustable from 2400 to 8000 amperes (A). GE publication GET-2779B, "Application and Selection Molded Case Circuit Breakers for Industrial and Commercial Requirements - 1969," indicates that these types of breakers should trip within ± 10% of the set point.

Specimen 2: THKM 826 F000 with a TKMA836T800 thermal magnetic trip unit. The time-current curves for these types of breakers, GE diagram GES-6111C, indicate that the breaker should trip between 5760A (90%) and 7200A (112.5%) when set on HI (6400A).

Specimen 3: THKM 1200 magnetic-only with a THKMA3TM612 trip unit. GET-2779B indicates that the trip unit is adjustable between 2400-8000A with ±10% tolerance.

	SPECIMEN 1 (set at 8000A)	SPECIMEN 2 (set at 6400A)	SPECIMEN 3 (set at 8000A)
Duke	62-85%	7¼-88¼%	49%-69%
Farwell & Hendricks		68.6-78.6%	
GE NE		75-92%	52-81%

The above data indicate that none of the breakers tested tripped within the minus-10% manufacturer's trip current tolerance. However, ED&C pointed out that the 10-percent tolerance is a design value meant to be applicable for installed breakers with all three phases loaded under plant service conditions. Nevertheless, some of the trips occurred outside the NEMA AB-4 recommended field test tolerances as well. Duke uses these breakers in applications where time versus current coordination is important, and any reduction in the instantaneous current trip point below the published values could result in an unwanted trip of these breakers which would be a safety concern if a Class 1E load was lost. The issue was discussed during the inspection in a conference call with Duke and was resolved to the point that Duke was to send to ED&C several of the MCCBs that either failed tests or were of the same lot, but had not yet been tested or installed so that they could be inspected and tested at ED&C. This issue is designated Inspector Followup Item 93-01-03.

2.4 CR124 Overload Relays-Temperature Compensation Problems

On April 2, 1991, GE NE issued a "Germane to Safety" (GTS) letter concerning GE CR124 Overload Relays (Tracked under Part 21 Log No. 91-033). The manufacturer, ED&C-Bloomington, had discovered that on relay models CR124K028, K128, L028, and L128, manufactured before October 1990, many of the ambient temperature compensating bimetal elements had been installed upside down due to a problem with marking of the elements. These overload relays are typically used in conjunction with starters or motor controllers, many of which may serve safety-related loads. The ambient temperature compensating bimetal element or spring is intended to adjust the trip forces inside the relay so that the trip time as a function of overload current is consistent with the design characteristic curves over a wide range of ambient temperatures at the relay. According to GE, the improperly installed ambient compensating bimetals will permit the overload relays to work correctly within a temperature range of 15-20°C (59-68°F). However, at low or high ambient temperatures such as 0-15°C (32-59°F) or 20-40°C (68-104°F), the ambient compensation would cause trip times outside of published specifications.

GE NE stated that any of the affected models made before October 1990 should be considered suspect and should be replaced. To identify when the relays were built, they are marked with date codes consisting of two letters. The first letter, "N" through "Z" (skipping "Q"), indicates the month of manufacture. The second letter indicates the year with "E" meaning 1990, "F" meaning 1991, etc. Hence relays built in September 1990 and earlier (date codes "WE" and earlier) are affected. ED&C also recommended testing installed and in-storage relays at least every 5 years at room temperature (e.g. 25°C/77°F) and also after thermal soaking at 40°C/104°F and verifying that the trip times at some overload level (e.g. 300%) are within 10% of each other. If not, ED&C recommended replacement because these relays cannot be repaired.

ED&C reportedly corrected the problem on these models in September 1990 so that date codes for October 1990 and later, e.g."XE" (October 1990), "YE" (November 1990), "ZE" (December 1990), and "NF" (January 1991), should not be affected. During this inspection, ED&C could provide no further information on this issue except to confirm that none of its Service Advice Letters (SALs) had been issued. Also, the GE NE representative stated that none of its Service Information Letters (SILs) had been issued in addition to the GTS to BWRs and the NRC. This issue is designated Inspector Followup Item 93-01-04.

2.5 Replacement GE TJK426400 and TJJ426400 MCCBs for Point Beach

In a December 13, 1991, letter to the NRC reporting the status of MCCB replacements pursuant to NRC Bulletin 88-10 at Point Beach Nuclear Plant (Point Beach), Wisconsin Electric Power Company stated that GE had encountered problems with the internally-mounted auxiliary switches ordered by Wisconsin Electric and with performance testing of the MCCBs. During this inspection, the inspectors inquired of ED&C and GE NE as to the status of the testing, nature of the problems, etc. ED&C agreed to research the matter and provide an update to the NRC as soon as possible. Subsequent to the inspection, the inspectors received information from ED&C that GE NE had shipped the MCCBs to Point Beach in December 1991 and June and July 1992. No information was provided regarding the reported problems. This issue is designated Inspector Followup Item 93-01-05.

3 PERSONNEL CONTACTED

GE-ED&C

Dougherthy, J.J., Manager, Systems
Mallon, J., Application Engineer
Reiler, S.M., Development Engineer
Sailer, H.P., Development Engineer
Saunders, R.E., Product Manager, Industrial Breakers
Sheen, Ray, Manager, Distribution Components
Smith, J.I., Development Engineer
St. John, S., Quality Control Engineer

GE-NE

Sanders, G., Lead Engineer, Power Delivery Services

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 18, 1993

Docket Nos. 52-004 and 99900403

Mr. Patrick W. Marriott, Manager
Licensing & Consulting Services
GE Nuclear Energy
175 Curtner Avenue
San Jose, California 95125

Dear Mr. Marriott:

SUBJECT: NOTICE OF NONCONFORMANCE
(NRC INSPECTION REPORT NO. 99900403/93-01)

This letter addresses the inspection of your facility at San Jose, California, conducted by Richard P. McIntyre and Billy H. Rogers of the Nuclear Regulatory Commission's (NRC's) Vendor Inspection Branch, Alan E. Levin of the Reactor Systems Branch, Joseph L. Staudenmeier of the Analytical Support Group, and Frederick R. Allenspach of the Performance and Quality Evaluation Branch on August 9 through 13, 1993. The details of the inspection were discussed with you and your staff during the inspection and at the exit meeting on August 13, 1993.

The purpose of the inspection was to determine if activities performed as part of the Gravity-Driven Cooling System (GDCS) Integrated Systems Test (GIST) program were conducted under the appropriate provisions of the GE Nuclear Energy (GE-NE) 10 CFR Part 50, Appendix B, quality assurance program, as implemented by the "Advanced Light Water Reactor Program Quality Assurance Program Plan" (QA Plan), dated November 26, 1986, prepared for Department of Energy Contract Number DE-AC03-86SF16563 and also to review the input modeling of the TRACG computer code for the GIST facility.

Areas examined during the NRC inspection and our findings are discussed in the enclosed inspection report. The inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations by the inspectors.

The results of the inspection indicate that the GIST program and supporting independent design verification activities for the TRACG computer code were conducted without fully implementing appropriate Appendix B quality assurance measures and controls expected for a safety-related activity. Specifically, the Code Qualification Document (CQD), Licensing Topical Report NEDE-32177P, "TRACG Qualification," February 1993, was submitted to the NRC for review and approval for referencing in licensing actions for the Simplified Boiling Water Reactor (SBWR). The CQD, which provides a description of the qualification of TRACG against various activities including the GDCS integrated systems test, did not receive independent design verification as is required for a level 1 code used to support design basis analyses. Also, the TRACG input deck reviewed contained elevation errors that directly affected the results of the

TRACG analyses for GIST. GE-NE was in the process of rerunning TRACG for GIST to correct these errors.

The classification of the GIST test program as a non-safety-related developmental test is not consistent with GE-NE's procedural requirements considering that (1) the GIST program represents the only integral systems test of the SBWR's gravity-driven cooling system (GDCS), and (2) GIST results were used directly in a licensing application, i.e., to demonstrate the applicability of TRACG to SBWR analyses in the CQD, in support of GE-NE's SBWR design certification application. The review of Design Record File (DRF) A00-02917, for GIST, identified that documentation required to be contained or referenced in the DRF was not included therein. Specific documents that should have been included or referenced in the DRF were: the Final Test Report for the GIST Program, NEDO-31680; instrument calibration records; and as-built design drawings for the facility.

Other deficiencies in the DRF include: (1) failure to reference the original data tapes from the GIST tests, which should be appropriately referenced as retrievable information; (2) failure to include verified input from TRACG analyses related to GIST; (3) failure to generate and include in the DRF, non-conformance reports for tests that did not meet acceptance criteria and were classified as being "invalid," for various reasons; and (4) failure to include documentation of analytical or experimental verification of engineering calculations. For instance, the heat loss to the environment from the facility was a necessary datum for accurate analysis of the test results. A single page with an estimate of the heat loss was located in the DRF, but no documentation was included to show the basis for the estimate of effective heat transfer coefficient (e.g., thermophysical properties of insulation, film coefficient on outside of insulation, etc.), nor was there any indication that the calculated estimate was verified experimentally.

In response to the above findings, GE-NE committed to (1) verify the input deck for the TRACG code and rerun TRACG for GIST once TRACG becomes an independently verified level 2 code and, (2) upgrade the GIST DRF to include, to the extent possible, the missing information and documents described above.

During a meeting with you at NRC Headquarters on October 4, 1993, we discussed our technical concerns prompted by the above described inspection findings, as well as continuing NRR concerns that the GIST facility does not adequately represent components and interaction paths in the SBWR. During the meeting at your Rockville, Maryland office on November 16, 1993, you responded to these concerns and stated that you expect to respond formally to the concerns in the near future. Until the staff has had an opportunity to carefully evaluate the information you have already provided and will be sending us shortly, be aware that GE-NE's failure to properly classify the GIST test program and its associated analyses, the failure to thoroughly evaluate the test data, and the failure to adequately verify calculations of both GIST and SBWR behavior may require additional GDCS testing in an integral facility to support SBWR design certification.

Please provide us within 30 days from the date of this letter a written statement in accordance with the instructions in the enclosed Notice of Nonconformance. We will consider extending the response time if you can show good cause for us to do so.

The responses requested by this letter and the enclosed Notice of Nonconformance are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511

In accordance with 10 CFR Part 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC's Public Document Room.

Should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

R.W. Borchardt

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

Enclosures:
1. Notice of Nonconformance
2. Inspection Report No. 99900403/93-01

Mr. Patrick W. Marriott
General Electric Company

Docket No. 52-004
99900403

cc: Mr. Laurence S. Gifford
GE Nuclear Energy
12300 Twinbrook Parkway
Suite 315
Rockville, Maryland 20852

Director, Criteria & Standards Division
Office of Radiation Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
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Mr. Sterling Franks
U.S. Department of Energy
NE-42
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Mr. John E. Leatherman
SBWR Licensing Manager
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Mr. Frank A. Ross
Program Manager, ALWR
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AECL Technologies
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Rockville, Maryland 20850

Enclosure 1

NOTICE OF NONCONFORMANCE

GE Nuclear Energy
San Jose, California

Docket Nos. 52-004
99900403

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted on August 9-13, 1993, it appears that certain of your activities were not conducted in accordance with NRC requirements.

A. 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 GDCS 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)

B. 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)

C. 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)

D. 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, 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)

E. 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 Files."

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 test; 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)

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each nonconformance: (1) a description of the steps that have 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 your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 18th day of November, 1993

Enclosure 2

ORGANIZATION:	GE Nuclear Energy San Jose, California
REPORT NO.:	99900403/93-01
CORRESPONDENCE ADDRESS:	Mr. Patrick W. Marriott, Manager SBWR Project GE Nuclear Energy 175 Curtner Avenue San Jose, California 95125
ORGANIZATIONAL CONTACT:	Mr. Kenneth W. Brayman, Manager Quality Assurance Systems (408) 925-6587
NUCLEAR INDUSTRY ACTIVITY:	GE Nuclear Energy (GE-NE) is engaged in the supply of advanced boiling water reactor designs to utilities. GE-NE also furnishes engineering services, nuclear replacement parts, and dedication services for commercial grade electrical and mechanical equipment.
INSPECTION CONDUCTED:	August 9 through 13, 1993
SIGNED:	Richard P. McIntyre 10/29/93 Richard P. McIntyre, Team Leader Date Reactive Inspection Section No. 1 Vendor Inspection Branch (VIB)
APPROVED:	Uldis Potapovs 11-4-93 Uldis Potapovs, Chief Date Reactive Inspection Section No. 1 Vendor Inspection Branch (VIB)
INSPECTION BASES:	10 CFR Part 50, Appendix B and 10 CFR Part 21
INSPECTION SCOPE:	To determine if activities performed as part of the Gravity-Driven Cooling System (GDCS) Integrated Systems Test (GIST) program were conducted under the appropriate provisions of the GE-NE 10 CFR Part 50, Appendix B, QA program, as implemented by the "Advanced Light Water Reactor Quality Assurance Program Plan", prepared for Department of Energy Contract Number DE-AC03-86SF16563 and also to review the input modeling of the TRACG computer code for the GIST facility.
PLANT SITE APPLICABILITY:	None

1 INSPECTION SUMMARY

1.1 Nonconformances

1.1.1 Contrary to Criterion III of Appendix B to 10 CFR Part 50 and Section 4.4.1 of Engineering Operating Procedure (EOP) 40-3.00, "Engineering Computer Programs" (ECPs), (1) the TRACG input decks used to model the gravity-driven cooling system integrated systems test (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 gravity-driven cooling system (GDCS) integrated systems test, was submitted to the NRC for review and approval for referencing in licensing actions for the Simplified Boiling Water Reactor (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)

1.1.2 Contrary to Criterion XVII of Appendix B to 10 CFR Part 50, EOP 42-10.00, "Design Record Files" (DRF), EOP 35-3.00, "Engineering Tests," and the GIST Program Test Plan and Procedure (TP&P) 521.1322, Revision 2, dated November 29, 1988, certain documentation required to be contained or referenced in the DRF was not included therein. Specific documents that should have been part of 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)

1.1.3 Contrary to Criterion III of Appendix B to 10 CFR Part 50, and Section 3.11 of the GE-NE QA Program Description topical report, NEDO-11209-04A, "Design Change Control," there was no documentation or 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)

1.1.4 Contrary to Criterion XII of Appendix B to 10 CFR Part 50, Section 2.2 of EOP 35-3.20, "Calibration Control," and Section 4.1.2 of the GIST Program TP&P 521.1322, GE-NE purchased flow meters used in the GIST tests from a commercial grade supplier, 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)

1.1.5 Contrary to Criterion XI of Appendix B to 10 CFR Part 50, EOP 35-3.00, "Engineering Tests," EOP 42-10.00, "Design Record Files," and Section 4.2.4 of the GIST Program TP&P 521.1322, 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 test; 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)

1.2 Unresolved Item

The lack of independent design verification for the TRACG computer code raises questions concerning the validity of other calculations included in Chapters 6 and 15 of the SSAR for SBWR. This issue is considered an unresolved item and will be discussed with GE-NE in future meetings. (93-01-06)

2 STATUS OF PREVIOUS INSPECTION FINDINGS

No previous inspections have been conducted in this area.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Quality Assurance Program

The quality assurance program implemented for the GIST program is described in the Advanced Light Water Reactor Program Quality Assurance Program Plan (QA Plan) that was prepared for the Department of Energy, Contract No. DE-AC03-86SF16563. This DOE QA Plan mandates the application, as appropriate to the contract scope, of the QA program described in Revision 6, dated June 30, 1986, of the NEDO-11209-04A, "Quality Assurance Program Description." This is the GE-NE topical report that has been reviewed and approved by the NRC and meets Appendix B of 10 CFR Part 50.

The DOE QA Plan contains a work element/implementing procedure matrix that contains 18 major subdivisions which correlate with the 18 criteria of Appendix B. The 18 subdivisions are further broken down into 78 work elements committed to the QA Plan. Four types of GE-NE procedures are described that implement the work elements of the QA Plan. These are Nuclear Energy Business Operations (NEBO) Policies and Procedures (P&Ps), BWR Engineering Operating Procedures (EOPs), Nuclear Systems and Technology Operation (NSTO) Policies and Instructions, and Nuclear Service Procedures (NSPs). During the time frame of the GIST program, the NSPs were phased out and folded into the EOPs.

The NEBO P&Ps are high level GE-NE policies that establish overall policies and responsibilities for NEBO. As a result of a reorganization, GE-NE nuclear activities are currently under the Vice President of GE Nuclear Energy and NEBO no longer exists. The EOPs are a series of procedures that implement GE-NE policies and the QA program. NSTO Policies and Instructions deal with subjects such as cost schedules, budgeting, contract award, and business management and, as such, have no importance in implementing the QA plan. The NSPs have been subsumed by the EOPs. This process was ongoing during the GIST test period.

The GIST test program and QA program both fell within the NEBO. The Quality Assurance Operations within NEBO was a staff organization assigned responsibility for establishing the NEBO-level quality related P&Ps, and auditing the functional organizations involved in the activity. The QA program covered the design, procurement of parts and testing equipment, instructions and drawings, document control, inspection, test control, control of measuring and test equipment, corrective actions, quality assurance records, and audits.

3.2 Instruction, Procedures and Drawings

The quality requirements utilized for GIST are contained in the following GE-NE documents reviewed by the inspection team:

- NEBO P&P 70-11, "Quality Systems Requirements"
- EOP Nos. 15-2.00, "EOP Application"
- 30-5.00, "Engineering Records Documentation Supplied by External Sources"
- 30-7.00, "Technical Design Procedures"
- 35-3.00, "Engineering Tests"
- 40-3.00, "Engineering Computer Programs"
- 40-7.00, "Design Reviews"
- 42-5.00, "Engineering Requirements Document Release"
- 42-6.00, "Independent Design Verification"
- 42-8.00, "Document Issue and Application by ERM"
- 42-10.00, "Design Record Files"
- 55-2.00, "Engineering Change Control"
- 60-3.10, "Engineering Records Retention"
- 60-6.00, "Drafting Manual Control"
- 65-2.00, "Product Safety Requirements"

3.3 Document Control

Document control is prescribed by NEBO P&P 70-11, "Quality Systems Requirements" and numerous EOP's such as: 15-2.00, "EOP Application;" 30-5.00, "Engineering Records Documentation Supplied by External Sources;" 40-7.00, "Design Reviews;" 42-5.00, "Engineering Requirements Document Release;" 42-6.00, "Independent Design Verification;" 42-8.00, "Document Issue and Application by ERM;" 55-2.00, "Engineering Change Control;" and 60-6.00, "Drafting Manual Control."

The team found poor control of some design and calculation documents. Some calculations documents were kept in an individual's desk, and original design drawings were kept in an unlabelled shop drawing file. Considerable effort was needed to locate and determine what drawings contained the as-built elevations of key components of the test facility. Additionally, there were no final approved revisions for the drawings reviewed. See Section 3.5 below on Design Control.

3.4 Quality Assurance Records

Quality Assurance records are prescribed by NEBO P&P 70-11, "Quality Systems Requirements," and numerous EOP's such as: 35-3.00, "Engineering Tests;" 40-7.00, "Design Reviews;" 40-9.00, "ASME Code Design Verification;" 42-6.00, "Independent Design Verification;" 42-10.00, "Design Record Files;" and 60 2.10, "Engineering Records Retention."

EOP 42-10.00 describes Design Record Files (DRFs) as formal, organized accumulations of information, which provide a controlled system for retention of documented engineering activities, necessary to substantiate significant design decisions. The DRF provides a mechanism for controlling and archiving important design records, such as design verification, studies and analyses. It does not include documents, such as drawings and specifications, which are maintained under separate corporate design controls. However, the DRF is to include documentation and pertinent references that support the design. The procedure also says that the DRF should provide for design notes, calculations, records and other supporting information, and cross-reference to related or supporting DRFs.

The team found that record retrievability was lacking in that the DRF did not contain all relevant records or a reference to important test records such as design drawings (or reference to their location, since the DRF is not required to contain drawings not easily reproducible into such media as a microfiche), the final test report, instrument calibrations, and reason(s) for not repeating a test. The location of several records was determined by calling in the retired responsible test engineer. Some calculation records were in another DRF and some were located in an individual's desk drawer. This resulted in the team spending considerable effort in finding if records existed and being able to obtain the record that did exist. The DRF did not provide traceable and retrievable evidence to support the GIST test and results.

3.5 Design Control

The NRC inspectors examined the DRF for the GIST test program, DRF A00-02917, to determine if the documentation in the DRF complied with the QA Plan requirements in effect during the GIST program, and associated EOPs 42-10.00, "Design Record File;" 42-6.00, "Independent Design Verification;" 40-7.00, "Design Reviews;" and 35-3.00, "Engineering Tests."

EOP 42-10.00 requires, in part, that the DRF contain or reference (as applicable) design and evaluation records, test reports, and controlled documents. Evaluation records are further defined in EOP 35-3.00 as including instrument calibration records. Design records include drawings for the facility, specifically showing nominal and as-built dimensions for components and the facility as a whole. These drawings should be numbered documents that are retained and retrievable, and that can be referenced as part of the DRF.

The inspectors found that documentation required to be contained or referenced in the DRF was not included therein. Specific documents that should have been part of the DRF were: the Final Test Report for the GIST Program, NEDO-31680;

instrument calibration records, which were located in a desk drawer in another building; and design drawings for the facility, some of which were found in a cabinet at the facility itself. This set of drawings, however, did not include final numbered and approved, as-built design drawings, which the QA Plan requires to be retained for the lifetime of the item. Sketches found in the DRF, apparently made by the responsible test engineer and containing some as-built dimensions, are not acceptable substitutes for numbered, retrievable, as-built drawings. In addition, the drawings that were located did not in all cases represent a final as-built configuration, and determining which drawings had been superseded and which were representative of the final facility was difficult.

Other deficiencies in the DRF include: (1) failure to reference the original data tapes from the GIST tests, which should be appropriately referenced as retrievable information; (2) failure to include verified input from TRACG analyses related to GIST; and (3) failure to include documentation or experimental verification of engineering calculations. For instance, the heat loss to the environment from the facility was a necessary datum for accurate analysis of the test results. A single page with an estimate of the heat loss was located in the DRF, but no documentation was included to show the basis for the estimate of effective heat transfer coefficient (e.g., thermophysical properties of insulation, film coefficient on outside of insulation, etc.), nor was there any indication that the calculated estimate was verified experimentally. As a result, Nonconformance 93-01-02 was identified during this part of the inspection.

GE-NE acknowledged the shortcomings in the DRF, and committed to upgrade the DRF to include, to the extent possible, the missing information and documents described above or references thereto, where appropriate.

3.6 Test Control

EOP 35-3.00, "Engineering Tests," describes the classification system of test program types. Appendix B to EOP 35-3.00 describes five test program types. Type B1 is a development type, B2 is a design basis type, B3 is a design qualification type, B4 is a manufacturing type, and B5 is a special test. Type B5 is classified as not safety related. The GIST test was considered a type B1 and was not classified as a safety-related test.

The inspectors reviewed the records relating to control of the GIST test program, including the Test Requirements and Test Specifications (TR&TS) and the Test Plan and Procedures (TP&P) documents. Conformance with the requirements of EOP 35-3.00 was also checked. The inspectors determined that the classification of the GIST test program as a non-safety-related type B1 (developmental) test, per Appendix B of EOP 35-3.00, was not consistent with the use of the results of the test program. This inconsistency had a significant impact on several of the activities associated with the test program, including GIST-related computer analyses using the TRACG code, QA and control of equipment and instrumentation purchased for use in the facility, independent design verification of the facility, and treatment of the data.

The NRC asserts that the GIST test program comprised a safety-related activity, and that the program's purpose was, in part, to obtain design basis data for the proposed SBWR gravity-driven cooling system. The SBWR design is being considered for certification as a "passive" reactor design under the requirements of 10 CFR Part 52. Included in Part 52 are specific requirements for the data and testing requirements; these are found in 10 CFR 52.47(b)(2)(i)(A), and state, in part, that certification of a passive standard design will be granted only if:

(1) The performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof;

(2) Interdependent effects among the safety features of the design have been found acceptable by analysis, appropriate test programs, experience, or a combination thereof; and

(3) Sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions.

Documentation in the DRF clearly shows that the GIST test program was considered, at the time it was being developed, to be the only program of its kind needed to demonstrate the principle and test the performance of a gravity-driven cooling system. The intent of the test program, as stated in various memoranda in the DRF and in the GIST program Final Report, GEFR-00850, has been to use the test data to demonstrate the performance of the GDCS, as required in (1) above, and to establish a database for code qualification to perform safety analyses, as required in (3) above. In the view of the NRC staff, it appears that there is a clear and direct connection between the performance of the GIST tests and the safety analyses contained in the SBWR Standard Safety Analysis Report. Therefore, the use of the data constitutes a type B2 test classification of EOP 35-3.00 and should have been conducted as a safety-related activity with appropriate QA controls in place commensurate with the requirements for safety-related tests.

Furthermore, since GIST testing was a safety-related activity, the use of the data in the TRACG Code Qualification Document (CQD) that was submitted to the NRC for review and approval for referencing in licensing actions for the SBWR, constitutes a design application of the TRACG02 (Level 1) computer code, and as such requires independent verification or design team review of all calculations. Failure to properly classify the test program led to a failure to recognize the design application of TRACG02, which in turn led to a failure to independently verify GIST-related code calculations as well as the CQD for TRACG. As a result, part of Nonconformance 93-01-01 was identified during this part of the inspection.

Insofar as the test data themselves are concerned, it appears that GE-NE was not consistent with EOP 35-3.00 requirements with regard to disposition of the data in a Final Test Report (FTR). Item 4.3.16 in EOP 35-3.00 instructs the responsible test engineer to "prepare FTR providing for the complete description of the components tested and reduction, interpretation, and correlation of the data as specified in the work authorization. Obtain required evaluations of technical validity by the Test Requestor and Responsible Test Manager and approval to issue the FTR as a traceable document consistent with EOP 42-10.00." As noted in section 3.5 of this report on Design Control, the FTR was not included or referenced in the DRF. Furthermore, there is no evidence in the FTR that the data were "interpreted and correlated." Specifically, no attempt appears to have been made to estimate the errors associated with the data, either from instrument uncertainties or from basic experimental uncertainties, such as heat losses from the facility. No evidence of verification of facility operating characteristics was available, such as steady-state heat balances to verify calculations of facility heat loss or loss coefficients for flows through facility components and piping. Failure to provide such information renders the data of questionable validity.

GE-NE personnel also raised two issues regarding classification of the test program in discussions during the inspection. First, the point was made that 10 CFR 52 was incorporated into the Code of Federal Regulations in April 1989, after the GIST program was completed. The implication by GE-NE was clearly that, since the regulation did not exist when the program was performed, its requirements related to passive reactor testing programs were inapplicable to the GIST tests. The NRC staff disagrees with this position. Memoranda in the DRF state clearly that the GIST program was to be a one-time-only test program; thus, there was never any intention to use the GIST tests as a developmental step in an integrated design and test effort. The intent to use these data to qualify TRACG for SBWR safety analyses was also clear, since such analyses of the early stages of design basis accidents in the SBWR were used to help establish the required initial conditions for the GIST tests. Comparisons of GIST results to expected SBWR behavior are made in GEFR-00850. The safety-related nature of the tests should therefore have been recognized by GE-NE, whether or not Part 52 existed at the time of the tests. Additionally, the submission of both the SBWR SSAR and the TRACG CQD, and the inclusion of GIST information as supporting documentation, occurred <u>after</u> issuance of Part 52. Any material submitted to the NRC must therefore conform to the requirements of the regulations.

It was also asserted initially by GE-NE that the requirements for independent design verification in EOP 35-3.00 did not apply to type B1 tests. This claim was made on the basis of item 4.1.3(b) in the EOP, which gives as examples type B2 and B3 tests, but does not mention type B1 tests. In subsequent discussions between the NRC and GE-NE QA personnel, GE-NE admitted that this was an erroneous interpretation of the EOP requirement, and that type B1 tests were also covered. In fact, the DRF contains a memorandum requesting an exemption from independent design verification of the GIST test facility, with the justification that no controlled drawings of the SBWR design existed at that time (ca. 1986) against which to verify the design. The independent verification process per EOP 42-6.00 was therefore waived. However, an internal design review process was established through use of Engineering Review Memoranda (ERMs) and a Design Review Team (DRT). Appropriate records of ERMs and their resolution, and of the review by the DRT, are contained in the DRF. The NRC inspectors consider these processes to constitute an adequate design review, and regard the documentation of this process in the

DRF as acceptable. The NRC also notes that an external design review was performed by the Electric Power Research Institute, documentation of which is contained in the DRF.

3.7 Instruments, Calibration, and Procurement

The QA Plan stated that the control of measuring and test equipment was covered by EOP 35-3.20, "Calibration Control." Section 2.2 of EOP 35-3.20 stated 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 stated that calibration services should be classified as safety-related services unless justified and documented otherwise. GE-NE TP&P 521.1322, Revision 2, dated November 29, 1988, stated in section 4.1.2 that test equipment should be calibrated against auditable standards traceable to the National Bureau of Standards.

The GIST test facility used approximately 120 instruments to monitor process parameters such as temperature, pressure, conductivity (level), and flow. The NRC inspectors asked to see the calibration records for the instruments used during performance of the GIST tests. It was determined that the calibration records were not part of the DRF and that they were not on file in the Instrument Laboratory or the Calibration Laboratory. GE-NE located the calibration records in the GIST test facility. Review of the records and discussion with GE-NE indicated that the thermocouples and pressure transducers had been purchased as commercial grade items, and the conductivity probes manufactured by GE-NE. All of the thermocouples, pressure transducers and conductivity probes had been calibrated by the GE-NE Instrumentation Laboratory in accordance with established procedures and the requirements of the GE-NE Appendix B quality assurance program and that the calibrations were against auditable standards as required by the TP&P.

Although verification of the quality of the performance of test instruments purchased as commercial grade could be accomplished by calibration under an Appendix B quality assurance program, this would not apply to construction material. However, review of purchase orders associated with the GIST tests indicated that GE-NE had also purchased the material used to construct the test facility as commercial grade items without any further dedication activities. GE-NE did indicate that consideration of quality was indicated for the piping used in the GIST facility which was purchased to ASME specifications.

GE-NE had purchased the flow meters as commercial grade items from Flow Technology Inc., of Santa Clara, California, by purchase order number 190-RP666, dated September 8, 1987. The purchase order specified that the instruments were to be calibrated by the supplier, although it did not request a certificate of conformance. The purchase order did not specify that the calibrations performed by the supplier were required to meet any specified quality assurance program, 10 CFR Part 50 Appendix B, or 10 CFR Part 21. Flow Technology Inc., was not on GE-NE's approved suppliers list as qualified to provide safety-related instruments or to perform safety-related calibrations of instruments and GE-NE had not performed any audits or surveys of Flow

Technology Inc., to support acceptance of the calibrations.

GE-NE had received calibration records from the supplier and used this information as computer input for performance of the GIST tests although the quality of this information, from an unapproved commercial grade supplier, was not verified. GE-NE had performed a single point check of the instruments at zero flow but this did not meet the criteria of a calibration of the instruments or verify the required operation over the specified range.

GE-NE had not classified the calibration of the flow meters as a safety-related service as required by EOP 35-3.20 and did not procure the service from a qualified supplier, take actions to qualify the supplier, or perform the service under the GE-NE quality assurance program. Since GE-NE had not audited Flow Technology Inc. for their approved suppliers list or performed surveys to support the calibration activities, GE-NE did not have a basis for accepting the calibration of the flow meters by Flow Technology Inc., and therefore had not ensured that the instruments had been adequately or correctly calibrated against auditable standards as required by the Program Plan and the TP&P. In addition, GE-NE had not verified that the flow meters, instruments used in an activity affecting quality, were properly controlled, calibrated, and adjusted to maintain accuracy with necessary limits as required by Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. As a result, Nonconformance 93-01-04 was identified during this part of the inspection.

3.8 Nonconformances and Corrective Actions

TP&P 521.1322 stated in section 4.2.3 that deviations and out of specifications should be documented on the Deviation Log, figure 1-7 of the TP&P, and reported to the Responsible Test Engineer. Section 4.2.4 of the TP&P stated that a nonconformance report should be generated for test results which did not meet the acceptance criteria, expected results, or contained anomalies. The TP&P required that the Test Requestor establish a test disposition and approve all dispositions prior to resuming the test and include a copy of the completed, approved nonconformance reports in the DRF.

The inspectors reviewed the Final Test Report - Testing of the Gravity-Driven Cooling System for the Simplified Boiling Water Reactor (Final Test Report), NEDO-31680, dated July 1989, and the SBWR Program GDCS Integrated Systems Test Final Report (Final Report), GEFR - 00850, dated October 1989, and determined that at least three anomalies occurred during performance of the matrix texts which required a change to an input parameter or the test configuration and met the definition of nonconformance provided in the TP&P. The three matrix tests (C01, D01, and D03) were indicated in test reports as being "invalid," for various reasons. These tests were rerun successfully as tests C01A, D01A, and D03A and are described below.

- GDCS Line Break - Base Case (Tests C01 and C01A)

  The Final Report stated the following: Test C01 was repeated because the vacuum breakers between the wetwell and the upper drywell were not functioning. The broken GDCS line injected not only hot water and steam from the vessel but also cold water from the suppression pool. This cold water condensed the steam in the upper drywell, lowering its pressure below that of the wetwell. Since the vacuum breakers were out of service in Test C01, there was a danger of back-flow from the suppression pool through the main vents. This could have caused such a rapid (and non-SBWR typical) depressurization in the upper drywell that the GIST facility could have been damaged. To prevent this, the operator continually injected steam into the upper drywell during the test. Since this injection was not measured and the containment behavior was not typical of the SBWR (as all base cases were required to be), the test was invalid. The vacuum breakers were functional in Test C01A and all other GDLB tests.

In addition, a note was found on the folder in the DRF in which hard-copy data plots were stored which indicated that a problem had existed concerning the power during the test. This was not consistent with the actual reason given in NEDO-31680 for the test's invalidation (incorrect valve alignment).

- No Break - Base Case (Tests D01 and D01A)

  The Final Report stated that during performance of test D01 the power (in the reactor pressure vessel) did not decay as expected such that a repeat test was necessary.

- No Break - Appendix K Decay Heat (Tests D03 and D03A)

  The Final Report stated that during performance of Test D03 the power provided to the heater coils was too low. In Test D03A the correct power was provided to the heater coils.

GE-NE did not document the reasons for the failure of the tests to meet acceptance criteria as either deviations or nonconformances in accordance with the TP&P, although in each case a change to an input parameter or the test configuration was required. Ultimately, these anomalies were described in the Final Report and the Final Test Report (but not documented as deviations or nonconformances and thus not available for inclusion in the DRF). During the period of time between performance of the test (fall 1988) and issuance of the Final Test Report (July 1989) and the Final Report (October 1989) there was no documentation of the anomalies or actions taken. GE-NE had not ensured that test results were documented and evaluated to assure that test requirements had been satisfied as required by Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. As a result, Nonconformance 93-01-05 was identified during this part of the inspection.

3.9 TRACG Computer Modeling of GIST

Several concerns were identified in the TRACG computer modeling of GIST and in TRACG configuration control. EOP 42-10.00, "Design Record File," requires that supporting information on calculations be included or referenced in the DRF. The computer model calculational notebook was not part of the GIST DRF and the DRF did not contain enough information to generate a TRACG computer model. However, a calculation notebook for the GIST TRACG input deck used for the calculations included in the GIST final report was maintained by the modeler. It contained enough information to generate a TRACG input model for GIST but it did not adequately document where the information came from. The calculation notebook was not independently checked for accuracy. The input models contained an error in the elevation of the GDCS tank. Different input decks contained different elevations for the GDCS tank, which resulted in errors in the input to TRACG02. As a result, part of Nonconformance 93-01-01 was identified during this part of the inspection. Since the errors involved, in part, elevations of components in the simulated GDCS in GIST, which determine the driving head available for gravity-driven injection, they have a direct impact on the results of GIST analyses, and call into question all safety calculations related to the GIST program.

The subject of other SBWR SSAR Chapter 6 and Chapter 15 safety calculations performed with TRACG was discussed with GE-NE. The calculations were performed with a level 1 version of TRACG, which means that the input, output and code range of applicability must be determined for each calculation performed. GE-NE stated that the calculations were not yet independently verified and that the NRC should be aware of this fact. It was mutually agreed that this issue will be discussed with GE-NE in a future meeting. Therefore, this issue is considered an unresolved item (93-01-06).

A separate calculation notebook was kept for the TRACG GIST calculations included in the TRACG Code Qualification Document. This calculation notebook did not contain enough information to construct the TRACG model and only documented the differences between the input model used for the GIST final report and the input model used for code qualification. This calculation notebook also was not independently checked. These input decks also had the same elevation errors for the GDCS tank until the errors were discovered by an Idaho National Engineering Laboratory (INEL) staff member doing an independent analysis of GIST for the NRC Office of Nuclear Regulatory Research. A recent calculation of one GIST experiment using correct elevation information showed 20 percent less GDCS flow than the calculation presented in the code qualification document. These elevation errors could have been prevented by checking the code messages which provide a warning when there are improperly closed loops. GE-NE may consider identifying this as a fatal input error instead of just a warning, considering the importance of natural circulation in BWR systems. Heat losses to the environment for the computer modeling were taken from a hand calculation and not from experimentally measured data. The memo with the hand calculation indicated that the engineer in charge of the experiment remembered that the heat losses may have been twice the amount of the hand calculation. Even with the uncertainties and heat losses that may have been as high as 15 to 20 percent of the total power input, no sensitivity studies were performed in the TRACG computer studies of the GIST experiments.

The inspection also examined computer code changes made for the GIST program. The specific changes include changes to the interfacial shear and heat transfer when a two-phase level is present, changing the model for condensation on cold walls when air is present, and the implementation of a horizontally stratified flow model. In GE-NE's code classification system a level 1 computer code is a developmental code. It may be used for design calculations provided that the input, output, and range of applicability are independently verified. A level 2 computer code is a design code. When using a design code, only the input and the range of validity have to be verified. The inspection team was told that documentation on the implementation and testing of these new code models is not required for a level 1 computer code and does not exist in any official form. GE-NE seems to have not performed the more extensive documentation and testing required to change a level 2 code by declaring the changed code a new level 1 code. This also circumvents the responsibility of assessing how the changes to the code affects previous calculations done with the old level 2 code. The inspection team was also told that GE-NE does not use a code librarian such as HISTORIAN or UPDATE for configuration control of TRACG. Code changes and configuration control are not maintained manually by the code responsible engineer. The lack of documentation for testing of new models, the method of implementation into the computer code and the lack of independent verification may allow programming errors to slip by undetected. As in the case of the input deck errors, code changes could have significant effects on calculated results and still not be discovered through the design review process.

Independent of the lack of verification at the present time are the issues of the minimum standards that must be met in order to independently verify a calculation and what kind of checks must be made of the calculational notebooks and input decks. GE-NE uses a process called design review in order to meet the independent verification requirements of Appendix B. Design review is covered by EOP 40-7.00. While this procedure has some suggested means of independent verification, it does not have any minimum requirements. The level of independent verification performed is decided upon by the design review team.

In the case of the TRACG design review, the committee was only reviewing the models that were stated to be in the code and the code output for test cases. The review committee seemed to be assuming that the inputs for the test cases were already verified to be correct. This assumption was found not to be correct. None of the individual test cases had been treated as a design calculation and therefore none were independently verified. Comments and questions from the design review team indicated that no review team member had any questions about the incorrect GIST calculations since the output of the calculations looked "reasonable." The NRC staff considered this an example of how the GE-NE design review process could fail to detect errors when no minimum level of independent verification is required. GE-NE's methods of independent verification and record keeping do not appear to meet the requirements of its QA Topical Report. As a result, Nonconformance 93-01-03 was identified during this part of the inspection.

4 PERSONNEL CONTACTED

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 28, 1993

Docket Nos. 52-001 and 99900403

Mr. Patrick W. Marriott, Manager
Licensing & Consulting Services
GE Nuclear Energy
175 Curtner Avenue
San Jose, California 95125

Dear Mr. Marriott:

SUBJECT: NOTICE OF NONCONFORMANCE
(NRC INSPECTION REPORT NO. 99900403/93-02)

This letter addresses the inspection of your facility at San Jose, California, conducted by Richard P. McIntyre, Robert L. Pettis, and Billy H. Rogers of the Nuclear Regulatory Commission's (NRC's) Vendor Inspection Branch, George Thomas of the Reactor Systems Branch, Joseph L. Staudenmeier of the Analytical Support Group, Robert A. Gramm of the Performance and Quality Evaluation Branch, and Sampath K. Malur of the Special Inspection Branch on September 7 through 10, 1993. The details of the inspection were discussed with Mr. Robert Berglund, General Manager, Advanced Reactor Programs, and other members of your staff during the inspection and at the exit meeting on September 10, 1993.

The purpose of the inspection was to determine if quality activities performed as part of the design of the Advanced Boiling Water Reactor (ABWR) project were conducted under the appropriate provisions of the GE-NE 10 CFR Part 50, Appendix B, quality assurance (QA) program, as implemented by the Quality Assurance Program Description topical report (NEDO-11209-04A) that has been approved by the NRC.

The scope of the inspection included the review of the Design Record Files (DRFs) for computer code input modeling and independent design verification for the computer codes ODYNA, REDYA, and SAFER; the review of the implementation of the QA controls in place for activities performed as part of ABWR Full Integral Simulation Test (FIST) used to qualify SAFER; the review of certain Standard Safety Analysis Report (SSAR) Chapter 6 and 15 safety analyses calculations that will not be reanalyzed if the combined operating license (COL) uses the certified design reference core fuel design; and the review of residual heat removal (RHR) and reactor building cooling water (RCW) system calculations for which GE-NE and the Japanese technical associates (Toshiba and Hitachi) have the design lead.

The inspection results indicate that some of the design, testing, and verification activities that support the ABWR Standard Safety Analysis Report (SSAR) and the certified design were conducted without fully implementing the QA commitments contained in the ABWR SSAR, the GE-NE topical report, and as required by Appendix B to 10 CFR Part 50.

Chapter 17 of the ABWR SSAR states that common engineering design documents are reviewed and approved by GE-NE and that GE-NE is responsible for the design and supporting calculations and records for the ABWR project. The inspection team reviewed the DRF for the reactor building cooling water system (RCW), for which a Japanese technical associate had the design lead. While the common engineering documents were reviewed by GE-NE, the inspection team found no evidence that the supporting engineering calculations performed by the technical associates for RCW had been similarly reviewed. Additionally, GE-NE's annual audits of the technical associates did not examine the technical adequacy of the supporting calculations.

The review of input modeling and ve...ication of selected computer codes identified significant QA deficiencies. The FIST, which was used to qualify the SAFER computer code, was apparently conducted as a non-safety-related activity, although it is used to support the ABWR SSAR accident analysis. The following records and documentation, which are required to be contained or referenced in the DRF, were missing: (1) final as-built facility drawings, (2) reference to original data tapes from the tests, (3) records of disposition of all test anomalies, (4) test log and QA forms for each test, and (5) documentation of analytical or experimental verification of engineering calculations. In addition, the FIST rod thermocouples were purchased from an unapproved commercial supplier and their calibration was not verified by GE-NE.

The DRFs for the computer codes reviewed did not document adequate independent verification of code changes and GE-NE's procedures did not require that such documentation be maintained. For the REDYA, ODYNA, and SAFER codes, independent verification was accomplished through a design review process. This process relied on a design review team's evaluation of a description of the code models and of the results of test cases selected by the code developer. However, this process did not include an independent verification of implementation of the changes in the models described to the design review team, nor a quantitative evaluation of the accuracy of the results of test cases. Examples of failure to perform quantitative assessments of results of code changes include changes to REDYA and ODYNA for the internal recirculation pumps and to SAFER for the isolation condensers, which did not compare calculational results to measured data. The test cases only verified that the code results were qualitatively correct.

Several ABWR calculation notebooks were poorly maintained and lacked sufficient information. For example, the internal pump flow area in the ABWR SAFER model was based on a combination of an undimensioned drawing assumed to be to scale and an individual's memory of the pump shaft diameter. In general, the notebooks lacked sufficient information to enable an independent review by a technically qualified person without the assistance of the analyst or system designer.

In two instances the inspection team identified technical inconsistencies between the ABWR design and information contained in the ABWR SSAR. We are concerned that the design control process has not ensured the accurate translation of information into the SSAR which is relied upon for our design certification safety judgement.

The above findings do not appear to have major safety significance for the ABWR design at this point in time. This conclusion is based on the fact that there is a significant thermal hydraulic design margin built into the ABWR codes ODYNA, REDYA, and SAFER, that was demonstrated through thermal hydraulic computer analyses and the FIST test program. There is significant safety margin, especially in SAFER for LOCA analyses where Appendix K analysis requirements are fairly conservative. In addition, the calculated peak cladding temperature (1116° F) is considerably less than the allowable value (2200° F).

However, based on the recent SBWR and ABWR QA inspections, there is a lack of attention to QA by GE-NE in many of the activities related to the Advanced Light Water Reactor Program (ALWR). If not properly addressed by GE-NE, it could have the potential to cause significant safety concerns. The lack of significant immediate safety concerns does not relieve GE-NE of the responsibility for implementing adequate design and test control.

Please provide us within 30 days from the date of this letter a written statement in accordance with the instructions in the enclosed Notice of Nonconformance. We will consider extending the response time if you can show good cause for us to do so. In addition, your response should specifically address (1) the safety significance of the concerns identified in this report, (2) the general integrity of the GE-NE QA program implementation for the ALWR program, (3) Unresolved Items (93-02-08) and (93-02-09), and (4) actions planned to be taken to rectify the adverse conditions identified.

The responses requested by this letter and the enclosed Notice of Nonconformance are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

In accordance with 10 CFR Part 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC's Public Document Room.

Should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

Jerry N. Wilson for

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

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 99900403/93-02

Mr. Patrick W. Marriott
General Electric Company

Docket No. 52-001
99900403

cc: Mr. Joseph Quirk
GE Nuclear Energy
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Enclosure 1

NOTICE OF NONCONFORMANCE

GE Nuclear Energy
San Jose, California

Docket Nos. 52-001
99900403

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted on September 7-10, 1993, it appears that certain of your activities were not conducted in accordance with NRC requirements.

A. 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.

   Section 3.10 of the GE-NE QA Program Topical Report, NEDO-11209-04A, "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, changes made to the computer codes REDYA, ODYNA, and SAFER were not being documented and verified in any formal manner. No official records of the changes are required to be kept and the changes themselves do not have to be reviewed independently. (93-02-01)

B. 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.

   Section 4.4.1 of Engineering Operating Procedure (EOP) 40-3.00, "Engineering Computer Programs (ECPs)," states 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, the flow area of the internal recirculation pump used for the modeling of the SAFER code was based on an unverified hand drawn sketch with a reference to an individual who provided the information, instead of a reference to the applicable dimensioned design drawing. (93-02-02)

C. 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.

Contrary to the above, GE-NE had not filed the quality assurance documents or the test log required by Test Plan and Procedure (TPP) TP-515.1078, "ABWR Full Integral Simulation Test (ABWR FIST)," Revision A, dated October 17, 1983, for the ABWR FIST tests in DRF E00-149 and subsequently could not produce the documents. (93-02-03)

D. 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.

Sections 1.1 and 4.2.b of EOP 35-3.20, "Calibration Control," stated 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.

Contrary to the above, GE-NE purchased thermocouples used in the ABWR FIST tests from a commercial grade supplier, 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. (93-02-04)

E. Chapter 17 of the ABWR SSAR commits to ANSI/ASME NQA-1-1983. NQA-1 states, in part, "Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator."

Contrary to the above, the calculation notebooks for the inputs to the SAFER, REDYA and ODYNA computer codes did not have this level of detail and in some cases were inadequately referenced. In addition since changes to computer codes are design analyses they should also be documented in this level of detail. (93-02-05)

F. Criterion V of Appendix B to 10 CFR Part 50, "Instructions, Procedures, and Drawings," states, in part, that activities affecting quality shall be accomplished in accordance with these instructions, procedures, or drawings.

GE Nuclear Energy Standard Safety Analysis Report (SSAR) for the ABWR, Chapter 17, Section 17.1.2, "Quality Assurance Program," states "Agreements between GE and its associates require an annual review to assure that the quality systems are being implemented. All associates are committed to correct discrepancies noted during these reviews."

Contrary to the above, GE-NE failed to perform an annual implementation review of Hitachi and Toshiba's QA program for the 1991 period. This failure resulted in a 16 month interval between the audits performed in 1990 and the 1992 audits. (93-02-06)

G. Criterion V of Appendix B to 10 CFR Part 50, "Instructions, Procedures, and Drawings," states, in part, that activities affecting quality shall be accomplished in accordance with these instructions, procedures, or drawings.

Criterion VII of Appendix B to 10 CFR Part 50, "Control of Purchased Material, Equipment and Services," states, in part, that the effectiveness of the control of quality by contractors and subcontractors shall be assessed at intervals consistent with the importance, complexity, and quantity of the product or services.

Section 7 of the GE-NE QA Program Topical Report, NEDO-11209-04A, "Control of Purchased Material, Equipment and Services," states, in part, that each supplier of safety-related equipment or services is audited or evaluated initially to determine acceptability of their QA Program and if acceptable, the supplier is placed on the Approved Suppliers List (ASL). Active suppliers of safety-related items are audited at least every three years.

Contrary to the above, GE-NE failed to perform audits of Bechtel's ABWR QA Program Plan implementation for engineering services associated with GE-NE PO No. 190-ALWR-31387, and accepted safety-related services from Bechtel without them being listed on GE-NE's ASL for such services. (93-02-07)

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each nonconformance: (1) a description of the steps that have 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 your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 28th day of October, 1993

Enclosure 2

ORGANIZATION: GE Nuclear Energy
San Jose, California

REPORT NO.: 99900403/93-02

CORRESPONDENCE ADDRESS: Mr. Patrick W. Marriott, Manager
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GE Nuclear Energy
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San Jose, California 95125

ORGANIZATIONAL CONTACT: Mr. Kenneth W. Brayman, Manager
Quality Assurance Systems
(408) 925-6587

NUCLEAR INDUSTRY ACTIVITY: GE Nuclear Energy (GE-NE) is engaged in the supply of advanced boiling water reactor designs to utilities. GE-NE also furnishes engineering services, nuclear replacement parts, and dedication services for commercial grade electrical and mechanical equipment.

INSPECTION CONDUCTED: September 7 through 10, 1993

SIGNED: Richard P. McIntyre — 10/22/93
Richard P. McIntyre, Team Leader — Date
Reactive Inspection Section No. 1
Vendor Inspection Branch (VIB)

APPROVED: Richard P. McIntyre — 10/26/93
for Uldis Potapovs, Chief — Date
Reactive Inspection Section No. 1
Vendor Inspection Branch (VIB)

INSPECTION BASES: 10 CFR Part 50, Appendix B and 10 CFR Part 21

INSPECTION SCOPE: To determine if quality activities performed as part of the design of the Advanced Boiling Water Reactor (ABWR) project were conducted under the appropriate provisions of the GE-NE 10 CFR Part 50, Appendix B, quality assurance program, as implemented by the Quality Assurance Program Description (NEDO 11209-04A) that has been approved by the NRC.

PLANT SITE APPLICABILITY: None

1 INSPECTION SUMMARY

1.1 Nonconformances

1.1.1 Contrary to Criterion III of Appendix B to 10 CFR Part 50 and Section 3.10 of the GE-NE QA Program Topical Report, NEDO-11209-04A, changes made to the computer codes REDYA, ODYNA, and SAFER were not being documented and verified in any formal manner. No official records of the changes are required to be kept and the changes themselves do not have to be reviewed independently. (93-02-01)

1.1.2 Contrary to Criterion III of Appendix B to 10 CFR Part 50 and Section 4.4.1 of Engineering Operating Procedure (EOP) 40-3.00, "Engineering Computer Programs" (ECPs), the flow area of the internal recirculation pump used for the modeling of the SAFER code was based on an unverified hand drawn sketch with a reference to an individual who provided the information, instead of a reference to the applicable dimensioned design drawing. (93-02-02)

1.1.3 Contrary to Criterion XVII of Appendix B to 10 CFR Part 50, GE-NE had not filed the quality assurance documents or the test log required by Test Plan and Procedure (TPP) TP-515.1078, "ABWR Full Integral Simulation Test (ABWR FIST)," Revision A, dated October 17, 1983, for the ABWR FIST tests in DRF E00-149 and subsequently could not produce the documents. (93-02-03)

1.1.4 Contrary to Criterion XII of Appendix B to 10 CFR Part 50 and Sections 1.1 and 4.2.b of EOP 35-3.20, "Calibration Control," GE-NE purchased thermocouples used in the ABWR FIST tests from a commercial grade supplier, 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. (93-02-04)

1.1.5 Contrary to Chapter 17 of the ABWR Standard Safety Analysis Report (SSAR) which commits to ANSI/ASME NQA-1-1983, the calculation notebooks for the inputs to the SAFER, REDYA and ODYNA computer codes did not have a sufficient level of detail and in some cases were inadequately referenced. In addition since changes to computer codes are design analyses they should also be documented in a sufficient level of detail. (93-02-05)

1.1.6 Contrary to Criterion V of Appendix B to 10 CFR Part 50 and GE-NE SSAR for the ABWR, Chapter 17, Section 17.1.2, "Quality Assurance Program," GE-NE failed to perform an annual implementation review of Hitachi and Toshiba's QA program for the 1991 period. This failure resulted in a 16 month interval between the audits performed in 1990 and the 1992 audits. (93-02-06)

1.1.7 Contrary to Criteria V and VII of Appendix B to 10 CFR Part 50 and Section 7 of the GE-NE QA Program Topical Report, NEDO-11209-04A, "Control of Purchased Material, Equipment and Services," GE-NE failed to perform audits of Bechtel's ABWR QA Program Plan implementation for engineering services associated with GE-NE PO No. 190-ALWR-31387, and accepted safety-related services from Bechtel without them being listed on GE-NE's Approved Suppliers List for such services. (93-02-07)

1.2 Unresolved Items

1.2.1 GE-NE has the following statement in Chapter 17 of the ABWR SSAR: "The lead responsibility to produce each specification and drawing is formally assigned to one design organization. However, the content of each document is reviewed and approved by GE-NE. While all common engineering documents reflect the formal consensus of all parties, GE-NE is responsible for the design and supporting calculations and records for the ABWR project." It is not clear to the staff how GE-NE has met their SSAR commitment.

The ABWR system design record files (DRFs) have the Japanese plant (K6/K7) system design specification, process flow diagram (PFD), piping and instrument diagram (P&ID), and instrument block diagram for each system. These received a formal GE-NE review via Engineering Review Memoranda (ERMs) and the resolution of comments is well documented. However, there is a scarcity of information on supporting calculations, particularly for those systems where the technical associates had the design lead. GE-NE had not documented a review of the supporting calculations for the reactor building cooling water system and the audit process of the technical associates did not examine the technical adequacy of the supporting calculations. (93-02-08)

1.2.2 The GE-NE ABWR SSAR (Document 23A6100) contained inconsistent design information in that Figure 9.2-1a, the PFD, did not depict the US ABWR reactor building cooling water (RCW) system configuration and Table 6.3-1 contained the incorrect main steam flow rate.

The team identified that the system P&ID, Figure 9.2-1, sheet 1 of 9, represented the ABWR configuration with 3 heat exchangers while the associated PFD, Figure 9.2-1a, showed only 2 heat exchangers that is representative of the Japanese plant (K6/K7) design. The system flow and pressure drop information on the PFD had not been re-calculated for the ABWR configuration as the analysis had been performed by the international associate. The team also pointed out that the main steam flow rate listed in Table 6.3-1 of the SSAR was inconsistent with the value used in the computer code SAFER03 input. (93-02-09)

1.2.3 The team reviewed the RCW system DRF, P21-00001, and determined that within the DRF there were several pages (sheets 554-560) of unchecked/unverified calculations that evaluated the ABWR system differences from the K6/K7 design, including additional heat loads and the addition of a third heat exchanger. These calculations therefore would support the US ABWR certification. The evaluation was very informally done and was not sufficiently detailed as required by ANSI N45.2.11-1974, "Quality Assurance Requirements for the Design of Nuclear Power Plants," with respect to: purpose, method, assumptions, design input, and references so that a technically qualified person could review and understand the analysis without recourse to the originator. In addition, EOP 42-10.00 states that when a DRF is closed, the completed record shall be reviewed to ensure design verification requirements, where applicable, have been met.

The RCW calculations that extrapolated the K6/K7 design to the certified ABWR design were performed in a manner not consistent with the GE-NE QA topical report (NEDO-11209-04A) commitment to ANSI N45.2.11-1974. (93-02-10)

2 STATUS OF PREVIOUS INSPECTION FINDINGS

No previous inspections have been conducted in this area.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Quality Assurance Program

The quality assurance (QA) program implemented for the ABWR program is described in the Advanced Light Water Reactor Program Quality Assurance Program Plan (QA Plan) that was prepared for the Department of Energy, Contract No. DE-AC03-86SF16563. This DOE QA Plan mandates the application, as appropriate to the contract scope, of the QA program described in Revision 6, dated June 30, 1986, of the NEDO-11209-04A, "Quality Assurance Program Description." This is the GE-NE topical report that has been reviewed and approved by the NRC and meets Appendix B of 10 CFR Part 50.

The DOE QA Plan contains a work element/implementing procedure matrix that contains 18 major subdivisions which correlate with the 18 criteria of Appendix B. The 18 subdivisions are further broken down into 78 work elements committed to the QA Plan. Four types of GE-NE procedures are described that implement the work elements of the QA Plan. These are Nuclear Energy Business Operations (NEBO) Policies and Procedures (P&Ps), BWR Engineering Operating Procedures (EOPs), Nuclear Systems and Technology Operation (NSTO) Policies and Instructions, and Nuclear Service Procedures (NSPs). During the 1986-1987 time frame, the NSPs were phased out and folded into the EOPs.

The NEBO P&Ps are high level GE-NE policies that establish overall policies and responsibilities for NEBO. As a result of a reorganization, GE-NE nuclear activities are currently under the Vice President of GE Nuclear Energy (GE-NE) and NEBO no longer exists. The EOPs are a series of procedures that implement GE-NE policies and the QA program. NSTO Policies and Instructions deal with subjects such as cost schedules, budgeting, contract award, and business management and as such have no importance in implementing the QA Plan. The NSPs have been subsumed by the EOPs.

The team reviewed the organizational hierarchy and found that several QA organizations are involved with performing verification activities for the ABWR design efforts. All of these organizations appeared to have the necessary independence to carry out their charter. Documentation reviews and personnel interviews were conducted with selected staff from the various GE-NE organizations involved with implementation of the GE-NE QA program. This included Nuclear Quality Assurance (NQA), Services Quality Assurance (SQA), Advanced Reactor Programs (ARP) Quality Assurance, and ARP engineering and management staff. Selected aspects of the QA program elements were examined in further detail as described below.

3.1.1 Scope Of QA Program Implementation for Design

The team was informed that all ABWR engineering work is performed in accordance with the guiding Engineering Operations Procedures (EOPs) and that none of the work is classified as non-safety-related. The generic application of EOPs was observed during the course of the inspection.

3.1.2 Quality Council

The Quality Council is comprised of QA representatives from a number of GE-NE organizations. The purpose of the council is to assure uniformity in application of the QA program and to resolve QA issues. The team reviewed the minutes from the following Quality Council meetings: 3/19/93, 12/14/92, 7/9/92, and 3/20/92. Only a cursory mention was made in the minutes of one issue related to the ABWR, that being a letter from a Japanese utility involving positive audit results of GE-NE. The meeting minutes did not reflect any other Quality Council review of ABWR issues. The NRC Safety Evaluation Report (SER) for the ABWR design certification refers to the Quality Council as an aid for NQA to fulfill its responsibilities. It was not evident that the Council was making substantive contributions with respect to ABWR quality issues.

3.1.3 Engineering Training

The team reviewed EOP 70-30, "Personnel Proficiency in Quality Related Activities." The EOP states that employees shall be trained on the quality system and that they shall read or be instructed in applicable procedures. The team randomly selected two lead engineers associated with the ABWR project. Their self-study indoctrination records were reviewed. Each document stated that the engineers had read and understood the pertinent quality procedures.

3.2 Instructions and Procedures

3.2.1 NQA Procedures

The team reviewed the following NQA Practices and Procedures:

- 1.1 "Files and Records"
- 1.2 "Standard Distribution List"
- 2.1 "Conduct of Audits"
- 2.2 "Preparation of Corrective Action Requests"
- 2.3 "Audit Corrective Action Performance Report"
- 2.4 "Auditor and Lead Auditor Qualification and Certification"

The procedures were found consistent with the governing QA policies. The procedures provided working level directions for performance of NQA activities.

3.2.2 Engineering Operating Procedures (EOPs)

The team reviewed a selection of EOPs that govern the implementation of the QA program by both design/engineering and QA personnel. The following procedures were examined:

- EOP 55-2.00, "Engineering Change Control"
- EOP 60-3.10, "Engineering Records"
- EOP 65-2.00, "Product Safety Requirements"
- EOP 65-5.00, "Licensing Documentation"
- EOP 75-2.00, "Qualification and Certification of Personnel"
- EOP 75-3.00, "Corrective Action and Audits"

EOP 65-2.00 specified that Product Safety Requirement (PSR) documents are to be prepared that define the safety and licensing requirements for standard plants. This EOP was found to be in the process of being revised to clearly reflect that the standard plant Safety Analysis Report (SAR) will serve as the PSR. This information was confirmed through discussions with engineering management and review of internal GE-NE memoranda. Thus for the ABWR, the SSAR is treated as a controlled design document from which safety and licensing requirements are translated into other design documentation.

3.2.3 Services Quality Assurance (SQA) Procedures

The instructions utilized by the SQA QA group were reviewed. In particular the following procedures were examined:

- AG-004, "Corrective Action"
- AG-008, "Processing Quality Records"
- AG-017, "Internal Audit Scheduling, Internal Au[illegible] and Auditor/Lead Auditor Qualification/Certification"

As discussed in section 3.9 of this report, the team identified to GE-NE that while the procedural instructions for audits discuss the Corrective Action Requests and recommendations for handling audit findings, several audit reports were found to contain a variety of findings called: observations, unresolved items, and concerns.

3.3 Document Control

Document control is prescribed by NEBO P&P 70-11, "Quality Systems Requirements" and numerous EOP's such as 15-2.00, "EOP Application;" 30-5.00, "Engineering Records Documentation Supplied by External Sources;" 40-7.00, "Design Reviews;" 42-5.00, "Engineering Requirements Document Release;" 42-6.00, "Independent Design Verification;" 42-8.00, "Document Issue and Application by ERM;" 55-2.00, "Engineering Change Control;" and 60-6.00, "Drafting Manual Control."

The team found poor control of design and calculation documents related to the FIST, SSAR calculations, and computer code modeling. Some calculation documents were kept in individuals' desks, and original design drawings were kept in an unlabelled shop drawing file. Refer to Sections 3.5 - 3.8 of the report for details.

3.4 Quality Assurance Records

Quality Assurance records are prescribed by NEBO P&P 70-11, Quality Systems Requirements, and numerous EOP's such as 35-3.00, "Engineering Tests;" 40-7.00, "Design Reviews;" 40-9.00, "ASME Code Design Verification;" 42-6.00, "Independent Design Verification;" 42-10.00, "Design Record Files;" and 60-3.10, "Engineering Records Retention."

EOP 42-10.00 describes DRFs as formal, organized accumulations of information, which provide a controlled system for retention of documented engineering activities, necessary to substantiate significant design decisions. The DRF provides a mechanism for controlling and archiving important design records, such as design verification, studies and analyses. It does not include documents, such as drawings and specifications, which are maintained under separate corporate design controls. The procedure also states that the DRF should provide for design notes, calculations, records and other supporting information, and cross-reference to related or supporting DRFs.

The team interviewed GE-NE configuration management staff in regards to practices for generating DRFs. DRFs are created by cognizant design engineers to include the necessary design documents. When the associated design activities are completed, the DRF is reviewed and forwarded for permanent retention on microfilm. Periodic reports are distributed to cognizant managers in the event DRFs are not being completed and microfilmed in a timely fashion.

The reproduction area was examined and the process for handling incoming DRFs was reviewed. The GE-NE records management personnel review the DRF for legibility prior to sending the DRF to the microfilming contractor. The hard copy records are shipped to a vendor to be microfilmed and three microfilms are returned to GE-NE. One copy of the film is kept in the GE-NE library vault area, one is sent to the permanent repository, and one film along with the hard copy is given to the cognizant engineer. The team examined the library DRF files. These were maintained in locked storage containers that are only accessible to personnel authorized by the appropriate DRF custodian.

Based on the DRF reviews, the team questioned GE-NE with respect to an SSAR statement that GE-NE is responsible for common engineering documents that are used for certification including the supporting calculations. These supporting calculations are not always included in the DRF. GE-NE currently has the following statement in SSAR section 17.1.1: "The lead responsibility to produce each specification and drawing is formally assigned to one design organization. However, the contents of each document is reviewed and approved by GE-NE. While common engineering documents reflect the formal consensus of all parties, GE-NE is responsible for the design and supporting calculations and records for the ABWR project."

The GE-NE DRF files do have the Japanese (K6/K7) plant design specification, process flow diagram (PFD), piping and instrument diagram (P&ID), and instrument block diagram for each system. These received a formal GE-NE review via Engineering Review Memoranda (ERMs) and the resolution of comments is well documented. However, there is a scarcity of information on supporting calculations, particularly for those systems where the international technical associates had the design lead. The team reviewed the system calculations for the reactor building cooling water (RCW), a system where the technical associates had the design lead and identified that GE-NE has not documented a review of the supporting calculations and their QA audit process did not examine the technical adequacy of the supporting calculations.

GE-NE management indicated that GE-NE engineering reviews conducted of common engineering documents, participation in design meetings with the international associates, review of other design documents, and performance of QA audits of the associates fulfilled their responsibilities with respect to supporting calculations. As a result, Unresolved Item (93-02-08) was identified during this part of the inspection.

3.5 Design Control

3.5.1 Design Action List (DAL)

The team reviewed EOP 55-2.00 which identified that the Change Control Board (CCB) would maintain the DAL. The Chairman and secretary of the CCB explained the DAL process and provided a supplementary GE-NE administrative guideline that is used for the DAL process. GE-NE stated that the DAL items are those design issues which represent potential design changes for the US ABWR, such as changes required to meet the US regulatory requirements and US codes and standards. The DAL tracks the differences between the K6/K7 design and the certified US ABWR design. When a difference is identified between the designs, it is listed on the DAL and a decision is made whether to proceed with an Engineering Change Approval (ECA) for generic changes or an Engineering Change Notice (ECN) for singular changes. The DAL serves as a placeholder to track changes that need to be made at a later date affecting lower tier engineering documents. The First-of-a-Kind-Engineering (FOAKE) effort will translate the DAL items into the implementing design documents. The team was informed that the majority of the DAL resulted from licensing review comments made by the NRC that necessitated changes from the K6/K7 design.

The team found no formal GE-NE procedure which ensured that each responsible engineer reviewed the international ABWR design to verify that it complied with the current set of applicable US requirements for each system. GE-NE stated that the international ABWR was, in their opinion, licensable in the US. Therefore, the changes to the design that are captured in the DAL are those that were agreed to by GE-NE to resolve the NRC staff comments on the SSAR. According to GE-NE, the latest issue of the SSAR incorporates all DAL items issued to date. However, the actual implementation of the DAL will be addressed during the FOAKE activities.

3.5.2 Design Change Control

3.5.2.1 SSAR Material

The team was informed that an international technical associate had the design lead for the reactor building cooling water (RCW) system. The team identified that the system piping and instrument diagram (P&ID), Figure 9.2-1, sheet 1 of 9, represented the ABWR configuration with 3 heat exchangers while the associated process flow diagram (PFD), Figure 9.2-1a, showed only 2 heat exchangers that is representative of the K6/K7 design. The system flow and pressure drop information on the PFD had not been re-calculated for the ABWR configuration as the analysis had been performed by the international associate. The team identified this inconsistency to GE-NE management. They stated that they would either remove the PFD from the SSAR or revise the PFD information to be consistent with the US ABWR design.

The team pointed out that the main steam flow rate listed in Table 6.3-1 of the SSAR was inconsistent with the value used in the SAFER03 input. GE-NE agreed to correct this error in Amendment 32 to the SSAR. The team checked samples of other design input data against the SSAR and found them to be consistent.

The existence of inconsistent design information in the controlled SSAR is identified as Unresolved Item (93-01-09) as GE-NE was in the process of certifying the SSAR material to be submitted in Amendment 32 and the SSAR is a formal design document that is utilized by the staff to reach a safety judgement on the ABWR.

GE-NE does not have a procedure for controlling changes to the certified ABWR design. Currently GE-NE is exploring several ways of controlling the ABWR design after certification, and will adopt the approach recommended by the nuclear industry that is acceptable to the NRC.

3.6 Review of Safety Analyses and Design Calculations

The team selected for review examples of DRFs related to system design and analyses in support of SSAR Chapters 6 and 15. The analyses files selected were A11-0009, A00-03024, A21-00001, and A21-00001-1. The review consisted of verifying that input data and assumptions were properly documented and that independent review was performed.

The requirements in EOP 42-10.00, "Design Record Files," were general and broad-based, and the DRFs met the intent of this procedure. For most of the inputs the source references were listed. However, the team found that input information that was based on assumptions, engineering judgement, or previous GE-NE experience, was not identified as such. The documentation included in analyses files was lacking in clear definition of the purpose, methodology and assumptions such that an independent reviewer who had not performed the analyses would find it very difficult to review these files. The team could not confirm that the independent verification of the SAFER03 analysis included checking of the data entry of inputs used in the computer runs because the printout of the input data and evidence of verification were not found in the DRF.

An example of the poor documentation of input assumptions to the analyses was found in DRF A11-00009. The flow area of the internal recirculation pump was based on a hand drawn sketch with a reference to an individual who provided the information, instead of a reference to the applicable design drawing. GE-NE produced a vendor drawing from 1981 as the source of the flow area information. This drawing did not include any dimensions and indicated no scaling information. However, GE-NE stated the flow area was scaled from this drawing based on the referenced individual's recall from memory of the pump shaft diameter and based on the assumption that the drawing was to scale. This method of independent verification is not consistent with the GE-NE topical report referenced in the ABWR SSAR. As a result, Nonconformance (93-02-02) was identified during this part of the inspection.

The above analyses were performed during the preliminary stages of the ABWR design, and GE-NE has not assessed the impact of the current ABWR design parameters on the conclusions reached in these analyses.

3.6.1 Residual Heat Removal System

The team reviewed portions of the DRF associated with the residual heat removal (RHR) system, E11-00052, which is still open. Volume 3 of the DRF included Engineering Review Memorandum (ERM) DMH5432AY on the SSAR verification effort for the RHR system. The GE-NE verification appeared to be a comprehensive review of SSAR material (text, figures, and tables) for accuracy with respect to P&IDs, instrument block diagrams (IBDs), PFDs and selected Design Action List items (DALs). Over 100 GE-NE verification review comments were generated. The verification was completed on 6/25/93.

The team also reviewed DRF E11-00032-1, Volumes 1 and 5 that included pertinent information on the RHR system. The DRF had been microfilmed on March 31, 1988. Design verification check sheets were included for GE-NE and the international associates for the common engineering documents. The design verifications provided for a comprehensive review by all three design organizations involved with the K6/K7 design and documented the reconciliations of the comments.

The DRF for the RHR system did not contain the original calculations in support of the design but provided references, scoping calculations by the responsible engineer to verify acceptability of the design parameters, agreements on design parameters reached between the parties responsible for the international design, comparisons with other BWRs, and engineering judgement. The system design specification along with the responsible engineer's justification of the design parameters was independently verified.

3.6.2 Reactor Building Cooling Water system

The team reviewed the reactor building cooling water (RCW) system DRF, P21-00001. The RCW system DRF clearly documented the multi-party engineering reviews of common engineering documents and associated dispositions. However, within the DRF there were several pages (sheets 554-560) of unchecked/unverified calculations that evaluated the ABWR system differences from the K6/K7 design, including additional heat loads and the addition of a third heat exchanger. These calculations, therefore, would support the US ABWR certification. The evaluation was very informally done and was not sufficiently detailed as required by ANSI N45.2.11-1974, "Quality Assurance Requirements for the Design of Nuclear Power Plants," with respect to: purpose, method, assumptions, design input, and references so that a technically qualified person could review and understand the analysis without recourse to the originator. In addition, EOP 42-10.00 states that when a DRF is closed, the completed record shall be reviewed to ensure design verification requirements, where applicable, have been met.

DRF P21-00001 was identified as closed on a DRF status run dated September 9, 1993. No formal process appeared to be in-place to ensure that while the DRF had been microfilmed, an outstanding activity had to be accomplished with respect to design verification of the calculations. The failure to ensure that the RCW calculations were design verified prior to closeout of the associated DRF appears to be inconsistent with EOP 42-10.00 requirements.

The team questioned the lead system engineer as to how the RCW surge tank capacity had been sized as the ABWR ITAAC includes a verification of 16 cubic meter volume for the tank. The RCW design specification includes a statement that the tank is sized so that it can function for 30 days without makeup following a seismic disturbance that could cause a failure in some portion of the system piping. No supporting calculations existed in the GE-NE DRF that provided the details for the tank sizing, and the team was informed that such calculations had not been reviewed during GE-NE interaction with the international technical associates. At the end of the inspection, the team was informed that forthcoming SSAR amendment 32 will contain additional information about the surge tank capacity.

The RCW calculations that extrapolated the K6/K7 design to the certified ABWR design were performed in a manner not consistent with the GE-NE QA topical report (NEDO-11209-04A) commitment to ANSI N45.2.11-1974 and with GE-NE EOP 42-1.00 requirements. As a result, Unresolved Item (93-02-10) was identified during this part of the inspection.

3.6.3 Containment Pressure and Temperature Calculations

The ABWR containment pressure and temperature calculations in DRF T11-0008 were approved and issued during the inspection. This file generally complied with the format and content requirements for calculations specified in procedure EOP 42-1.00, "Design Process," which was issued in December 1992. The short-term and long-term accident response analyses for the U.S. ABWR containment were performed using the international ABWR data except for decay heat data, wetwell temperature, and ultimate heat sink temperature. In response to the team's query regarding the inconsistency between SSAR Table 6.2-1 and the DRF, GE-NE stated that the SSAR table would be revised and submitted along with Amendment 32.

3.7 ABWR Full Integral Simulation Tests (FIST) Test Control

3.7.1 ABWR FIST Background

The teams reviewed documentation for the ABWR Full Integral Simulation Tests (FIST), performed October 18, 1983, through January 18, 1984, to verify implementation of GE-NE's QA program. The tests were performed at the GE-NE FIST facility site in San Jose, California, which was used for other FIST tests in addition to the ABWR FIST tests.

Test Plan and Procedure (TPP) TP-515.1078, ABWR Full Integral Simulation Test (ABWR FIST), Revision A, dated October 17, 1983, provided information on test objectives, quality assurance requirements, procedures to be followed when performing the test, and the instrument list. In addition, the TPP referenced other documents which were applicable to the tests such as facility drawings and information related to the FIST tests performed prior to and following the ABWR FIST tests.

The TPP stated that the objective of the tests was to obtain and evaluate basic thermal-hydraulic data from the test system configuration which had calculated performance characteristics similar to an ABWR with 8x8 fuel bundles during hypothetical loss-of-inventory and limited operational transients. The FIST facility was developed to closely simulate the ABWR with one full-size fuel bundle of electrically-heated rods producing full bundle heat output. Other components included an external recirculation pump to provide specified core flow, a scaled steam separator, a heated feedwater supply system, and three emergency core cooling systems. The facility was run at realistic pressures, temperatures, bundle power, and coolant flow rates. Approximately 500 instruments were connected to the system and the information was supplied to a highspeed data acquisition system which monitored pressures, temperatures, water levels, and flows throughout the facility.

3.7.2 FIST Test Control

Section 2.0 of the TPP provided the QA requirements for the ABWR FIST tests. Paragraph 2.1.4 of the TPP, "Q/A Forms," listed the following set of forms to be completed and filed in DRF E00-149 for each test: (1) FIST Facility Configuration Confirmation, (2) Quality Surveillance Check Sheet, (3) FIST Pre-test Check List, (4) FIST Run Log, (5) FIST Test Procedure, and (6) Test Instrument List. These forms were to provide the quality assurance basis for each test performed. The team reviewed the applicable portions of DRF E00-149 and was unable to locate these forms for the tests that had been performed and GE-NE personnel were unable to provide these forms from a source other than the DRF.

Section 4.3.i of EOP 35.300, "Engineering Test," dated February 4, 1982, stated that the responsible test engineer should assure that test logs were established and maintained. The team was unable to locate the test log in DRF E00-149 and GE-NE personnel were unable to produce the document. The team concluded, based on the review of DRF E00-149, that GE-NE had not filed the required QA documents for each test or the test log in the DRF and subsequently could not produce the documents. GE-NE had not maintained sufficient records, identifiable and retrievable, to furnish evidence of activities affecting quality such as the results of reviews, inspections, tests as required by Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. As a result, Nonconformance (93-02-03) was identified during this part of the inspection.

The following records and documentation, which are required to be contained or referenced in the FIST DRF, were missing: (1) as-built facility drawings, (2) reference to original data tapes from the tests, (3) records of disposition of all test anomalies, (4) test log and a complete set QA forms for each test, and (5) documentation of analytical or experimental verification of engineering calculations. In addition, the Joint Study Final Test Report, NEDC-30622, contained obsolete design drawings. Considerable effort was needed to determine what drawings contained the as-built elevations of key components of the test facility. Additionally, there were no final approved revisions for the drawings reviewed.

The team reviewed the six summary reports for the ABWR FIST tests: (1) NEDC-22185, "Internal Pump Plant Blowdown Test," (4/1/82-9/30/82), dated September 1982; (2) NEDC-30031, (10/1/82-3/31/83) dated March 1983; (3 & 4) NEDC-30214 (two reports) (4/1/83-9/30/83), dated September 1983; and (5 & 6) NEDC-30516 (two reports) (10/1/83-3/31/84), dated March 31, 1984; and the final report, NEDC-30622, "Internal Pump Plant Blowdown Test - Final Report," dated June 1984. Figure G-2d, sheet 4, of the Final Report had one signature block filled ("drawn"), three left blank ("checked," "DRTG," and "ENGRG"), and the issue date block left blank. Figure G-1 of the Final Report, "FIST Piping and Instrumentation Drawing," had one signature block ("ENGRG") left blank, the revision block left blank, and the issue date block left blank although NEDC 30031, dated March 31, 1983, an earlier document, contained the drawing with all signature blocks signed, the revision block filled, and an issue date of March 25, 1983.

The team also examined the ABWR FIST testing and SAFER code qualification based on ABWR FIST. GE-NE stated that the FIST test was a "licensing" test and had appropriate QA measures in place to assure the integrity and accuracy of the data acquired and that only programs that related directly to reactors require a safety-related classification. The DRF indicated that the testing was conducted as a non-safety-related activity.

The NRC asserts that the FIST test program comprised a safety-related activity, and that the program's purpose was, in part, to obtain design basis data for the ABWR. Therefore, the use of the data falls under type B2 of EOP 35-3.00, and also constitutes a safety-related activity. Appropriate QA procedures should therefore have been in place, commensurate with the requirements for safety-related tests, per the requirements of Appendix B to 10 CFR Part 50 and GE-NE's QA program description.

3.7.3 Instruments, Calibration, and Procurement

Sections 1.1 and 4.2.b of EOP 35-3.20, "Calibration Control," dated January 2, 1981, stated 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. Section 2.2 of the TPP, "Instrumentation," discussed the instrumentation used to gather data during performance of the tests and indicated that the differential pressure transducers and other instruments were calibrated by GE-NE personnel, that manufacturer's calibrations were to be used for thermocouples, and that the calibration histories were to be filed in DRF E00-149.

The thermocouples used for the ABWR FIST tests were purchased by GE-NE from Claude S. Gordon Co. as commercial grade items without further verification of the adequacy of the calibration or performance characteristics. GE-NE had not audited or performed surveys of Claude S. Gordon Co. and had not placed them on the GE-NE approved suppliers list. The purchase orders did not specify that any quality assurance program was to be in place, or that the criteria of 10 CFR Part 50 Appendix B or 10 CFR Part 21 applied. Therefore, GE-NE did not have assurance that the performance of the thermocouples was as specified by the manufacturer or traceable to certified equipment having known valid relationships to nationally recognized standards. GE-NE had not verified that the thermocouples, instruments used in an activity affecting quality, were properly controlled, calibrated, and adjusted to maintain accuracy with necessary limits as required by Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. As a result, Nonconformance (93-02-04) was identified during this part of the inspection.

3.7.4 Documentation of Test Anomalies and Deficiencies

The teams reviewed DRF E00-149 and the summary and final test reports for disposition of anomalies. The DRF contained a "Questionable - Channel List" which listed changes made to instrumentation such as changed orifice constants, the addition of instruments, and failure of instruments. The items typically listed the channel identification and a brief description of the reason for the entry. The form also provided an area for a "decision or action" in which disposition of the item could be documented. A number of items entered, which described failed thermocouples, did not have any disposition entered. GE-NE personnel indicated that the instrumentation system had been designed to be redundant to account for failures of thermocouples and that a disposition was not required.

The TPP did not provide for a method to document test anomalies or deficiencies other than the Questionable Channel List which was specific to instrumentation channels. The team noted that one test was required to be re-performed due to an inadequately sized blowdown orifice. The repeat of this test was documented on an Engineering Work Authorization sheet and included in DRF E00-149.

3.8 <u>ABWR Computer Code Modeling</u>

The team reviewed the code qualification and computer modeling for the GE-NE ABWR thermal-hydraulics calculations included in Chapters 6 and 15 of the SSAR. The three computer codes and associated modeling examined were REDYA, ODYNA and SAFER. REDYA is a point kinetics transient analysis code that is only used for slow transients. ODYNA is a one dimensional (1D) kinetics transient analysis code that is used for fast transients including all pressurization transients. SAFER is GE-NE's LOCA evaluation computer code. A review of the DRF for each computer code revealed that no official documentation of the implementation, testing, and independent verification of computer code changes exists in the DRF. In some cases, the developer keeps his own personal records of this implementation and testing. In one case the code developer stated that code changes were not even documented through internal code comment statements. As a result, Nonconformance (93-02-01) was identified during this part of the inspection.

GE-NE's method of independent verification is called a Design Review. During the design review, the results of code qualification calculations are presented to the design review team. This "high level" independent verification seems to assume that low level verification of the implementation of code changes and modeling has already been done. Since this is not required, the high level review can allow errors to slip through as previously identified in the August 1993 inspection of the SWBR and TRACG for the GIST test. In the case of REDYA and ODYNA, GE-NE qualified the codes for modeling internal pump plants without comparison to experimental data. An unreferenced and later report compared the codes to internal pump data from two European internal pump plants. GE-NE also has not been able to obtain internal pump experimental data from the technical associates. The technical associates will only supply GE-NE with the information needed for code inputs and not the data they were obtained from.

The ABWR calculation notebooks reviewed were found to be sloppily kept and not self-contained enough to review without the analyst present. The calculation notebooks and analysis DRFs also do not seem to meet the GE-NE topical report which requires stand alone documentation with all assumptions clearly stated and that a technically qualified person is able to review it without any outside help. As a result, Nonconformance (93-02-05) was identified during this part of the inspection.

3.9 Quality Assurance Audits

3.9.1 Nuclear Quality Assurance (NQA)

The team reviewed the NQA audit plans that had been prepared for 1990 through 1993. Two audits, Q9008 and Q9306, involved ABWR activities. In addition, audit Q9107 had been planned then was cancelled as it was determined by GE-NE to be a redundant verification with a Quality System Review effort.

The team reviewed the associated ABWR audit documentation including: audit checklists, auditor qualifications, audit plans, audit findings, completed audit checklist, summary audit report, NQA audit report, and associated Corrective Action Requests (CARs). Audit Q9008 was performed between September 24, 1990, and October 5, 1990, by two audit personnel. The audit reviewed the ABWR Reactor Pressure Vessel (RPV) design specification. The audit uncovered the fact that some DRFs had not been microfilmed in a timely manner. Appropriate corrective action and preventive action was specified for the Corrective Action Request. Audit Q9306 had been partially completed. The audit checklist included attributes such as DRF technical completeness which had not yet been audited.

3.9.2 Services Quality Assurance (SQA)

The team reviewed the SQA audit planning for 1993. No audits were planned in the ABWR area as the manager of Advanced Reactor Programs (ARP) QA had not requested any audit assistance from SQA. However, SQA (formerly PQA) has audited the ABWR project in the past. The team reviewed a sample of those audits and associated documentation as discussed below:

- PQA Audit 91-2: This audit principally covered Japanese work on the K6/7 project, there were no findings of import for the ABWR.

- PQA Audit 92-1: Two auditors participated on this audit. Aspects of the interface between GE-NE and Japanese partners was audited.

- PQA ABQ 91-1: This audit related to the control and issuing of the ABWR Standard Safety Analysis Report (SSAR). The audit identified a concern that some diagrams had been submitted in the SSAR that had not been verified.

3.9.3 Advanced Reactor Programs (ARP) QA

The 1993 audit plan for the Advance Reactor Program (ARP) QA group for 1993 was reviewed and it was found that no audits were planned for the ABWR. However, the team was informed that a scheduled audit on the First-of-a-Kind-Engineering (FOAKE) would actually cover the ABWR follow-on engineering work. That audit is planned for the fourth quarter of the year.

ARP QA had performed one ABWR audit in 1992, Q9203. The team reviewed ARP audit Q9203 that was conducted on both the ABWR and SBWR. The audit report was issued on January 25, 1993. The following aspects were documented as having been examined for the ABWR: review and status of design verification items for the SSAR, review and status of Design Action List (DAL) items and associated engineering change documentation, review and status of SSAR preparation, and follow-up to a previously identified SQA audit issue. The audit checklist and audit report did not contain sufficient information to document that the audit scope had covered the breadth of QA aspects claimed to have been performed (Appendix B Criterion 1, 2, 3, 4, 5, 6, 7, 16, 17, and 18). During discussions with the lead auditor, the team was informed that the report had been structured in a brief format to conform to management expectations. The team expressed a concern that audit reports should contain sufficient information regarding the scope of audit activities to allow the evaluation of the audit at a later date.

The team was informed that ARP QA surveillances are also performed by quality personnel to supplement the formal audit process. The team reviewed ARP QA surveillances for reviews on several DRFs. The QA staff had compiled a checklist of several attributes to check with respect to DRF administrative content. These surveillances had been performed for the Control Rod Drive (CRD) restraint, reactor pressure vessel (RPV) and fuel transfer DRFs. The QA review found some unsatisfactory aspects that the team was informed has been rectified. The performance of supplemental surveillances is a good practice to augment the more formal and infrequent ARP QA audits.

The team questioned QA management about the technical composition of the audit teams. GE-NE management stated that over the last 5 years, none of the ARP QA audit teams has been supplemented with technical personnel to perform a deep review of the integrity of the design process.

3.9.4 Audits Performed By External Groups

In June of 1992, a Nuclear Procurement Issues Committee (NUPIC) audit was performed by auditors from Florida Power and Light, Entergy, Wolf Creek, Nebraska Public Power District (NPPD), and Illinois Power. Audit finding SA92-05-02 was generated because GE-NE engineering calculations in two DRFs (involving NPPD work) were found to not always conform to the requirements of ANSI N45.2.11 that had been contractually invoked. GE-NE implemented corrective action that included generating a new EOP, 42-1.00, "Design Process," that implements the ANSI N45.2.11 requirements and GE-NE rectified the two DRFs as needed. GE-NE had not evaluated the adequacy of the pre-existing ABWR calculations with respect to the new EOP requirements. GE-NE management stated that prior ABWR work was suitably controlled. See Section 3.4 of this report regarding reviews of DRFs and associated calculational files.

3.9.5 GE-NE Audits of Hitachi Limited and Toshiba Corporation

The NRC inspectors reviewed several GE-NE audits performed of Hitachi Limited and Toshiba Corporation (Japanese technical associates) which are approved for engineering services related to the design of safety-related systems and components for the Japanese ABWR plant K6/K7. GE-NE is required to perform an annual review of Hitachi and Toshiba's QA program implementation in accordance with GE-NE's Joint Venture Agreement (JVA) and GE-NE's QA Plan. The audits reviewed during the inspection included the 1988, 1989, 1990, and 1992 audits performed by GE-NE at the Hitachi Works, located in Hitachi City, Japan, and Toshiba's Isogo Nuclear Energy Center, located in Yokohama, Japan. The audits were performed by one member from GE-NE QA, located in San Jose, California, and one member from the General Electric Technical Service Company (GETSCO) office, located in Japan. Each audit was usually one to two days in duration.

The audits of the Japanese technical associates were performed to review the implementation of the Joint Venture QA Basic Plan and focused on various aspects of their overall QA program which included document and design control, engineering computer codes, design reviews, quality training, QA program changes, document maintenance, and internal QA audits. The QA programs are based on "Quality Assurance Guidelines for Nuclear Power Plants" (JEAG 4101), which was established on the basis of Appendix B to 10 CFR Part 50. The first edition of this guideline was issued in 1972 and was later modified on the basis of International Atomic Energy Agency (IAEA) Code of Practice 50-C-QA and issued as a second edition (JEAG 4101-1981). Reflecting IAEA Safety Guides Series 50-SG-QA, the guidelines were modified once again and issued as a third edition (JEAG 4101-1985). In addition, a series of detailed guidelines (JEAG 4102-4109) have been issued as supplementary material for JEAG 4101-1985. These were introduced during the period 1985 to 1988, however they thereafter came to be reviewed on the basis of IAEA safety standard 50-C-QA (Revision 1) and were eventually issued in a comprehensive version (JEAG 4101-1990) which remains effective today.

The NRC inspector's review of these audits identified weaknesses in that the audit file documentation did not reflect the necessary detail to support an effective implementation audit of the QA program areas reviewed. The eight audits reviewed by the NRC inspectors did not identify any findings or weaknesses which required corrective action, however two audits of technical associates identified that the quality system was effective in assuring the quality of common engineering and the JVA activities, with several exceptions. One exception, documented in a 1988 audit report of a technical associate, identified that the associate's method of verification, attesting to the completion of individual design reviews performed for design verification, was not always documented per Section 5.3 of JEAG 4101-1985. This exception appeared to have the potential of a nonconformance. It was also noted that GE-NE failed to perform an annual audit of the technical associates' QA program as required by the JVA commitments and GE-NE procedures. As a result, Nonconformance (93-02-06) was identified during this part of the inspection.

3.9.6 GE-NE Audits of Bechtel North American Power Corporation

The NRC inspection team reviewed several purchase orders (POs) between GE-NE and Bechtel North American Power Corporation (BECHTEL), San Francisco, California, for engineering services associated with the ABWR contract. BECHTEL, acting as a subcontractor to the U.S. Department of Energy (DOE), is providing engineering services to GE-NE under DOE Contract DE-AC03-86 SF16563, "Technology Programs in Support of Advanced Light Water Reactor Plants," dated August 27, 1986. The contract includes work scopes for both the Simplified Boiling Water Reactor (SBWR) and the ABWR program development and requires all contractors to establish, implement, and maintain a QA Program Plan which meets the requirements of Appendix B to 10 CFR Part 50 (Appendix B), and ANSI N45.2-1977. Work scopes for the ABWR include structural reanalysis and design verification of the reactor building and other facilities (Task 110.1), and dynamic analysis (Task 130.1) used to support Chapter 3, "Design of Structures, Components, Equipment and Systems," of the ABWR SSAR, which is associated with ABWR licensing certification.

The NRC inspection team reviewed GE-NE PO No. 190-ALWR-31387, issued to BECHTEL on April 22, 1987, which included Tasks 110.1 and 130.1. The PO invoked no QA requirements with respect to the manner in which the work was to be processed and referenced the "General Provisions" section of the DOE contract. The work scope section of the GE-NE PO stated, in part, that "Bechtel would furnish engineering services in support of GE-NE's contract with DOE to provide a licensing submittal to the NRC in support of Chapter 3 of the ABWR SSAR. This task is for <u>safety-related</u> systems (emphasis added)." An audit of BECHTEL was performed by GE-NE in August 1991 (QE 9104) which verified satisfactory implementation of Bechtel's QA program used to support the SBWR. However, no implementation audit of BECHTEL was ever performed in support of the ABWR. In addition, BECHTEL appears on GE-NE's Approved

Suppliers List (ASL) only for the Advanced Liquid Metal Reactor project, and not for the ABWR. Since 1987, over 21 amendments to the PO have been processed by GE-NE for additional work scope associated with the ABWR certification program without the benefit of an audit of the Bechtel QA Program Plan (latest version is Revision 4, dated November 5, 1992). As a result, Nonconformance (93-02-07) was identified during this part of the inspection.

During the NRC inspection, BECHTEL provided a letter to GE-NE (BLG-0100, dated September 10, 1993) which confirmed that although the GE-NE PO did not reference or invoke quality program requirements, all work supporting safety-related activities under the PO was processed in accordance with Bechtel's Nuclear QA Program Plan and Nuclear QA Manual, which complies with Appendix B.

3.9.7 Observations of QA Audit Activities

Based upon a review of audit activities performed by several GE-NE QA organizations, the team had the following observations:

- Audit reports had a variety of ways of categorizing the resultant findings, such as CARs, concerns, observations, recommendations, and unresolved items. The procedural controls only identify that CARs and recommendations result from audits. The team was informed that a draft procedure was under preparation for unresolved items. The other findings, while a reasonable explanation was given by GE-NE regarding their use, had not been explicitly described to ensure common use among the auditors and recipient organizations regarding corrective and preventive action requirements.

- A weakness in the GE-NE audit approach was that audit teams were not supplemented with technical engineering experts to perform more intensive design reviews to supplement the QA programmatic audits.

- The ARP QA follow-up of previously identified areas of concern is a good practice to ensure that corrective actions have been effectively implemented.

- Another identified weaknesses in the GE-NE audit approach is that the audit file documentation for the technical associates did not reflect the necessary detail to support an effective implementation audit of the QA program areas reviewed.

4 PERSONNEL CONTACTED

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Nuclear Regulatory Commission:

Richard P. McIntyre, Team Leader, Vendor Inspection Branch (VIB)
Leif J. Norrholm, Chief, VIB,
George Thomas, Nuclear Engineer, Reactor Systems Branch
Robert Pettis, Senior Reactor Engineer, VIB
Billy Rogers, Reactor Engineer, VIB
Robert Gramm, Section Chief, Performance and Quality Evaluation Branch
S.K. Malur, Senior Operations Engineer, Special Inspection Branch
Joseph Staudenmeier, Reactor Engineer, Analytical Support Group
H.S. Cheng, Physicist, Brookhaven National Laboratory

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

March 19, 1993

Docket No.: 99901260

Mr. Nicholas Dudas, President
Klockner-Moeller Corporation
Corporate Headquarters (USA)
25 Forge Parkway
Franklin, Massachusetts 02038

Dear Mr. Dudas:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO.: 99901260/93-01)

This refers to the inspection conducted by Messrs. Stephen D. Alexander and Charles J. Paulk of this office January 12 through 14, 1993. The inspection included a review of activities authorized for your Corporate Headquarters facility at Franklin, Massachusetts. At the conclusion of the inspection, the inspection findings were discussed with you and Mr. Thomas Erskine.

Areas examined during the inspection are identified in the report. Within these areas, the inspection consisted of selective examination of procedures and representative records, review of technical documentation, and interviews with personnel. The major areas reviewed included (1) the failure of the switch latch support levers in certain Klockner-Moeller (K-M) molded-case circuit breakers, (2) your program and its implementation for evaluation and reporting of these failures in accordance with Part 21, "Reporting of Defects and Noncompliance," of Title 10 of the Code of Federal Regulations (10 CFR Part 21), and (3) your corrective actions with regard to findings by Virginia Power and others during audits of your quality assurance program based on Appendix B, "Quality Assurance Requirements for Nuclear Power Plants and Fuel Reprocessing Facilities," to 10 CFR Part 50.

Based on the results of this inspection, certain of your activities appear to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). The violation of 10 CFR Part 21 is related to your not having an adequate procedure, to ensure that affected licensees or purchasers are informed of deviations in basic components supplied to them (in cases where K-M does not have the capability to determine if the deviation constitutes a defect) and for failing to update your procedure pursuant to 10 CFR Part 21 to be consistent with the latest (October 29, 1991) version of the regulation. The specific findings and references to the pertinent requirements are identified in the enclosed Notice and inspection report.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

We acknowledge your stated intention to discontinue supplying electrical equipment to NRC-licensed facilities as basic components (safety-related or Class 1E) under a 10 CFR Part 50, Appendix B, quality assurance program. However, as a manufacturer of electrical equipment, formerly supplied as basic components to NRC-licensed facilities, you nevertheless are responsible for reporting of defects and noncompliance in accordance with 10 CFR Part 21 for those basic components you supplied. You are also responsible under Part 21 for informing all affected licensees or purchasers of any deviations from technical procurement specifications you may discover in those basic components, if you are unable to evaluate the potential for a substantial safety hazard.

The response directed by this letter and the enclosed Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511. In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

We appreciate your cooperation and the information you provided us about the molded-case circuit breaker failures. While the root cause of the failures may not involve a deviation from technical procurement specifications per se, the information is important to promulgate to our licensees so that they can take appropriate actions to avoid similar problems.

Should you have any questions regarding this inspection, we would be pleased to discuss them with you.

Sincerely,

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosures:
1. Notice of Violation
2. Inspection Report 99901260/93-01

NOTICE OF VIOLATION

Klockner-Moeller Corporation
Franklin, Massachusetts

Docket No. 99901260
Report No. 93-01

During an NRC inspection conducted January 12-14, 1993, a violation of NRC requirements was identified. In accordance with the provisions of Appendix C (1992), "General Statement of Policy and Procedures for NRC Enforcement Actions," to 10 CFR Part 2, the violation is listed below:

Section 21.21, "Notification of Failures to Comply or Existence of a Defect and Its Evaluation," of 10 CFR Part 21, "Reporting of Defects and Noncompliance," requires, in part, that each individual, corporation, or entity subject to the regulations in this part adopt appropriate procedures to ensure the evaluation and proper reporting of deviations and failures to comply (§21.21(a)) and that if a deviation or failure to comply is discovered by a supplier of basic components or services associated with basic components, and the supplier determines it does not have the capability to perform the evaluation to determine if a defect exists, the supplier will inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply (§21.21(b)).

Contrary to the above, as of January 14, 1993, the Klockner-Moeller Corporation (K-M) procedure (Section 21 of the K-M Quality Assurance Manual), revision dated July 1989, for implementing 10 CFR Part 21: (1) did not contain provisions to ensure that affected licensees or purchasers are informed of deviations or failures to comply in basic components supplied to them, if K-M is unable to evaluate to determine if a defect exists (i.e., if the deviation or failure to comply could create a substantial safety hazard) so that the affected licensees or purchasers can perform the evaluation, and (2) had not been updated to be consistent with the latest version of 10 CFR Part 21 (effective October 29, 1991), which had instituted substantial changes in evaluation and reporting requirements.

This is a Severity Level V Violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Klockner-Moeller Corporation is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within thirty (30) days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked "Reply to Notice of Violation" and should include for each violation (1) the reason for the violation, or if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. When good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland,
this 19th day of March, 1993

Enclosure 2

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR INSPECTION AND LICENSEE PERFORMANCE
VENDOR INSPECTION BRANCH INSPECTION REPORT

ORGANIZATION:	Klockner-Moeller Corporation
REPORT NO.:	99901260/93-01
CORRESPONDENCE ADDRESS:	Mr. Nicholas Dudas, President Klockner-Moeller Corporation Corporate Headquarters (USA) 25 Forge Parkway Franklin, Massachusetts 02038
CONTACT:	Mr. Thomas Erskine, Quality Assurance Manager (508) 520-7080
NUCLEAR INDUSTRY ACTIVITIES:	Manufacturer and supplier of safety-related electrical equipment to nuclear power plants
INSPECTION CONDUCTED:	January 12-14, 1993
ASSIGNED INSPECTOR:	Stephen D. Alexander 2/26/93 Date Reactive Inspection Section No. 2 Vendor Inspection Branch
APPROVED:	Gregory C. Cwalina, Chief 2/26/93 Date Reactive Inspection Section No. 2 Vendor Inspection Branch
OTHER INSPECTORS:	Charles J. Paulk
INSPECTION BASES:	10 CFR Part 21 and 10 CFR Part 50, Appendix B
INSPECTION SCOPE:	Review of switch latch support lever failures in Klockner-Moeller molded-case circuit breakers, quality assurance audit corrective actions, and 10 CFR Part 21 compliance
PLANT SITE APPLICABILITY:	Various

1 INSPECTION SUMMARY

1.1 Violations

1.1.1 (99901260/93-01-01) Contrary to the requirements of 10 CFR 21.21, the Klockner-Moeller Corporation (K-M) procedure (Section 21 of the K-M Quality Assurance Manual) for implementing 10 CFR Part 21 (1) did not contain provisions to ensure that affected licensees or purchasers are informed of deviations or failures to comply in basic components supplied to them that K-M is unable to evaluate to determine if a defect exists and (2) had not been updated to be consistent with the latest version of 10 CFR Part 21 (effective October 29, 1991), which had instituted substantial changes in evaluation and reporting requirements. (see Section 3.4.3 of this report).

1.2 Nonconformances

No nonconformances were identified during this inspection.

1.3 Unresolved Items

1.3.1 (99901260/93-01-02) The effectiveness of the reporting interface maintained with the K-M factory in order to support the Part 21 program was of concern to the inspectors and will be reviewed further in a future NRC inspection. See Paragraphs 3.4.1 and 3.4.2 of this report.

1.3.2 (99901260/93-01-03) Technical and linguistic ambiguities in K-M's root-cause analysis of the support lever failures will be resolved in a future NRC inspection. See Paragraphs 3.2.2 and 3.4.2 of this report.

1.4 Open Item

(99901260/93-01-04) For future sales of K-M electrical equipment to U.S. nuclear utilities as basic components, National Testing Services, (NTS) Acton, Massachusetts, will become the principal (if not exclusive) supplier. NTS is to maintain an interface with K-M in Germany and/or through K-M's U.S. facilities and is expected to take credit for some K-M factory activities, such as commercial quality controls and some testing. In dedicating K-M equipment for safety service, such activities constitute or are related to activities affecting quality. Therefore, the K-M activities (particularly in Germany) in support of NTS's dedication program may be reviewed in a future NRC inspection. See Paragraph 3.5 of this report.

2 STATUS OF PREVIOUS INSPECTION FINDINGS

This was the first NRC inspection at this K-M facility.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

At the entrance meeting on January 12, 1993, the inspectors discussed the scope of the inspection and coordinated the interactions with K-M management.

During the exit meeting on January 14, 1993, the NRC inspectors discussed their findings and concerns with K-M management. In addition, the inspectors discussed with K-M the need for an NRC inspection in the near future at the K-M facilities in Germany in order to resolve Open Items 99901260/93-01-02, -03, and -04. K-M management was receptive to this idea and agreed to assist in arranging for the inspection.

3.2 Failure of K-M Molded-Case Circuit Breakers (MCCBs)

3.2.1 Background:

On July 1, 1992, Virginia Power, licensee for North Anna Power Station, Units 1 and 2 (NAPS1 and NAPS2), as Virginia Electric and Power Company (VEPCO), reported to the NRC in accordance with 10 CFR Part 21 that three K-M model NZM6-63, 480-Vac MCCBs had tripped without any load or fault condition or other electrical or mechanical transient, each on a separate occasion, over a 3-month period in 1992. The three failed MCCBs were part of a group of similar MCCBs manufactured in Germany by K-M in 1972 and supplied to VEPCO in K-M Series 170 motor control centers (MCCs). They were located in the cable vault and tunnel area of NAPS2 and supplied power to motor operated valves in the charging and safety injection systems. Although the MCCBs had not been carrying their normal starting or running loads when they tripped, they were found in the trip-free position and could not be relatched and reclosed.

VEPCO's internal examination of one of the three failed MCCBs revealed that its switch latch support lever (also described by VEPCO as a "spring arm"), located in the rear compartment of the MCCB case, had fractured, thus causing the MCCB to trip and to become incapable of being reclosed.

In response to the NRC's inquiries into this matter, VEPCO provided the NRC a copy of its Materials Engineering Laboratory Report, NESML-Q-037, dated July 27, 1992. This report classified (generically) the material of the failed support levers as a polycarbonate-glass fiber composite. According to the report, the VEPCO laboratory performed infrared spectroscopy, scanning electron microscopic examination, and associated energy-dispersive-X-ray spectroscopic (EDS) analysis on the support lever from the MCCB examined at NAPS2. The laboratory also conducted similar tests and also cyclic stress tests on the same part from two other MCCBs that had been in service, but had not failed. It then compared the results with the failed parts. On the basis of this testing and comparison, the VEPCO laboratory concluded that the fracture in the failed support lever it examined was stress cycle related with cracks initiating at the inside of a shaft hole in the support lever. Although the MCCBs have a design life of 20,000 cycles (opening and closing), the three failed MCCBs had been cycled only a few times a year and have been in service since about 1977.

The VEPCO laboratory results suggested that similar MCCBs exposed to similar service conditions as these might fail in a similar manner, with the failure probability related to the number of cycles. Since the NAPS2 failures had occurred at significantly fewer cycles than the design value, and because the stress tests on the non-failed MCCBs produced similar initial cracks at the inside surface of the shaft hole, the VEPCO laboratory report attributed the premature failures to a design deficiency However, this idea is not borne out by reported service experience.

VEPCO has made several inquiries regarding these MCCBs on the Nuclear Network and other industry forums. According to the responses to the licensee's inquiries from five utilities, the responding users did not have records of similar failures. The manufacturer's records indicated that similar K-M model MCCBs are used by at least six nuclear utilities in the U.S., via direct sales to or for the utility and others have been sold as commercial grade through distributors. However, K-M stated that they had not received reports of similar failures.

VEPCO sent the other two (of the three) failed MCCBs to the manufacturer's factory in Germany (via K-M'[illegible] Corporate Headquarters in Franklin, Massachusetts) for its root [illegible] analysis. In August of 1992, K-M submitted to VEPCO and to the NRC the rep[illegible] by the German factory laboratory of the examination and analysis of these two failed MCCBs. The English translation of the report summary provided by the factory laboratory, "Investigation Results of Circuit Breaker NZM6-63/ZM6-40 from Power Station Virginia Power (OB 610 12-144504)," dated July 31, 1992, stated that there were no "blowholes or sinkholes" on the surface of the fract[illegible] and that "a material removed from the lever can be excluded as the evaluat[illegible] the relative shows." Although it was not clear what the significance of [illegible] finding was, the report concluded that the fractures in the support levers resulted from "stress corrosion cracking caused by mechanical loads inside the circuit breaker and environmental influences, e.g., solvent exhalation CKW (chlorinated hydrocarbon), which effected the fracture." [sic].

3.2.2 MCCB Failure Inspection Findings

According to K-M, from 1965 to 1972, th[illegible] [illegible]pport levers in this type MCCB were made of steel. However, from review of [illegible] [illegible]ufacturer's technical documentation during this inspection, including the Underwriters Laboratories listing documents and reports, the inspectors determined that from 1972 on, the support levers in only K-M NZM6 type (models NZM6b and NZMH6) MCCBs, rated for 100 amperes and below, have been made of the same Underwriters Laboratories-recognized component plastic used for the support levers in the MCCBs that failed at NAPS2. The name of the actual material used is K-M proprietary information.

3.2.2.1 Influence of Chemical Contaminants

During this inspection, the NRC inspectors developed a more rigorous translation of the original German report. The German version used the term "spannungsrisskorrosion" which would be translated as "voltage stress corrosion." The inspectors questioned this (1) because according to K-M personnel, the part in question (support lever) should not be subject to voltage stress and (2) because stress corrosion, or other corrosion, per se, is not usually associated with non-metallic materials. In addition, the so-called solvent exhalation CKW was better translated as off-gassing associated with arc extinguishing. Therefore, it was not clear whether the laboratory had actually found any traces of chlorinated hydrocarbons, which would be contrary to the VEPCO laboratory results. K-M agreed to contact, and/or put the inspectors in contact with, the appropriate personnel at the factory in Germany and obtain clarification on these ambiguities, both technical and linguistic. This issue will be tracked as Unresolved Item 99901260/93-01-03.

Although there may have been opportunities for exposure to a contaminant of the type suggested by K-M, VEPCO's infrared spectroscopy and EDS analysis did not reveal the presence of any chlorinated hydrocarbons and VEPCO also maintained that the MCCBs had not been exposed to such substances while in its possession. Nevertheless, K-M has indicated that exposure of the support levers made of the material in question in the affected MCCBs could contribute to or hasten their premature failure.

3.2.2.2 Influence of Thermal Service Conditions

In response to NRC inquiries prior to this inspection, VEPCO reported that the failed MCCBs at NAPS2 had been subjected to room ambient temperatures averaging between about 100 °F (38 °C) and 120 °F (49 °C) in the summers for about 13 years until air conditioning was installed in 1990. This reduced the average ambient temperature in this area to about 80 °F (27 °C). Although the heat rise at these MCCBs was not specifically reported, the MCCBs were not normally under more load than that of valve position indicating lights.

K-M provided a Wyle Laboratories aging report on K-M motor control center equipment, including NZMH6 MCCBs (100-amp-rated and less), to aid in determining the effect of the ambient service conditions on these failures. Wyle Laboratories Report 46968-1, Revision A, dated March 15, 1985, "Thermal Aging Program on a Series 170 480 VAC Motor Control Center," indicated that the support lever in one of these MCCBs (made of the same material as those that failed at NAPS2) failed in a similar manner after extensive accelerated thermal aging. The failure was discovered when, after aging, in preparation for the mechanical endurance or cycling portion of the test program, the MCCB had been reinstalled in the MCC cubicle, but could not be relatched and reclosed. The NZMH6 MCCB in which the support lever failed had been aged for a total of 2280 hours at 257 °F (125 °C), indicating that a support lever of the same material could fail after an equivalent amount of thermal aging degradation. However, other support levers in 100-amp or less-rated NZMH6 MCCBs did not fail after aging at 257 °F (125 °C) for 1104 hours. These lower aging parameters were intended to simulate 18 years at an average ambient service temperature of 138 °F (59 °C). They were chosen assuming a 104 °F (40 °C) average room ambient temperature with a heat rise of 34 °F (19 °C).

The parties involved have generally agreed that the proximate cause of the support lever failures at NAPS2 was cyclic stress fatigue. However, the lack of other failures in the industry suggests that other contributing factors may be needed to cause failure with so few cycles. In particular, unexpectedly rapid thermal aging and possible chemical exposure can cause weakening or embrittlement of the material in the support lever of 100-amp or less-rated NZM6, NZM6b, and NZMH6 K-M MCCBs such that the support lever can fail prematurely, i.e. with significantly fewer cycles than the design value.

The only other data available for NRC review relating to the performance of K-M MCCs and associated components at higher than normal ambient temperatures was a test report prepared for K-M by American Environments Company (AE), Incorporated. AE test report STR-132778-1, "Abnormal Environment Qualification Test Report on Series 170 Motor Control Centre for Klockner-Moeller Limited," was intended to demonstrate that these K-M MCC components could function in a moderately abnormal environment for a short period of time. The sample MCC components (including MCCBs of the type in question) were subjected to ≥ 95-percent relative humidity and a temperature of 145.2 °F ± 3 °F (62.9 °C ± 1.7 °C). The humidity was maintained for a 24-hour period while the temperature was permitted to decrease to 134 °F ± 3 °F (56.7 °C ± 1.7 °C). The specimen components had been irradiated, but not thermally aged. The test included no elevated pressure or spray. Some components exhibited performance anomalies and failures during the test. However, the report did not mention any anomalous performance of the MCCBs.

3.3 QA Audit Corrective Actions

The inspectors reviewed the actions taken by K-M to address the findings identified in "Virginia Power Quality Assurance Audit of Klockner-Moeller Corporation, QAA 92-26." The audit, conducted in May 1992, identified four findings that resulted in VEPCO's conclusion that K-M had not fully implemented a quality assurance (QA) program for supplying MCCs and replacement parts. The inspectors found that K-M had responded to the audit findings, but all corrective actions had not yet been completed.

The answers K-M provided in its response were, in general, responsive to the audit findings. However, K-M's response to the finding that it had not audited its QA program with respect to engineering activities appeared to indicate a lack of understanding of what was necessary for a performance-based audit. In discussing this issue with the inspectors, K-M stated its intention to adopt performance-based audit techniques and that a performance-based audit would be performed on its engineering activities in the near future.

With regard to personnel qualification, the inspectors noted that K-M had developed a form to document the qualification of personnel responsible for performing QA functions. The form included training classes and a list of the audits in which they participated. The audit checklists were being upgraded to provide documentation of what was reviewed, what the corrective actions were, and that completion of the corrective actions had been verified.

The VEPCO audit had identified an instance in which K-M did not specify the requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B, on contracts for calibration services. VEPCO also noted that K-M had not audited the companies performing the calibration services. The inspectors found that K-M had subsequently audited the companies and had revised Internal Policy Manual Procedure AV-24 to require all purchase orders for safety-related activities be processed through its office in Franklin, Massachusetts. The purchase orders identified in the VEPCO audit had been issued through a K-M office in Germany. K-M stated that a single contract would be issued for calibration services and that the selected provider would be audited as required.

K-M explained that it was correcting its QA program because it still had not shipped all the deliverables under its current (and ostensibly final) contract for safety-related equipment with a nuclear utility (in this case, more MCCs for VEPCO). K-M stated its intention to fulfill its current contract with VEPCO, but not to accept any new contracts for safety-related components, and to discontinue, for all practical purposes, its 10 CFR Part 50, Appendix B, QA program.

K-M stated that it had an agreement with National Testing Services (NTS), Incorporated, of Acton, Massachusetts, to whom it would provide components as commercial grade items (CGIs). NTS was supposed to take the steps necessary to demonstrate that the CGIs were suitable for nuclear safety-related applications under its own 10 CFR Part 50, Appendix B, QA program, and then supply the items as basic components to licensees. Under this agreement, NTS is to serve as the principal, if not exclusive, outlet to the U.S. nuclear industry of K-M components and equipment for safety-related applications and K-M is supposed to provide technical support to NTS as required to facilitate its commercial grade dedication activities.

3.4 10 CFR Part 21 Program and Implementation

3.4.1 Continued 10 CFR Part 21 Responsibilities

In light of the developments described above, the inspectors discussed with K-M, its continued responsibilities with regard to 10 CFR Part 21, since it had supplied basic components in the past. Specifically emphasized was the need to maintain the program and capability in accordance with the effective revision of 10 CFR Part 21 (1) to identify and evaluate deviations from technical procurement specifications that may be discovered which affect basic components supplied and/or failures to comply (as defined in 10 CFR Part 21) associated with such basic components, (2) to make the required notifications if such deviations or failures to comply are evaluated to be defects (i.e., they could create a substantial safety hazard), and (3) in cases in which K-M is not capable of performing the evaluation, to inform all affected licensees or purchasers so that they can evaluate the deviations or failures to comply. The type of reporting interface to be maintainec with the K-M factory to support the Part 21 program was of concern to the inspectors and will be reviewed further in a future NRC inspection. This is designated Unresolved Item 99901260/93-01-02.

3.4.2 10 CFR Part 21 Evaluations

The inspectors reviewed K-M's Part 21 evaluation files and noted that there were two evaluations on record. The first one was the evaluation and reporting of the MCCBs' failure at NAPS2. This issue was reported to the NRC and VEPCO was aware of it since they reported it to K-M. However, K-M had not informed any other potentially affected customers because K-M's position was that the failures did not constitute a deviation from technical procurement specifications and that the service conditions were the cause of premature failure as opposed to some design or manufacturing flaw. K-M's compliance with Part 21 on this issue remains unresolved pending resolution of the technical ambiguities identified above. (Unresolved Item 99901260/93-01-03).

The second evaluation on file concerned an MCCB that had failed in service at LaSalle County Station. The failure was attributed to old age and the MCCB had been operating satisfactorily for at least 15 years, substantially its entire expected service life. K-M had determined that this issue also did not constitute a deviation or failure to comply; therefore no further evaluation under Part 21 was performed. With K-M equipment of this type having a relatively long service history at numerous plants in the U.S., the inspectors found it remarkable that so few evaluations were in the files. Although no specific deficiencies were identified in this inspection, the need was apparent to examine further K-M's system for acquiring, handling, and dispositioning failure information from the field in the U.S. as well as from the facilities in Germany. Whether K-M's disposition of these issues was in compliance with 10 CFR Part 21 remains unresolved pending resolution of the reporting questions identified above and will be tracked under Unresolved Item 99901260/93-01-02).

3.4.3 10 CFR Part 21 Program Review

In evaluating K-M's current program pursuant to 10 CFR Part 21, in addition to verifying correct posting, and reviewing Part 21 evaluation and reporting records for implementation, the inspectors reviewed the latest revision (dated July 1989) of K-M's procedures that describe and prescribe the program, which are contained in Section 21 of the K-M QA Manual.

The most significant finding was that the procedure did not contain provisions to ensure that affected licensees or purchasers of basic components are informed of deviations or failures to comply if K-M is unable to evaluate them to determine if a defect exists (i.e., if the deviation or failure to comply could create a substantial safety hazard), so that the affected licensees or purchasers can perform the evaluation. This was a specific requirement for Part 21 procedures (§ 21.21(b)) from the previous as well as the current revision of Part 21. The current revision merely added a 5-day limit on this notification following the determination that the supplier is incapable of performing the evaluation of a deviation.

Paragraph 4.2 required notification of the party designated in the procedure as the "First Reviewer" by the supervisor of the originator within three working days. The First Reviewer was to perform an evaluation as to creation of a substantial safety hazard and forward the results to a "Second Reviewer," all via the QA Manager, but no time limit was given. The Second Reviewer was required in Section 4.5 to forward the results of his evaluation to the responsible officer, but the 5-day time limit for this, as required by the October 1991 revision to Part 21, was not present. There also were no provisions in the procedure for the current requirements of the October 1991 revision of Part 21 regarding (1) the 60-day limit on the evaluation period, nor (2) the interim report to the NRC within 60 days if the evaluation cannot be completed within 60 days. K-M's failure to adopt adequate procedures in accordance with 10 CFR Part 21 and failure to update its procedures to reflect the substantial changes in Part 21 requirements in the October 29, 1991, revision constituted a violation of § 21.21 of 10 CFR Part 21 and is designated Violation 99901260/93-01-01.

The inspectors made other observations with regard to this procedure as follows: Paragraph 2.1 defined deviations and stated that no evaluation in accordance with this procedure was required if "an item has been corrected before it is identified as a deviation." However, it did not state how a deviation would be evaluated, if corrected before shipment as addressed in 10 CFR Part 21.

Paragraph 2.3 coined the term "potential defect," defining this as a deviation in a basic component that has been shipped. While undefined in Part 21, K-M considered this term useful in its distinction from the K-M definition of a deviation.

Paragraphs 2.5 and 2.6 defined "potential failure to comply" and failure to comply in a similar manner as in Paragraph 2.3, but the distinction was again, not strictly consistent with Part 21 definitions.

Paragraph 2.7 defined a basic component, but included "all QA Category 1 items such as certain Security and Fire Protection Systems." Although these were qualified further as those that could contribute to a substantial safety hazard, most safety classification criteria do not result in these systems being classified as basic components per se.

Paragraph 3.0, "General," discussed reporting by (although not to) a responsible officer of conditions deemed to be reportable under Part 21 and stated that the procedure provides for notification of all affected licensees or purchasers. However, as stated in the discussion of the violation above, informing affected licensees or purchasers of deviations not capable of being evaluated by K-M for the existence of a defect was not addressed. Paragraph 4.5.1.3 discussed conditions that may be reportable, but no clear point of determination of deviation or defect was identified.

A strength of the procedure was noted in Section 4.0 which called for a form for recording identified deviations and required that, if a supervisor did not judge a reported condition to meet the criteria for further evaluation, he was to state his reasons in writing and forward a copy of his determination to the originator as well as to the party designated as the First Reviewer.

Paragraph 4.6.1 required the responsible officer to make the final determination of reportability and to make a report (method not specified) to the NRC within 48 hours with a written report within 5 days if not submitted within the 48 hours as was previously required by Part 21. The procedure did not incorporate the current requirement of the October 1991 revision of Part 21 for the use of facsimile or telephone for the initial report, nor did it adopt the 30-day limit on the final written report. Although K-M's 5-day requirement for the written report was more restrictive, and therefore technically not a violation of Part 21, it was less conducive to complete and accurate reporting. K-M stated it would consider the inspectors comments for a future revision to the procedure.

3.5 Dedication of K-M Equipment by NTS

K-M stated that it was in the process of developing, with NTS, a procedure to establish measures to ensure commercial grade items were acceptable for use in safety-related applications. This procedure was reportedly being developed in accordance with Electric Power Research Institute (EPRI) Report NP-5652, "Guideline for Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)." The inspectors informed K-M about NRC Generic Letters 89-02 and 91-05, which constitute the current NRC staff positions on this subject.

As stated above, K-M will be providing technical support to NTS as required to facilitate its commercial grade dedication activities. For example, K-M explained that NTS might, in certain instances, take credit for some factory testing, such as interrupting capacity testing of MCCBs under its Underwriters Laboratories (UL)-489 program. According to K-M, this was presumably to be documented in certificates of conformance from the factory, validated on some basis such as commercial grade surveys or source verifications, etc. To the extent that NTS is to maintain an interface with K-M in Germany and/or through K-M's U.S. facilities and is expected to take credit for certain K-M factory activities, such as commercial quality controls and some testing, in dedicating K-M equipment for safety service, such activities constitute or are related to activities affecting quality. Therefore, the K-M activities (particularly in Germany) in support of NTS's dedication program may be reviewed in a future NRC inspection. Accordingly, this issue is designated Open Item 99901260/93-01-04.

4 PERSONS CONTACTED

Mr. Nicholas Dudas, President, Klockner-Moeller Corporation (USA)

Mr. Thomas Erskine, Manager, Quality Assurance, K-M (USA) Corporate Headquarters

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 2, 1994

Docket No. 99901235

Mr. Hans Herlof Hardtke
Geschäftsführer - President
Lisega GmbH
Postfach 13 57
Industriegebiet Hochkamp
D-2730 Zeven, Germany

Dear Mr. Hardtke:

SUBJECT: NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE (NRC INSPECTION REPORT NO. 99901235/93-01)

This letter transmits the report of the U.S. Nuclear Regulatory Commission (NRC) inspection conducted by Steven M. Matthews and Stephen D. Alexander of this office on September 28 through October 1, 1993, and the discussion of their findings with you and other members of your staff at the conclusion of the inspection. The purpose of the performance-based inspection at the corporate offices of Lisega GmbH (Lisega), Zeven, Germany, was to evaluate your quality program and its implementation related to the supply of standard component supports to the nuclear industry, and to review the corrective actions that you had taken in response to the Notice of Nonconformance issued with our letter to you dated October 19, 1992.

Areas examined during the inspection and our findings are discussed in the enclosed report. This inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations by the team.

The inspection resolved certain issues related to the procurement and commercial grade dedication of materials used in safety-related spring hangers, constant supports, rigid struts, and hydraulic snubbers that Lisega supplied to the U.S. nuclear industry as complying with the requirements of the American Society of Mechanical Engineers, Boiler and Pressure Vessel Code, and the NRC's requirements in Appendix B to Part 50 of Title 10 of the Code of Federal Regulations, (10 CFR Part 50) and 10 CFR Part 21. The team also reviewed Lisega's corrective actions taken for nonconformances identified during previous NRC inspections and determined that the actions taken to achieve full compliance were adequate to resolve the concerns and close the nonconformances.

However, based on the results of this inspection, certain parts of your 10 CFR Part 21 implementation program appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation. The violation of 10 CFR Part 21 is related to your procedure adopted pursuant to the regulation. The procedure had not been updated to include certain provisions of the regulation in accordance with the version of 10 CFR Part 21 that became effective on October 29, 1991. However, the team found no instances in which potential 10 CFR Part 21 issues were not properly dispositioned. The specific findings and references to the pertinent requirements are identified in the enclosed Notice of Violation and inspection report.

Also, during this inspection, it was found that the implementation of your quality assurance program failed to meet certain NRC requirements. Specifically, your process for acceptance of hydraulic snubber fluid failed to identify that according to the fluid manufacturer's specifications, the fluid would not meet your customer's hydraulic snubber procurement specifications for minimum fluid viscosity at elevated temperatures. The specific findings and references to the pertinent requirements are identified in the enclosed Notice of Nonconformance and inspection report.

You are requested to respond to this letter and should follow the instructions specified in the enclosed Notices when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Please provide your written response within 30 days from the date of this letter.

In accordance with 10 CFR 2.790(a) of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room. The responses requested by this letter and the enclosed Notices are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Should you have any questions concerning this inspection, we will be pleased to discuss them with you. Thank you for your cooperation during this inspection.

Sincerely,

Leif J. Norrholm

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99901235/93-01

Enclosure 1

NOTICE OF VIOLATION

Lisega GmbH
Zeven, Germany

Docket No. 99901235
Report No. 93-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted September 28 through October 1, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the violation is listed below:

Section 21.21(a) of Part 21 of Title 10 of the Code of Federal Regulations, (10 CFR 21.21(a)), "Reporting of Defects and Noncompliance," requires, in part, that each individual, corporation, or entity subject to the regulations in this part adopt appropriate procedures to ensure the proper evaluation of deviations and failures to comply and report defects and failures to comply related to a substantial safety hazard to a director or responsible officer in accordance with specified time requirements and that an interim report be made to the NRC if the evaluation cannot be completed in the required time.

Contrary to the above, as of September 29, 1993, Revision 0 of Lisega GmbH's "Procedural Guidelines Quality: Quality Assurance Program" (Verfahrensbeschreibung Qualitätssicherungsprogramm, or VQSP) VQSP 34, "State of Product-Information and Report" (Berichtwesen über Produktverhalten), dated April 1989, would not, as written, ensure proper evaluation and reporting in accordance with the version of 10 CFR Part 21 that became effective on October 29, 1991. Specifically, the procedure had not been updated to include the new provisions in 10 CFR 21.21(a) that (1) limit the time for evaluating deviations or failures to comply to not more than 60 days from discovery, (2) require an interim report to the NRC within the 60 days if this evaluation cannot be completed within the 60 days, and (3) limit the time for informing a director or responsible officer of Lisega GmbH of the defects or failures to comply associated with a substantial safety hazard to 5 working days from completion of the evaluation. (93-01-01)

This is a Severity Level V Violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Lisega GmbH is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include the following: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland
this 2nd day of March, 1994

Enclosure 2

NOTICE OF NONCONFORMANCE

Lisega GmbH
Zeven, Germany

Docket No. 99901235
Report No. 93-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted September 28 through October 1, 1993, it was found that certain of your activities were not performed in accordance with NRC requirements imposed on you by purchase order contracts with NRC licensees or their contractors.

Criterion III, "Design Control," of Appendix B to Part 50 of Title 10 of the Code of Federal Regulations, (10 CFR Part 50, Appendix B) requires, in part, that measures be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of structures, systems, and components.

Contrary to the above, Lisega failed to perform an adequate review for suitability of application for the hydraulic fluid used in hydraulic snubbers for Arkansas Power and Light Company's Arkansas Nuclear One Power Station because the hydraulic fluid manufacturer's viscosity specification did not meet the licensee-specified minimum viscosity requirements for elevated temperatures. (93-01-02)

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include the following: (1) a description of steps that have been or will be taken to correct this item, (2) a description of steps that have been or will be taken to prevent recurrence, and (3) the dates your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 2nd day of March, 1994

Enclosure 3

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR INSPECTION AND LICENSEE PERFORMANCE

ORGANIZATION:	Lisega GmbH Zeven, Germany
REPORT NO.:	99901235/93-01
CORRESPONDENCE ADDRESS:	Mr. Hans Herlof Hardtke Geschäftsführer - President Lisega GmbH Postfach 13 57 Industriegebiet Hochkamp D-2730 Zeven, Germany
ORGANIZATIONAL CONTACT:	Mr. Herbert Bardenhagen Leiter Qualitätssicherung - Quality Assurance Manager
NUCLEAR INDUSTRY ACTIVITY:	Safety-related spring hangers, constant supports, rigid struts, and hydraulic snubbers supplied as standard component supports.
INSPECTION DATES:	September 28 through October 1, 1993
LEAD INSPECTOR:	Steven M. Matthews 2-23-94 Steven M. Matthews, Team Leader Date Reactive Inspection Section 1 Vendor Inspection Branch
OTHER INSPECTOR:	Stephen D. Alexander, Equipment Qualification & Test Engineer
APPROVED BY:	Uldis Potapovs 2-24-94 Uldis Potapovs, Chief Date Reactive Inspection Section 1 Vendor Inspection Branch
INSPECTION BASES:	10 CFR Part 21, Appendix B to 10 CFR Part 50, and ASME Code Section III, Subsections NCA and NF.
INSPECTION SCOPE:	To review corrective actions taken for the findings and unresolved items from previous inspections and evaluate the quality assurance program and its implementation in selected areas such as material procurement, audit of subsuppliers, material certification, and dedication and upgrading of stock material.
APPLICABLE PLANTS:	Numerous

1 INSPECTION SUMMARY

1.1 Violation

Contrary to the U.S. Nuclear Regulatory Commission's (NRC's) requirements in Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of Part 21 of Title 10 of the Code of Federal Regulations, (10 CFR 21.21), the Lisega GmbH (Lisega) procedure for implementing the regulation had not been updated to include the new provisions in 10 CFR 21.21(a) that (1) limit the time for evaluating deviations or failures to comply to not more than 60 days from discovery, (2) require an interim report to the NRC within the 60 days if this evaluation cannot be completed within the 60 days, and (3) limit the time for informing a director or responsible officer of Lisega of the defects or failures to comply associated with a substantial safety hazard to 5 working days from completion of the evaluation. (93-01-01)

1.2 Nonconformance

Contrary to the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, Lisega failed to perform an adequate review for suitability of application for the hydraulic fluid used in hydraulic snubbers for Arkansas Power and Light Company's (APL's) Arkansas Nuclear One Power Station because the hydraulic fluid manufacturer's viscosity specification did not meet the licensee-specified minimum viscosity requirements for elevated temperatures. (93-01-02)

2 STATUS OF PREVIOUS INSPECTION FINDINGS

2.1 Unresolved Item 91-01-03 (CLOSED)

Lisega had not determined whether Georgia Power Company (GPC) had approved the use of specific Cases of the American Society of Mechanical Engineers (ASME), Boiler and Pressure Vessel Code (Code), Section III, "Rules for Construction of Nuclear Power Plant Components" (Section III), in the manufacture of standard component supports supplied to GPC.

During the NRC's inspection conducted on August 18 through 21, 1992, (Inspection Report (IR) 99901235/92-01 enclosed with NRC's letter to Lisega dated October 19, 1992) the team determined that the ASME Code Cases in question were authorized for use by the Bechtel design specification applicable to this procurement. However, the team also noted that Bechtel's authorization was subject to the restrictions imposed in NRC Regulatory Guide (RG) 1.85, "Materials Code Cases Acceptability, ASME Section III, Division 1." At the time of the 1992 inspection, Lisega neither had a copy of RG 1.85 nor had Lisega reviewed it for its applicability to GPC's procurement. A review of the procurement requirements for other current contracts identified similar restrictions on the use of ASME Code Cases as well as specific restrictions concerning the use of the small parts exclusion provided for in paragraph NF-2610(c) of ASME Code, Section III, Subsection NF, "Component Supports."

In its response to IR 99901235/92-01, dated November 19, 1992, Lisega replied that it had obtained RG 1.84, "Design and Fabrication Code Case Acceptability, ASME Section III, Division 1," RG 1.85, and RG 1.124, "Service Limits and Loading Combinations for Class 1 Linear-Type Component Supports." Lisega stated that it had confirmed that the materials (i.e., the American Society for Testing Materials (ASTM) specifications ASTM A-500-84, Grade B and A-668-83, Class F) used in the component supports for GPC's procurement complied with GPC's Specification SS-Z102-190, Revision 1, date August 9, 1992, and ASME Code Case N-71-10-1981, as permitted in RG 1.85.

During this inspection, the team determined that Lisega had obtained the applicable RGs and had adequately evaluated the restrictions imposed by the RGs. Lisega's evaluation of the RGs determined that it had complied with the applicable restrictions imposed by the RGs for the use of certain ASME Code Cases and ASTM materials used in the component supports supplied to GPC and other licensees. The NRC staff considers this nonconformance closed because Lisega's corrective actions reviewed during this inspection have satisfied the concerns.

2.2 Nonconformance 92-01-01 (CLOSED)

Lisega had certified certain items as meeting the requirements of ASME Code, Section III, Subsection NF, when the material and test documentation for these items did not fully support Lisega's certification. The following instances were identified in IR 99901235/92-01 and the Notice of Nonconformance dated October 19, 1992. The NRC Staff considers this nonconformance closed because Lisega's corrective actions reviewed during this inspection have satisfied the concerns, as described below.

(1) Lisega issued its Certified Material Test Report (Zertifikat für Materialprüfung, or CMTR) 113377 for SA-479, Type 410(1) bar used for piston rods in large bore hydraulic snubbers ordered by APL for steam generator supports. Lisega purchased this material from Gustav Grimm, Edelstahl-Werk GmbH (Grimm) as SA-182, Grade F6a, Class 2 forgings. Grimm provided a CMTR for this material, including the mill heat analysis, heat treatment description, and nondestructive examination (NDE) certification on their letterhead. However, Grimm is not a holder of an ASME Quality Systems Certificate (QSC), nor did their certification to Lisega include the statement that this material had been produced under the requirements of ASME Code, Section III, Subsection NCA, "General Requirements for Division 1 and Division 2," paragraph NCA-3800, "Metallic Material Manufacturer's and Material Supplier's Quality System Program," (i.e., no evidence that Grimm had been qualified by Lisega to supply ASME Code material). A CMTR from the melting mill was not included in this documentation and there was no evidence that the mill had been qualified by either Grimm or by Lisega.

    In its response to IR 99901235/92-01, dated November 19, 1992, Lisega replied that the material represented by its CMTR 113377 was supplied by Grimm and that Lisega had audited and qualified Grimm to the requirements of ASME Code NCA-3800. Grimm issued a revised CMTR, dated November 16, 1992, that included its product analysis of the forgings and a statement that the material was manufactured in accordance with Grimm's Quality Assurance Manual (QAM), dated February 1987. Grimm's QAM was audited by Lisega on January 11, 1990, and found to meet the requirements of ASME Code NCA-3800, the order, and the material specification. Lisega issued Revision B of its CMTR 113377, dated November 19, 1992, which certified the material as ASME SA-182, Grade F6a, Class 2, tested in accordance with ASME SA-370. Lisega's revised CMTR included a statement that the material was fabricated by Grimm in accordance with Grimm's QAM, dated February 27, 1987, which was audited by Lisega on January 11, 1990, in accordance with ASME Code NCA-3800 and the requirements of Lisega's QAM.

During this inspection, the team determined that Lisega had audited and qualified Grimm to the requirements of ASME Code NCA-3800 and that the applicable CMTRs were revised, as described above. Lisega's corrective actions taken to address the issues described above and reviewed by the team during this inspection appear to have adequately satisfied these concerns.

(2) Lisega issued its CMTR 111183 for ASTM A-668, Class C (Lisega Material Specification 122) for the material used for articulated joints in rigid struts supplied to Arizona Public Service Company (APS) for its purchase order (PO) 33801236. Lisega purchased this material from Lenhauser Hammerwerk GmbH (Lenhauser). Lenhauser provided a CMTR for this material, including the mill heat analysis, on their letterhead. Lenhauser is not an ASME QSC holder and the Lenhauser CMTR did not demonstrate that this material was produced under an ASME Code NCA-3800 program that had been approved by Lisega. A CMTR from the melting mill was not included in this documentation and there was no evidence that the mill had been qualified by either Lenhauser or by Lisega. Additionally, although Lisega Material Specification 122 restricts the chromium (Cr) content of this material to 0.30 percent, the Lisega product analysis for Cr content was marked "not applicable."

In its response to IR 99901235/92-01, dated November 19, 1992, Lisega replied that the material represented by its CMTR 111183 was supplied by Lenhauser and that Lisega had audited and qualified Lenhauser. Attached to Lenhauser's CMTR, Lenhauser provided a statement that the material had been manufactured in accordance with Lenhauser's QAM, Revision 2, that was audited and qualified by Lisega, and that the material had not been repaired by welding. Lisega issued Revision A of its CMTR 111183, dated August 28, 1992, which certified the material as ASTM A-668, Class C, tested in accordance with ASME SA-370, included the Cr content, and included a statement that the material was supplied in accordance with Lisega's ASME QSC No. 522, expiring October 1993.

During this inspection, the team determined that Lisega had procured the material from Lenhauser and had verified the melting mill's certificate during its audit of Lenhauser. A test lab, audited and qualified by Lisega, performed a product analysis on a test specimen from each heat and lot of material supplied by the mill. After forging the articulated joint, Lenhauser, acting as Lisega's qualified subcontractor, performed testing, in accordance with ASME SA-370 as qualified by Lisega, to verify the physical and impact properties for each heat number and heat-treatment lot of material. Lisega's corrective actions taken to address the issues described above and reviewed by the team during this inspection appear to have adequately satisfied these concerns.

(3) Lisega issued its CMTR 115217 for ASME SA-53 S, Grade A, pipe used in rigid struts supplied to APS. The ASME SA-53 material specification provides restrictions on the maximum content of each of the following elements: copper, nickel, chromium, molybdenum, and vanadium; and the maximum total content of these elements can not exceed 1.00 percent. The pipe material was procured from Benteler Aktiengesellschaft (Benteler) who certified that the pipe material complied with Deutsches Institut für Normung e.V. (DIN), standard DIN 2448-81/17175-79. However, Benteler's CMTR did not document an analysis of the trace elements. Lisega's CMTR 115217 documented only that the average combined total of the trace elements was less than 1.00 percent, and therefore, did not provide assurance that the specified amounts for each trace element was not exceeded. Lisega's CMTRs 115431, 115284, 115232, and 115243 had the same deficiency.

In its response to IR 99901235/92-01, dated November 19, 1992, Lisega replied that its CMTRs 111183, 115431, 115284, 115232, and 115243 were corrected to document the actual contents for each trace element.

During this inspection, the team determined that Lisega had revised its material specifications to include the required controls for trace elements. To enhance its assurance that all CMTRs are correct, Lisega established measures for a second level of CMTR review before certification. Lisega's corrective actions taken to address the issues described above and reviewed by the team during this inspection appear to have adequately satisfied these concerns.

(4) Lisega issued its CMTR 115399 for ASME SA-479, Type 410(1) bar used for pin-bolts in rigid struts supplied to APS. Lisega purchased this material from Krupp Stahlag. However, neither the CMTR provided by Krupp Stahlag nor Lisega's CMTR described, as required by the material specification, the product's heat treatment and hardness. Krupp Stahlag provided this information via telefax during the 1992 NRC inspection of Lisega.

In its response to IR 99901235/92-01, dated November 19, 1992, Lisega replied that its CMTR 115399 was corrected during the 1992 NRC inspection.

During this inspection, the team determined that Lisega had revised its CMTR to describe the product's heat treatment and hardness. Lisega's corrective actions taken to address the issues described above and reviewed by the team during this inspection appear to have adequately satisfied these concerns.

2.3 Nonconformance 92-01-02 (CLOSED)

As of August 21, 1992, Lisega had not established measures in either its QAM nor the "Procedural Guidelines Quality: Quality Assurance Program" (Verfahrensbeschreibung Qualitätssicherungsprogramm, or VQSP) for dedicating items purchased as commercial grade for use in safety-related standard component supports.

In its response to IR 99901235/92-01, dated November 19, 1992, Lisega described its corrective actions taken to establish measures for the dedication of items purchased as commercial grade (as defined in 10 CFR Part 21) and used in safety-related standard component supports. And in its supplemental response to IR 99901235/92-01, dated January 13, 1993, Lisega submitted VQSP 37, "Material Procurement and Goods Receiving Control," dated January 1993, and VQSP 44, "Qualification, Certification and Admission of Lisega Sub-Contractors."

During this inspection, the team reviewed Lisega's Revision A of VQSP 37, dated April 8, 1993. The team determined that Lisega's overall program description was generally consistent with the dedication philosophy described in Electric Power Research Institute (EPRI) report NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)." However, the program description, including the implementing procedures documented in VQSPs 37 and 44, did not completely address the issues contained in NRC Generic Letters 89-02, "Actions to Improve the Dedication of Counterfeit and Fraudulently Marketed Products," dated March 21, 1989, and 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, which specified certain restrictions or conditions concerning the use of EPRI NP-5652 dedication methods to achieve compliance with Appendix B to 10 CFR Part 50. The team reviewed these issues in detail with Lisega's Quality Assurance (QA) Manager to address the NRC's expectations with regard to Lisega's commercial grade procurement and dedication program. Lisega's procurement practices include purchasing items from (1) qualified suppliers with an ASME QSC (e.g., pipe, plate, and bars), (2) qualified suppliers audited by Lisega to ASME Code NCA-3800 (e.g., pipe, plate, bars, and forgings), (3) suppliers of commercial grade items (e.g., pipe, plate, bars, and forgings) that are required by Lisega to provide Acceptance Test Certificates in accordance with standard DIN 50049, "Articles of Test Certification" (Arten von Prüfbescheinigungen), and (4) qualified suppliers of commercial grade items (e.g., seals and fluids) and services (e.g., calibration, machining, materials testing, and NDE).

The NRC staff considers this nonconformance closed because Lisega's corrective actions taken and reviewed during this inspection have satisfied the concerns raised by the nonconformance. However, with appropriate modifications to address the additional issues discussed by the team with the QA Manager, the Lisega program, if properly implemented, should provide adequate control over Lisega's commercial grade procurement and dedication process.

2.4 Nonconformance 92-01-03 (CLOSED)

Lisega purchased items from suppliers, who either held a current ASME QSC or were listed in document TÜV 1253/1, "Register of Approved Material Manufacturers," published by Technischer Überwachungs-Verein (TÜV), without performing assessments, such as implementation audits, to verify the suppliers' quality programs or testing the supplied material.

In its response to IR 99901235/92-01, dated November 19, 1992, Lisega described its corrective actions taken to establish measures to properly qualify its suppliers, in part, as described in Lisega's response to Nonconformance 92-01-02, and that VQSP 37 was revised, in part, to address this concern.

During this inspection, the team reviewed Lisega's Revision A of VQSP 37, dated April 8, 1993, and determined that, as stated above in Section 2.3 of this report, Lisega's overall commercial grade procurement and dedication program description was generally consistent with the accepted dedication philosophy. However, the program description, including the implementing procedures documented in VQSPs 37 and 44, did not completely address the issues in NRC's guidance, as published in the Generic Letters referenced above in Section 2.3 of this report. These issues were also discussed during the team's discussions with Lisega's QA Manager.

The NRC Staff considers this nonconformance closed because Lisega's corrective actions taken and reviewed during this inspection have satisfied the concerns raised by the nonconformance. However, with appropriate modifications to address the additional issues discussed by the team with the QA Manager, the Lisega program, if properly implemented, should provide adequate control over Lisega's commercial grade procurement and dedication process.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

During the entrance meeting in Zeven, Germany, on September 28, 1993, the NRC's inspection team met with members of Lisega's Zeven staff and other representatives of Lisega, discussed the scope of the inspection, and established working interfaces. The team observed activities, held discussions with Lisega's staff, and reviewed certain records and procedures. The specific areas, documentation reviewed, and the team's findings are described in this report. The persons who participated in and who were contacted during the inspection are listed in Section 4 of this report. During the exit meeting on October 1, 1993, the team summarized the inspection findings, observations, and recommendations with Lisega's management and staff.

3.2 Background

The inspection resolved certain issues related to the procurement and commercial grade dedication of materials used in safety-related spring hangers (sicherheitsrelevante federhängern), constant supports (konstanthängern), rigid struts (stützen), and hydraulic snubbers (stoßbremsen) that Lisega supplied to the U.S. nuclear industry as complying with the requirements of ASME Code, Section III, Appendix B to 10 CFR Part 50, and 10 CFR Part 21. The team also reviewed Lisega's corrective actions taken to address unresolved items and nonconformances identified during previous NRC inspections and determined that Lisega's corrective actions taken were adequate to resolve the concerns.

3.3 Review of 10 CFR Part 21

The team reviewed Revision 0 of Lisega VQSP 34, "State of Product-Information and Report" (Berichtwesen über Produktverhalten), dated April 1989, adopted pursuant to 10 CFR 21.21, and found that it would not, as written, ensure proper evaluation and reporting. The procedure had not been updated to include the new provisions of the regulation required to be included in procedures adopted pursuant to the regulation in accordance with the version of 10 CFR Part 21 that became effective on October 29, 1991. Missing from Lisega's VQSP 34 were the new provisions in 10 CFR 21.21(a) that (1) limit the time for evaluating deviations or failures to comply (to determine if they could create or are associated with a substantial safety hazard) to not more than 60 days from discovery, (2) require an interim report to the NRC within the 60 days if this evaluation cannot be completed within the 60 days, and (3) limit the time (not previously specified) for informing a Lisega director or responsible officer of defects or failures to comply associated with a substantial safety hazard to 5 working days from completion of the evaluation. Although the procedure contained provisions for informing affected customers of problems affecting safety of parts and products, the time limit prescribed in 10 CFR 21.21(b) for informing affected licensees or purchasers of deviations or failures to comply that Lisega cannot or chooses not to evaluate was also not included. The procedure had also not been updated to address the means of transmission of reports to the NRC, the time limits, and the address.

On the basis of the team's review of VQSP 34, it was not clear how Lisega employees would recognize discrepancies or nonconformances, described as problems affecting safety of parts or products, as reportable to management under 10 CFR Part 21 because deviations from the technical procurement specifications or failures to comply as defined in the regulation were not clearly defined. According to Lisega's VQSP 39, "Handling of Nonconforming Supplies," Revision 0, dated June 1991, and VQSP 40, "Handling of Nonconforming Parts, Assemblies and Final Products," nonconformances were to be reported to QA on QSF-13 forms and dispositioned on QSF-10 forms. However, these procedures did not refer to 10 CFR Part 21 or VQSP 34, nor did VQSP 34 refer to VQSPs 39 and 40. Section 13, "Control of Nonconforming Products," and Section 14, "Revision and Correction Procedures," of Lisega's QAM referred to 10 CFR Part 21 and the German version of these QAM sections referred to VQSP 34 by its German title only (the English version of these QAM sections referred to VQSP 34 by two different names, both of which were different from the English title on VQSP 34 itself). However, neither of these two sections of the QAM referred to VQSPs 39 and 40.

The team noted that Lisega had chosen to post Section 206 of the Energy Reorganization Act of 1974 and a notice that was intended to meet the requirements of 10 CFR 21.6(b). However, the notice provided for the inspectors review lacked certain items required by the regulation. Specifically, the notice: (1) described the regulation, but did not name or describe Lisega's procedures adopted pursuant to the regulation; (2) stated where translations of the regulation may be viewed, but not the procedures; and (3) did not contain the name (or title) of the person to whom employees are to make reports.

Also, on the basis of the team's review of the applicable VQSPs, it was not clear on what basis nonconformances would be evaluated for reporting or that they would be evaluated for creation of a substantial safety hazard. Finally, there was no provision for informing a Lisega director or responsible officer of defects or failures to comply associated with a substantial safety hazard at the completion of the evaluation. As a result, Violation 93-01-01 was identified during this part of the inspection.

3.4 Review of Dedication of Purchased Commercial Grade Material

As part of the team's evaluation of Lisega's process for procurement and dedication of commercial grade materials and subcomponents/parts for use as basic components in Lisega's standard component supports, the team reviewed the procurement and dedication records of selected purchased materials used in Lisega's hydraulic snubbers. During the review of records associated with hydraulic damper fluid for snubbers manufactured for APL's Arkansas Nuclear One Power Station under Entergy Operations, Incorporated (the plant's operating organization), PO 932471, Release 000, dated May 27, 1993, the team discovered that the product technical information in the catalog published by the manufacturer of the hydraulic damper fluid indicated that the fluid's viscosity (i.e., kinematic viscosity, expressed in centistokes (cSt)) at elevated temperatures was not consistent with the requirements in the specification referenced in Lisega's customer's procurement documents. The Entergy PO invoked Specification ANO-M-2455, "Procurement of Lisega Series 30 Hydraulic Snubbers." Section 6.5 of Revision 0, dated March 10, 1992, specified type AK-350 hydraulic fluid and required, in part, that the viscosity of the hydraulic fluid at the temperature specified shall be as follows:

25°C (77°F)	350 cSt (± 10 cSt)
150°C (302°F)	65 cSt (± 5 cSt)
200°C (392°F)	42 cSt (± 5 cSt)

However, the graph on page 4 of Wacker Silicone's AK type Fluids catalog, "Viscosity/Temperature Correlation of Silicone Fluids AK," showed that the viscosity of AK-350 would be as follows:

150°C (302°F)	48 cSt (< 60 cSt minimum required)
200°C (392°F)	30 cSt (< 37 cSt minimum required)

These deviations from Entergy's Specification ANO-M-2455 had not been previously identified by Lisega because, according to Lisega's staff, the fluid supplier was responsible for ensuring that the fluid complied with its own material specification. However, the team pointed out that even if the fluid itself complies with the supplier's specifications (which was also not verified under Lisega's system for product acceptance), Lisega was responsible for ensuring that the fluid manufacturer's specifications met all Lisega's customer's specifications. As a result, Nonconformance 93-01-02 was identified during this part of the inspection.

Additionally, the team, using this instance (where Lisega relied entirely upon the fluid manufacturer to verify that the fluid supplied met the manufacturer's specifications without Lisega sampling the product, or surveying or auditing the supplier, or using some other appropriate means of accepting the fluid) pointed out to Lisega's QA Manager how this instance was an example of the type of deficiency previously identified in Lisega's commercial grade procurement and dedicating program. The dedication issues raised by this instance were discussed by the team with Lisega's QA Manager, as described in Sections 2.3 and 2.4 of this report. As a result, Lisega's QA Manager committed to resolve the observed deviations, in part, by (1) evaluating the effect of reduced fluid viscosity at elevated temperatures on the performance of the snubbers and (2) changing the dedication procedures to ensure an adequate review for suitability of application including verifying that the material suppliers' specifications comply with Lisega's (and/or its customers') material specifications.

4 PERSONNEL CONTACTED

Listed below are the Lisega GmbH personnel contacted during this inspection, who also attended both the entrance meeting on September 28, 1993, and the exit meeting on October 1, 1993, and the U.S. Nuclear Regulatory Commission staff who conducted this inspection.

Lisega GmbH:

Hans Hardtke	Geschäftsführer - President and CEO
Herbert Bardenhagen	Leiter Qualitätssicherung - Quality Assurance Manager
Herbert Aberle	Area Sales Engineer
Harald Lange	International Sales Engineer
Wolf-Rüdieer Wagner	Purchasing Manager
Falk Löffler	Fabrication Control
Förg Bernet	Hanger Design
Gerhard Lüders	Production Engineer

U.S. Nuclear Regulatory Commission:

Stephen D. Alexander	Equipment Qualification & Test Engineer
Steven M. Matthews	Team Leader, Quality Assurance Engineer

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON D.C. 20555-0001

March 8, 1994

Docket No. 99901270

Mr. E. A. George, Jr., Vice President
Mid-South Nuclear, Inc.
40-B Sayreton Drive
Birmingham, Alabama 35202

Dear Mr. George:

SUBJECT: NOTICE OF VIOLATION AND NONCONFORMANCE
(NRC INSPECTION REPORT NO. 99901270/94-01)

This letter addresses the U. S. Nuclear Regulatory Commission (NRC) inspection of your facility at Birmingham, Alabama, conducted by Messrs. L. L. Campbell and D. H. Brewer of this office January 25 through 28, 1994, and the discussions of their findings with you and members of your staff at the conclusion of the inspection. The inspection was conducted to evaluate Mid-South Nuclear, Inc.'s (MSN's) quality program and its implementation in selected areas such as (1) The American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (Code), Section III, "Rules for Construction of Nuclear Power Plant Components," (Section III) material upgrade, (2) commercial grade item dedication, (3) receipt inspection and material testing, and (4) preparation of quality documentation and material certification.

Areas examined during this NRC inspection and our findings are discussed in the enclosed inspection report. This inspection consisted of an examination of procedures and representative records, discussion and interviews with personnel, and observations by the inspectors.

Based on the results of this inspection, certain of your activities appear to be in violation of NRC requirements, as specified in the enclosed Notice of Violation. The violation identified that MSN's procedures did not address the requirements of Section 21.21, "Notification," of Title 10 of the Code of Federal Regulations (10 CFR) as revised and effective on October 29, 1991 (e.g., the 60 day period for evaluating potential defects and failures to comply; filing an interim report).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In addition, during this inspection it was found that the implementation of your quality assurance (QA) program failed to meet certain NRC requirements. Although MSN has prepared a procedure which addresses the essential elements of the commercial grade item dedication process, MSN failed to properly identify the necessary critical characteristics for ensuring that certain product forms such as pipe, fittings, plates, shapes, and bars met specification requirements.

Generally, vendors such as MSN receive purchase orders for metallic products that invoke the requirements of: (1) Appendix B to 10 CFR, or an equivalent customer approved vendor Quality Assurance Program, (2) 10 CFR Part 21, and (3) the governing material specification. When the product is certified by the vendor to be supplied in accordance with these or similar requirements, the customer generally considers that the product meets all of the technical requirements specified in its purchase order and, therefore, can be used in any safety-related application where design documents specifically identify the use of such products.

Also, it was found that MSN issued a Certificate of Compliance stating that 1/4 inch outside diameter by 0.049 inch wall thickness, SA-213, Type 304, seamless stainless steel tubing had been furnished to TVA in accordance with the requirements of the ASME Code, Section III, NC-2610, 1989 Edition, without the required involvement of a Certificate Holder.

Please provide us within 30 days from the date of this letter a written statement in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you can show good cause for us to do so.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosed inspection report will be placed in the NRC Public Document Room.

The responses requested by this letter and the enclosed Notices are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

If there are any questions concerning this inspection we will be pleased to discuss them with you.

Sincerely,

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 999001270/94-01

ENCLOSURE 1

NOTICE OF VIOLATION

Mid-South Nuclear, Incorporated
Birmingham, Alabama

Docket No. 99901270
Report No. 94-01

During a NRC inspection conducted at Mid-South Nuclear, Inc. (MSN), January 25 through 28, 1994, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1993), the violation is listed below:

A. Section 21.21, "Notification," of 10 CFR Part 21, requires, in part, that each individual, corporation, partnership, or other entity subject to the regulations in this part adopt appropriate procedures for evaluating deviations and failures to comply, or informing the licensee or purchaser of the deviation or failure to comply. Also, 10 CFR 21.21, requires that if an evaluation of a deviation or failure to comply cannot be completed within 60 days of discovery, an interim report must be prepared and submitted to the NRC.

   Contrary to the above, MSN failed to adopt procedures to implement the substantive revisions to 10 CFR Part 21 that became effective on October 29, 1991. Major changes not incorporated in the MSN procedure include: establishment of a time limit for evaluating potential defects and failures to comply; establishment of a time limit for initial and follow up notifications of the NRC; and establishment of channels of communications with the NRC for initial and follow up notifications. (Violation 99901270/94-01-01)

   This is a Severity Level V violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, MSN is hereby required to submit a written statement or explanation to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Wasnington, D. C. 20555, with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland
this 8th day of March 1994.

ENCLOSURE 2

NOTICE OF NONCONFORMANCE

Mid-South Nuclear, Inc.
Birmingham, Alabama

Docket No.: 99901270/94-01

Based on the results of an NRC inspection conducted on January 25 through 28, 1994, it appears that certain of your activities were not conducted in accordance with NRC requirements.

A. Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, requires, in part, that measures shall be established to assure that purchased material conforms to procurement documents.

   Paragraph 3.6 of Section 3, "Order Processing," of the Mid-South Nuclear, Inc. (MSN) Quality Assurance (QA) Manual, Revision 1, dated March 25, 1992, requires, in part, that applicable requirements necessary to meet the customer's purchase order (PO) shall be documented on appropriate documents.

   Contrary to the above, neither the applicable MSN material critical characteristics forms nor the sales orders for the following purchase orders identified adequate critical characteristics and verifications to ensure that the items being supplied met the customer's procurement document requirements. (Nonconformance 99901270/94-01-02)

   Dedication activities performed by MSN for the following POs included reviewing nonqualified material manufacturer certifications, verifying material identifications, dimensional checks, and chemical and/or hardness overchecks. However, MSN did not perform any overchecks to verify that the tensile properties and heat treatment of the material met the customer's procurement document requirements.

   1. Sales Order No. 3225, Item 1, for the supply of one 3 foot long, 5 inch nominal diameter, schedule 120, A-312, Type 304, seamless stainless steel pipe in accordance with Bechtel Corporation (Bechtel) PO No. 21042-T-0504Q, Revision 0, dated January 5, 1993, for use at the Browns Ferry nuclear plant.

   2. Sales Order No. 3309, Item 1, for the supply of one A-234, Grade WPB, butt weld connection, reducing pipe tee with openings of 3 inch diameter by 4 inch diameter by 4 inch diameter, in accordance with Bechtel PO No. 21042-T-0536Q, Revision 0, dated February 24, 1993, for use at the Browns Ferry nuclear plant.

   Dedication activities performed by MSN for the following POs included reviewing nonqualified material manufacturer certifications, verifying material identifications, dimensional checks, and hardness checks. However, MSN did not perform any overchecks to verify the material chemistry or to confirm the actual tensile strength listed on the material manufacturer's certification.

3. Sales Order No. 3292, Item 1, for the supply of six pieces of 16 inch nominal diameter, schedule 30, SA-105, Class 150, raised face weldneck pipe flanges, in accordance with Bechtel PO No. 21042-SW-2012AQ, Revision 0, dated February 11, 1993, for use at the Browns Ferry nuclear plant.

4. Sales Order No. 3381, Item 1, for the supply of 2 1/2 inch diameter by 10 foot long, A-36 carbon steel round bar, in accordance with Bechtel PO No. 21042-C-0227Q, Revision 0, dated April 16, 1993, for use at the Browns Ferry nuclear plant.

5. Sales Order No. 3428 for the supply of Items 1-6, A-36 structural steel plate, angle, and bars of various sizes, lengths, and qualities supplied in accordance with Tennessee Valley Authority (TVA) PO No. P-93PJX-36732H-001, dated April 12, 1993, for use by the TVA Muscle Shoals Distribution Center, Muscle Shoals, Alabama.

6. Sales Order Nos. 3376 and 3376A for the supply of Items 1-19, A-36 structural steel items such as plates, angles, channels, and bars, of various sizes, lengths, and qualities in accordance with TVA PO No. P-93PGC-36737H, dated May 13, 1993, for use by TVA Muscle Shoals Distribution Center.

B. NC-2610 of The American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (Code), Section III, "Rules for Construction of Nuclear Power Plant Components," (Section III) permits certain small products to be furnished as ASME Code, Section III, Class material with a Certificate of Compliance certifying that the material is furnished in accordance with the applicable material specification and the applicable requirements of the ASME Code, Section III. However, NC-2610 requires, in part, that for these small products, the Certificate Holder's Quality Assurance Program (NCA-4000) shall provide measures to assure that the applicable specification and Code requirements are met.

NCA-9000 of the ASME Code, Section III, defines the Certificate Holder as an organization holding a valid N, NPT, or NA Certificate of Authorization issued by the society.

Contrary to the above requirements, MSN issued a Certificate of Compliance that indicated approximately 7000 feet of 1/4 inch outside diameter by 0.049 inch wall thickness, SA-213, Type 304, seamless stainless steel tubing had been furnished to TVA (Bechtel Constructors PO No. 21042-TS-990Q, for use at Browns Ferry) in accordance with the requirements of ASME Code, Section III, NC-2610, 1989 Edition, without the required involvement of a Certificate Holder. The Certificate of Compliance also indicated that the material met Material Specification SA-213 and ASME Code, Section III, Class 2, 1989 Edition, requirements.

Because MSN holds an ASME Q. lity System Certificate and is not an ASME Certificate holder, MSN should have furnished the tubing in accordance with NCA-3800 requirements. (Nonconformance 99901270/94-01-03)

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each nonconformance: (1) a description of steps that have been or will be taken to correct these items; (2) a description of steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 8th day of March, 1994.

ENCLOSURE 3

ORGANIZATION:	Mid-South Nuclear, Inc. Birmingham, Alabama
REPORT NO.:	999001270/94-01
CORRESPONDENCE ADDRESS:	Mr. E. A. George, Jr., Vice President Mid-South Nuclear, Inc. 40-B Sayreton Drive P.O. Box 10063 Birmingham, Alabama 35202
NUCLEAR INDUSTRY ACTIVITY:	Supplies pipe and steel products for use at commercial nuclear power plants
INSPECTION CONDUCTED:	January 25 through 28, 1994
INSPECTOR: Date	Larry L. Campbell 2/16/94 Larry L. Campbell, Reactor Engineer Reactive Inspection Section No. 1 Vendor Inspection Branch
OTHER INSPECTORS:	David H. Brewer, Metallurgical Engineer
APPROVED:	Uldis Potapovs 2-28-94 Uldis Potapovs, Chief Date Reactive Inspection Section No. 1 Vendor Inspection Branch
INSPECTION BASIS:	10 CFR Part 21 and Appendix B to 10 CFR Part 50
INSPECTION SCOPE:	To review and evaluate the Mid-South Nuclear, Inc. (MSN) quality assurance program and its implementation in selected areas such as (1) ASME Code, Section III, material upgrade, (2) commercial grade item dedication, (3) receipt inspection and material testing, and (4) preparation of quality documentation and material certification.
PLANT SITE APPLICABILITY:	Bellefonte (50-438, 50-439) Browns Ferry (50-259, 50-260, 50-296) Sequoyah (50-327, 50-328) Edwin I. Hatch (50-321, 50-399) Joseph M. Farley (50-348, 50-364) Other plants using MSN products

1. INSPECTION SUMMARY

1.1 Violations

Contrary to Section 21.21, "Notification," of Title 10 of the Code of Federal Regulation (10 CFR), Mid-South Nuclear, Inc. (MSN) failed to adopt a procedure to implement the provisions of 10 CFR Part 21 that were effective October 29, 1991, (Violation 99901270/94-01-01, see Section 3.2 of this report).

1.2 Nonconformances

Contrary to Criterion VII of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50 and Section 3 of the Mid-South Nuclear Inc. (MSN) Quality Assurance (QA) Manual, neither the applicable MSN material critical characteristics forms nor the sales orders for certain pipe, fittings, plates, shapes, and bars identified adequate critical characteristics and verifications to ensure that the items being supplied met the customer's procurement document requirements (Nonconformance 99901270/94-01-02, see Sections 3.4.1 and 3.4.2 of this report).

Contrary to the requirements of NC-2610 of The American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (Code), Section III, "Rules for Construction of Nuclear Power Plant Components," (Section III) 1989 Edition, MSN issued a Certificate of Compliance that indicated approximately 7000 feet of 1/4 inch by 0.049 inch thick, SA-213, Type 304, stainless steel tubing had been furnished to TVA in accordance with the requirements of ASME Code, Section III, NC-2610, 1989 Edition, without the required involvement of a Certificate Holder (Nonconformance 99901270/94-01-03, see Section 3.5 of this report).

2 STATUS OF PREVIOUS INSPECTION FINDINGS

This was the first inspection at MSN.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

In the entrance meeting on January 25, 1994, the NRC inspectors discussed the scope of the inspection and established interfaces with MSN management. During the exit meeting on January 28, 1994, the NRC inspectors discussed their findings and concerns with MSN management and other staff.

3.2 10 CFR Part 21

3.2.1 Implementation of the MSN 10 CFR Part 21 Procedure

The NRC inspectors observed that MSN maintained the required 10 CFR Part 21 postings, however the posted copy of MSN Procedure SOP-601, "Identifying and

Reporting Defects and Noncompliances Under the Requirements of 10 CFR Part 21," Revision 0, dated March 16, 1991, failed to incorporate the changes to 10 CFR Part 21 that were effective October 29, 1991. Major changes not incorporated in the MSN procedure included: (1) establishment of a time limit for evaluating potential defects and failures to comply; (2) establishment of a time limit for initial and followup notifications of the NRC; and (3) establishment of channels of communications with the NRC for initial and followup notifications. Also, the posted copy of 10 CFR Part 21 was dated October 31, 1989.

3.3 MSN Commercial Grade Dedication Program

3.3.1 Methodology

The requirements for MSN's dedication process are prescribed in Procedure No. SOP-701, "Dedication of Commercial Grade Items," Revision 3, dated July 15, 1993. The NRC inspectors reviewed Procedure No. SOP-701 and other interfacing procedures controlling MSN's dedication activities. The implementation of MSN's dedication process was also reviewed and is discussed in Section 3.4 of this report.

Incoming customer purchase orders (POs) are initially reviewed by the Sales Department and a sales order is generated. The sales order includes a description of the material to be supplied and instructions for processing the material. Procedure No. SOP-701 requires that critical characteristics for an item to be dedicated be determined by a person who holds an engineering degree and who is familiar with the item, and be documented on MSN Form No. 701, "Material Characteristics Form." A Form No. 701 is not prepared for each sales order, but is prepared for specific types and, in some instances, specific sizes of material (e.g., 4 inch and smaller A-105 carbon steel socket weld fittings or A-36 carbon steel angle). The completed Form No. 701 is reviewed by the QA Manager or the MSN President.

Before releasing the sales order for processing, the QA department reviews it to ensure that adequate instructions have been given, including the verification of critical characteristics identified on the applicable Form No. 701. Also, when a supplier is being used to control and verify a quality-related activity, the QA review ensures that the supplier has been audited or surveyed and approved for performing the activity.

3.3.2 MSN's Supplier Performance Program

MSN Procedure No. SOP-105, "Generation, Control, and Evaluation of Supplier/Item Performance Records," Revision 0, dated July 15, 1993, provides requirements for the generation and control of supplier performance records. The supplier performance information would be used, according to MSN's interpretation of EPRI NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)," issue date June 1988, to justify reduced sampling of chemistry and physical properties during material dedication testing. The NRC inspectors concluded that tracking of a supplier's performance appeared to be a strength in MSN's dedication program, and, if properly implemented, may provide a bases for sampling certain material critical characteristics. However, the NRC inspectors reviewed Procedure No. SOP-105 and its implementation and found the following weaknesses in MSN's supplier performance program:

(1) The procedure did not prescribe the rationale for the amount of historical product information required to be accumulated before reduced sampling would be permitted. Further, the procedure did not prescribe the plan for reduced sampling. The NRC inspectors determined that MSN Procedure No. SOP-701 addressed the tracking of a nonqualified supplier's performance as the bases for establishing heat and lot traceability, but the bases for the type and amount of data to support a reduced sampling of items from a nonqualified manufacturer was not provided.

(2) The procedure did not prescribe the basis for adding conforming and nonconforming product data to the data base (e.g., the procedure did not prescribe the entry of failures or nonconformances reported by customers or the basis for such entries). Additionally, there is no guidance as to whether or not nonconforming data will be entered into the data base when the product is authorized for use "as is."

(3) The procedure did not prescribe limits on historical product information used in justifying reduced sampling for a product. For example, if a steel producer makes austenitic stainless steel bar, tubing, plate, and shapes, and similar carbon and alloy steel products, historical product data from physical overchecks performed on carbon steel plate by MSN should not be used to justify reduced sampling of the chemistry of another specific product such as stainless steel pipe. The NRC inspectors and MSN discussed that historical data used to justify reduced sampling of a product's critical characteristic should be based on historical data for similar products having similar chemistry and form produced using the same process, equipment, and procedures.

3.3.3 Dedication Program Weaknesses

The NRC inspectors reviewed MSN's QA Manual, Revision 1, dated March 25, 1992, and determined that it failed to identify responsibilities and controls for the commercial grade dedication process. Although the title of Section 9, "Control of Manufacturing Processes, Upgrading of Stock Material, Dedication of Commercial Grade Items, and Supply of Component Support Material (NF)," implies that its scope includes the dedication process, this section only requires that a procedure be developed to control the dedication process.

The NRC inspectors concluded that Procedure No. SOP-701 addresses the essential elements of the dedication process and that sufficient guidance for performing activities such as inspection and testing are given in other procedures and instructions. However, the NRC inspectors determined that the following program weaknesses appear to have contributed to the unacceptable dedication packages reviewed by the NRC inspectors (see Nonconformance 99901270/94-01-02 in Sections 3.4.1 and 3.4.2 of this report):

(1) Procedure No. SOP-701 does not contain requirements or guidance for selecting critical characteristics.

(2) The bases for not verifying certain material specification requirements (considered to be critical characteristics) are not required to be documented on the Material Critical Characteristics Form No. 701.

(3) When material overchecks, such as chemistry and tensile testing, are performed to verify critical characteristics and to validate the manufacturer's material certifications, there are no procedural requirements or guidance provided in MSN's dedication program for determining the amount that these test results may deviate from those listed on the manufacturer' certification.

(4) The NRC inspectors questioned MSN's practice of including nonqualified supplier material certifications (stamped "QA Accepted" during the initial screening of incoming commercial grade items) in documentation packages supplied to customers and not including in its documentation to its customers the results of confirmatory overchecks performed by MSN.

(5) MSN's QA Manual does not identify: (a) individuals in its organization responsible for or programmatic controls for its commercial grade dedication activities.

(6) The vendor performance data base is being used as the basis for confirming adequate material traceability controls for nonqualified material manufacturers. The bases for using the data base in lieu of an audit or survey of the material manufacturer's traceability controls is considered an area requiring significant improvement (see Section 3.3.2 of this report).

3.3.4 Dedication Program Strengths

The NRC inspectors considered the following to be strengths in MSN's dedication program:

(1) MSN personnel performing testing, inspection, and document review activities were knowledgeable about their work and had a positive attitude.

(2) A material certification for each item supplied is obtained from the manufacturer (qualified and non-qualified manufacturers) and reviewed for conformance with the applicable material specification.

(3) The tracking of material physical and chemical overchecks to determine a supplier's performance appeared to be a strength in MSN's dedication program, and if properly implemented, should provide a basis for sampling material (see Section 3.3.2 of this report).

3.4 MSN Commercial Grade Dedication Program Implementation

3.4.1 Review of Material Critical Characteristics Forms

The NRC inspectors reviewed several completed material critical characteristics forms and found them unsuitable for providing reasonable assurance that dedicated basic components would perform their intended safety function in all applications. For example, A-36 steel plate, could be used to fabricate a cut and drilled base plate for a heat exchanger in a mild environment or a welded critical seismic pipe support. MSN's past practice required that only a hardness check be performed on A-36 material. MSN's present practice (for certain customers) is to perform chemistry and hardness checks on A-36 material. Depending on the application, certain A-36 specification requirements may be essential for the item to perform its safety function (e.g., when the item is used in a welded critical seismic pipe support, all specification requirements may be essential or in the case where the item is used as a base plate, only a portion of the requirements may be essential). When the specific application is not known, the commercial grade item dedication process should provide reasonable assurance that the item supplied meets all of the specified requirements and would perform its safety function in all applications.

The verification of critical characteristics specified on several MSN material critical characteristics forms may provide reasonable assurance that an item will perform its intended safety related function if used in less critical applications. However, as discussed previously, verification of the specified critical characteristics may not provide reasonable assurance that the item would perform its safety function if used in more critical applications. According to MSN's dedication methodology, the selected critical characteristics, when verified, would provide reasonable assurance that a dedicated basic component would perform its safety function regardless of the criticality of its safety function. The following material critical characteristics forms appear to be typical of critical characteristics selected and verified:

(1) A-36 structural steel channel, beams, plate, flat bar, round bar, angles, and tees: Markings and selected dimensions are verified, the nonqualified manufacturer's material test reports are reviewed for compliance to the applicable material specification requirements, and a hardness test is performed. MSN did not perform any overchecks to verify that the chemistry and actual tensile properties of the material met specification requirements and were acceptable (Nonconformance 99901270/94-01-02).

    Note: For the above and following material characteristics forms and POs in this report, the term nonqualified manufacturer, distributor, or supplier indicates that the manufacturer, distributor, or supplier was not audited or surveyed by MSN and was not on MSN's approved vendor list at the time of the purchase.

    MSN informed the NRC inspectors that for TVA orders received after August 1993 and for all Georgia Power Company orders received in 1993, at least one piece of material from each nonqualified manufacturer's heat was subjected to a chemical analysis. The NRC inspectors reviewed TVA PO No. 93P2I-36770H and MSN Sales Order No. 3552, dated September 2, 1993, and Georgia Power Company PO No. 60120920000 and MSN Sales Order No. 3339, dated March 25, 1993, and verified that at least one piece of A-36 material from each heat, supplied by the nonqualified supplier, had been subjected to a chemical analysis.

(2) A-105 carbon steel fittings, flanges (all sizes); A-333 pipe; and A-285 vessel plate: Markings and selected dimensions were verified, the nonqualified manufacturer's material test reports were reviewed for compliance to the applicable material specification requirements, and a hardness test was performed. For these items, MSN material critical characteristics forms did not require the performance of any overchecks to verify that the chemistry and tensile properties of the material met specification requirements and were acceptable (Nonconformance 99901270/94-01-02).

(3) A-312 and A-376 austenitic stainless steel pipe; A-182 forged austenitic stainless steel flanges and fittings; and A-276 stainless shapes: Markings and selected dimensions were verified, the nonqualified manufacturer's material test reports were reviewed for compliance to the applicable material specification requirements, and a chemistry check was performed. For these items, MSN material critical characteristics forms do not require the performance of any overchecks to confirm that the material had the physical properties or had been subjected to any heat treatment required by the applicable material specification (Nonconformance 99901270/94-01-02).

MSN informed the NRC inspectors that NRC licensees had audited them and that they believe auditors from TVA and Georgia Power Company had reviewed some of the material critical characteristics forms during their audit of MSN's commercial grade dedication program.

3.4.2 Review of Sales Order Packages

The NRC inspectors reviewed the following in-process and completed commercial grade material dedication sales order packages to determine if the critical characteristics for materials had been properly identified and verified, and if adequate procedural controls were in place. The NRC inspectors also observed in-process inspection activities and processing of sales orders.

1. Sales Order No. 3381, Item 1, was for the supply of 2 1/2-inch-diameter by 10-foot-long, A-36 carbon steel round bar, in accordance with Bechtel Corporation (Bechtel) PO No. 21042-C-0227Q, Revision 0, dated April 16, 1993. MSN purchased this material from a nonqualified supplier, North Star Steel, Michigan Division, Monroe, Michigan. MSN verified that markings and selected dimensions were correct, reviewed the nonqualified manufacturer's material test report for conformance with the material specification requirements, and performed a hardness test. MSN did not perform any overchecks to verify that the chemistry and tensile properties of the material met specification requirements

and were consistent with the test results reported on the nonqualified manufacturer's material certification.

Note: For this PO and other Bechtel POs identified in this report Bechtel was acting as purchasing agent for TVA's Browns Ferry Nuclear Plant.

2. Sales Order No. 3309, Item 1, was for the supply of one A-234, Grade WPB, butt weld connection, reducing pipe tee with openings of 3 inch diameter by 4 inch diameter by 4 inch diameter, in accordance with Bechtel PO No. 21042-T-0536Q, Revision 0, dated February 24, 1993. Two tees were purchased from a nonqualified distributor, Dodson Company, Ellenwood, Georgia. The Dodson Company purchased these tees from a nonqualified manufacturer, Hackney, Inc., Dallas, Texas.

   MSN verified that markings and selected dimensions were correct, reviewed the nonqualified manufacturer's material test reports for conformance with the material specification requirements, and performed a hardness test on the tee shipped to TVA. The hardness value reported by MSN showed acceptable correlation to that reported by the manufacturer. Also, MSN contracted with Newton Engineering and Metallurgical Services (NEMS), a qualified test laboratory, for performing a chemical analysis by destructively testing the second tee. The chemical analysis performed by NEMS showed acceptable correlation to that reported on the manufacturer's certified material test report (CMTR). Chemical analysis and hardness testing were required by the MSN Material Critical Characteristics Form No. A-234-1, "Butt Weld Fittings," Revision 0, dated February 18, 1992, however no testing was required to be performed to verify tensile properties of the material. Because no traceability program provided assurance that the pieces came from the same starting piece, the tee shipped may not have the same chemistry as the tee subjected to the chemical analysis by NEMS.

3. Sales Order No. 3225, Item 1, was for the supply of one 3-foot-long, 5 inch nominal diameter, schedule 120, A-312, Type 304, seamless stainless steel pipe in accordance with Bechtel PO No. 21042-T-0504Q, Revision 0, dated January 5, 1993. The pipe was purchased from a nonqualified distributor, Prudential Stainless Pipe, Newark, New Jersey. Prudential Stainless Pipe purchased the pipe from a nonqualified manufacturer, Sumitomo, Tokyo.

   MSN verified that markings and selected dimensions were correct, reviewed the nonqualified manufacturer's material test reports for conformance with the material specification requirements, and contracted with NEMS for chemical analysis on a piece of pipe cut from the pipe shipped to TVA. The chemical analysis performed by NEMS showed acceptable correlation with that reported by the manufacturer. Chemical analysis was the only testing required by the MSN Material Critical Characteristics Form No. A-312-1, "Austenitic Stainless Steel Pipe," Revision 0, dated February 18, 1992. This material critical characteristics form did not require the performance of any overchecks to confirm that the pipe had the physical properties or heat treatment required by the material specification.

4. Sales Order No. 3292, Item 1, was for the supply of six pieces of 16 inch nominal diameter, schedule 30, SA-105, Class 150, raised face weldneck pipe flanges, in accordance with Bechtel PO No. 21042-SW-2012AQ, Revision 0, dated February 11, 1993. The Bechtel PO required that the flanges be supplied in accordance with the requirements of NCA-3800 of the ASME Code, Section III, (NCA-3800), but identified no Code Class. MSN purchased the flanges from Daniel Industrial, Houston, Texas, a nonqualified supplier.

   MSN issued a Certificate of Compliance, dated February 12, 1993, indicating that these flanges were supplied in accordance with the requirements of NCA-3800. To upgrade this material MSN only performed a hardness test on each of the six flanges and a dimensional evaluation of one flange. MSN did not perform chemical analysis or tensile testing on any of the flanges. The NRC inspectors and MSN discussed the upgrade requirements of NCA-3800 and agreed that the requirements of NCA-3800 had not been met. MSN informed the NRC inspectors that because no ASME Code Class was identified on the Bechtel PO, the flanges were processed in accordance with its commercial grade item dedication program.

   MSN further explained that after shipping the flanges on February 12, 1993, a request was received from Bechtel on February 25, 1993, to revise the material description on its Certificate of Compliance to include ASME Code, Section III, Class 2. In a response to Bechtel, dated February 26, 1993, MSN stated that the material shipped on February 12, 1993, did not meet the requested requirements. On March 2, 1993, MSN issued a revision to the Certificate of Compliance, deleting reference to NCA-3800, and stating that the flanges were supplied in accordance with the MSN Quality Assurance Program, Revision 1, dated March 25, 1992, which met the requirements of ANSI N45.2.

   Although the NRC inspectors reviewed the revised documentation package for the flanges and determined that the flanges were processed in accordance with MSN's commercial grade item dedication program, the traceability requirements of ANSI N45.2 do not appear to have been met. There was no objective evidence in MSN's vendor qualification files or in any of the documentation reviewed indicating the flanges came from the same starting piece. Hardness testing was the only testing required by the MSN Material Critical Characteristics Form, A/SA105-1, "Forged Carbon Steel Flanges," Revision 0, dated February 18, 1992. MSN did not perform any overchecks to verify that the chemistry and actual tensile properties of the flanges met specification requirements.

5. Sales Order No. 3428 was for the supply of Items 1-6, A-36 structural steel plate, angle, and bars of various sizes, lengths, and quantities supplied in accordance with TVA PO No. P-93PJX-36732H-001, dated April 12, 1993. The TVA PO required that these items be delivered to the TVA Muscle Shoals Distribution Center in Muscle Shoals, Alabama.

MSN purchased some of these items from a distributor, Siskin Steel & Supply Company (Siskin) located in Birmingham, Alabama. MSN had audited and qualified Siskin for maintaining control of material within its facility. Siskin performs no audits of its suppliers and performs no material overchecks. Siskin purchased these items from the following nonqualified manufacturers: (1) Tuscaloosa Steel Corporation, (2) SMI Steel Inc., (3) Birmingham Steel Corporation, and (4) Geneva Steel.

MSN verified that markings and selected dimensions were correct, reviewed the nonqualified manufacturers' material test reports for conformance with the material specification requirements, and performed a hardness test on each item in a heat. MSN did not perform any overchecks to verify that the chemistry and tensile properties of the items met specification requirements and were consistent with the test results reported on the nonqualified manufacturers' material certifications.

6. Sales Order Nos. 3376 and 3376A were for the supply of Items 1-19, A-36 structural steel items such as plates, angles, channels, and bars, of various sizes, lengths, and quantities in accordance with TVA PO No. P-93PGC-36737H, dated May 13, 1993. The TVA PO required that these items be delivered to the TVA Muscle Shoals Distribution Center in Muscle Shoals, Alabama. MSN purchased these items from a distributor, Siskin, and from nonqualified manufacturers. Siskin purchased these items from nonqualified manufacturers. Siskin was only qualified by MSN for maintaining material identification for items from receipt in its facility through shipping to MSN (see Item 5 above). Manufacturers for these items were: (1) Tuscaloosa Steel Corporation, (2) Bethlehem Steel Corporation, (3) Hanna Steel Corporation, (4) SMI Steel, Inc., (5) Northwestern Steel and Wire Company, (6) Florida Steel Corporation, (6) North Star Steel Kentucky, Inc., and (7) Bayou Steel Corporation.

   MSN verified that markings and selected dimensions were correct, reviewed the nonqualified manufacturers' material test reports for conformance with the material specification requirements, and performed a hardness test on at least one item from each manufacturer's heat and in some cases on each item in a heat. MSN did not perform any overchecks to verify that the chemistry and tensile properties of the items met specification requirements and were consistent with the test results reported on the nonqualified manufacturers' material certifications.

Each MSN documentation package furnished for the above POs included the nonqualified manufacturer's CMTRs, but did not contain or identify the overchecks performed by MSN. The CMTRs were stamped MSN QA accepted and there was no indication that the CMTRs were from nonqualified manufacturers.

The NRC inspectors concluded that the critical characteristics verified by MSN for the above POs did not provide reasonable assurance that the specified PO requirements had been met (Nonconformance 99901270/94-01-02).

3.5 ASME Code Upgrade Program Implementation

The NRC inspectors reviewed the following in-process and completed material upgrades to determine if the requirements of NCA-3800 of the ASME Code, Section III, had been met.

1. Sales Order No. 3536, Item 1, was for the supply of one 12-inch nominal diameter pipe cap, schedule 80, ASME SA-234, Grade WPB, starting with SA-516, Grade 70, ASME Code, Section III, Class MC, 1971 Edition with Summer 1971 Addenda, in accordance with Alabama Power Company PO No. QP931465, dated August 5, 1993, for Joesph M. Farley Nuclear Plant (Farley). MSN purchased two pipe caps from Alloy Piping Products, Inc. (APP), Shreveport, Louisiana, which had a qualified material traceability program and was on the MSN approved suppliers list for that program. To upgrade this material, MSN contracted Laboratory Testing, Inc. (LTI), an approved supplier for testing services, to perform chemical analysis, tensile testing, hardness testing, and impact testing. The chemical analysis was performed on chips removed from the pipe cap delivered to the customer. All other tests were performed on the second pipe cap, destroyed for testing purposes. Test results produced by LTI showed reasonable correlation with results reported by APP except for the carbon content of the chemical analysis. Carbon content determined by LTI was 0.11% compared to 0.24% determined by APP. MSN explained this discrepancy as possible surface decarburization in the specimen taken from the pipe cap that MSN shipped.

2. Sales Order No. 3528, Item 1, was for the supply of approximately 7000 feet of 1/4 inch diameter, 0.049 inch wall thickness, ASME Code, Section III, Class 2, SA-213, Type 304, stainless steel seamless tubing, in accordance with Bechtel PO No. 21042-TS-990Q, Revision 0, dated August 10, 1993, and Revision 1, dated September 7, 1993. Revision 1 of this PO was issued to inform MSN that, as of August 31, 1993, Bechtel would cease to act as an agent for TVA at the Browns Ferry nuclear plant and would cease to administer this PO. MSN purchased the tubing from Salem Tube Inc. (Salem Tube), Greenville, Pennsylvania. Salem Tube purchased the starting material from which the tubing was drawn (24 pieces of Type 304/304L redraw hollows, 1.315 inch outside diameter by 0.133 inch wall thickness) from TUBACEX, a nonqualified Spanish material manufacturer.

   The NRC inspectors reviewed the MSN approved supplier list and its audit of Salem Tube and determined that no audits or surveys had been performed at TUBACEX to support material traceability for the 24 hollows. MSN performed an audit at Salem Tube on September 9, 1993, and determined that Salem Tube did not audit its suppliers of material or services. The MSN audit report documented objective evidence to support Salem Tube's capabilities to perform significant activities such as: (1) having adequate controls to provide assurance that heat code identity is maintained during all of the manufacturing processes, (2) maintaining an adequate test laboratory for mechanical testing (e.g., the calibration standards for the tensile tester referenced NIST trace numbers), (3) hydrostatic testing of tubing was observed during the audit and the in-house calibrations for gauges used during the hydrostatic testing referenced a NIST trace number, and (4) the MSN auditor witnessed MSN's order for the tubing being processed which included 20 different manufacturing steps. The audit also identified several areas where Salem Tube did not have adequate controls such as (1) calibration of its furnaces, (2) control of its subsuppliers (e.g., chemical analyses performed by outside sources), and (3) performance of internal audits.

The documentation reviewed by the NRC inspectors and discussions with MSN revealed that from the 24 hollows (TUBACEX and Salem Tube Heat Code MPA), Salem Tube produced approximately 360 tubes in 4 separately heat treated lots (Lot Nos. 1, 1A, 2, and 2A). One tube from each lot was subjected to mechanical testing by Salem Tube and MSN performed a chemical analysis on one (1) of the 360 tubes, and the test results indicated conformance to the SA-213, Type 304, requirements. The NRC inspectors expressed the following concern to MSN about the number of tests performed on the tubing.

There were 24 starting hollows from which the 360 tubes were produced. There was no objective evidence to indicate that the 24 hollows came from the same starting ingot. Also, there were no chemical overchecks performed on the 24 hollows to confirm that material traceability had been maintained. Under these circumstances, the stock material upgrading requirements of NCA-3800 would require a chemical analysis be performed on each tube. Because material traceability had not been established, the 4 mechanical tests and one chemical analysis may not provide reasonable assurance that all tubes were properly annealed and their mechanical properties and chemistry met specification requirements.

MSN's response to the NRC's concern was that they considered the 24 hollows supplied by TUBACEX to be traceable to the same heat based on the historical performance of other materials manufactured by TUBACEX and independently tested by MSN. MSN informed the NRC inspectors that it had performed mechanical and chemical overchecks on 5 heats of TUBACEX stainless pipe in 1993 prior to performing its chemical overcheck of the one piece of 1/4 inch tubing, and according to MSN Procedure No. SOP-105, these previously satisfactory test results may be used as the basis for establishing heat traceability for a manufacturer that has not been audited.

The NRC inspectors discussed with MSN the use of Procedure No. SOP-105 for the supply of ASME Code, Section III, class material. As written, Procedure No. SOP-105 is used for determining when credit can be given to an unquailifed manufacturer as being capable of maintaining material traceability based on the results of historical chemical and physical overchecks performed by MSN on material supplied by the manufacturer. Also, Procedure No. SOP-105 is applicable for manufacturers supplying commercial grade items to be dedicated as basic components. Because material is being supplied in accordance with the ASME Code, Section III, Class 2, (nuclear unique requirements), MSN should not have used the commercial grade item dedication provisions of 10 CFR Part 21 and Procedure No. SOP-105 for supplying the 1/4 inch tubing on MSN's Sales Order No. 3528, but should have used provisions contained in the ASME Code, Section III, (e.g., NCA-3800).

MSN informed the NRC that they had not supplied the 1/4 tubing in accordance with NCA-3800, but in accordance with the requirements of NC-2610 of the ASME Code, Section III, (NC-2610), 1989 Edition. The NRC inspectors questioned the initial MSN Certificate of Compliance, dated September 29, 1993, because it did not state that the tubing was supplied in accordance with NC-2610. MSN provided the NRC inspectors with a revised Certificate of Compliance, dated January 14, 1994, stating the tubing was supplied in accordance with NC-2610 and was to be used for instrument tubing and not for heat exchanger tubing.

After reviewing MSN correspondence with TVA and the quality record package for the 1/4 inch tubing, the NRC inspectors asked to review TVA's authorization for supplying the tubing in accordance with NC-2610, and not NCA-3800. The NRC inspectors found no changes to the TVA PO No. 21042-TS-990Q indicating that the tubing was not going to be used for heat exchanger applications or that MSN was authorized to supply the tubing in accordance with the provisions of NC-2610.

According to MSN, TVA verbally informed it that the tubing could be provided in accordance with NC-2610 and that the tubing would only be used for instrumentation tubing. MSN stated that this was the basis for MSN revising its certification.

Also, MSN informed the NRC inspectors that they were in error by initially processing this order in accordance with NC-2610 because the applicable material specification, SA-213, "Specification for Seamless Ferritic and Austenitic Alloy-Steel Boiler, Superheater, and Heat-Exchanger Tubes," 1989 Edition, includes the manufacture of heat exchanger tubes and that the ASME Code, Section III, prohibits heat exchanger tubing from being supplied to NC-2610 requirements.

The NRC inspectors informed MSN that NC-2610 permits, in part, that certain small products may be furnished as ASME Code, Section III, class material with a Certificate of Compliance certifying that the material is furnished in accordance with the applicable material specification and the applicable requirements of the ASME Code, Section III. However, NC-2610 furthers requires that for these small products, the Certificate Holder's Quality Assurance Program (NCA-4000) shall provide measures to assure that the applicable specification and Code requirements are met. NCA-9000 of the ASME Code, Section III, defines Certificate Holder as an organization holding a valid N, NPT, or NA Certificate of Authorization issued by the ASME.

Contrary to the above requirements, MSN issued a Certificate of Compliance that indicated approximately 7000 feet of 1/4 inch outside diameter by 0.049 inch wall thickness, SA-213, Type 304, seamless stainless steel tubing had been furnished to TVA in accordance with the requirements of ASME Code, Section III, NC-2610, 1989 Edition, without the required involvement of a Certificate Holder. The Certificate of Compliance also indicated that the material met Material Specification SA-213 and ASME Code, Section III, Class 2, 1989 Edition, requirements. Since MSN is not a Certificate Holder and only holds a Quality System Certificate, MSN should have furnished the tubing in accordance with NCA-3800 requirements (Nonconformance 99901270/94-01-03).

3. Southern Nuclear Operating Company PO No. QP941017, dated January 12, 1994, Item 2, was for the supply of five, SA-403, WP304/304L, ASME Code, Section III, Class 3, schedule 40, 8 inch nominal diameter, 90 degree elbows for the Alabama Power Company's Farley nuclear plant. The elbows were purchased from APP, Shreveport, Louisiana, which had a qualified material traceability program and was on the MSN approved suppliers list. MSN was processing this PO during the performance of the NRC inspection, and planned to upgrade the material by destructively testing one elbow (for tensile testing and chemical analysis) and performing chemical analysis on shavings from each elbow to be shipped.

4 PERSONNEL CONTACTED

Mid-South Nuclear, Inc.

* + Earl A. George, President
* + E. A. George, Jr., Vice President and Quality Assurance Manager
* + Jim Moore, Sales Representative
\+ Elaine Chastain, Quality Assurance Representative
Henry Wollek, Quality Control Inspector

* Attended the Entrance Meeting
\+ Attended the Exit Meeting

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 4, 1994

Docket No. 99900271
EA 94-049

Mr. Steve M. Quist, President
Rosemount Nuclear Instruments, Incorporated
8200 Market Boulevard
Chanhassen, Minnesota 55317

Dear Mr. Quist:

SUBJECT: NRC INSPECTION REPORT 99900271/93-01 AND NRC OFFICE OF INVESTIGATIONS (OI) REPORT 4-90-009

This letter addresses the U.S. Nuclear Regulatory Commission (NRC) inspection led by Mr. J.J. Petrosino of this office on February 1 through 4, and March 8 through 12, 1993, of the Rosemount, Incorporated, Measurement Division (Rosemount) facilities in Eden Prairie, and Chanhassen, Minnesota, and the discussions of our findings with Mr. Kenneth Ewald and other members of your staff at the conclusion of the inspection. The inspection findings, concerns and proprietary information within the report were further discussed between March 15, 1993, and March 3, 1994, and as a result additional correspondence was exchanged between the Rosemount staff and the NRC. This letter also addresses NRC Office of Investigations (OI) Case 4-90-009, which has been completed. A copy of the OI Report synopsis is enclosed with this letter.

The specific areas examined during the inspection and our findings are discussed in the enclosed report. The inspection team evaluated the effectiveness of the quality assurance (QA) program that Rosemount established to control the quality-related activities affecting components that Rosemount supplies for use in NRC-regulated, safety-related systems at commercial nuclear reactor power plants. The team also evaluated the program that Rosemount established and executed to implement the provisions of Title 10 of the Code of Federal Regulations, Part 21 (10 CFR Part 21). Within these areas, the inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations of activities in progress.

The team noted several strengths during the evaluation of your activities at the Eden Prairie and Chanhassen facilities. Most notable among these was the level of knowledge and experience of the technicians, operators, engineers, nuclear QA staff, and other personnel who were interviewed during the inspection. The majority of those employees also exhibited a sense of ownership and pride in the work that was being performed.

Based on the findings of the inspection, however, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation. Rosemount failed to establish or implement a procedure to ensure that the applicable provisions of 10 CFR Part 21 were executed at its Chanhassen facility, did not maintain adequate records of evaluations in all cases, did not establish an adequate employee posting and also did not adequately describe 10 CFR Part 21 and its implementing procedures in the posting. You are required to respond to this letter and should follow the instructions in the enclosed Notice of Violation when preparing your response. In your response you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice of Violation, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The inspection team also found weaknesses in Rosemount's current QA program in both the areas of QA program establishment and implementation that, when viewed collectively, indicated that the effectiveness of the overall quality program that was observed in February and March, 1993, did not provide adequate control over the activities affecting the quality of Rosemount transmitters to an extent consistent with their importance to safety. This program controlled the manufacturing and testing of Rosemount transmitters and sub-assemblies that were used in nuclear power reactor safety-related applications. The identified QA program weaknesses are specifically discussed in the enclosed Notice of Nonconformance, for example:

- Rosemount's failure analysis (FA) facility did not have formal procedures to control root cause evaluations and failure analyses that could identify potential deviations in safety-related products returned by licensees.

- Rosemount did not establish or implement an independent QA inspection or verification function in its sensor cell and printed circuit (PC) card manufacturing areas at the Chanhassen facility.

- Rosemount did not perform QA overview, inspection, monitoring, or surveillance functions for many of its safety-related sensor module fabrication and testing activities at its Eden Prairie facility.

- Rosemount did not perform receipt inspection activities for its nuclear sensor cells that were received at its Eden Prairie facility, even though it was required to be performed in accordance with a Rosemount nuclear group procedure.

The specific findings and references to the pertinent requirements are identified in the enclosures to this letter. Please provide us within 30 days from the date of this letter a written statement in accordance with the instructions specified in the enclosed Notice of Nonconformance.

Finally, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C (1993). It would appear that Rosemount did not ensure that all affected customers were appropriately informed as required by 10 CFR

Part 21 of an oil-loss deviation identified by Rosemount in its Model 1150 series transmitters. Specifically, as evidenced by various documents, from approximately August 1984 until December 1988, Rosemount failed to inform all its customers of an oil-loss deviation that could have resulted in undetectable degraded operation in Model 1150 series Rosemount nuclear safety-related pressure transmitters which could have caused safety limits to be exceeded or caused "substantial safety hazards" in licensee facilities. Examples of degraded transmitter operation as a result of sensor cell oil-loss were mainly identified in Model 1153 and 1154 pressure transmitters that had been returned for analysis by NRC licensees or found by Rosemount field service personnel. Rosemount did not begin to inform all of its nuclear licensee customers until December 1988.

It is possible that the NRC or its licensees would have taken action earlier if Rosemount: (1) had either recognized the potential generic implications and performed an adequate review and disposition of the problem in accordance with Rosemount's procedure that was adopted to implement Part 21 when the deviation was first identified, or (2) had established adequate requirements to ensure that individual problems were reviewed collectively to determine whether they indicated the existence of a generic problem. Because escalated enforcement action is being considered for this matter, no Notice of Violation is presently being issued for this inspection finding. Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review.

As discussed with Mr. Kenneth Ewald of your staff on March 3, 1994, an enforcement conference to discuss this apparent violation will be scheduled in the near future. The purposes of this conference are to discuss the apparent violation, its cause and the significance; to provide you the opportunity to point out any errors in our inspection report; to discuss the OI Report Synopsis which concluded that Rosemount acted with careless disregard in fulfilling their obligations under 10 CFR Part 21; and to discuss any other information that will help us to determine the appropriate enforcement action in accordance with the NRC Enforcement Policy. In particular, we expect you to address: (1) the Rosemount intracompany memoranda discussed in the report regarding transmitters exhibiting oil-loss, (2) the associated Rosemount communications with the applicable NRC licensees regarding the oil-loss deviation, (3) the Rosemount rationale for not informing customers earlier than 1988 of the common mode failure or degradation of Rosemount transmitters, and (4) any other circumstances that could affect our decision in this matter. You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding this apparent violation is required at this time.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and Enclosures 1, 2, and 4 will be placed in the NRC Public Document Room. A nonproprietary version of the inspection report (Enclosure 3) will be placed in the NRC Public Document Room following resolution of the proprietary issues.

The responses requested by this letter and the enclosed Notices are not subject to the clearance procedures of the Office of Management and Budget, as required by the Paperwork Reduction Act of 1980, Public Law 96-511.

Sincerely,

Charles E. Rossi

Charles E. Rossi, Director
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

cc: See next page

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99900271/93-01
4. OI Report Synopsis 4-90-009

cc: Mr. Kenneth E. Ewald, Business Unit Manager
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Mr. Mark Van Sloan, VP and General Manager
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ENCLOSURE 1

NOTICE OF VIOLATION

Rosemount, Incorporated

Docket No. 99900271
Report No. 93-01

During a U. S. Nuclear Regulatory Commission (NRC) inspection conducted at the Rosemount, Incorporated (Rosemount) facilities, from February 1-4, 1993, and March 8-12, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1993), the violations are listed below:

A. Section 21.21 of 10 CFR Part 21 requires that each individual, corporation, partnership, or other entity subject to the regulations in this part adopt appropriate procedures to evaluate deviations and failures to comply.

Contrary to the above, as of March 12, 1993, Rosemount failed to establish or implement a procedure to evaluate deviations and failures to comply at its Chanhassen facility. (93-01-01)

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

B. Section 21.6, "Posting requirements," of 10 CFR Part 21 requires that each corporation or other entity subject to the regulations in Part 21 post current copies of 10 CFR Part 21, Section 206 of the Energy Reorganization Act (ERA) of 1974 and procedures adopted pursuant to the regulations in 10 CFR Part 21, or, if posting of the regulations in Part 21 or procedures is not practicable, the licensee or firm subject to the regulations in Part 21 may in addition to posting Section 206 of the ERA, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

Contrary to these requirements, as of March 12, 1993, the postings at Rosemount's Eden Prairie and Chanhassen facilities did not adequately describe either 10 CFR Part 21 or the procedure adopted to implement it. In addition, the postings were found to contain outdated names and telephone numbers of personnel to whom reports were to be made. (93-01-02)

This is a Severity Level V violation (Supplement VII).

C. Section 21.51, "Maintenance and inspection of records," of 10 CFR Part 21 requires, in part, that each individual, corporation, or other entity shall maintain such records as may be required to accomplish the purpose of 10 CFR Part 21.

Contrary to this requirement, Rosemount records regarding a review of suspect resistors used in Rosemount 710 DU products did not contain adequate information to accomplish the purpose of Part 21. In particular, the records were insufficient to demonstrate whether Rosemount customers were appropriately informed of the deviation. (93-01-03)

This is a Severity Level V violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Rosemount, Incorporated is hereby required to submit a written statement or explanation to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D. C. 20555, with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland
this 4th day of March 1994.

ENCLOSURE 2

NOTICE OF NONCONFORMANCE

Rosemount, Incorporated

Docket No.: 99900271
Report No.: 93-01

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Rosemount, Incorporated (Rosemount), facilities from February 1-4, 1993, and March 8-12, 1993, it appears that certain of your activities were not conducted in accordance with NRC requirements.

A. Criterion II, "Quality Assurance Program," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 requires, in part, that the quality assurance (QA) program shall provide controls over activities affecting the quality of components to an extent consistent with their importance to safety. The program shall take into account the need for verification of quality by inspection and test.

   Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 requires, in part, that activities affecting quality be prescribed by appropriate instructions, procedures or drawings and be accomplished according to those instructions, procedures or drawings.

   Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 requires, in part, that measures shall be established to assure that purchased material, equipment, and services conform to the procurement documents.

   Section 2, "Quality Assurance Program," of Rosemount's Nuclear Quality Manual (NQM), D9000115, Revision A, which replaced Rosemount Quality Assurance Manual 1742 for nuclear and corporate procedures pertaining to quality, states, in part, that "The design, manufacturing and servicing of the Measurement Division nuclear products shall be managed in accordance with a comprehensive Nuclear Quality Program. The Nuclear Quality Program shall be structured to comply with the provisions of 10 CFR 50, Appendix B, NQA-1, applicable industry standards, and Company Policies...."

   Section 5, "Instructions, Procedures, and Drawings," of Rosemount's NQM states, in part, that "Activities that affect quality shall be prescribed by clear and complete documented procedures and instructions of a type appropriate to the circumstances and shall be accomplished in accordance with these documents... Procedures shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished...."

Section 10, "Inspection," of the Rosemount NQM states, in part, that "Inspection shall be performed on activities affecting quality to verify conformance with related drawings, specifications, and other controlled documents...."

Contrary to these requirements, as of March 12, 1993, the NRC inspection team identified the following nonconformances:

1. Rosemount did not establish QA program procedures, instructions, or drawings to control activities affecting quality in its Failure Analysis (FA) Laboratory. (93-01-04)

2. Rosemount did not establish an overall Appendix B to 10 CFR Part 50 QA program for the control of "basic components" manufactured in its Chanhassen facility. Although Rosemount provided its Chanhassen facility with Nuclear Department approved drawings and procedures for certain of its activities, other activities were not adequately controlled or performed. (93-01-05)

3. Rosemount did not implement the receipt inspection requirements delineated in Section 2.5, "Dedication," of Nuclear Department Procedure (NDP) N-0730, "Dedication of Subassemblies from Chanhassen," for the sensor cells used in all of its safety-related nuclear transmitters. (93-01-06)

B. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 requires, in part, that measures shall be established to assure that the design basis for those components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components. The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.

Section 3, "Design Control," of the Rosemount NQM states, in part, that "Changes made to previously verified designs shall be evaluated for... effects of the change on the overall design... "

Contrary to these requirements, as of March 12, 1993, the NRC inspection team identified the following nonconformances:

1. Rosemount did not perform an adequate verification of the design change authorized by Engineering Change Order (ECO) 601919, dated May 23, 1983, and the associated Rosemount Model 1153 Equipment Qualification Report was not reconciled. This design change relaxed the process flange O-ring groove dimension tolerance of the Model 1153 and subsequently the 1154 transmitters.

The engineering justification did rot address long-term or other effects on the qualified life that the changed dimensional tolerance and resulting variable force might have had on the sensor cell seal integrity and potential loss of oil.

Similarly, Rosemount did not perform an adequate verification of the design changes authorized by ECO 603675, dated February 1, 1984. This design change relaxed the process flange O-ring groove dimension tolerance of the Model 1152 transmitter. The Rosemount engineering justification used a similarity rationale indicating that the dimensional change on the Model 1152 was acceptable based on the acceptability of the same change on the Model 1153. However, the similarity rationale appeared to be invalid because the Model 1152 used an O-ring different in material from the Model 1153 transmitter O-ring. (93-01-07)

2. Rosemount did not consider by test or evaluation the manufacturer's recommendations regarding application or shelf life, and did not have a documented basis for the operating temperature limits of the fluid used in sensor cells of nuclear-qualified transmitters. (93-01-08)

C. Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50 requires, in part, that a comprehensive system of planned and periodic audits be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

Section 18.3.3, "Internal Audits," of the Rosemount NQM requires that internal audits of selected aspects of activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to assure that an audit of all activities within the scope of the Nuclear Quality Program will be completed annually.

Section 4.21, "Quality Assurance Audit," of the Rosemount QAM-M Quality Assurance Manual No. 1742, Revision M, dated October 28, 1988, required that all quality related functions be audited at some time in each calendar year, and that implementation of the controlling documents be audited to verify compliance with the QA program at least every 14 months.

Section 3.0, "Responsibilities," of NDP N-0730 requires, in part, that the Nuclear Quality Department audit the Chanhassen facility to verify conformance of a quality system and its capability to mee ') CFR Part 21.

Contrary to these requirements, as of March 12, 1993, the NRC inspection team identified that Rosemount did not schedule or conduct any internal audits in 1989. Additionally, since December 1991, Rosemount has failed to audit quality-related activities at the Chanhassen facility to determine compliance with applicable portions of Appendix B to 10 CFR 50 and 10 CFR Part 21. (93-01-09)

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance," and should include for each nonconformance: (1) a description of steps that have been or will be taken to correct these items; (2) a description of steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective actions and preventative measures were or will be completed.

Dated at Rockville, Maryland
this 4th day of March 1994.

SYNOPSIS

This investigation was initiated on February 9, 1990, at the request of the Nuclear Regulatory Commission (NRC) Executive Director for Operations (EDO) to determine if Rosemount, Inc. (RM) had provided inaccurate and incomplete information to the NRC during a meeting conducted on April 13, 1989, regarding the loss of fill oil failure experienced by the RM 1152 transmitter; determine if RM deliberately delayed notification to the NRC by not reporting the loss of fill oil failures of the RM 1153 and 1154 transmitter by a formal 10 CFR Part 21 notification; determine if RM had discriminated against an employee for raising a safety concern; and determine if Ventech Controls, Inc., was counterfeiting and refurbishing RM transmitters for sale to the nuclear industry.

Based on the testimonial and documentary evidence developed during the investigation, the Office of Investigations concluded that the allegation that RM provided inaccurate and incomplete information to the NRC during an April 13, 1989, public meeting regarding the failure experience of the RM 1152 transmitter was not substantiated. From the evidence developed during the investigation it is concluded that RM acted in careless disregard by failing to adequately identify and report potential defects as required by 10 CFR 21. The evidence did not substantiate the allegation that an RM employee was discriminated against for raising safety concerns. The evidence developed did not substantiate the allegation that Ventech, Inc., was counterfeiting/refurbishing RM transmitters and selling them to the nuclear industry.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 17, 1994

Docket No. 99900271/93-01

EA 94-049

Mr. Kenneth Ewald, Business Unit Manager
Rosemount Nuclear Instruments, Incorporated
1256 Trapp Road
Eagan, Minnesota 55121

Dear Mr. Ewald:

SUBJECT: PROPRIETARY INFORMATION IN NRC INSPECTION REPORT 99900271/93-01

This letter is to inform you that the U.S. Nuclear Regulatory Commission (NRC) staff has finished reviewing and deliberating on the December 16, 1993, request by Rosemount Nuclear Instruments, Incorporated (Rosemount), to withhold certain information from NRC Inspection Report 99900271/93-01 in accordance with Section 2.790 of Part 2 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 2.790). A copy of the nonproprietary (public) version of this subject inspection report is enclosed.

In our February 2, 1994, response letter to Rosemount's request to withhold certain proprietary information, we stated that we disagreed with Rosemount's reasons for withholding several statements in this inspection report. Subsequently, Rosemount and NRC staff had several discussions to resolve the matter, and Rosemount demonstrated to the staff's satisfaction that certain information in the report could give Rosemount's competitors a business advantage. Therefore, in accordance with 10 CFR Part 2.790, the NRC has agreed to withhold additional information from its inspection report. In the public version of the report, the NRC has briefly summarized the deleted sections. However, the staff informed Rosemount between March 4-14, 1994, that several items that Rosemount requested to withhold will remain in the report because Rosemount did not justify their exclusion.

If you have any further questions on this matter, please contact Greg Cwalina at (301) 504-2984 or Joe Petrosino at (301) 504-2979.

Sincerely,

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosure:
Inspection Report 99900271/93-01

cc: Mr. Jerry Valley, Quality Assurance Manager
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** Revision 1

U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR INSPECTION AND LICENSEE PERFORMANCE

ORGANIZATION:	Rosemount Nuclear Instruments, Incorporated Eagan, Minnesota	** **
REPORT NO.:	99900271/93-01	
ORGANIZATIONAL CONTACT:	Mr. Kenneth E. Ewald, Business Unit Manager (612) 681-5814	 **
CORRESPONDENCE ADDRESS:	1256 Trapp Road Eagan, Minnesota 55121-1282	** **
NUCLEAR INDUSTRY ACTIVITY:	Designer, manufacturer, and supplier of pressure and differential pressure transmitters and temperature detectors used extensively in nuclear safety-related applications.	
INSPECTION CONDUCTED:	February 1-4, and March 8-12, 1993	
INSPECTION TEAM LEADER:	Original proprietary version signed on March 1, 1994, by _______________________ Date Joseph J. Petrosino, Team Leader Reactive Inspection Section 2 (RIS-2) Vendor Inspection Branch (VIB)	
OTHER INSPECTORS:	Kamalakar R. Naidu, RIS-2: VIB S.D. Alexander, RIS-2: VIB C. Paulk, NRC Region IV: Division of Reactor Safety K. Sullivan, Brookhaven National Laboratory T.L. Tinkel, Brookhaven National Laboratory	
APPROVED:	Original proprietary version signed on March 3, 1994, by _______________________ Date Gregory C. Cwalina, Chief, RIS-2: VIB Division of Reactor Inspection and Licensee Performance Office of Nuclear Reactor Regulation	
INSPECTION BASES:	10 CFR Part 21 and 10 CFR Part 50, Appendix B	
INSPECTION SCOPE:	The implementation of the Rosemount 10 CFR Part 50, Appendix B QA program and its procedures adopted pursuant to 10 CFR Part 21 were evaluated.	
PLANT SITE APPLICABILITY:	Numerous	

** Changes were made to page 1 only, as indicated.

1 INSPECTION SUMMARY

1.1 Apparent Violation

Contrary to Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of the version of 10 CFR Part 21 (Part 21) in effect at the time, Rosemount, Incorporated, Measurement Division (Rosemount) did not ensure that all affected customers were appropriately informed of identified deviations. Specifically, from approximately August 1984 until December 1988, Rosemount did not inform all its customers of deviations involving sensor cell oil-loss that could cause degraded operation in its 1150 series of nuclear safety-related pressure transmitters. Degraded transmitter operation as a result of sensor cell oil-loss was identified mainly in Model 1153 and 1154 pressure transmitters that had been returned for analysis by NRC licensees or found by Rosemount field service personnel. Rosemount documents cited in this report showed that Rosemount had identified potential deficiencies in the transmitter's design and its manufacturing and testing processes and had implemented changes to the processes to correct the deficiencies.

In a March 25, 1988, letter, Northeast Utilities (NU) notified the NRC pursuant to Part 21 of a substantial safety hazard in Unit 3 of its Millstone facility as a result of failed Model 1153HD5PC Rosemount transmitters. NU's letter to the NRC stated, in part, that "the manufacturer [Rosemount] had indicated to us [NU, that] the failures are random and there is no generic problem."

Through an examination of various Rosemount documents it was determined that Rosemount was aware of numerous transmitter failures prior to March 1988, the cause of the failures, and the symptoms exhibited by the failed transmitters. However, Rosemount did not begin to inform affected nuclear licensee customers until December 1988, and formally informed its customers in accordance with its 10 CFR Part 21 procedure in February and May 1989. Consequently, as much as four years elapsed before all applicable NRC licensees were made aware of potentially suspect transmitters that may have been installed in applications where sometimes undetectable degraded operation could have caused safety limits to be exceeded or caused "substantial safety hazards."

1.2 Violations

1.2.1 Contrary to Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of 10 CFR Part 21, Rosemount failed to establish or implement a procedure to ensure that the provisions of 10 CFR Part 21 were executed at its Chanhassen facility. (93-01-01)

1.2.2 Contrary to Section 21.6,"Posting requirements," the 10 CFR Part 21 posting at Rosemount's Eden Prairie and Chanhassen facilities did not adequately describe the 10 CFR Part 21 regulation or the procedure adopted to implement 10 CFR Part 21. In addition, the postings were found to contain outdated names and telephone numbers of personnel to whom reports were to be made. (93-01-02)

1.2.3 Contrary to Section 21.51, "Maintenance and inspection of records," of 10 CFR Part 21, Rosemount records regarding a review of suspect resistors used in Rosemount 710 DU products did not contain adequate information to enable the team to determine whether Rosemount customers were appropriately informed of the deviation. (93-01-03)

1.3 Non-cited Violation

Contrary to Section 21.31, "Procurement documents," of 10 CFR Part 21, Rosemount did not invoke 10 CFR Part 21 before 1990 on most of its purchase orders for certain basic components, specifically, metal o-rings used in Model 1153 and 1154 transmitters. Purchase orders since then have invoked 10 CFR Part 21. This violation is not being cited because the enforcement criteria specified in Section VII.B of 10 CFR Part 2, Appendix C, "General Statement of Policy and Procedure for NRC Enforcement Actions," were satisfied.

1.4 Nonconformances

1.4.1 Contrary to Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 and Section 5, "Instructions, Procedures, and Drawings," of Rosemount's Nuclear Quality Manual (NQM), Rosemount did not establish adequate procedures, or instructions to control activities affecting quality, such as, analyzing and determining the root cause of problems with safety-related pressure transmitters in its Failure Analysis (FA) Laboratory. (93-01-04)

1.4.2 Contrary to Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, Rosemount did not have an adequate Appendix B QA program for the control of "basic components" manufactured in its Chanhassen facility. Although Rosemount provided Chanhassen with its Nuclear Department-approved drawings and procedures for certain of its activities affecting quality, some QA functions were not appropriately controlled or performed. (93-01-05)

1.4.3 Contrary to Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50, Rosemount did not implement the receipt inspection requirements delineated in Section 2.5, "Dedication," of NDP N-0730, "Dedication of Subassemblies from Chanhassen," for the sensor cells used in all of its safety-related nuclear transmitters. (93-01-06)

1.4.4 Contrary to Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, and Section 3, "Design Control," of Rosemount's NQM, as of March 12, 1993, the NRC inspection team identified the following nonconformances:

- Rosemount did not perform an adequate verification of the design change authorized by Engineering Change Order (ECO) 601919, dated May 23, 1983, and no evidence was found to indicate that the design change was compared to or met the existing Rosemount Model 1153 Equipment Qualification Report. Additionally, Rosemount did not perform an adequate verification of the design changes authorized by ECO 603675, dated February 1, 1984. Although these design changes were later superseded by subsequent changes, the team was concerned that Rosemount was making design changes without an adequate engineering evaluation to assure that previous equipment qualifications remain valid. (93-01-07)

- Rosemoun+ did not adequately justify the use of fluids in its transmitters having an expired shelf life and did not state its basis for the operating temperature limits of the fluid used in sensor cells of nuclear-qualified transmitters. (93-01-08)

1.4.5 Contrary to Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, Section 18.3.3, "Internal Audits," of Rosemount's NQM, and Section 3.0, "Responsibilities," of NDP N-0730, Rosemount failed to schedule or conduct any internal audits in 1989. Additionally, since December 1991, Rosemount has failed to audit quality-related activities at its Chanhassen facility to determine compliance with applicable portions of Appendix B to 10 CFR 50 and 10 CFR Part 21. (93-01-09)

1.5 Inspector Follow-Up Items

Inspector Follow-Up Items are items that were identified during the inspection team activities that are perceived by the team to either need additional inspection time or to be of interest for future inspection follow-up.

1.5.1 The NRC inspectors started a review of how Rosemount handles incoming NRC licensee telephone calls regarding potential deviations. However, the NRC inspectors did not complete their review. In accordance with the provisions of Rosemount's Nuclear Department Procedure N-1697, "Returned Products From a Nuclear Facility," Revision A, Rosemount's marketing personnel enter the content of conversations with their customers in a log book. The team's review of incoming telephone calls that were entered in the 1989 log book showed that as of March 12, 1993, some calls did not appear to have been completely dispositioned. Since licensee related problems could potentially affect other customers or products the team was interested in further reviewing the manner in which Rosemount dispositions these telephone calls. (93-01-10)

1.5.2 The team conducted a design change review of changes to the metal o-ring drawing. The drawing revision history record that the team reviewed indicated that Rosemount made a number of changes to the metal o-ring drawing. However, contrary to what the drawing revision history indicated, the Rosemount Engineering staff stated that the actual o-ring configuration never physically changed, and that the drawing changes were administrative attempts to correct the drawing rather than physically change the o-ring. The Rosemount o-ring drawing revisions, particularly around the period of Revision E, December 13, 1981, and Revision F, February 6, 1984, will be reviewed during a future inspection. (93-01-11)

1.5.3 The team had questions based on its review and observations of the HP/Aging 1 (HP1) tests and associated activities. The team noted that sensor cells used in Model 1153 and 1154 transmitters undergo testing to ensure leak-tightness of the sensor cell over time. Rosemount determined that these time and pressure test values are sufficient to identify excessive leakage over the qualified life of the sensor. The team asked for the Rosemount basis related to the amount of oil that may leak before being detected by visual inspection. Rosemount presented a document entitled "Rosemount Sensor Life Calculations Based on Oil Loss in Model 1153 and 1154 Pressure Transmitters."

[Deleted pursuant to 10 CFR 2.790 - Document discusses calculations, performance characteristics, and testing. Notes that testing should adequately identify transmitters with potential for failure.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses calculations, performance characteristics, and testing. Notes that testing should adequately identify transmitters with potential for failure.]

This area, including the synergistic effects of temperature and pressure on the physical characteristics (e.g. viscosity) of the sensor fill fluid will be reviewed during a future NRC inspection. (93-01-12)

1.5.4 Rosemount representatives stated that the current level of in-process testing that is performed by production personnel is sufficient to identify manufacturing deficiencies. For example, Rosemount stated that response time testing (performed after the sensor is mounted in its housing) is adequate to identify cells with low levels of fill oil.

The team subsequently identified that the ability of response time testing to accurately identify improperly filled cells may not be adequate in all cases because, depending on the transmitter range code, as much as 73 percent of the fill fluid may be lost before the response time test would reliably identify a sensor cell as having low-oil.

The team was in agreement with the Rosemount staff that the response time test verified that a certain degree of oil-fill had taken place and the transmitters would operate under certain conditions. However, the team questioned the validity of the response time test to assure whether or not the nuclear transmitters that are passed will perform within their designed and tested spectrum of operating conditions. (93-01-13)

1.5.5 The team reviewed Rosemount Field Instruction Manual No. 4302, for Model 1153, Series B, transmitters. The NRC inspectors reviewed the sequence of steps that licensee staff would use when changing out a sensor cell at their facility. The team questioned whether the Rosemount field manual contained an appropriate assembly sequence to allow licensee staff to adequately perform a field change out of sensor cells on Rosemount transmitters that require using stainless steel o-rings in their process flange area, as discussed in Section 4.4 below. Therefore, the information that Rosemount provided to certain NRC licensees will be discussed further with Rosemount representatives. (93-01-14).

1.5.6 The NRC inspection team review included areas that were associated with the dedication of commercial grade items (CGI). However, the appropriateness of Rosemount's overall program for dedication of CGIs used in its products destined for use in nuclear power plant safety-related systems was not specifically reviewed during this inspection. Therefore, Rosemount's dedication of CGIs for use in products shipped for use in NRC licensee applications will be reviewed during a future NRC inspection. (93-01-15)

2 STATUS OF PREVIOUS INSPECTION FINDINGS

No previous NRC inspection findings were left open or unresolved from the previous NRC inspections at Rosemount.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

During the NRC entrance meeting on February 1, 1993, the inspectors explained the scope of the inspection to the Rosemount staff. During an interim exit meeting on February 4, 1993, the team leader explained to Rosemount management that the NRC inspection would be continued because the team was not able to make adequate progress toward completing its inspection goals. The NRC team leader conducted an inspection continuation entrance meeting on March 8, 1993, and reiterated the inspection scope to Rosemount management and staff. At the exit meeting on March 12, 1993, the team leader summarized the team's concerns and findings for Rosemount management and staff.

3.2 Background

In January 1956, the Rosemount Engineering Company was incorporated as Rosemount, Incorporated (Rosemount). In 1969, Rosemount started to market and supply its Model 1151 solid-state, capacitance, industrial differential pressure (DP) transmitter. In 1974, Rosemount qualified its Model 1152 to the Institute of Electrical and Electronics Engineers, Incorporated (IEEE) Standard 323-1974. In 1975, the Model 1152 was seismically qualified to IEEE Standard 344-1971. In 1976, Rosemount was acquired by the Emerson Electric Company as a wholly owned subsidiary. During the 1970s and 1980s, Rosemount developed and qualified its Model 1153 and 1154 transmitters to the NRC's harsh environment equipment qualification regulations.

At the time of this NRC inspection, the Nuclear Business Unit (NBU) of the Rosemount, Incorporated Measurement Division controlled the design, qualification, manufacture, supply and other aspects of the nuclear-qualified Model 1152, 1153, and 1154 transmitters. However, the majority of the Rosemount NBU activities were in the process of being transferred from the Rosemount, Incorporated Measurement Division to Rosemount Aerospace, Incorporated (RAI).

Since the early 1980s, the NRC staff has become aware of several problems with Rosemount's 1150 series transmitters. Rosemount considered these problems as isolated, and handled them as they believed to be appropriate. In 1987, the NRC conducted an inspection at Rosemount because of a potentially generic problem concerning degraded transmitter operation associated with contaminates in sensor cell oil, a condition referred to as "latch-up." Subsequently, another problem surfaced, regarding degraded transmitter operation associated with oil-loss in the sensor cell. The oil-loss problem was discussed in NRC Information Notice (IN) 89-42, "Failure of Rosemount Models 1153 and 1154 Transmitters." As noted in the IN, Rosemount indicated to the NRC staff that the failures appeared to be random and not related to any generic problem with Rosemount pressure transmitters. Further discussions were conducted between Rosemount and industry groups, and Rosemount initially informed its customers of a potentially generic problem on December 12, 1988, and February 9, 1989.

3.3 Review of 10 CFR Part 21 Program

The NRC inspection team reviewed the procedures that Rosemount identified as implementing the provisions of 10 CFR Part 21, and historical records of problems that appeared to be potential deviations. The objective of this review was to determine the effectiveness of Rosemount's established 10 CFR Part 21 program and its implementation. The team reviewed the following Rosemount procedures: Quality Implementation Procedure (QIP) 126(N), "Potential Defect or Deviation in Products for Nuclear Application," issued March 18, 1981; Nuclear Department Procedure (NDP) N-1626, "Handling Potential Defects or Deviations in Nuclear Products per 10 CFR Part 21," Revision A, dated April 21, 1992, which superseded QIP 126(N); and NDP N-1697, "Returned Products From a Nuclear Facility," Revision A, dated May 8, 1992.

The team also assessed whether Rosemount had adequately implemented Section 3.2 of NDP N-0730, "Dedication of Subassemblies From Chanhassen," Revision A, dated May 8, 1992, which mandated that the "Supplier [Chanhassen] will implement a procedure for reporting defects or deviations per 10 CFR Part 21." The NRC team's evaluation of Rosemount's 10 CFR Part 21 program included:

- review of correspondence (dating back to 1979) concerning deviations and transmitter failure analysis data
- discussions with Rosemount staff members regarding their training in and knowledge of the requirements of 10 CFR Part 21 and its implementation
- observation of the location and adequacy of Rosemount's posting of the required 10 CFR Part 21 documents at the Chanhassen and Eden Prairie facilities.

3.3.1 <u>Review of QIP 126(N) and Associated Rosemount Records of Problems</u>. The team's review of QIP 126(N) identified that Rosemount's company position, as stated in Section 1.3, was

> Because a supplier of industrial instruments cannot control how they may be applied or misapplied, and because only the system design agency can determine the effect any "defect" or "deviation" may have on operational safety, a means of prompt review and communication has been elected. The position RMT [Rosemount] has taken regarding 10 CFR Part 21 is detailed in the letter attached. This letter is sent to all customers regarding products destined for application in Nuclear facilities within the United States of America.

The team considered that the Rosemount Company Position in QIP 126(N) could be a strength if properly executed because the policy would tend to expeditiously transmit all deviations to NRC licensees as soon as they were identified and dispositioned by Rosemount. This would allow each NRC licensee to evaluate the deviation in accordance with 10 CFR Part 21 to determine whether or not a "substantial safety hazard" could exist. However, problems were identified by the inspectors with the adequacy and implementation of the procedure and Rosemount's execution of the Company Policy.

The procedure required that any employee who detected or was notified of a potential defect or deviation immediately notify a Nuclear Review Committee member. The Committee member then was to gather all pertinent information and arrange a Committee meeting within one day. After the Committee completed their review (which may have taken several meetings), a recommendation was to be made to the Rosemount officer accountable for nuclear products. That officer was then to determine if customer notification was needed. If so, the officer was to prepare and issue a letter within two working days. Based upon a review of the procedure and the sample letter that was attached to QIP 126(N), the team concluded that the Nuclear Review Committee should have reviewed all problems to determine if they constituted a deviation in accordance with Part 21. (Note: as stated above, Rosemount's company position was, and still is, that they cannot evaluate deviations to determine if they constitute a defect.)

The team reviewed Rosemount's intracompany memoranda and other correspondence written mainly before 1988, to determine how effectively the procedure had been implemented and whether identified problems were adequately reviewed to determine whether deviations existed and whether the Nuclear Review Committee was convened to review the deviations. Section 3.3.7.1 below also discusses other examples of Rosemount's implementation of its 10 CFR Part 21 program. Examples of correspondence that was reviewed by the team are as follows:

A Rosemount Intracompany Memorandum (RIM), dated August 27, 1984, that was copied to Rosemount staff and management in several departments including nuclear QA, manufacturing, and contracts, stated, in part, that:

> ...*of greatest concern **are** four failures of **model** 1153 HA5*, all measuring Reactor Coolant Flow...***determined** failure **mode** in 3 units to be loss of oil*, but could not determine cause. [emphasis added].

An RIM, dated April 23, 1986, stated, in part:

> [Deleted pursuant to 10 CFR 2.790 - Document discusses oil leaks, leakage paths, leakage testing, testing criteria and results.]

An RIM, "Nuclear Sensor Oil Leaks," dated May 7, 1986, stated, in part:

> [Deleted pursuant to 10 CFR 2.790 - Document discusses testing, loss of oil failures, and failure analysis and results. Document notes that leakage rate is so slow that detection may require long test periods.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses testing, loss of oil failures, and failure analysis and results. Document notes that leakage rate is so slow that detection may require long test periods.]

A Rosemount letter to [a customer's] Nuclear Power Plant [name deleted] staff, dated September 17, 1986, stated, in part:

[Deleted pursuant to 10 CFR 2.790 - Document identifies customer and sales volume. Document also states that Rosemount considers failures to be unique to customer facility.]

A letter from the [customer] staff to Rosemount, dated September 25, 1986, stated, in part:

[Deleted pursuant to 10 CFR 2.790 - Document discusses manufacturing process and design characteristics. Document also discusses potential testing method shortcomings.]

An RIM, dated March 19, 1987, from a Rosemount manager to Rosemount staff stated, in part, that:

> ***One of our larger field failure problems is the loss of sensor fill fluid in nuclear pressure transmitters.*** It's important that we be able to identify the cause of these failures in order to take corrective action in production. ***A transmitter which has lost oil exhibits unique performance characteristics, typically as slow response to input pressure or no response at all.*** Effective immediately, the module from <u>any</u> returned transmitter which you suspect has failed due to loss of oil must be submitted for failure analysis [emphasis added].

Another RIM, "Meeting on Nuclear Sensor Oil Leaks," dated March 25, 1987, stated, in part, that:

[Deleted pursuant to 10 CFR 2.790 - Document discusses manufacturing process, and testing and acceptance criteria.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses manufacturing process, and testing and acceptance criteria.]

Another RIM, "Oil Leakage Status Report," dated July 14, 1987, stated, in part, that:

> **[Deleted pursuant to 10 CFR 2.790 - Document discusses design characteristics, testing and acceptance criteria and experiments. The document identifies that transmitters with visually detectable leaks will ultimately fail.]**

The team examined another RIM, dated August 5, 1981, from Rosemount's Houston office which identified operational problems in 47 industrial Model 1151 transmitters and requested that the Rosemount Eden Prairie staff investigate the various causes. An associated RIM, dated April 22, 1982, to Rosemount management from the failure analysis laboratory, indicated that approximately half of the 47 modules that were sent to Eden Prairie for investigation exhibited oil-loss (some were damaged). Additionally, the team reviewed a Rosemount Failure Analysis Request/Report (FAR) package, FAR 497, dated July 9, 1985, that analyzed 5 Model 1151 transmitter modules that were from **[an off-shore (foreign) nuclear power station] [Deleted pursuant to 10 CFR 2.790 - Document identifies customer and sales volume. Document also states that transmitter modules lost oil.]** The transmitters were supplied to the **[nuclear power]** station between May 1981 and August 1984. The Rosemount FAR was found to state, **[Deleted pursuant to 10 CFR 2.790 - Document identifies customer and sales volume. Document also states that transmitter modules lost oil.]** The team found that, at those times, the nuclear sensor cells went through the same process and manufacturing controls that were used for the industrial units. According to Rosemount QA staff, during this time period, "***except for traceability requirements, the industrial sensor cell was identical to the nuclear sensor cell*** [emphasis added]." The inspection team considers this staff knowledge of Model 1151 sensor cell problems relevant because Rosemount should have been aware that an industrial sensor cell oil-loss problem was a potentially generic problem that could also affect its nuclear sensor cells since nuclear and industrial type sensor cells were controlled, manufactured and fabricated almost identically. However, it appears that Rosemount did not appropriately recognize or adequately address the potential nuclear sensor cell implications of the failed industrial sensor cell problem when it was first documented by Rosemount in 1981 nor several subsequent occasions when failed or degraded transmitters due to oil-loss were found, returned or reported to Rosemount by NRC licensees as discussed herein.

The NRC team also reviewed Rosemount records pertaining to the Nuclear Review Committee meetings from 1982 to 1991. The inspectors' review for the 1982-1987 time period appeared to indicate that the first Rosemount Nuclear Review Committee meeting regarding oil-loss was held in April 1986, and that subsequent meetings took place in July 1986 and February 1987 (further discussed in Section 3.3.6.1 below). An RIM announcing the February 1987 Nuclear Review Committee meeting stated under "topic of concern" that, "low oil in nuclear transmitters [was the subject]... Please bring all information that you may possess. We will try to determine the nature and scope of the problem and if it is generic."

Further, the team also found that approximately 70 instances of failed or degraded nuclear transmitters (due to oil-loss) had been discussed with or identified to Rosemount personnel prior to the time that the oil-loss problem was first addressed in the 1986-1987 Nuclear Review Committee meetings. However, it appears that Rosemount did not compile nor maintain any type of all-encompassing list of these failures until sometime in the late 1986-1987 time period when the nuclear quality group commenced a review of the oil-loss problem. One Rosemount document that was reviewed and discussed with Rosemount QA staff represented one of the first attempts by the Nuclear quality group to compile all of the known transmitter oil-loss failures. The quality group was attempting to understand the scope of the oil-loss problem and to determine commonality. That list started with four Model 1153HA5 transmitter failures in 1984 at Surry due to oil-loss (those 1984 failures were documented by Rosemount in an August 1984 intracompany memorandum discussed above in this Section) and ended with two Model 1153DB5 transmitter failures at Nine Mile Point in 1986. This list contained approximately 92 individual nuclear transmitter failures, of which, about 70 were traced back by the team and found to have been reviewed by Nuclear Review Committee members.

The Rosemount staff also informed team members that in the early to mid-1980s, all of the nuclear transmitter failures or customer problems with degraded transmitter operations would not necessarily be handled by the same Rosemount group or department. Prior to the late 1980s, the Rosemount service center staff would not necessarily involve the nuclear quality or engineering staff when it was resolving customer problems that might involve degraded operation of nuclear transmitters. According to Rosemount staff, these customer service activities and service center activities regarding NRC licensees are presently coordinated through the Rosemount nuclear quality and engineering group.

The team reviewed Rosemount's failure data information that its Engineering Department had compiled. The NRC team reviewed Rosemount Nuclear Engineering staff records that related to oil-loss problems. These consisted of various documents and graphs containing manufacturing and field return data for the Rosemount Model 1152, 1153 and 1154 nuclear transmitters. This information covered a period from about 1979 through 1992. The records, which included Rosemount field return failure data, appeared to indicate that the major cause of oil-loss from the sensor cell was leakage through the sensor cell glass-to-metal (G-M) interface. The team also reviewed Rosemount graphical data for confirmed G-M failures of Model 1152, 1153, and 1154 nuclear transmitters sorted by sensor cell weld date. The weld date is the date that the sensor cell diaphragms were welded, and represents the approximate Rosemount manufacturing date for a transmitter. Rosemount used these dates to provide approximate estimates of the manufacturing time-frame of nuclear transmitters with confirmed G-M failures. The confirmed number of failures due to oil-loss by weld date were found to be lowest in 1980 (1), 1989 (0), and 1990 (0). The highest number of failure occurred in 1982 (22), 1983 (23), 1984 (64), 1985 (29), and 1986 (10). These dates only represent the year that the failed units were manufactured and not the dates when Rosemount became aware of the failures.

The team also reviewed Rosemount graphical data on Model 1152, 1153, and 1154 nuclear transmitters with confirmed oil-loss failures sorted by return date. The return date is an indication of the time frame when Rosemount became aware of these nuclear transmitter oil-loss failures and when they were shipped back to Rosemount for analysis. The team notes that the basis for this data differs somewhat from that of the G-M failure data discussed above. There are two reasons for this according to the Rosemount Engineering staff. First, the confirmed oil-loss failure data include G-M failures as well as other types of failures that can also cause oil-loss (such as defective welds or broken fill tubes). Second, the oil-loss data do not include some confirmed failures that were known to Rosemount, but not actually returned to Rosemount for reasons such as radioactive contamination. Rosemount's documented oil-loss transmitter failures that were confirmed in their failure analysis laboratory ranged from a low in 1984 (1) and 1985 (2); to the highest in 1986 (17), 1987 (27), 1988 (23), 1989 (10), 1990 (14), and 1991 (10).

Some of the graphs reviewed by the team contained time-lines for various corrective actions in Rosemount process control and design parameters aimed at correcting the oil-loss problem. From its review of this graphical and engineering data, the team concluded that Rosemount was aware as early as 1986 (and perhaps even earlier) that the number of transmitters failing as a result of oil-loss had increased and was implementing corrective action. However, Rosemount did not formally inform its nuclear licensee customers about its transmitter oil-loss problem until December 12, 1988.

The inspectors concluded, based upon a review of the above records, procedures and discussions with Rosemount staff that:

- Rosemount did not adequately ensure that the Nuclear Review Committee was aware of deviations in the operation of Rosemount's products in safety-related applications at NRC licensed facilities.

- Rosemount did not ensure that identified problems from operating nuclear plants where Rosemount products were used in safety-related applications were appropriately reviewed to determine whether a deviation, as defined in Section 21.3(e) of the revision of 10 CFR Part 21 that was in effect at the time, existed. Such a deviation could include a change in the transmitter response time or in its qualified life. Since Rosemount failed to adequately review or disposition its Model 1150 series transmitter oil-loss problems that could cause degraded operation or premature failures, Rosemount failed to inform its customers pursuant to 10 CFR Part 21 so that affected customers could determine if the deviations could create a "substantial safety hazard."

- Rosemount was aware of several transmitter failures prior to December 1988, the cause of the failures, and the symptoms exhibited by the failed transmitters. The oil-loss problem was discussed in Rosemount Nuclear Review Committee meetings in April and July 1986, and generic considerations were identified as early as February 1987.

One common thread found by the team in many of the Rosemount records was an interest among Rosemount staff to determine the cause of the problem in the manufacturing process and to take corrective action. This interest was viewed as a strength by the team. However, the team's examination of the records and

10 CFR Part 21 procedures identified some weaknesses that the team considered important when performing an evaluation or review of a potential deviation or anomaly. These weaknesses were:

- The documents did not address the determination of whether or not the anomaly or problem was potentially generic.
- The documents did not address whether the anomaly applied to basic components that were previously shipped to customers.
- The documents did not address whether the Nuclear Review Committee was informed so that disposition of the anomaly pursuant to 10 CFR Part 21 was accomplished.

This information was used to characterize the apparent Violation.

3.3.2 Review of NDP N-1626. The same Rosemount Company Policy and letter required by QIP 126(N) was found to be required by Procedure N-1626. The team verified by a review of a sample of current incoming purchase order (PO) packages from NRC licensees that Rosemount had typically transmitted this subject letter to its customers and the intent of the Rosemount company policy was properly expressed. The inspectors identified several weaknesses in Rosemount Procedure N-1626. Rosemount did not incorporate the time limits for the evaluation of deviations and failures to comply, and other new requirements that were first specified in the July 31, 1991, revision of 10 CFR Part 21.

This has not been identified as a violation because Rosemount's Company Position stated that it would not attempt to evaluate deviations since it was not in a position to determine whether a substantial safety hazard existed. Rosemount stated that it would promptly inform its customers of any deviations that it identified. Therefore, Rosemount's Company Policy complied with the intent of Section 21.21 (b) of 10 CFR Part 21. Further, Rosemount performed corrective action immediately by revising the procedure to adequately address the time limits and other NRC staff concerns. Additionally, the team would consider it a strength if Rosemount's nuclear customer service activities regarding potential deviations are coordinated through Rosemount's nuclear quality and engineering groups.

3.3.3 10 CFR Part 21 Procedure at Chanhassen. The inspection team reviewed Rosemount's activities at the Chanhassen manufacturing facility. That facility manufactures Rosemount industrial (commercial grade) Model 1151 transmitters. The same facility also manufactures safety-related sensor cells up to the oil-fill step. Manufacturing activities for the safety-related sensor cells at Chanhassen are controlled by separate procedures issued and approved by the nuclear department. In conjunction with these procedures, different or specific manufacturing process controls and some traceability requirements are also employed that are not typically used for the commercial grade items. The team concluded, in consultation with Rosemount, that the Chanhassen manufacturing activities associated with sensor cells used in safety-related pressure transmitters have relied on unique nuclear requirements and, therefore, would be subject to 10 CFR Part 21 requirements. Additionally, the Chanhassen facility was specifically required by Paragraph 3.2 of Procedure N-0730 to establish a 10 CFR Part 21 procedure. However, the inspectors determined that Rosemount had not established or implemented such a procedure. Violation 93-01-01 was identified in this area.

The inspectors identified one other area of concern regarding some Rosemount personnel's view of the activities being conducted at the Chanhassen facility. On two different occasions, between February 1-4, 1993, different NRC team members asked one Rosemount QA auditor why the 10 CFR Part 21 posting was outdated at Chanhassen. The auditor informed the NRC team members that it did not matter that the posting was outdated because 10 CFR Part 21 was not applicable to the Chanhassen facility activities. Further, some Rosemount managers also stated to the team that Chanhassen was a commercial grade operation. However, as discussed above, the team determined that Chanhassen was manufacturing safety-related sensor cells and that Rosemount Procedure N-0730 stated that 10 CFR Part 21 was applicable (indicating Rosemount's corporate viewpoint). The team is concerned that all Rosemount personnel may not be aware of Chanhassen's involvement in manufacturing nuclear grade sensor cells and, therefore, may not recognize their duty to comply with Part 21 when they recognize potential deviations.

3.3.4 Posting Requirements. The NRC inspection team determined that safety-related activities were being conducted at both the Chanhassen and Eden Prairie facilities; therefore, the inspectors observed the location and reviewed the adequacy of the 10 CFR Part 21 posting at both facilities.

The posting is required by Section 21.6, "Posting requirements," of 10 CFR Part 21. Section 21.6 of 10 CFR Part 21, requires, in part, that each individual, corporation, partnership, or other entity post current copies of either:

- 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974 (ERA), and procedures adopted pursuant to 10 CFR Part 21; or

- Section 206 of the ERA, and a notice which describes 10 CFR Part 21 and procedures adopted to implement 10 CFR Part 21, including the name of the individual to whom reports may be made and the location of where the procedures may be examined.

The NRC inspectors found that the 10 CFR Part 21 postings at Rosemount's Eden Prairie and Chanhassen facilities did not adequately describe the 10 CFR Part 21 regulation or the procedure that Rosemount adopted to implement 10 CFR Part 21. Specifically, the "Description of 10CFR21" was actually a description of Section 206 of the Energy Reorganization Act of 1974, the postings described 10 CFR Part 21 as being applicable only to NRC-licensed facilities or those conducting NRC-licensed activities, and under "Notifications," the postings listed the NRC Region III phone number and indicated that NRC regional offices would accept collect calls; however, the posting did not mention the NRC Headquarters Operations Center, nor its phone number, as specified in the current revision of 10 CFR Part 21. Also, the list of Rosemount contact personnel was out of date. In addition, the inspectors found that the 10 CFR Part 21 posting at the Chanhassen facility was an older, outdated, version of the one posted at the Eden Prairie facility. Violation 93-01-02 was identified in this area.

3.3.5 Procurement Documents. Section 21.31, "Procurement documents," of 10 CFR Part 21, requires, in part, that entities impose the provisions of Part 21 on purchase orders (POs) to suppliers of components. During a review of engineering change orders (ECOs) the NRC inspectors found that ECO 642650, that was dated July 22, 1991, contained a note stating that the provisions of 10 CFR Part 21 were applicable, and Rosemount staff stated that the purpose of that note was to impose the regulation on the o-ring vendor. This drawing then became part of Rosemount's PO. Therefore, Rosemount imposed Part 21 to the supplier on the drawing which became part of the PO package documents.

However, Rosemount also stated that before July 22, 1991, it did not pass down the requirements of 10 CFR Part 21 to the vendor. The NRC inspectors requested a sample of pre-1991 POs to the o-ring supplier and confirmed that Rosemount failed to invoke the 10 CFR Part 21 requirements on the metal o-ring vendor prior to July 22, 1991. Examples of POs that did not invoke the regulation are as follows: EK 5737, dated July 19, 1990; EK 5620, dated May 16,1990; EK 0493, dated October 19, 1989; and EK 2169, dated November 4, 1988. This violation is not being cited because the enforcement criteria specified in Section VII.B of 10 CFR Part 2, Appendix C, "General Statement of Policy and Procedure for NRC Enforcement Actions," were satisfied.

3.3.6 10 CFR Part 21 Evaluation Records. The team reviewed Rosemount records that were applicable to its review of identified potential deviations or failures to comply to determine whether Rosemount had performed the required review, and whether those reviews were adequate (this issue is also discussed in Section 3.3.1). The team examined records of Rosemount activities that were performed from approximately 1978 through 1992. Since July 1991, entities that are required to comply with 10 CFR Part 21 were only required to maintain records associated with evaluations for a maximum period of five years; however, Rosemount has maintained the majority of its evaluation records from as early as 1978. The team noted that, in addition to the requirements of Part 21, Rosemount had additional requirements stated in its Procedure QIP 126(N) as discussed in Section 3.3.1 above.

Based on its review, the team concluded that the Rosemount records did not contain adequate information in all cases to enable the team to determine whether the review and disposition of Rosemount's deviation evaluation was adequately performed in accordance with the applicable requirements. Specifically, on August 15, 1989, Rosemount staff discovered a problem with wire-wound resistors (1 ohm to 10,000-ohm range) used in the assembly of its Model 510 and 710 DU Trip Calibration System instruments (TCSs). The manufacturing process required brazing leads to the resistors, which were wound with wire that had a diameter of 0.0004 inch or less. Until 1988, the manufacturer cleaned the brazed leads before coating the resistors. In 1988, the manufacturer revised the manufacturing process and required the brazed leads to be cleaned after the resistors were coated. When the revised process was implemented, remnants of the flux that had been used during the brazing process remained on the brazed joint and caused contamination. When combined with voltage, humidity, temperature, and time, this contamination resulted in discontinuity between the leads and the resistor, and subsequently in failures. The failure mode regarding Rosemount TCSs is a shift in resistance (either high or open). The concern was that, if left uncorrected or if it were undetected, this condition could cause a trip unit to lose the stability provided by the reset differential circuitry. Rosemount's corrective action was to rid the inventory of the resistors and request that the vendor rescind the change in manufacturing process. However, the team could not ascertain from the records whether Rosemount had determined if the suspect resistors had been used in products that had already been shipped and whether Rosemount had informed the affected customers. Violation 93-01-03 was identified in this area.

3.3.6.1 Nuclear Review Committee Meetings Regarding Oil-Loss Problems. The team's review of Rosemount documents indicates that the Rosemount Nuclear Review Committee convened at least on three different occasions during 1986-1987. The first meeting that took place appears to have been conducted on April 11, 1986. An RIM from the Rosemount QA Director, dated April 9, 1986, "Subject: Meeting Notice - Nuclear Review Committee," stated, in a hand-written note, that the topic of concern was oil leaks in transmitters. The RIM also stated that any transmitter found with loss of oil would go through failure analysis.

Another RIM from the QA Director, same subject as above, undated, indicated that a Nuclear Review Committee meeting would be conducted on Friday, July 11, 1986, and the topic of concern was, "low oil in cells of nuclear returned transmitters." The RIM also stated that the failures were random and that testing on-line would eliminate the problem.

Still another RIM from the QA Director, same subject, undated, indicated that a Nuclear Review Committee meeting was conducted on February 12, 1987. The hand-written note regarding the topic of concern on this RIM was "low oil in nuclear transmitters - Please bring all the information that you possess." The RIM simply stated that, "***We will try to define the nature and scope of the problem, and if it is generic*** [emphasis added]."

The team noted that it would appear that Rosemount's Nuclear Review Committee was informed of the oil-loss transmitter problem and convened to discuss the problem as early as April 1986. This information was also considered in the characterization of the apparent Violation described herein.

3.4 Inspection for Compliance with Appendix B to 10 CFR Part 50

The NRC inspection team reviewed selected portions of the quality assurance (QA) program that Rosemount established and implemented to comply with Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 (Appendix B). The team also inspected selected process control implementation aspects of Rosemount activities that could affect the reliability and quality of Rosemount transmitters supplied to NRC licensees. The team's review of the quality-related Rosemount activities included the Chanhassen failure analysis laboratory and sensor cell manufacturing and fabrication areas; and the Eden Prairie sensor cell degassing, oil fill and sensor module fabrication, assembly and testing activities. Additionally, the team conducted discussions with Rosemount staff regarding the printed circuit (PC) card manufacturing area at Chanhassen.

The team concluded from its inspection activities and reviews of records that the Rosemount Nuclear Quality Manual (NQM), Revision A, appeared to be comprehensively written and well suited to ensure compliance with the requirements of Appendix B. Nevertheless, as discussed below, the team also identified areas in which Rosemount has failed to adequately implement its established QA program procedures and instructions.

Rosemount's NQM, D9000115, Revision A, stated, in part:

> This Nuclear Quality Manual is a new manual structured and organized according to 10CFR50, Appendix B Criteria, and NQA-1-1986. The manual replaces Rosemount Quality Assurance Manual 1742 for Nuclear and corporate procedures pertaining to quality. The Nuclear Program this manual addresses does not change.

Despite this Corporate policy, the team identified three important areas in which the program did not meet Appendix B requirements. These three areas included the Failure Analysis (FA) Laboratory, Chanhassen manufacturing QA controls, and certain QA inspection activities at the Eden Prairie fabrication and testing areas and are discussed below.

3.4.1 Failure Analysis Laboratory. The inspection team evaluated the Rosemount FA Laboratory to determine whether the activities being performed complied with NRC regulations. The team observed in-process activities, conducted interviews with FA personnel, reviewed FA request/report forms, and reviewed the qualifications of personnel who performed the failure analyses on returned safety-related series 1150 pressure transmitters.

The team asked to review the procedures or instructions that were being used by FA staff to perform the analyses on transmitters that were returned by licensees. The team was informed that there were no formal procedures to address the root cause analyses activities performed by the FA staff but that there were some informal instructions and guidance that were being used. Nonconformance 93-01-04 was identified in this area.

The team examined FA personnel records that indicated that the FA staff were qualified in accordance with ANSI N45.2.6-1978. The FA personnel qualification and training documents indicated that the FA personnel were qualified and capable of performing root cause failure analysis. However, the FA laboratory supervisor stated that the FA staff had not received any formal training on root cause analysis and that they were only capable of identifying the proximate cause of transmitter failures. Additionally, the responsible Nuclear Product Group engineer stated that formal root cause analysis training had not been provided. The lack of adequate root cause analysis training is considered a weakness in the Rosemount corrective action program.

3.4.2 Activities Affecting Quality at Chanhassen. On February 1-4, 1993, the NRC inspection team was informed that all of Rosemount's activities that would come under an Appendix B to 10 CFR Part 50 program were located at the Eden Prairie facility. The team was also informed that Rosemount's Chanhassen facility manufactured the sensor cell units for both the industrial Model 1151 transmitter and the nuclear-qualified Model 1152, 1153 and 1154 transmitters under a quality assurance program prescribed by International Organization for Standardization (ISO) Standard 9001:1987, "Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing." Rosemount stated that the activities at Chanhassen were commercial-grade activities; hence, Chanhassen was treated as a commercial-grade supplier by Rosemount's Nuclear Department of the Instrument Division (This issue is also discussed in Section 3.3.4).

The team was informed that Rosemount "dedicated" the CGIs upon receipt inspection at the Eden Prairie facility, in accordance with Rosemount Procedure NDP N-0730, "Dedication of Subassemblies from Chanhassen," Revision A, dated April 6, 1992. The team was provided with a copy of Procedure NDP N-0730. The team toured the Chanhassen facility to observe and evaluate the in-process manufacturing controls that were implemented for sensor cell fabrication activities. The team asked the Rosemount staff to demonstrate how they controlled the quality of commercial-grade items (CGIs) for nuclear use.

During discussions with Rosemount staff while inspecting the Chanhassen facility, the team evaluated the differences between the industrial Model 1151 sensor cells with Model 1151 type printed circuit (PC) cards and the nuclear Model 1152, 1153, and 1154 sensor cells with the nuclear type PC cards. The main programmatic difference in the process controls between the Model 1151 and the Model 1152, 1153, and 1154 transmitters was the procedures used. The Nuclear Department supplied its approved drawings and procedures for the Model 1152-1154 transmitters, while the industrial procedures were used for the Model 1151 transmitters. Based upon the technical discussions and tour of the Chanhassen facility, the team concluded that it did not appear that all of the Model 1152-1154 transmitter parts manufactured at Chanhassen were CGIs. By their nature, the sensor cell and certain PC cards made at Chanhassen cannot legitimately be considered CGIs because they do not fit the definition of CGIs in Part 21. Rosemount has applied to those parts requirements that are unique to nuclear facilities, such as the use of radiation-resistant parts in the PC cards and additional controls on the glassing process. The team asked the Rosemount staff why they characterized the Chanhassen facility Model 1152-1154 transmitter sensor cell and PC card manufacturing activities as commercial grade activities. The Rosemount staff explained that the company had made a business-driven decision to treat the Chanhassen facility as a CGI supplier and then perform what they described as a dedication on these parts because this arrangement was deemed more acceptable by their customers.

The team observed some NRC licensee orders for safety-related transmitters being processed, evaluated some of the differences in the processes and process controls and conducted discussions with several technicians that were performing the activities. For example, while observing the operations involved in fabricating the cell cups for a batch of Model 1153 transmitter sensor cells, the NRC inspectors examined the traveller package for the group of cell cups undergoing one of the machining operations and noted that the control sheet (the traveller itself) called for the machining instruction (Manufacturing Instruction 1153-3063) to be in the package and in use; instead, the inspectors found the glassing procedure (Manufacturing Instruction 1153-3064). Not only had the wrong procedure been included by Production and Inventory Control (P&IC) when making up the traveller package for this assembly level of this batch, but the instrument builder performing the operations apparently had not discovered the error. Although the inspectors concluded that the instrument builder had not been actually referring to the procedure, no hardware problems were found by the team.

This was observed and acknowledged by the Rosemount representative escorting the inspectors who said that the instrument builder should have caught the error. The representative brought this to the attention of the instrument builder and the supervisor who took action to correct the situation. This type of error was pointed out to Rosemount as an example of the type of discrepancy that could be minimized by instituting a program of an appropriate level of some type of independent, random, periodic monitoring or other QA oversight.

The team generally found the Chanhassen facility to be a modern manufacturing facility with knowledgeable staff and management. However, the team found that "basic components" were being manufactured without the benefit of some of the elements of an Appendix B QA program. Rosemount indicated that certain sensor cell and PC card manufacturing areas were previously controlled under a QA program that was in compliance with Appendix B but, in 1991, Rosemount decided to control all of its Chanhassen activities under an ISO 9001 QA program, and abolished the majority of its Appendix B controls for the Chanhassen facility activities. Based on the team's understanding of Rosemount's actions, the only aspects of Rosemount's Appendix B QA program at Chanhassen that was retained were design, document, and procedure controls. The team found that there was no independent oversight or verification of the Chanhassen activities. Rosemount stated that there was in-process verification of many process control aspects, but confirmed that no independent QA/QC type of monitoring or oversight activities were performed. The team found that, because Rosemount considered the Chanhassen facility to be a commercial grade manufacturing facility, no planned or periodic audits were performed to verify compliance with necessary aspects of the quality assurance program and verify its effectiveness. Nevertheless, many of the Chanhassen activities were relied upon to "dedicate" the sensor cells at Eden Prairie yet were not verified even by a commercial grade survey. The team recommended Rosemount review the Chanhassen QA program in light of Appendix B and augment the program as necessary to comply with Appendix B for their nuclear grade transmitters. This was identified as Nonconformance 93-01-05 by the team and was discussed with Rosemount personnel.

3.4.3 Activities Affecting Quality at Eden Prairie. The scope of inspection at the Eden Prairie facility consisted of an inspection for adequacy of selected aspects of Rosemount's implementation of its Appendix B QA program. Generally, the review encompassed an inspection of the majority of the Eden Prairie fabrication activities and some engineering activities. Eden Prairie receives sensor cells and sensor module subassemblies with installed PC cards. The team evaluated activities such as: sensor cell receipt inspection controls, sensor cell de-gassing, oil-fill, and the suitability of engineering design change and manufacturing process and test controls related to pressure transmitters that are manufactured for use in safety-related (Class 1E) systems at nuclear power stations.

3.4.3.1 Lack of QA Oversight at Eden Prairie. The team noted that, as a given lot of sensor cells is routed through the Eden Prairie production area, it is accompanied by a Production and Inventory Control document known as a "traveller." In addition to identifying the serial number of each cell in the specific lot being processed, the traveller specifies the sequence of activities performed, the applicable procedure to be followed for each operation, and the person responsible for performing each task. The team's review of the applicable Rosemount procedure, No. T01153-0218, "Traveller, Cell, Sensor Oil Fill," found that it indicated that a quality control (QC) inspection was performed following completion of the cell oil-fill and fill-tube welding operations. The team requested several travellers for its review that would be representative of previous production lots of various range code sensors. Each traveller was found to be signed in the appropriate section by the person performing the activity, and QA inspection points were found to be appropriately stamped by a member of the QA organization. From a review of these documents alone, it appeared that QA had verified the acceptable performance of operations preceding the inspection point, such as verification of proper oil fill.

The team reviewed the travellers in conjunction with the applicable QA inspection procedure, 01153-3321, Revision J, dated January 29, 1992. The team found that only range code 9 and 10 sensor cells were actually verified or over-inspected by QA/QC for proper oil fill level. The team voiced the concern to Rosemount that a traveller may be misleading if viewed as a stand-alone document. If NRC licensees reviewed the Rosemount travellers without the benefit of the associated procedure, they could conclude that QA/QC involvement was required and was present for all range codes, when, in fact, it was not.

As a result of finding this problem, the team focused on inspecting required QA involvement for other activities affecting quality at the Eden Prairie facility. The team found that few activities affecting quality are verified by members of the QA organization. Discussions with responsible Rosemount representatives revealed that, in previous years, the Rosemount QA organization had played a more active role in verifying the quality of work performed by production personnel. However, approximately three years ago, this philosophy was changed to place greater reliance on the ability of the individual operator to perform high-quality work and to identify and report discrepancies observed during production. This change eliminated the majority of the QA independent verification activities. Rosemount representatives stated that the principal factors for initiating this change were an excessively high scrap rate and a perception by production personnel that the QA verification process was overly "police-like." The team discussed this matter with Rosemount to assure them that a "police-like" QA organization was not intended, but that some degree of QA oversight is needed. Further, an excessively high scrap rate is insufficient justification for eliminating QA independent verification activities.

3.4.3.2 Required Receipt Inspection of Chanhassen Sub-Assemblies. During the initial inspection on February 1-4, 1993, the team toured the Eden Prairie receipt inspection area to observe work in progress and assess the implementation of Rosemount's procedures and policies for the receipt of components procured for use in nuclear-qualified Model 1152, 1153, and 1154 transmitters. In general, the receipt inspection area appeared to be well organized with parts received for nuclear orders categorized by unique Rosemount order numbers. An N prefix is used to identify "catalog," commercial-grade, items used in a nuclear product. The team also found that the receipt inspection area based its determination of sample size (number of components to be inspected from a given lot) on the U.S. Department of Defense, Military Standard (MIL-STD) 105D, "Sampling Procedures and Tables for Inspection by Attributes." In addition, for each part or sub-component that is manufactured by others and used in nuclear transmitters, Rosemount had developed receipt inspection procedures. The team found that Rosemount maintained these procedures in a separate file cabinet designated specifically for nuclear applications. A review of a random sample of procedures did not identify any concerns. The procedures and attached drawings appeared to adequately identify critical characteristics of each purchased part and appeared to provide suitable instructions for determining both the sample lot size and acceptance/rejection criteria.

Subsequently, during further inspection of this area on March 8-12, 1993, the team discovered that sensor cells manufactured at the Rosemount Chanhassen facility and used in nuclear-qualified pressure transmitters did not go through the Eden Prairie receipt inspection area and were not receipt inspected as required by Procedure N-0730. Instead, it was determined that these devices were shipped directly from Chanhassen to the Eden Prairie nuclear process manufacturing area without the benefit of the required receipt inspection.

According to Rosemount QA staff, Rosemount only performed a formal receipt inspection on parts and materials procured from outside Rosemount. Rosemount staff stated that sensor cells were manufactured as commercial-grade units at the Chanhassen facility in accordance with an ISO 9001 QA program. These units were then shipped directly to the Eden Prairie nuclear manufacturing and fabrication area, where they were filled with fluid and "dedicated for use in nuclear applications" by in-process testing that was performed in that area. It appeared to the team that pressure testing alone did not verify that all critical characteristics are adequate, such as materials and radiation resistant properties of printed circuit cards. Additionally, the team noted that sample size and acceptance/rejection criteria such as those promulgated in MIL-STD 105D were not applicable to the sensor cells; instead, the acceptance/rejection criteria was only applicable to components produced by non-Rosemount manufacturers.

Following the walk-through of the Eden Prairie receipt inspection area, the NRC inspectors reviewed Rosemount Procedure N-0730, and determined that Section 2.5 of this procedure required receiving inspection to verify that subassemblies conform to the applicable drawings, bills of material, and other defined nuclear requirements. This document went on to state that every lot must be inspected and found acceptable before it was released to production. Contrary to the documented procedural requirements, however, as discussed above, sensor cells manufactured at the Chanhassen facility for use in safety-related nuclear transmitters were not verified for conformance to design documents by the Eden Prairie receipt inspection area. Nonconformance 93-01-06 was identified in this area.

3.4.4 Engineering Design Review. During the early to mid-1980s, various nuclear licensees began to report that some Rosemount Model 1153 and 1154 transmitters were not performing properly in their safety-related service applications. Subsequently, it was found by the industry that many of the reported problems were related to oil-loss from the transmitters' sensor cells. Due to the Rosemount transmitter design, oil leakage from the sensor cell is internal and cannot be detected by an external, visual inspection of the transmitter. As discussed in Section 3.3.2 above, Rosemount had compiled failure data that encompassed returned transmitters from approximately 1980-1992. The team reviewed the time frame during which oil-loss problems were reported to determine whether the problems were related to sensor cell and module design issues. During this design review, the team evaluated several selected areas and noted three different problems; one concerning the translation of design parameters and the other two related to design change control, as follows:

- Engineering Change Order (ECO) 601919, May 1983.

  [Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

The team was concerned that Rosemount may be making design changes without an adequate engineering evaluation to assure that previous equipment qualifications remain valid. The team discussed this concern with the Rosemount Nuclear Engineering Supervisor and concluded that Rosemount failed to perform an adequate verification of the design change. Nonconformance 93-01-07 was identified in this area.

- ECO 603675, February 1984.

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

Therefore, the team disagreed with Rosemount's conclusion, and discussed this concern with the Rosemount Nuclear Engineering Supervisor, and concluded that Rosemount failed to perform an adequate verification of this design change. This is another example of Nonconformance 93-01-07.

- ECO 630229, July 1989.

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

- ECO 630618, August 1989.

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

- ECO 649042, September 1992. During an inspection of the Eden Prairie safety-related activities, the team discovered that the viscosity test date recorded on a container of [Manufacturer] sensor fill fluid, located in the nuclear production sensor oil fill area, identified the contents as being beyond the manufacturer's certified shelf life. The team noted that, upon receipt of this material, Rosemount Receipt Inspection verified its viscosity value and wrote that value and the date of test on the outside of each container.

  The applicable [manufacturer] product specification data sheet states, "when stored in the original, sealed container, at or below 77 degrees F, [manufacturer]... fluids have a shelf life of 12 months from the date of shipment, although no inherent limitations on the useful life of this product are known to exist." The team discussed this issue with Rosemount engineers, who stated that, as a result of product liability concerns, [manufacturer] changed the certified shelf life of the fluid in 1992 from "indefinite" to 12 months. Rosemount, however, still considers the shelf life to be indefinite. On September 9, 1992, Rosemount issued ECO 649042 to modify its procurement drawings (N10485 and N11981) to reflect this position.

  The concern about the specified shelf life versus usable life of the [manufacturer] fluid was the topic of two letters received by Rosemount from [manufacturer]. With regard to one of the [manufacturer] fluids used by Rosemount, a letter dated April 14, 1992, from [manufacturer] to Rosemount stated, in part, that:

  > [Manufacturer] certifies that [Manufacturer] [type A] fluid will meet the sales specification requirements for 12 months from date of shipment when properly stored in the original unopened container ... Because the sensor is completely sealed and free from contaminates and air it shouldn't change chemically over a long period of time... It is the responsibility of our customers to test and evaluate our products in their specific applications ... the usable life of the [manufacturer] fluid is up to our customers to determine.

  The team also reviewed a letter from [manufacturer] to Rosemount, dated August 31, 1992, regarding the useable life of [manufacturer] [type B] fluid. Although this letter stated that no inherent limitations on useful life of the product are known to exist, it also clearly stated that, "It is the responsibility of Rosemount to test and evaluate our products in your specific application to determine compatibility...."

Model 1153 and 1154 transmitters use [manufacturer] [type B] fluid. Based on environmental qualification testing of these transmitters, the team concluded that it appears that Rosemount has demonstrated the usefulness of this fluid when placed in a sealed sensor cell (at a certain point in time). However, the technical justification for assigning an indefinite shelf life to unused fluid, as stated on ECO 649042, does not appear to be sufficiently supported by the information supplied by the manufacturer. Although the manufacturer stated that it is Rosemount's responsibility to test and evaluate the fluid for specific applications Rosemount did not perform additional testing of the product. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, requires that a review for suitability of the application of materials and processes that are essential to the safety-related functions of components be performed.

The team also noted that Rosemount ECO 649042 attributed the company's justification for indefinite shelf life to a lack of experience with any adverse effects either in the field or in the manufacturing process. The technical basis for Rosemount's justification for the use of fluids having an expired shelf life does not appear to be well demonstrated without performing periodic verifications of unused fluid (such as verification of chemical properties) to ensure that the fluid has not changed from the date of Rosemount qualification and without a review for suitability of application. Nonconformance 93-01-08 was identified in this area.

The team related these inconsistencies in the Rosemount performed activities that affect the quality of safety-related components in part to the lack of monitoring, surveillance or other type of independent QA verification activities which has been discussed earlier.

3.4.5 Internal Audits. The NRC inspection team reviewed several Rosemount activities to determine whether adequate internal audits were performed. Section 18, "Audits," of the Rosemount NQM, dated February 1, 1991, stated, in part, that:

> Internal audits of selected aspects of activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to assure that an audit of all activities within the scope of the Nuclear Quality Program will be completed annually.

The team also noted that paragraph 4.21.4 of the 1988 Rosemount QAM-M, required that all quality-related activities be audited at some time in each calendar year and that audit frequency will not exceed 14 months. Paragraph 4.21 of QAM-M also required that the implementation of the controlling documents be audited to verify compliance with the QA program, and to verify that corrective action requests are complete. The team reviewed the audit schedule from 1989 to the present, and found that the audits had been performed as scheduled since 1990; however, there were no audits scheduled or performed for the entire year of 1989. Additionally, the quality related activities used to manufacture "basic components" at the Chanhassen facility had not been audited under Appendix B since December 1991. Nonconformance 93-01-09 was identified in this area.

4 OTHER ISSUES AND COMMENTS

4.1 Review to Correlate Observed Failure Trends with Transmitter Design Features and Design Changes

The NRC team attempted to determine whether observed failure data trends correlated with any particular transmitter design features or design changes after reviewing Rosemount failure data, design similarities, and differences between transmitter models. Because the team decided that the most significant problem identified to them was the loss of oil from the transmitter sensor cell, the review focused primarily on the sensor cell module assembly. Various drawings for the sensor cell and its module assembly were reviewed to identify design features as well as design changes that were made by Rosemount. Parts and drawings reviewed by the team included fill tubes, elastomer o-rings, and metal o-rings. The team made the following observations:

- The drawing revision history showed that Rosemount made a number of changes to the metal o-ring drawing. However, contrary to what the drawing revision history indicated, the Rosemount Engineering staff stated that the actual o-ring configuration never physically changed, and that the drawing changes were administrative attempts to correct the drawing rather than physically change the o-ring. As a result of the disparity between the Rosemount records and staff recollections, the Rosemount o-ring drawing revisions, particularly around the period of Revision E, December 13, 1981, and Revision F, February 6, 1984, will be reviewed during a future inspection to resolve the disparity. See Inspector Follow-up Item 93-01-11.

- The team concluded that the metal o-ring drawing appeared to be inadequately controlled. This matter was discussed with the Rosemount Engineering staff. Rosemount staff stated that the latest drawing change corrects the dimensional discrepancies that previously existed between the part and the drawing.

- Rosemount has changed the dimension or tolerance (or both) on the sensor cell module assembly o-ring groove on a number of past occasions. This dimension affects the compression of the process flange o-ring. In general, the smaller the dimension, the greater the o-ring compression and the greater the force on the o-ring joint. Further, the greater the tolerance, the greater the variation in the o-ring compression and the greater the variation of the forces in the joint. The o-ring forces and joint compression directly affect the seal of the process fluid joint in the transmitter. Additionally, the joint forces contribute to the stress levels in the sensor cell. Further, the nonuniform geometry and dissimilar materials in the region where glass seals the fill tube holes create an additional stress concentration. Thus, higher o-ring joint forces may impair the bond between the glass and metal that contains the oil in the sensor cell.

- Because of the potential importance of the o-ring flange joint dimensions on the sensor cell G-M seal, potential for oil-loss, and subsequent transmitter performance, the June 1983 Model 1153 (ECO 601919 and Drawing No. 1153-0221, Revision E) and July 1984 Model 1154 (Drawing No. 01154-0004, Revision A) design changes that expanded the transmitter process flange o-ring groove tolerance are considered to be potentially important in explaining at least some of the transmitter oil-loss failures that occurred in the mid-1980s.

4.2 Employee Awareness of 10 CFR Part 21

The NRC inspectors interviewed several employees at the Chanhassen facility regarding their understanding and knowledge of 10 CFR Part 21, with respect to the requirement in NDP N-0730, Paragraph 2.4.3, "Reporting of defects or deviations per 10 CFR Part 21 is required." The inspectors asked various employees what they knew about their responsibilities under 10 CFR Part 21.

Some employees stated that they had attended a training session on 10 CFR Part 21. Most knew of the posting regarding 10 CFR Part 21, and that the posting listed the names of personnel to be contacted regarding Part 21 matters. In general, the employees stated that it was their understanding that they were expected to bring to the attention of their immediate supervisors or persons listed on the Part 21 posting any unsatisfactory conditions of which they were aware in any nuclear sensor cells or parts that had gone through production or had been shipped, in which the condition remained uncorrected, or where they did not know that it had been corrected. Some also stated that it was their understanding that they could inform the NRC of such conditions if they felt it necessary.

4.3 Sensor Cell Oil-Fill Concern

Based upon the NRC inspection activities discussed in Section 3.4 above, the team identified a concern regarding the adequacy of the Rosemount transmitter sensor cell oil filling and verification. The Rosemount representatives who were interviewed stated that the current level of in-process testing (performed by the same personnel who perform the actual activity) is sufficient to identify manufacturing deficiencies. For example, when questioned on the apparent lack of conformance to Appendix B requirements regarding inspection for sensor cell oil-fill activities other than range codes 9 and 10, Rosemount representatives stated that independent verification is not necessary because subsequent response time testing (performed after the sensor is mounted in its housing) is adequate to identify cells with low levels of fill oil. However, the team was concerned whether or not the response time testing was an appropriate test that would accurately reflect the actual amount of oil in the sensor cell. Based upon discussions with Rosemount representatives and a review of associated records, the team appeared to have identified that the ability of response time testing to accurately identify improperly filled cells may not be adequate because, depending on the transmitter range code, as much as 73 percent of the fill fluid may be missing before the response time test would reliably identify a cell as having low oil.

The approximate percentage of oil that must be missing before the response time test identified that response time performance was not within the required specification for ranges 3 through 9, varied between 36-73 percent. Therefore, the team was concerned that it could be possible for a transmitter with a relatively low oil level to be determined to be acceptable by successful response time testing. It is not clear whether an initially low oil level could manifest itself in a manner similar to subsequent loss of oil resulting in degraded operation, but do so much earlier. This concern will be addressed during a future inspection. Inspector Follow-Up Item 93-01-13.

4.4 Field Instruction Manual No. 4302

The team's review of the transmitter process flange field assembly instructions, contained in Rosemount user instruction manuals for 1150 series transmitters, revealed that the assembly sequence appeared to be inappropriate for transmitters using stainless steel process flange O-rings. For example, the procedure in Rosemount Instruction Manual 4302 for Model 1153, Series B, pressure transmitters called for placing both stainless steel O-rings (when two are used, e.g., for a differential pressure unit) into the isolator wells of the sensor cell and then fitting the process flanges to the sensor module. This sequence appeared to be appropriate for elastomer o-rings because their outside diameters are slightly larger than the inside diameter of the isolator wells and the o-rings should remain in place under slight compression. However, new metal o-rings did not stay in place by themselves when the team attempted to perform the assembly process. Therefore, following the sequence of steps in the procedure as written would be impractical for one or more metal O-rings given the orientation of the sensor module in most installations or even if the sensor was held so that the isolator wells were oriented in a vertical position on a workbench.

Although the 1153 and 1154 manuals call for the stainless steel O-rings, the process flange assembly instructions were apparently not revised with an appropriate assembly sequence and technique, such as those given in the instructions used in Rosemount's Eden Prairie shop (and demonstrated to the team). In this procedure, one metal o-ring is placed in the well with the module on its side and its process flange is fitted and held in place by hand to retain the o-ring while the unit is inverted. The second o-ring is then installed, the second flange fitted and the flanges are bolted together.

Another perceived problem with the field instructions was that, although the description of the correct orientation of the metal o-ring was technically understandable, it is difficult to identify the correct orientation in practice without the technique demonstrated by an experienced instrument builder. Further, for fitting the process flange to the sensor module, the field instructions stated: "Evenly seat the flanges on the sensor housing, using a hand torque wrench." However, in observing this process in the Eden Prairie shop, the team learned that with metal o-rings, and with the variance in the dimensional tolerance stack-up of the rings and the isolator well depths, in many cases, the flanges never fully seat on the sensor housing even with the maximum specified torque applied. Attempting to evenly seat the flanges on the housing as required by the procedure might require exceeding the specified torque, if it were possible at all, and possibly result in putting excessive stress on the sensor cell. In a communication subsequent to the inspection, Rosemount informed the NRC of its position that these procedures were not intended necessarily to be followed verbatim, but stated that the procedures would nevertheless be revised appropriately. This will continue to be discussed with Rosemount until this matter is resolved. Inspector Follow-up Item 93-01-14.

4.5 Transformer Discrepancy

During the review of some Nuclear Review Committee files and records, the team noted that a Nuclear Review Committee meeting on May 28, 1991, discussed a problem with a transformer (Rosemount Part No. 01151-0163-0001) that is used in the electronic component package of the Model 1151, 10-50 milliampere (mA) transmitter. This same transformer is also used with a different part number on the Model 1153 and 1154 units. Rosemount Procedure NDP N-1697, "Returned

Products from a Nuclear Facility," Revision A, provides guidance on tracking deficiencies and keeping historical records. This procedure requires nuclear marketing or contract personnel to initiate a returned material authorization (RMA) or an event report (ER) to document information received from a customer regarding impaired performance of a Rosemount product.

The team also reviewed Rosemount's Division Operating Procedure (DOP) 440, "Engineering Change Order," (ECO) Revision C, to determine if Rosemount's procedural controls were being implemented to preclude the use of products known to cause failures. This procedure requires the design engineer who initiates a change to identify the affected item and to contact the originator of the ECO to determine the impact of the proposed change, timing, and the next process step. If the item is used in more than one product, the engineer must route the ECO to the Nuclear Design Engineering Department so that engineers responsible for other products can review and approve or disapprove the change. In the case of the transformer ECO, the ECO was routed to the nuclear engineers and the engineers did not recommend the change.

The team inspected the review process and determined that the designated engineers from the Nuclear Design Engineering Department had reviewed the manufacturer's proposed design or manufacturing changes and had complied with the requirements of DOP 440.

4.6 PERSONNEL CONTACTED

Rosemount, Incorporated (Rosemount) and Rosemount Aerospace, Incorporated (RAI)

G. Anderson	1	Nuclear QA Supervisor, Rosemount
R. Ballintine	2	VP Government Relations, RAI
S. Brown	1	Nuclear Engineering Supervisor, Rosemount
K. Ewald	1	Nuclear Business Unit Manager, RAI
L. Halsne	2	VP Quality Assurance, RAI
D. Moffatt	2	President, Rosemount Aerospace, Inc.
P. Olson	1	Quality Auditor, Rosemount
J. Sandstrom	1	Product Marketing Manager, Rosemount
J. Valley	1	Nuclear QA Manager, RAI
M. Van Sloun	1	Director, Distribution, Rosemount
R. Volsted	1	Contract Supervisor, Rosemount

1 Attended all entrance and exit meetings.

2 Attended March 12, 1993 exit meeting only.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 16, 1994

Docket No. 99901269

Mr. Robert C. Davis, President
Schulz Electric Company
30 Gando Drive
New Haven, Connecticut 06513

Dear Mr. Davis:

SUBJECT: NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE (NRC INSPECTION REPORT NO. 99901269/94-01)

This refers to the inspection conducted by B. H. Rogers, S. D. Alexander, and J. J. Petrosino of this office on January 24 through 28, 1994. The inspection included a review of activities at the Schulz Electric Company facility at New Haven, Connecticut. At the conclusion of the inspection, the findings were discussed with you and the members of your staff identified in the enclosed report.

Areas examined during the inspection and our findings are identified in the report. This inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations by the inspectors. The inspectors noted several strengths during the inspection including strong commercial grade dedication and safety-related repair programs, and comprehensive quality assurance (QA) employee indoctrination.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). The violations are of concern because they potentially impacted your ability to evaluate and report defects in basic components in accordance with the requirements of 10 CFR Part 21.

Although Section 2.201 requires you to submit to this office, within 20 days of your receipt of this Notice, a written statement of explanation, we note that the violations had been corrected and those actions were reviewed during this inspection and determined to be satisfactory. Therefore, no response with respect to this matter is required.

In addition, during this inspection it was found that the implementation of your QA program failed to meet certain NRC requirements. It was determined that there were discrepancies in your records concerning calibration dates, calibration due dates, and equipment activity status for test equipment intended for use under your QA program. The specific findings and references to the pertinent requirements are identified in the enclosures of this letter.

Please provide us within 30 days from the date of this letter a written statement in accordance with the instructions specified in the enclosed Notice of Nonconformance.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The response requested by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99901269/94-01

NOTICE OF VIOLATION

Schulz Electric Company
New Haven, Connecticut

Docket No. 99901269
Report No. 94-01

During a U. S. Nuclear Regulatory Commission (NRC) inspection conducted at the Schulz Electric Company (Schulz) facilities, between January 24-28, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1993), the violations are listed below:

A. Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of 10 CFR Part 21, requires each individual, corporation, partnership, or other entity subject to the regulations in this part to adopt appropriate procedures to evaluate deviations and failures to comply, in all cases, within 60 days of discovery. If an evaluation of a deviation or failure to comply cannot be completed within 60 days of discovery, an interim report must be prepared and submitted to the NRC. If the supplier of basic components does not have the capability to evaluate deviations or failures to comply then the supplier must inform the purchasers or licensees within five working days of discovery.

   Contrary to Section 21.21, Schulz failed to adopt adequate procedures to ensure that deviations and failures to comply were appropriately evaluated. Specifically, Schulz Shop Instruction (SI) SI-102, "Identifying and Reporting Under 10 CFR Part 21," did not contain provisions that would (1) ensure that Schulz would evaluate deviations within 60 days of discovery and provide an interim report to the NRC of any deviation evaluation that can not be completed within 60 days of discovery, and (2) ensure that Schulz would inform the purchasers or affected licensees within 5 working days of deviations that Schulz determined that it did not have the capability to perform an evaluation to determine if a defect exists. (94-01-01)

This is a Severity Level V violation (Supplement VII).

B. Section 21.6, "Posting requirements," of 10 CFR Part 21, requires each individual, corporation, partnership, or other entity subject to the regulations in this part to post current copies of either:

(1) 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974 (ERA), and procedures adopted pursuant to 10 CFR Part 21; or

(2) Section 206 of the ERA, and a notice which describes 10 CFR Part 21 and procedures adopted to implement Part 21, including the name of the individual to whom reports may be made, and states where they may be examined.

Contrary to the above, the NRC inspectors found that the 10 CFR Part 21 posting by Schulz at its facilities did not contain a copy of Section 206 of the Energy Reorganization Act of 1974. (94-01-02)

This is a Severity Level V violation (Supplement VII).

Although Section 2.201 requires you to submit to this office, within 20 days of your receipt of this Notice, a written statement of explanation, we note that the violations had been corrected and those actions were reviewed by the team and found satisfactory. Therefore, no response with respect to this matter is required.

Dated at Rockville, Maryland
this 16th day of March 1994.

Enclosure 2

NOTICE OF NONCONFORMANCE

Schulz Electric Company
New Haven, Connecticut

Docket No. 99901269
Report No. 94-01

Based on the results of an NRC inspection conducted on January 24 through 28, 1994, it appears that certain of your activities were not conducted in accordance with NRC requirements.

A. Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50 states: "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 the necessary limits."

   Quality Assurance Procedure 12, "Control of Measuring and Test Equipment," Revision 4, dated September 15, 1993, stated that the Quality Assurance Engineer is to maintain current records of instrument calibration and that any time an instrument was added, deleted, or the location changed the file should be correspondingly updated.

   Contrary to the above, Schulz had not maintained the calibration records and associated files as required to adequately ensure that the items listed in the measuring and test equipment calibration program would be properly controlled, calibrated, and adjusted as necessary. There were numerous discrepancies between the calibration files and the Meter and Test Equipment Calibration Log concerning calibration dates, calibration due dates, and equipment activity status.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Chief, Vendor Inspection Branch, Division of Reactor Inspection and Licensee Performance, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each nonconformance: (1) a description of steps that have been or will be taken to correct these items; (2) a description of steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective actions and preventive measures were or will be completed.

Dated at Rockville, Maryland
this 16th day of March 1994

Enclosure 3

ORGANIZATION:	Schulz Electric Company
REPORT NO.:	99901269/94-01
CORRESPONDENCE ADDRESS:	Mr. Robert C. Davis, President Schulz Electric Company 30 Gando Drive New Haven, Connecticut 06513
NUCLEAR INDUSTRY ACTIVITIES:	Performs dedication of commercial grade motors and sub-components for safety-related applications and repairs safety-related motors.
INSPECTION CONDUCTED:	January 24 - 28, 1994
PREPARED BY:	Bill H Rogers 3/1/94 Bill H. Rogers, Team Leader Date Reactive Inspection Section No. 2 Vendor Inspection Branch
APPROVED:	Gregory C Cwalina 3/3/94 Gregory C. Cwalina, Chief Date Reactive Inspection Section No. 2 Vendor Inspection Branch
OTHER INSPECTORS:	Stephen D. Alexander Joseph J. Petrosino
INSPECTION BASES:	10 CFR Part 21 and Appendix B to 10 CFR Part 50
INSPECTION SCOPE:	To evaluate selected portions of the Schulz Electric Company quality assurance program and implementation in dedicating commercial grade items for safety-related use and repairing safety-related motors in accordance with the requirements of Appendix B to 10 CFR Part 50.
PLANT SITE APPLICABILITY:	Numerous

1 INSPECTION SUMMARY

1.1 Violations

Contrary to the requirements of Section 21.21 of 10 CFR Part 21, "Notification of failure to comply or existence of a defect and its evaluation," Schulz Electric Company (Schulz) had not adopted appropriate procedures to ensure that Schulz would evaluate deviations within 60 days of discovery or provide an interim report to the NRC of any deviation evaluation that could not be completed within 60 days of discovery; and to ensure that Schulz would inform the purchasers or affected licensees within five working days of deviations that Schulz determined that it did not have the capability to evaluate to determine if a defect existed. (94-01-01)

Contrary to the requirements of Section 21.6 of 10 CFR Part 21, "Posting requirements," Schulz had not posted Section 206 of the Energy Reorganization Act (ERA) of 1974 as required by 10 CFR 21.6. (94-01-02)

1.2 Nonconformance

Contrary to Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, Schulz had not maintained the calibration records and associated files as required to adequately ensure that the items listed in the measuring and test equipment (M&TE) calibration program would be properly controlled, calibrated, and adjusted as necessary, as evidenced by numerous discrepancies between the calibration files and the Material and Test Equipment Calibration Log concerning calibration dates, calibration due dates, and equipment activity status. (94-01-03)

2 STATUS OF PREVIOUS INSPECTION FINDINGS

There was no previous NRC inspection of this facility.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

During the entrance meeting on January 24, 1994, the NRC inspectors discussed the scope of the inspection and the areas to be reviewed. During the exit meeting on January 28, 1994, the NRC inspectors discussed their findings and concerns with Schulz's management and staff.

3.2 Background

Schulz performs a wide variety of services related to the repair and sales of commercial grade and safety-related motors. Work on safety-related equipment includes basic overhauls through complete rewinds. Schulz also dedicates commercial grade motors for use in safety-related applications.

The facility maintains steam cleaning facilities and burnout ovens to assist in overhaul preparation and winding removal. Form, random, and edge wound replacement coils are produced on automated winding machinery. Rewound motors are finished in a vacuum-pressure-injection (VPI) tank where Epoxylite resin is applied followed by oven curing. Testing capabilities for use on rewound or dedicated motors include dynamometers, high potential testing, infrared thermographic imaging, vibration analysis, and dynamic balancing. The 48,000 square foot facility can support repairs on equipment up to 8000 HP, 7000VAC.

3.3 10 CFR Part 21 Program and Implementation

3.3.1 10 CFR Part 21 Procedure

The inspectors reviewed the Schulz 10 CFR Part 21 program which included the implementing procedure, Schulz Shop Instruction (SI) SI-102, "Identifying and Reporting Under 10 CFR Part 21." SI-102 appeared to include adequate provisions to ensure that Schulz employees would inform the Quality Assurance (QA) Manager of deviations identified in safety-related equipment. However, the inspectors determined that SI-102 was not in compliance with the current requirements of section 21.21 of 10 CFR Part 21, "Notification of failure to comply or existence of a defect and its evaluation," in that it did not contain provisions that would ensure that Schulz would (1) evaluate deviations within 60 days of discovery or provide an interim report to the NRC of any deviation evaluation that can not be completed within 60 days of discovery and (2) ensure that Schulz would inform the purchasers or affected licensees within 5 working days of deviations that Schulz determined that it did not have the capability to evaluate to determine if a defect exists. This was identified as Violation 94-01-01.

Schulz took corrective action during the inspection and revised, reissued, and reposted SI-102. The revision was reviewed by the inspectors who determined that it appeared to be adequate. Schulz indicated that it had just recently received the latest revision of 10 CFR Part 21 from an NRC licensee and had not yet performed a detailed comparison to SI-102 prior to the inspection. Schulz also stated that it intended to subscribe, through the Federal Superintendent of Documents, for an annual subscription of the "CFR Sections affected" in order to promptly take actions to revise its programs as necessary to prevent recurrence of having inadequate procedures or programs in the future. Since adequate corrective and preventive actions were taken regarding Violation 94-01-01, no response is required.

3.3.2 10 CFR Part 21 Posting

Section 21.6 of 10 CFR Part 21, "Posting requirements," requires that parties subject to the regulation post documents including Section 206 of the Energy Reorganization Act of 1974 (ERA). The NRC inspectors determined that Schulz had not posted Section 206 of the ERA. Schulz representatives indicated that they were not aware that Section 206 of the ERA was required to be posted. This was identified as Violation 94-01-02.

The inspectors supplied a copy of Section 206 to Schulz which took immediate corrective action by posting copies of Section 206 with its other posted documents. Schulz reviewed its procedures and discussed this aspect of 10 CFR Part 21 with the inspectors as actions to prevent recurrence. The inspectors noted that Schulz appeared to have adequately ensured that the reporting of deviations by Schulz employees to management was satisfactorily in place. Since adequate corrective actions were taken regarding Violation 94-01-02 no response is required.

3.3.3 10 CFR Part 21 Evaluations

The inspectors reviewed potential deviation evaluations that had been performed by Schulz. None of the evaluation packages that were reviewed indicated that a deviation to licensee procurement documents had been identified. The evaluation packages appeared to adequately document the rationale for the Schulz decision and generally provided a comprehensive background, scope of the situation and a detailed explanation. One potential deviation concerned a digital megohmeter (serial number 3191) that was found to be out-of-tolerance during a periodic calibration. Schulz determined the actual out-of-tolerance parameters of the device, identified the time period in question, identified the safety-related jobs that the device had been used for and demonstrated that the out-of-tolerance condition was within the acceptance criteria for each job. No concerns were identified in this area.

3.4 <u>10 CFR Part 50 Appendix B QA Program and Implementation</u>

3.4.1 Organization, Records, and Indoctrination

The inspectors interviewed the Schulz QA Manager to determine whether or not he was adequately independent of any cost and scheduling considerations. The inspectors determined that the QA Manager reported directly to the Schulz President and appeared to be appropriately independent from production and manufacturing considerations.

During the review of quality related documents it was determined that the Schulz documents related to quality were generally comprehensive and complete, the exception being those records associated with the calibration of measuring and test equipment (see Section 3.4.2).

The inspectors reviewed Schulz's QA training program and employee training records. The initial Schulz QA program indoctrination for its employees occurred on February 27, 1992, and appeared to have been accomplished within a reasonable period of time from the January 1, 1992, QA program start date. The team also noted that Schulz indoctrinated new employees within 60 days of their hire date and the new employee indoctrination included discussion of the QA Manual, QA procedures, Shop Instructions, Appendix B to 10 CFR Part 50, and 10 CFR Part 21. Based on the review of Schulz employee indoctrination and training records for different levels of Schulz employees, it appeared that Schulz's training and indoctrination program contained a comprehensive QA program outline and included 10 CFR Part 21 as one of the major topics. This area was considered a strength that added to the effectiveness of Schulz's QA program implementation.

3.4.2 Control of Measuring and Test Equipment

The inspectors reviewed section 12 of the Schulz QA manual, "Control of Measuring and Test Equipment," Revision 4, dated September 15, 1993. Section 12 required that a procedure be established and contain provisions to ensure that all measuring and test equipment used for activities affecting quality were calibrated and adjusted at intervals based on the characteristics of the individual instruments.

The inspectors also reviewed Quality Assurance Procedure (QAP) 12, "Control of Measuring and Test Equipment," revision 4, dated September 15, 1993, which implemented the requirements of Section 12 of the QA manual. QAP 12 required that a calibration file be established to retain the certificates of calibration and associated documentation. The certificates of calibration were required to be stamped with a due date indicating when the current calibration would expire.

The calibration files were arranged in two sections, active and inactive. The inspectors reviewed the active section and located fifteen files which displayed due dates that had passed, which indicated that the item was not currently calibrated. The inspectors then compared these files with the January 24, 1994, version of the Meter and Test Equipment Calibration Log (MTECL), a computer data base which listed the Schulz Electric Company item number (SEC number), an item description, the latest date of calibration, the calibration due date, and the item's location. Comparison of the calibration files to the MTECL showed several discrepancies as follows:

Seven items, SEC numbers 2018, 3030, 3054, 3060, 3097, 3101, and 3162, were not listed in the MTECL. Discussion with Schulz indicated that these items were no longer used and therefore not in the calibration program, and that the files should have been previously removed from the active file and placed in the inactive file.

Two items, SEC numbers 3088 (Simpson KW meter) and 3089 (Simpson volt meter), had latest calibration dates of October 25, 1993, and calibration due dates of April 25, 1994, indicating that the meters were currently in calibration, which conflicted with the calibration files. Schulz reviewed the calibration files, determined that the most recent calibration certificates had been misfiled, and located the calibration certificates for both items in the calibration file of a related piece of equipment which had been calibrated at the same time. The calibration dates and due dates on the certificates agreed with the dates in the MTECL.

The calibration certificate for SEC number 1016 (outside micrometer) listed the calibration date as February 8, 1991, and the due date as February 6, 1993. The MTECL listed the calibration date as February 6, 1991, the calibration due date as February 6, 1994, and the item location as "QA cabinet." Schulz indicated that this item was no longer in use at the facility and had been destroyed. Schulz further indicated that calibration due date of February 6, 1994, and the item location listed in the MTECL were erroneous, that the item listing should have been removed from that MTECL, and that the calibration file should have been removed from the active file and placed in the inactive file.

The calibration certificate for SEC number 1018 (inside micrometer) listed the calibration date as February 8, 1991, and the calibration due date as February 6, 1993. The MTECL listed the calibration date as February 6, 1991, and the calibration due date as February 6, 1994. Schulz located the item and inspection revealed the storage case (the item was a multi-piece set) to have a calibration sticker affixed which listed a calibration date of January 6, 1991, and a calibration due date of January 6, 1994. The calibration sticker dates did not agree with either the calibration certificate or the MTECL. Schulz did indicate that this item was no longer being used in a manner which required calibration (currently used as a transfer standard). Schulz further indicated that the calibration due date listed in the MTECL was erroneous, that the item listing should have been removed from the MTECL, and that the calibration file should have been removed from the active file and placed in the inactive file. Schulz did not provide an explanation for the date discrepancy between the calibration sticker and the calibration certificate.

The inspectors observed calibration stickers on a variety of items available for use in the facility, in addition to those previously discussed devices, and found all to be currently in-calibration and the listed calibration dates to be in agreement with those listed in the calibration files and the MTECL.

The inspectors concluded, based on the numerous discrepancies identified between the calibration files and the MTECL, that Schulz had not maintained the calibration records and associated files as required to adequately ensure that the items listed in the M&TE calibration program would be properly controlled. This was identified as Nonconformance 94-01-03.

3.4.3 Audits and Surveys of Suppliers

Schulz had not used safety-related items or services in the dedication of commercial grade motors or repair of safety-related motors (Schulz dedicated the commercial grade items and services which it used). Consequently Schulz had not performed any audits of Appendix B quality assurance programs. Schulz had performed commercial grade surveys of seven companies who provided commercial grade items or services for use in the repair of safety-related motors. Schulz had taken credit for these vendors' activities for a portion of the dedication process and therefore had performed commercial grade surveys to verify the adequacy of those activities. The companies surveyed performed calibration services, material analysis, viscosity tests, and rebarring and restacking of rotors.

The inspectors reviewed a report dated July 7, 1992, which documented the June 22, 1992, survey of a company providing calibration services. The survey verified that activities were in compliance with MIL-STD-45662A, that the standards used were substantiated by certificates of calibration traceable to the National Institute of Standards and Technology (NIST) and that work was performed in accordance with the supplier quality assurance program. In addition, the survey verified implementation of attributes specific to the work to be performed for Schulz including the primary and secondary standards associated with applicable instruments, laboratory environment, calibration interval, calibration records for instruments and standards, calibration procedures, audits or surveys of subvendors, calibration stickers, and storage and handling. The

Schulz team identified one deficiency related to subvendors which was adequately resolved. The NRC inspectors concluded that Schulz's activities in the area of external audits and surveys appeared to be adequate.

3.4.4 Internal Audits

The inspectors reviewed the most recent internal audit of Schulz which had been performed July 13-14, 1993. Schulz had determined that the internal audit would be most effective if performed by a consultant, which was contracted to perform the audit of Schulz and document the results in an audit report. The inspectors reviewed the audit report, dated July 27, 1993, and determined the audit to have been comprehensive and performance based. The NRC inspectors concluded that Schulz's activities in the area of internal audits appeared to be adequate.

3.5 Review of Qualification, Dedication, and Repair Program and Implementation

3.5.1 Environmental Qualification

Electrical equipment important to safety is required to be environmentally qualified under certain conditions as specified in 10 CFR 50.49, "Environmental qualification of electrical equipment important to safety for nuclear power plants." Regulation 10 CFR 50.49 covers safety-related (Class 1E) equipment and certain non-safety-related equipment. It requires that this equipment (which includes motors), which is exposed to the harsh environment of a design basis accident (DBA), and which must perform a safety-related function in that DBA, must be qualified to withstand the harsh environment and perform its safety-related function or not fail in a manner detrimental to safety. Therefore, those motors important to safety in plant applications in which they are not exposed to a DBA harsh environment, or which, even if exposed, have no safety-related function in that DBA, or which have no credible failure modes adverse to safety, are not required to be environmentally qualified. Therefore, there is no requirement for safety-related motors in a "mild environment" to be qualified under 10 CFR 50.49.

Standards which some licensees and vendors have used to establish environmental qualification are American National Standards Institute (ANSI)/Institute of Electrical and Electronic Engineers (IEEE) Standard 323, "Qualification of Class 1E Electrical Equipment for Harsh Environments in Nuclear Power Plants," and ANSI/IEEE Std 334, "Qualification of Class 1E Motors for Harsh Environments in Nuclear Power Plants," and ANSI/IEEE Std 344, "Seismic Qualification of Class 1E Electrical Equipment for Nuclear Power Plants."

The use of some of these standards by NRC licensees or their vendors and subcontractors in qualification activities has been endorsed (not required) in Regulatory Guide (RG) 1.89 (Revision 1), which endorsed the 1974 edition of IEEE-323 and RG-1.100, which endorsed the 1975 edition of IEEE-344. The regulatory position stated in RG 1.89, Rev 1, was that IEEE 323-1974, as modified by the conditions stated in the regulatory guide, provides an acceptable method of qualifying electrical equipment "important to safety" in accordance with the requirements of 10 CFR 50.49.

The inspectors reviewed Schulz's motor dedication and repair programs for adequacy as it related to environmental qualification. The inspectors found that in all cases except one, Class 1E motors supplied to NRC licensees or rewound for NRC licensees by Schulz were not required to be environmentally qualified and therefore would not have been required to conform to 10 CFR 50.49 or expected to conform to the qualification standards discussed above.

The one exception noted was when Schulz rewound an in-containment fan cooler motor for the New York Power Authority's (NYPA's) Indian Point Nuclear Plant, Unit 3 (IP3), in 1984. The motor had originally been required to be qualified under the NRC's previous Environmental Qualification (EQ) requirements, the Division of Operating Reactors (DOR) Guidelines. Because the similarity of the new insulation system installed by Schulz to the original could not be determined, requalification of the rewound motor was undertaken for NYPA by Schneider Consulting Engineers (SCE). The November 1984 SCE Report, P801-09-2, "Report of Environmental Qualification Testing of a Class H Insulated Motor Stator for a Reactor Containment Fan Cooler Motor Installed at Indian Point 3 Nuclear Power Plant," indicated that for this qualification effort, Schulz had built a section of a motor stator with the same insulation system used in the rewound fan cooler motor. The inspectors determined that Schulz had not supplied the qualification service and therefore was not responsible for its technical adequacy. Schulz had only supplied the rewind services, using an insulation system approved by the NYPA, for which Schulz supplied documentation of materials and processes used, and supplied the test specimen to SCE. The inspectors did not identify any concern with Schulz's activities related to the NYPA rewind work.

The inspectors determined that Schulz had previously developed a qualification report (through the use of a consultant) which was intended to meet the requirements of 10 CFR 50.49. The inspectors reviewed a version of this qualification report and determined it to be less than adequate. However, discussions with the present Schulz QA manager indicated that he had never approved the consultant's report and an entirely new program was currently under development. Schulz further indicated, and the inspectors confirmed, that it had delivered motors, certified to the qualification report, for only one PO. A Schulz sales representative had arranged the sale in 1993, during the tenure of the previous QA manager. The licensee's PO had invoked the qualification report and the associated Schulz certificate of conformance (CoC) certified the work to the qualification report. However, when the present QA manager determined, during a review of the files, that the motors had been sold, certified to the inadequate qualification report, he contacted the licensee to advise them of his review (as documented in a record of the telephone conversation). The inspectors reviewed the letter that Schulz had received from the licensee, in response to this call, which rescinded the EQ requirement for the motors in question. The inspectors concluded that Schulz had adequately resolved the situation and that its activities in this instance were not contrary to NRC EQ requirements. No other instances were identified in which Schulz had supplied motors or rewind services that did not meet (or were required to meet) NRC EQ requirements.

The inspectors discussed the new qualification program, currently in development by Schulz and a consultant (different from the group used for the previous qualification report), and determined that both the Schulz QA Manager and the consultant developing the program appeared to have an understanding of the previous qualification report's inadequacies and an intent and sufficient knowledge to develop a qualification program to meet the requirements of 10 CFR 50.49.

3.5.2 Seismic Qualification

Standards which some licensees and vendors have used to establish seismic qualification are ANSI/IEEE Standard 323, "Qualification of Class 1E Electrical Equipment for Harsh Environments in Nuclear Power Plants," and ANSI/IEEE Std 344, "Seismic Qualification of Class 1E Electrical Equipment for Nuclear Power Plants."

The use of these standards by NRC licensees or their vendors and subcontractors in qualification activities has been endorsed (not required) in Regulatory Guide (RG) 1.89 (Revision 1), which endorsed the 1974 edition of IEEE-323 and RG-1.100, which endorsed the 1975 edition of IEEE-344.

The regulatory position in RG 1.00 is that IEEE-344-1975, as modified by the RG, and when used in conjunction with IEEE-323, provides an acceptable method of seismically qualifying electrical equipment important to safety in accordance with General Design Criterion 3 of Appendix A to 10 CFR Part 50, the part of NRC regulations which requires seismic qualification of safety-related structures, systems, components and equipment.

The Schulz process for the dedication of motors for safety-related service was prescribed by Schulz Technical Evaluation (TE) 725. TE-725 was based on TE CGIM001, "Three-Phase Squirrel-Cage Induction Motors, NEMA Frame Size 680 and Smaller, Continuous and Intermittent Duty (Excluding Motor Operated Valves)," prepared by the Joint Utility Task Group (JUTG) of the Electric Power Research Institute (EPRI). CGIM001 addressed seismic qualification of motors by stating that the inherent seismic ruggedness of properly mounted and anchored motors, particularly of the type and size range covered by the TE had been demonstrated by seismic qualification testing and analysis and operating experience and therefore, it was not necessary to treat seismic performance of such motors as a critical characteristic that required verification as part of dedication.

The NRC has not endorsed any of the EPRI JUTG TEs. The latest NRC Safety Evaluation Report to address the Generic Implementation Plan (GIP) of the Seismic Qualification Utility Group (SQUG), whose position on motors is consistent with the JUTG, contained caveats for seismic qualification of motors in systems with regard to items such as mounting, anchoring and electrical connections. However, with respect to motors of the type in question, in the absence of evidence to the contrary for specific motors, the NRC has not challenged the inherent seismic ruggedness of the motor itself generically nor the verification of the seismic adequacy approach for these items as is described in the GIP.

Review of the documentation that Schulz provided to licensees indicated that Schulz was clear in the fact that it was not providing motors that were necessarily seismically qualified. In addition, the technical evaluation clearly addressed the issue and stated the rationale for not considering seismic performance a critical characteristic, including references. Schulz's documentation also contained the qualifying statement that the inherent ruggedness is for "typical building floor response spectra," but that motors in high amplification mountings may require further evaluation. The inspectors concluded that Schulz's performance had been adequate with respect to seismic qualification and that the responsibility for any further evaluation required had been clearly transferred to the licensee.

3.5.3 General Review of Dedication and Repair Methods

The inspectors reviewed Schulz's program and its implementation for performing safety-related repairs, including rewinds, and for the dedication of commercial grade motors for safety-related applications and the dedication of materials, parts and services used in the repairs and rewinds. This included a review of documentation, interviews with personnel, observation of work techniques, review of files containing the records of rewind and dedication jobs, and also review of the corresponding Schulz CoCs which typically certified only that the dedication activities were as stated in the customer-approved Schulz QA program.

The inspectors discussed the concepts of motor qualification and dedication with Schulz and noted that the existence of the various IEEE qualification and dedication standards, and their applicability to Class 1E motors, does not impose nuclear-unique design requirements on all motors or motor related materials. These items can meet the definition of commercial grade items, as contained in 10 CFR 21.3, and be dedicated for safety-related applications.

Schulz used TE-275 to determine the critical characteristics of motors being dedicated. Review of several dedication files indicated that weight had not been considered a critical characteristic related to seismic qualification. However, the weight of a dedicated motor would only have a bearing on the seismic qualification of the system or structure on which the motor is mounted, not on the seismic performance of the motor itself. The inspectors discussed consideration of motor weight with Schulz and noted that seismic qualification had been addressed in the Schulz Technical Evaluation as discussed above. A clarifying example was identified during the inspector's review in which Northeast Utilities requested that Schulz record the before and after weight of a motor they were having Schulz rewind and this was documented. Presumably, this was requested in order to enable the licensee to reanalyze the seismic response of the system in which the motor was installed to maintain qualification. However, absent such a specific application requirement in licensee procurement documents, Schulz would only be expected to comply with the stated requirements. It is clearly the licensee's responsibility to perform (or have performed) any additional evaluation that may be required as part of its own review for suitability of application under Criterion 3 of 10 CFR Part 50, Appendix B.

The inspectors reviewed the motor testing program and its implementation and determined it to be extensive and adequate. In addition to the required electrical and performance tests, testing was also performed by Schulz which demonstrated bearing, lubricant and seal performance under full load conditions (aging was not required). The lubricants and seals used were either identified to the licensee or, in many cases, the licensee provided the lubricant to be used.

The inspectors' review of the Schulz program for procurement and dedication of commercial grade materials used in Class 1E rewind jobs, as well as new motors being dedicated, indicated that in general, the program and its implementation was technically sound, properly controlled and was in all cases fully documented and disclosed to the licensees.

4 PERSONNEL CONTACTED

+ R. Dahman, Chief Executive Officer
*+ R. Davis, President
*+ P. Kleine, QA Manager
*+ K. Adams, QA Engineer
+ S. Yousif, Applied Energy Services

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* Attended the entrance meeting on January 24, 1994
\+ Attended the exit meeting on January 28, 1994

Selected Bulletins, Generic Letters, and Information Notices
Concerning Adequacy of Vendor Audits and
Quality of Vendor Products

	ISSUED	TITLE
1.	Information Notice 93-85	Problems With X-Relays in DB- and DHP- Type Circuit Breakers Manufactured by Westinghouse
2.	Information Notice 94-02	Inoperability of General Electric Magne-Blast Breaker Because of Misalignment of Close Latch Spring

CORRESPONDENCE RELATED TO VENDOR ISSUES

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 18, 1993

Docket No. 99901263

Mr. Steven W. Andrews
Quality Assurance Manager
Consolidated Power Supply
3556 Mary Taylor Road
Birmingham, Alabama 35235

Dear Mr. Andrews:

SUBJECT: REQUEST FOR INTERPRETATION ON COMMERCIAL GRADE DEDICATION PRACTICES

By letter dated March 18, 1993, you requested the U. S. Nuclear Regulatory Commission to provide guidance for the commercial grade dedication of metallic products to be used in commercial nuclear safety-related applications. You also stated in your letter that your request is focused on vendors/distributors that primarily dedicate and supply (but do not manufacture) products such as structural steel, flanges, fittings, tubular products without filler metal, reinforcing bars, and other similar non-nuclear unique material to recognized industry standards. Five examples, each with a descriptive text for its unique purchasing and quality conditions, were attached to your letter along with dedication questions for each example.

The five examples, related dedication questions, and our responses are discussed in Enclosure 1 to this letter. Enclosure 2 to this letter is a copy of NRC Inspection Procedure 38703, "Commercial Grade Dedication," dated November 8, 1993. This NRC procedure is applicable for performing inspections at NRC licensed facilities and Appendix A , "Dedication Issues," to this procedure provides for a graded approach in selecting critical characteristics to be verified. For example, the A 36 steel plate, in Enclosure 1, Example No. 4, could be used to fabricate a cut and drilled base plate for a heat exchanger in a mild environment, or, the plate could be used to fabricate a welded critical seismic pipe support. Depending on the specific application, all of the A 36 specification requirements may be essential for the item to perform its safety function and may have to be verified, or, in the case of the A 36 plate being used as a base plate, only a portion of the A 36 requirements may be essential for the item to perform its safety function.

Generally, vendors such as Consolidated Power Supply receive purchase orders for metallic products that invoke the requirements of: (1) Appendix B to Title 10 of the Code of Federal Regulations (10 CFR), or an equivalent customer approved vendor Quality Assurance Program, (2) 10 CFR Part 21, (3) technical requirements such as the governing material specification and any additional/supplementary requirements, and (4) documentation and/or certification requirements. When the product is certified by the vendor to be supplied in accordance with these or similar requirements, the customer generally considers that the product meets all of the technical requirements specified in its purchase order and, therefore, can be used in any safety-related application where design documents specifically identify the use of such products.

Because vendors certify that the requirements of its customer's purchase order have been met and, generally, do not know the intended safety-related applications for its products, the vendor should dedicate these products by confirming that all of the technical requirements specified by the customer have been met. For example, in the case where a supplier's material traceability controls have not been confirmed by the vendor as adequate and effectively implemented or where the vendor has not validated its supplier's test reports, each piece of material may have to be destructively and nondestructively tested, as discussed in the Enclosure 1 examples, in order for the vendor to determine that the material supplied meets specification requirements.

Unless a vendor knows the specific use of the metallic products it is supplying and has the capability to determine all of the attributes (critical characteristics) that should be verified to ensure that the product will perform its safety function, the vendor should not attempt to use the graded approach, discussed in Enclosure 2, for selecting critical characteristics.

Should you have any further questions, please contact Mr. Larry L. Campbell of my staff at (301) 504-2976 or Mr. Uldis Potapovs at (301) 504-2959.

Sincerely,

Leif J. Norrholm

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection
and Licensee Performance
Office of Nuclear Reactor Regulation

Enclosures:
1. NRC Responses to Consolidated Power Supply Questions
2. NRC Inspection Procedure 38703

NRC RESPONSES TO CONSOLIDATED POWER SUPPLY (CPS) REQUEST FOR INTERPRETATION ON COMMERCIAL GRADE DEDICATION PRACTICES

(Reference: Letter to Charles E. Rossi (NRC) from Steven W. Andrews (CPS), "Request for Interpretation on Commercial Grade Dedication Practices," dated March 18, 1993)

Example No. 1

A vendor procures ASTM A 36 angle directly from a melt facility (mill). The melt facility is surveyed on an annual basis for the scope of material traceability. The vendor's procurement document reflects invocation of the current mill quality program manual, and requires a conformance/compliance statement to such program on the mill certification document. The mill's quality manual does not meet all elements of 10 CFR 50 Appendix B. 10 CFR 21 is not invoked in the vendor's procurement document. Upon receipt by the vendor, the mill test report is reviewed by the inspector. Upon acceptance by the inspector, one piece from each heat of material is provided to a testing facility to conduct the destructive and nondestructive testing identified in the critical characteristic listing for the type and grade of material. A tension test and full chemical analysis is performed using equipment qualified under the vendor's 10 CFR 50 Appendix B quality program. No additional destructive or nondestructive testing is performed on the balance of the material. All pieces receive a dimensional inspection as the mill was not qualified for its control over measuring and test equipment, based on the fact that the mill does not conduct any type of qualification of calibration suppliers.

Question 1:

Is it possible to perform a sampling (10% for example) of the material received for conducting the dimensional inspection activities?

NRC Response:

Since the mill was not qualified for its control over measuring and test equipment (M&TE), verification of the A 36 angle's dimensions should not be based on dimensional inspections performed by the mill. For standard products having a simple design such as the A 36 angle, inspection to verify dimensions may be performed on a sample basis. Sample plans used for the performance of the dimensional inspection should consider lot/batch control as discussed in Appendix A, "Dedication Issues," to Enclosure 2, NRC Inspection Procedure No. 38703, "Commercial Grade Dedication," dated November 8, 1993.

Also, if a manufacturer has been producing a particular standard item for a long period of time, using essentially the same controls, and if the quality history of the item indicates that its significant characteristics performed satisfactorily, this satisfactory performance history could be used to support a general product homogeneity over the years and the use of standard statistical sampling methods to accept certain product characteristics. When this philosophy is used, it should be documented and substantiated by objective evidence.

Question 2:

Is it acceptable to perform destructive testing on only one piece from each heat as the mill was surveyed for traceability of material?

NRC Response:

When heat traceability of the material has been established (for this example material traceability was reviewed during the annual survey) and each piece of material (or container of material where permitted by code or specification and applicable implementing procedures) is marked with the material heat number, all chemical analysis and mechanical tests required to verify the critical characteristics identified by the material specification may be performed on one piece of this material. Other critical characteristics such as dimensions and surface finish would have to be verified either by sampling as discussed in the NRC response to Question No. 1 or by inspecting each item where sampling is not appropriate.

Question 3:

Is it necessary to perform destructive testing, such as tension tests and chemical analysis on the material, or only perform nondestructive testing such as hardness and/or alloy verification?

NRC Response:

Since the vendor does not know the specific safety-related application(s) for the A 36 angle, the vendor should verify that the angle has the chemical and mechanical properties required by the material specification.

Question 4:

Is it necessary to even perform a survey of the mill if the vendor's purchase order is placed directly with the mill? The material and certification would be provided directly to the vendor without the use of a distributor, and the material reflects appropriate mill identification (heat/lot number) to enable traceability of the material to the test report.

NRC Response:

When the dedication of a commercial grade item is based partially or entirely on certification and material identification by the mill, it is necessary to establish the validity of documents such as the mill test reports by survey.

If a vendor places a purchase order directly to the mill and the mill supplies products directly to the vendor and the vendor does not audit or survey the mill, the controls that the mill has in place for activities such as material manufacturing, traceability, testing, marking, and certification have not been confirmed as being adequate and effectively implemented. If a survey or audit is not performed, the vendor must implement alternate measures to validate that such activities affecting the quality of the product being supplied are adequate and are being effectively implemented by the mill.

Example No. 2

A vendor procures ASTM A 240 type 304 plate from a distributor who implements a quality program that does not meet 10 CFR 50 Appendix B requirements. The program is invoked by the vendor's procurement document without 10 CFR 21 requirements. The distributor's program is surveyed by the vendor on an annual basis and found to be satisfactory for maintaining traceability of material within their surveyed facility. Also, the distributor has a documented section in its quality program that addresses surveys of their suppliers. As the distributor does a large volume of commercial business, all material is procured directly from the mills that have been surveyed. The distributor does not invoke the quality program in its procurement documents utilized by the mill. In addition, the distributor may segregate the material within its surveyed facility, but does implement satisfactory controls for maintaining traceability for the subdivision of material as evaluated during the vendor's survey at the distributor's facility. The distributor provides certification that reflects a conformance/compliance statement to the program invoked in the vendor's procurement document, in addition to a copy of the material manufacturer's test report. Upon receipt by the vendor, one piece from each heat is tested in accordance with the critical characteristics reflected for this specification and type of material. This includes tension testing and chemical analysis, which is destructive. No other destructive or nondestructive testing is conducted on the balance of the material received by the vendor. All pieces receive a dimensional inspection as the distributor's program has not been qualified for appropriate measuring and test equipment control.

Question 1:

Is it possible to perform a sampling (10% for example) by heat or lot of material received to perform dimensional inspection activities?

NRC Response:

Since the example indicates that the distributor and its subsuppliers, the mills, do not have controls in place for dimensional inspection activities, any sample plan used by a vendor for accepting dimensions on A 240, type 304, plate needs to provide a high confidence level that dimensions are correct.

A tightened sample plan, with a sample size exceeding that required by standard statistical sampling methods which are based on sampling homogenous product lots, should be used for a lot of items, such as the plate, from multiple mills.

Question 2:

Is it acceptable to conduct the testing on one piece from each heat or lot if traceability to the melt facility is documented and verified?

NRC Response:

Yes, provided that the distributor's surveys of the mills confirmed that controls for maintaining traceability are being effectively implemented. However, if the heat or lot subdivided by the distributor consists of pieces of plate from more than one mill, one piece from each mill heat or lot should be tested.

Question 3:

Is the distributor's procurement document required to invoke the mill's controlling quality program manual to accomplish testing of one piece per heat? If so, should there be a statement of conformance/compliance to the mill's program on their certification document?

NRC Response:

The quality assurance requirements and the elements of the quality assurance program applicable to the item being purchased should be included or invoked by reference in the procurement document.

Prior to the distributor invoking or referencing quality requirements in its procurement documents to the mills, the mills should be surveyed to ensure that their commercial or quality control for the applicable critical characteristics are being effectively implemented. The mill's compliance to the distributor's purchase order requirements should be documented on the certification document.

Question 4:

Do the material markings have to be those of the original material manufacturer (mill) to conduct any sampling process?

NRC Response:

No, provided that each distributor's lot markings are traceable to each of the mill heats forming the lot and one piece from each mill heat is sampled for physical and chemical properties. However, for verifying critical characteristics such as dimensions, as discussed in NRC responses to Questions 1 and 2 of this example, if the mill's marking have been supplemented during the heat or lot subdivision by the distributor and the distributor's lot contains pieces from several mills, a tightened sample plan should be used.

Question 5:

Is nondestructive testing required on additional pieces of material to correlate to the destructive testing performed from the same heat of material?

NRC Response:

No, provided that heat traceability of the material has been established and each piece of A 240, type 304, plate is marked with the same mill heat number.

Question 6:

Is destructive testing, such as chemical analysis and/or tension testing, even required to dedicate the material, or could hardness testing or an alloy verification be conducted to reasonably assure the material is what was ordered?

NRC Response:

Because the vendor is certifying that the A 240, type 304, plate meets the requirements of Specification A-240, under its Appendix B quality assurance program, and does not know for what safety-related application(s) the plate will be used in at the nuclear power plant, the dedication of the plate must provide a high level of confidence that the requirements of Specification A 240 are met.

The performance of tension testing, hardness checks, chemical analysis, and verification of selected requirements of Specification A 480/A-480M will provide reasonable assurance that the plate meets the requirements of Specification A 240 (type 304).

Performance of a hardness test and/or an alloy verification using an alloy separator would not provide reasonable assurance that the plate is A 240, type 304. For example, a hardness of 92 Rockwell B or 202 Brinell would be acceptable for A 240, types (304, 316, and 347) plate and an alloy separator, as a rule, could not separate these 300 series materials.

Example No. 3

A vendor procures ASTM A 234 fittings from an un-surveyed distributor as commercial material. No program or programmatic controls are invoked in the vendor's procurement document. A material test report is required which must be traceable by heat or lot number to the fittings supplied. The material may or may not reflect the original material manufacturer's markings. The actual mill test report may or may not be supplied with the fitting manufacturer's test report. Upon receipt, the vendor verifies that all fittings reflect the heat or lot number which is traceable to the fitting manufacturer's test report. One fitting from each heat is destructively tested using tension testing and chemical analysis as reflected on the critical characteristics form, with no other destructive or nondestructive testing being performed on the balance of the material. Dimensional inspections would be performed on all fittings not destroyed by the testing for compliance to the applicable American National Standards Institute specifications.

NRC Discussion:

Since there are no requirements for the distributor to audit or survey its suppliers or to invoke specific quality assurance requirements in purchase orders to its suppliers, the distributor may not have performed these activities. Even if the distributor did perform audits or surveys of its suppliers and did invoke quality assurance requirements in purchase orders to its suppliers, the vendor could not take credit for these activities because the vendor did not perform any reviews or evaluate the distributor's control over these activities.

Based on the above discussion, if (1) the A 234 fittings do not reflect the original material manufacturer's marking, **and** (2) the actual manufacturer's test reports are not provided with the fittings, **and** (3) the actual mill certified material test reports are not provided, dedication would require, as a minimum, verification of all physical and chemical properties of each fitting, and dimensional inspections such as wall thickness and end preparations. Even with these dedication activities being performed, without the mill certified material test reports and the forger's product analyses, the vendor could not certify that the fittings meet all of the requirements of A 234 (e.g. Section 4, "Materials," Section 5, "Manufacture," Section 6, "Heat Treatment").

With the exception of the NRC Response to Question 4, the following responses are based on having manufacturer's and distributor's (if applicable) markings on the A 234 fittings and actual manufacturer (forger) test reports for each heat and actual mill test reports for each heat, and the fittings are not intended for use in critical safety applications (see NRC Comment 1 for this example).

Question No. 1:

Is it necessary to perform destructive testing, or could nondestructive testing such as hardness testing and/or alloy verification be utilized?

NRC Response:

Destructive testing to verify the physical properties specified by A 234 and any supplemental properties specified in the customer's purchase order, such as impact properties, should be performed on at least one fitting from each heat. Because the vendor purchased the A 234 fittings from an un-surveyed distributor as commercial grade, chemical analysis and hardness testing should be performed on each fitting to verify compliance to A 234 physical and chemical requirements.

Question 2:

In response to Question 1, if only nondestructive testing is required, could a sampling (10% for example) be tested, or should all fittings be testes, or could only one fitting be tested?

NRC Response:

Destructive testing of one fitting, from each of the distributor's heat or lot of fittings, should be performed as discussed in the NRC response to Question 1. Additionally, since material traceability has not been established, nondestructive testing should be performed on each fitting to verify that its chemical composition and hardness meet the requirements of A 234.

Question 3:

Is it possible to perform dimensional inspection activities on a sampling (10% for example) of the fittings?

NRC Response:

Since the example indicates that the vendor purchased the fittings from an un-surveyed distributor and no program controls were invoked in the vendor's procurement documents, there do not appear to be any validated controls in place for dimensional inspection activities performed by the distributor or its suppliers. Any sample plan used by a vendor for accepting dimensions on these A 234 fittings needs to provide a high confidence level that dimensions are correct.

Since material traceability has not been established, a tightened sample plan, with a sample size exceeding that required by standard statistical sampling methods which are based on sampling homogenous product lots, should be used for each of the distributor's heat or lot of items.

Question 4:

Is there a difference if the mill test report accompanies the fitting manufacturer's test report, and the fittings reflect the actual fitting manufacturer's marking as opposed to the distributor's marking of the material?

NRC Response:

Yes, the tightened sample plan for dimensional inspection should be adjusted accordingly to consider cases in which (1) the distributor is the sole source in maintaining the fitting identification markings and (2) identification markings by both the distributor and manufacturer are on the fittings. However, it is noted that, because material traceability has not been established, the responses to Questions 1 and 2 would still apply as previously discussed.

Question 5:

Is it acceptable to perform destructive testing on one fitting and then perform nondestructive testing such as hardness testing on the balance or a sampling (10% for example) of the balance.

NRC Response:

Because material traceability has not been established, nondestructive testing as described in the response to Questions 1 and 2 should be performed.

NRC Comments for Example No. 3

1. The above responses may not be adequate for ensuring that A 234 fittings in certain applications will perform their safety function . For critical nuclear safety-related applications (e.g. fittings in high pressure, high temperature, steam or water applications) where failure modes include fatigue, deformation, burst, wall thinning (caused by corrosion/erosion), and propagation of manufacturing defects, the following requirements would apply:

    a. Tensile tests and other physical tests (e.g., impact) should be performed using a prolongation obtained from the end of the fitting or using a fitting from the same heat. Material traceability of the test specimen and, if used, a fitting from the same heat, to the fitting being dedicated should be established by audit, survey, or source surveillance regardless of where the test specimens were obtained.

    b. Chemical analysis should also be performed on the actual fitting or specimen where material traceability to the fitting has been established as discussed in (a) above.

2. The vendor should exercise caution in preparing its certification statement addressing conformance to A 234. If the vendor only confirmed during dedication that the physical, chemical, and dimensional requirements of A 234 had been met, its certification should so state. The end user of the fittings would then determine if the fittings were acceptable for their intended safety-related applications.

Example No. 4

A vendor procures ASTM A 36 plate from a distributor that has nota been surveyed. No program or programmatic controls are invoked in the vendor's procurement document. A material test report is required with the material. The distributor provides a test report from the mill and marks the plate with the heat/lot number corresponding to the test report received with the plate. The vendor then performs tension testing and chemical analysis on each piece of plate. Also, each piece receives a dimensional inspection. Test reports from the qualified test facility confirm that the material meets the requirements of A 36, however review of the results against the manufacturer's test report reflects the material may be from another heat or even another plate manufacturer.

Question 1:

Is the product acceptable?

NRC Response:

In order to certify that the plate meets the requirements of A 36, the vendor would have to confirm that all of the requirements of A 36 have been met including the applicable requirements of A 6 (Specification for Structural Steel) as required by Section 4 of A 36. Because the vendor has determined that the documentation supplied with the plate is not for the plate received, the vendor should identify the test results and any other inspections it performed on each piece of plate and document these on its certification for the plates.

Question 2:

Is it possible to conduct the aforementioned destructive testing on only one piece of plate and perform nondestructive testing such as hardness on the balance or sampling of the balanced?

NRC Response:

No. The conditions described above clearly indicate that the distributor and/or his supplier have not maintained material traceability for the plates, therefore each plate has to be evaluated for compliance to A 36 requirements.

Question 3:

Is destructive testing necessary or could one piece, all pieces, or a sampling of the pieces be tested nondestructively?

NRC Response:

A. Because material traceability has not been maintained, each piece of plate should be destructively and nondestructively tested as previously discussed.

B. If the test reports from the qualified test facility had confirmed that the plate met the requirements of A 36 and the results were consistent with the manufacturer's test report, it would be acceptable to perform destructive testing on one piece of plate from each heat and to perform nondestructive testing on the balance of plate from each heat. Since the vendor does not know what applications the plate will be used in, nondestructive tests such as a hardness and/or alloy verification would not be sufficient to determine that the pieces of plate meet all of the requirements of A 36.

Question 4:

Is it possible to perform dimensional inspection on a sampling of material?

NRC Response:

Because evidence exists to question the material traceability and marking of the plates as well as the material certification supplied by the distributor, the vendor should not sample the material dimensions. However, as stated in previous NRC responses, sampling of product dimensions is acceptable under certain circumstances.

Example No. 5

A vendor procures ASTM A 569 sheet from a distributor. No quality program is invoked and no mill or material test report is available. The material may or may not reflect the manufacturer's markings, and may not even reflect a heat or lot number. The vendor tests each piece of sheet and verifies by testing all of the requirements of the material specification. The test results, which comply with A 569, are provided to the customer as the only verification that the material meets the specification. The vendor will mark the material with appropriate trace codes to tie the material to the test reports and other applicable certification.

Question 1:

Is the above practice acceptable?

NRC Response:

If the vendor has confirmed by test and inspection that all of the requirements of A 569, as required by the vendor's customer purchase order, as well as the applicable requirements of A 568/568M have been met, the above practice appears to be acceptable. However, the vendor should note on its certification that certain requirements such as the marking on the material is by the vendor and that the manufacturer's product marking requirements, Section 14 of A 568/568M, have not been met.

Question 2:

Is it possible to perform destructive testing on one piece only?

NRC Response:

When no mill/material test reports are provided (and in this case the material has no markings), material traceability has not be established. Therefore, a piece of steel from each A 569 sheet should be destructively tested.

Question 3:

Is it possible to perform destructive testing on one piece and perform nondestructive testing on the balance or sampling of the balance, to correlate to the destructive testing performed?

NRC Response:

If the A 569 sheets were properly marked with the manufacturer's heat or lot number and one piece from each heat or lot was destructively tested (e.g., physical and chemical properties tested) and the test results were confirmed to be consistent with those on the manufacturer's test report, the remaining pieces could be nondestructively tested to verify compliance with the material specification requirements.

Question 4:

Could only nondestructive testing be performed, such as hardness, provided the material specification had either hardness values to check against, or tensile values that could be approximated by the hardness?

NRC Response:

If the material specification or customer purchase order identifies required tensile/yield values and the A 569 sheets are properly marked by the manufacturer and the manufacturer has provided test reports, only one piece from each heat or lot needs to be destructively tested by the vendor to verify the material's tensile/yield strength. The remaining sheets of A 569 material (from each heat or lot) should be tested and inspected to confirm that other requirements (e.g. chemistry) of A 569 have been met. In addition, since adequate material control/marking by the distributor and manufacturer have not been confirmed by survey or audit, a hardness check on the remaining pieces should be performed to verify that the other sheets have the (approximate) required tensile/yield strength.

NRC GENERAL COMMENTS

1. Dedication of commercial grade items for use as basic components is a quality related activity and needs to be performed and controlled in accordance with the requirements of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50.

2. There are requirements in material specifications such as performance of hydrostatic tests, welding, and nondestructive examination of welds and weld repair areas that were not specifically discussed in these examples. When applicable, these and other specification requirements need to be confirmed during the dedication process or the failure to perform these tests noted on the material certification.

3. When the customer's purchase order invokes supplementary specification requirements or additional requirements not addressed in the material specification, care should be exercised during the dedication process to ensure that these additional requirements have been met.

4. If the dedication process only confirms that a portion of the applicable material specification requirements have been met, the vendor should so inform its customer.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

NRC INSPECTION MANUAL

RVIB

INSPECTION PROCEDURE 38703

COMMERCIAL GRADE DEDICATION

PROGRAM APPLICABILITY: 2515

SALP FUNCTIONAL AREA: ENGINEERING (SOETS-O)

38703-01 INSPECTION OBJECTIVES

01.01 To determine whether the failure of a safety-related system, structure, component (SSC), or part to perform its intended safety function was the result of a deficient commercial grade item (CGI) dedication process.

01.02 To verify that the licensee's process for dedicating CGIs, as implemented, meets the applicable portions of Appendix B to 10 CFR Part 50 and provides reasonable assurance that CGIs will perform their intended safety function.

38703-02 INSPECTION REQUIREMENTS

02.01 Reactive Inspection Requirements

a. Initial Evaluation. After reviewing the licensee's evaluation of the failed item, determine if the failed item was procured as a CGI and dedicated for safety-related applications. If the failed item was dedicated, review the complete procurement and dedication records to determine if the commercial grade dedication process was sufficiently thorough.

b. Further Assessments. If it is determined that the dedicated item failed as the result of certain critical characteristics not being identified and/or properly accepted, the inspector should perform the following assessments:

   1. Determine if other CGIs from the same accepted lot or batch as the failed dedicated CGI have been similarly dedicated and installed in other safety-related applications. If yes, determine if the licensee has evaluated the operability of the systems or components where these CGIs are installed. The inspector also should review licensee-provided data, if available, for some CGIs (non-dedicated) that failed in applications that were not safety-related. Explore the possibility that the same CGIs also may have been used (following dedication) in a safety-related application and may have the potential to affect the safe operation of a SSC.

2. If possible select and evaluate, as in step 1 above, at least three other dedicated CGIs having similar applications and critical characteristics as the CGI(s) that resulted in the identified failures.

3. If, after performing step 2 above, it is determined that there were weaknesses in the commercial grade dedication process, the inspector should perform a more comprehensive inspection of the licensee's dedication process in accordance with the inspection requirements in Section 02.02 below.

02.02 Programmatic Inspection Requirements

a. Review of Program and Procedures. Using the inspection guidance contained in Section 03.02 and Appendix A to this procedure, review the licensee's program and procedures for the procurement and dedication of CGIs in order to understand the basic operation of the licensee's program.

b. Selection of Dedication Packages. Select approximately 20 dedication packages for evaluation from a list of commercially dedicated items provided by the licensee. Request that the licensee provide (or make available for review) a complete package of the pertinent procurement and dedication records for each item.

c. Evaluation of Dedication Packages. Using the inspection guidance contained in Section 03.01 of this procedure, perform a detailed evaluation of the dedication packages selected in item b above.

d. Evaluation of Training Effectiveness. If the inspector's evaluation of commercial grade dedication activities indicates there are weaknesses in the way these activities are being performed, the inspector should investigate further to determine if weaknesses within the licensee's training program may have contributed to the cause. The inspector should determine if the licensee is implementing an effective training program.

38703-03 INSPECTION GUIDANCE

GENERAL GUIDANCE

Background. Licensees are required to ensure the quality of items purchased and installed in safety-related applications. In the past, licensees procured major assemblies from approved vendors who maintained quality assurance (QA) programs pursuant to Appendix B to 10 CFR Part 50. Because of the decrease in the number of qualified nuclear-grade vendors, licensees are increasing the numbers of commercial grade replacement parts that they procure and dedicate for use in safety-related applications.

Since commercial grade dedications have increased in number, the Nuclear Regulatory Commission (NRC) has developed this inspection procedure to provide guidance to assist the inspector in assessing the effectiveness of the implementation of the licensee's commercial grade procurement practices and provide for early identification of any adverse trends or emerging problems.

The Vendor Inspection Branch, of the NRC's Office of Nuclear Reactor Regulation, is available to assist with specific questions that arise during the performance of this procedure.

Scheduling the Inspection. This inspection procedure should be considered for implementation when there is reason to believe that the failure of a SSC or part to perform its intended safety function was the result of weaknesses in CGI dedication. This inspection procedure may be implemented independently or it may be used as a supplement to other major team inspections. Such inspections may include maintenance, modification, or system-specific inspections where review of failed SSCs or parts is appropriate, or an augmented inspection team investigating failures.

The NRC should contact the appropriate NRC and licensee personnel to schedule the inspection. When practical, inform the licensee of the objectives of the inspection 4-6 weeks before the inspection is to begin and advise them of information that will be needed, such as a list of items that the licensee purchased as commercial grade after July 1990 and subsequently dedicated for use in safety-related applications. Before the beginning of the onsite inspection, the inspector should request and review the licensee's program and procedures to become familiar with the licensee's procurement and dedication process. Also explore with the licensee the possibility of obtaining a list of recent component failures. Request this list only if the licensee states this type of information would be easily retrievable. The list of component failures can be used by the inspector during the selection of dedication packages for review described in Section 02.02 of this inspection procedure.

This inspection procedure is consistent with the Nuclear Management and Resources Council (NUMARC) initiative for improving the utilization of CGIs in nuclear safety-related applications that was implemented in July 1990. The methods used to commercially dedicate items procured by licensees before that date will not necessarily meet the guidance contained in this inspection procedure. If the inspector encounters a significant failure of a commercially dedicated item, which was dedicated before July 1990, the inspector may review the dedication of that item with the understanding that the licensee was not expected to meet the current guidelines.

SPECIFIC GUIDANCE

03.01 Reactive Inspection

a. Initial Evaluation. A failure resulting from general weaknesses in the commercial grade dedication program may occur when the important design, material, and performance characteristics that are necessary to provide reasonable assurance that the dedicated CGI will perform its intended safety function are not addressed during dedication. For example, failures of safety-related bolting have occurred when the dedication process did not verify that the material composition and/or mechanical properties met the specified requirements and nonconforming material was supplied.

   Review and discuss with licensee personnel the failure/root-cause analysis when required or applicable for the failed CGI. The inspector should attempt to determine if the failure was due to a design deficiency, failure unrelated to the item's safety function, or normal wear, and eliminate these from further review. The inspector should focus on the inspection of failures that appear to be due to weaknesses in the commercial grade dedication process. If none of the failures are due to weaknesses in the commercial grade dedication process, then the inspector should not continue using this inspection procedure. If the inspector decides to change the focus of the inspection to examine other issues related to the failures, such as the adequacy of corrective actions, other procedures should be used, such as NRC Inspection Procedure 92720, "Corrective Action." Once the failure mode and cause of failure have been postulated or determined, review the dedication package as described in Section 03.01a(1) to determine if appropriate critical characteristics had been identified by the licensee. Appendix A to this inspection procedure should not be interpreted as inspection requirements but only as a discussion of dedication issues including guidance on selection and verification of critical characteristics. Appendix A, if properly implemented, represents an acceptable means of complying with regulatory requirements. Individual licensee's may develop alternate methods of achieving Appendix B compliance. Appendix B provides definitions of terms used for commercial grade dedication activities, and Appendix C provides the typical contents of a dedication package.

The goal of the review of the dedication packages is to provide reasonable assurance that the CGIs dedicated for safety-related applications will perform their intended safety functions. Inspection effort should be directed towards the identification of weaknesses in the dedication process that could potentially render SSCs or parts inoperable. When reviewing licensee's operability determinations for dedication of CGIs, the inspector should refer to the "Technical Guidance" section of NRC Inspection Manual, Part 9900, for further guidance.

<u>a(1) Review of Dedication Packages</u>. After becoming familiar with the licensee's procurement and dedication program and procedures, perform a detailed review of the dedication package as described below.

- Determine if the safety function of the item for its intended use has been identified by reviewing the documents associated with the technical evaluation including, as applicable:

  - classification of the item
  - consideration of credible failure modes
  - item equivalency/substitution evaluations

- Determine if the important design, material, and performance characteristics relevant to the safety function have been identified. Determine whether the licensee verified the characteristics necessary to provide reasonable assurance that the item will perform its intended safety function. If appropriate, take into account post-installation testing and periodic surveillance testing and inspection. Review the basis for engineering judgment when it is used as the basis for selection or verification of critical characteristics.

- Determine whether the item is an equivalent replacement or a new item replacement of an obsolete item.

- Determine if the item is or may be used in a different safety-related application than previously evaluated in which different design, material, and performance characteristics may be applicable. This is especially applicable for generic dedications of bulk items and stock material. Determine if the dedication ensures those design, material, and performance characteristics relevant to the safety function.

- Determine why the item is being replaced. Have there been repeated failures? Is the degraded performance a result of adverse environment? Did it fail because it was a refurbished or fraudulent item? General information on similar activities subject to Appendix B to 10 CFR Part 50 is provided in American National Standards Institute (ANSI) ANSI N45.2-1977, "Quality Assurance Program Requirements for Nuclear Power Plants," Section 17, "Corrective Action."

- Determine how the identity of the item is controlled from the time it is receipt inspected until the time it is installed. General information on similar activities subject to Appendix B to 10 CFR Part 50 is provided in ANSI N45.2-1977, Section 9, "Control of Parts and Components."

- Determine if information learned during the dedication process is fed back to the appropriate persons to evaluate existing stock items, or installed items, and for future use in surveys and source verifications. This information could include positive and adverse findings obtained during surveys and source verifications. General information on similar activities subject to Appendix B to 10 CFR Part 50 is provided in ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants," Section 9, "Corrective Action."

Refer to the discussion of significant dedication issues in Appendix A for guidance during the review of dedication packages. Also refer to the specific guidance for each of the four dedication methods provided below.

Focus should be on those activities that are likely to affect the performance of the items being dedicated. It is not necessary to review the licensee's programmatic compliance to the 18 criteria of Appendix B to 10 CFR Part 50 as they may not apply to the activities reviewed. Appendix B to 10 CFR 50 does not apply to commercial grade activities which occur prior to dedication for use in a safety-related system. It also should be recognized that this appendix provides for the application of QA to safety-related systems and components consistent with their importance to safety (graded quality approach).

Although guidance concerning the application of graded quality assurance is discussed in the first paragraph of Appendix A to this inspection procedure, it is expected that the inspector will need to exercise considerable judgment in determining the adequacy of controls applied to a specific activity.

The following are the four acceptance methods that can be used to accept CGIs. These methods provide, either individually or in combination, a means to reasonably ensure that a CGI that is received meets the requirements of the item specified. The results of employing each method should be documented.

<u>Method 1 - Special Tests and Inspections</u>

General information on similar activities subject to Appendix B to 10 CFR Part 50 is provided in ANSI N45.2.13-1976, Section 10, "Acceptance of Item or Service." Use the following approach to review packages that were dedicated using this method:

- To the extent practicable, attempt to witness receipt inspections and tests of in-process dedication of CGIs that are similar to that of the failed item to verify the identified critical characteristics.

- Review receiving records and associated tests and inspections.

- Review post-installation test records.

- Verify that the tests and inspections specified for acceptance adequately verify the identified critical characteristics.

- Verify that sampling plans are controlled and have adequate technical basis, considering lot traceability and homogeneity, complexity of the item, and adequacy of supplier controls.

- Verify that CGI receiving inspection activities are adequately controlled under a quality program regardless of whether they are being performed in conjunction with other plant receipt inspection activities.

- Verify that receipt inspection activities establish and maintain traceability of CGIs by capturing and appropriately relating traceability documents through identification and monitoring of CGIs.

- Verify that measuring and test equipment was properly calibrated, that approved vendors were used to perform tests, and that personnel were qualified to perform the tests.

<u>Method 2 - Commercial Grade Survey</u>

Use the following guidance to review packages that were dedicated using this method:

- Determine if the guidance of Generic Letter 89-02, or an appropriate alternate, is included in the appropriate procedures. Specifically, confirm that (1) the documented commercial quality program was effectively implemented and (2) the surveys were conducted at the location necessary to verify that adequate controls were exercised on distributors as well as manufacturers.

- Through interview, determine if the persons who perform vendor surveys are knowledgeable in the following:

  - the use of performance-based surveys
  - screening third-party surveys
  - processing and evaluating adverse findings resulting from the review of third-party surveys to ascertain if those findings affect CGIs already installed or stored in the warehouse awaiting future installation

General information on similar activities subject to Appendix B to 10 CFR Part 50 is provided in ANSI N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants," and ANSI N45.2.23-1978, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants."

- Verify that the supplier's commercial quality controls are imposed in the procurement documents.

- Determine if the critical characteristics that are to be verified by the survey team are accurately and completely incorporated in the survey plans.

- Determine if the validity of supplier documentation, relied on in the dedication of the item, is verified during the survey.

- Determine if surveys of commercial grade suppliers are performance based as opposed to programmatic. Specifically, verify that the critical characteristics for the CGIs being surveyed are controlled by the supplier's quality activities.

- Determine if survey teams include technical and quality personnel, as appropriate, that are knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified, including any special processes such as welding and heat treatment that are specific to the critical characteristics.

- Determine if surveys are conducted at appropriate times relative to the procurement. Are surveys required to be updated on a regular basis to support dedication?

- Determine if the control of subvendors is adequately addressed by the surveys so that the supplier has an adequate basis to accept test results and certifications from the subvendor.

- Determine if pertinent information about a supplier or its products is used to plan, conduct, and report results of surveys and source verifications. Such information could have been available from source verifications, receiving inspections, the dedication process, supplier/product performance history, or outside sources such as NRC information notices and bulletins, nuclear plant reliability data system reports, or Nuclear Utility Procurement Issues Committee (NUPIC) commercial grade survey reports.

<u>Method 3 - Source Verification</u>

General information on similar activities subject to Appendix B to 10 CFR Part 50 is provided in ANSI N45.2.13-1976, Section 10.3.2, "Acceptance by Source Verification." Use the following approach to review packages that were dedicated using this method:

- Determine if source verifications involve witnessing the supplier performing quality activities on the actual items being procured and adequately verify the item's critical characteristics.

- Determine if personnel who participated in the source verification surveys were qualified for their specific assignment.

- Determine if appropriate hold points are imposed in the purchase orders. This would include a hold point to verify design, material, and performance characteristics relevant to the safety function that cannot be verified after the item has been completely manufactured.

- Determine if the results of the source verifications were adequately documented.

Method 4 - Acceptable Supplier/Item Performance Record

Use the following guidance to review packages that were dedicated using this method:

- Determine if the guidance of Generic Letter 89-02, or an appropriate alternate, has been incorporated. Specifically, (1) the established historical record is based on industry-wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application and (2) the manufacturer's measures for the control of design, process, and material changes have been adequately implemented as verified by survey (multi-licensee team surveys are acceptable).

- Determine if information pertinent to the CGI's quality of performance, obtained from outside sources (e.g., operational event reports, NRC, vendor equipment and technical information program, and Institute of Nuclear Power Operations) and from commercial grade surveys, source verifications, receipt inspections, previous dedication or qualification and operational history, is factored into the dedication process.

- Determine if the item or manufacturer is included in the licensee's performance trending program.

b. Further Assessments

1. No inspection guidance.

2. From the list of dedicated items provided by the licensee, the inspector should select for review approximately three other dedication packages having similar applications and critical characteristics as the CGI(s) that resulted in the identified failures. After the selections have been made, the inspector should request that the licensee compile a complete package of all the procurement and dedication records for each item. Typical contents of a dedication package are described in Appendix C of this inspection procedure. The inspector should review the dedication packages as described in Section 03.01a(1) of this inspection procedure.

3. No inspection guidance.

03.02 Programmatic Inspection

a. Review of Program and Procedures. The review of the program and procedures should be performed to familiarize the inspector with the licensee's CGI dedication process. For cases in which problems are identified with the licensee's CGI dedication process, the inspector may decide to perform a more extensive review of the program and procedures to determine if these problems are the result of inadequate procedures.

The inspector's review should include procedures that control: procurement activities; material control; the dedication of CGIs, including receipt inspection and acceptance testing; surveys of commercial grade suppliers; classification of components; training of personnel; trending of supplier performance; and equipment failures. Attempt to identify any apparent weak areas to concentrate on during the evaluation of the program implementation.

After arriving onsite, the inspector should request that the licensee explain its commercial grade dedication process and conduct a walkthrough of areas associated with it. Areas in the walkthrough could include the engineering, receipt inspection, component testing, and warehouse. The inspector should become familiar with key licensee personnel involved in the commercial grade dedication process. These key personnel should include the responsible engineer(s) who developed the dedication package(s) and systems engineers, procurement engineers, receipt inspectors, quality assurance engineers and inspectors, and warehouse personnel. The inspector should discuss the commercial grade dedication process with these key personnel to gain a better understanding of the process, including:

- How processing of CGI procurement documents is controlled under the quality program and how they receive review and approval. General information on similar activities subject to Appendix B to 10 CFR Part 50 is provided in ANSI N45.2.13-1976, Section 3, "Procurement Document Preparation, Review, and Change Control."

- How technical personnel participate in the preparation, review, and approval process of procurement documents.

- How consistency and coordination is maintained between corporate level, engineering/support level, and site level programs and implementing procedures.

b. Selection of Dedication Packages. As discussed in the general guidance section above, the NUMARC initiative for the utilization of CGIs in nuclear safety-related applications was not implemented until July 1990. Therefore, the methods used to perform commercial grade dedication of items procured or dedicated by licensees before that date will not necessarily meet the guidance contained in this inspection procedure.

The selection process should be performance oriented (e.g., weighted toward the review of dedication packages for equipment, components, or parts that have experienced failures). To accomplish this, the inspector should request from the licensee approximately 20 packages for review using the two-step approach described below. The licensee should be given sufficient lead time to prepare the 20 packages and make them available for the first day of onsite inspection.

Step 1: Review the licensee's records available at the plant site to identify recent failures (approximately the last 2 years) of equipment, components, or parts. Review these failures to determine if any were CGIs dedicated for use in safety-related applications. If available, select approximately 75 percent of the total sample from CGI failures.

Step 2: From the list of dedication packages supplied by the licensee, under the "Inspection Guidance" section of this procedure, select the remainder of packages for review. The total sample size including packages from steps 1 and 2 should be approximately 20 packages. However, the inspector can select a larger or smaller sample depending on the complexity of the packages and the time available. The inspector should select these packages on the basis of the following considerations:

- The inspector should select packages for items whose failure would have the most effect on the ability of the plant to safely operate, safely shutdown from an adverse condition, or maintain a safe shutdown condition. If time permits, review the plant-specific probabilistic risk assessment, individual plant examination, and risk-based inspection guides that provide information on the risk significance of safety-related plant equipment.

- The inspector should take a performance oriented approach to the selection process by including in the sample packages those items that have been problems in the past. Review available sources of information to identify any known failures of CGIs that were used in safety-related applications. These sources of information could include:

  - component failure lists or lists of items requiring frequent maintenance or replacement as provided by the licensee
  - misrepresented or fraudulent items reported in NRC information notices
  - licensee trending of equipment and supplier performance
  - previous history of component failures or malfunctions as reported in licensee event reports or plant nonconformance reports

- The inspector should include both simple and complex packages in the sample as well as packages that include a variety of dedication methods (e.g., Methods 1 through 4) described in Section 03.01a(1) above.

- In addition to selecting packages based on the above considerations (safety significance, complexity, and failures), the inspector should attempt to select samples from each of the following areas: electrical, instrumentation and control, mechanical equipment, and materials.

c. Evaluation of Dedication Packages. Perform a detailed review of the dedication packages as described above in Section 03.01a(1).

d. Evaluation of Training Effectiveness. Experience gained during the procurement assessments and pilot inspections suggested that training of personnel involved in CGI dedication activities was a very important factor in the development of a good CGI dedication program. The CGI dedication process generally requires more highly qualified/trained personnel than specified in Appendix B to 10 CFR Part 50 procurement. Personnel involved in this process need to be familiar with current industry and NRC guidance and have a strong interface with the licensee's design/engineering organizations. The training expectations, however, should not exceed what is required by the existing licensee's QA program.

As applicable to their job function, select and review the training records for individuals involved in the following areas:

- Determining the safety classification of an item. Training in this area is appropriate when the job function includes reclassification of items or establishing safety classification of piece parts of safety-related components.

- Specifying design, material, and performance characteristics relevant to the safety function and establishing the acceptance criteria for these characteristics.

- Specifying or performing commercial grade surveys, source verifications, and tests and inspections, including enhanced post-receipt verification testing or inspection.

- The preparation and review of procurement documents.

Through observation, interviews, and a review of records of work performed by the individuals:

- Determine if the individuals selected have adequate knowledge to perform the specific tasks assigned to them. Attend a training course, if available, or review the lesson plans for selected training courses.

- Determine if training inadequacies contributed to any of the deficiencies that may be identified during the inspection.

- Determine if the personnel are familiar with the program requirements and procedures and if they have been properly trained in the dedication process.

It should be noted that alternatives to a formal training program may be adequate to ensure satisfactory program implementation (e.g., on the job training). Additional information in this area is provided in NRC Inspection Procedure 41500, "Training and Qualification Effectiveness."

38703-04 INSPECTION RESOURCE ESTIMATE

The estimated number of onsite inspection hours required to complete all inspection requirements is 144 hours when both the reactive and programmatic options are implemented. This estimate is for broad resource planning and is not intended as a quota or standard for judging inspector or regional performance. The on-site hours can be expected to vary significantly depending on the specific circumstance and scope of each inspection.

38703-05 REFERENCES

The following documents are listed for the inspector's information only and are not considered regulatory requirements unless the licensee has formally committed to implementing any of these documents for application to safety-related activities. The inspector may wish to review these documents to become familiar with commercial grade dedication issues.

ANSI N45.2-1977, "Quality Assurance Program Requirements for Nuclear Power Plants," as endorsed by NRC Regulatory Guide 1.28, Revision 2.

ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants," as endorsed by NRC Regulatory Guide 1.123, Revision 1.

Electric Power Research Institute (EPRI) NP-5652, "Guidelines for the Utilization of Commercial-grade Items in Nuclear Safety Related Applications (NCIG-07)," as conditionally endorsed in NRC Generic Letter 89-02.

Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products" (microfiche 48960-001).

Generic Letter 91-05, "Licensee Commercial Grade Procurement and Dedication Programs" (microfiche 57468-264).

NRC Inspection Procedure 41500, "Training and Qualification Effectiveness."

SECY-90-304, "NUMARC Initiatives on Procurement" (microfiche 55277-049).

SECY-91-291, "Status of NRC's Procurement Assessments and Resumption of Programmatic Inspection Activity" (microfiche 59490-079).

END

Appendices:

A. Dedication Issues
B. Definitions
C. Contents of Dedication Packages

APPENDIX A

DEDICATION ISSUES

BASIS FOR THE SELECTION AND VERIFICATION OF CRITICAL CHARACTERISTICS

1. Consideration of Item's Safety Function

Critical characteristics should be based on the item's safety function. The licensee is responsible for (a) identifying the important design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function and (b) selecting from these characteristics a set of critical (or acceptance) characteristics that, once verified, will provide reasonable assurance that the item will perform its intended safety function. Criterion II of Appendix B to 10 CFR Part 50 provides for the application of quality assurance over activities affecting the quality of structures, systems, and components to an extent consistent with their importance to safety. This graded quality approach can be used in the selection and verification of critical characteristics for commercial grade items (CGIs). When an existing equipment specification is available that contains adequate technical requirements for the item being purchased, that specification can be used to select the critical characteristics for this item.

2. Graded Quality Assurance

The application of graded quality assurance to the CGI dedication process should include consideration of the item's importance to safety and other factors specific to the item being procured. Certain items and services may require extensive controls throughout all stages of development while others may require only a limited quality assurance involvement in selected phases of development. The following factors should be considered in determining the extent of quality assurance to be applied: (a) The importance of malfunction or failure of the item to plant safety, (b) the complexity or uniqueness of the item, (c) the need for special controls and surveillance over process and equipment, (d) the degree to which functional compliance can be demonstrated by inspection and test, and (e) the quality history and degree of standardization of the item. Additional guidance on the use of graded quality assurance can be found in the nonmandatory appendix to ANSI N45.2.13-1976.

3. Consideration of Failure Modes

An evaluation of credible failure modes of an item in its operating environment and the effects of these failure modes on the item's safety function may be used in the safety classification of an item and as a basis for the selection of critical characteristics.

4. Reasonable Assurance

The dedication process represents an acceptable method of achieving compliance with Appendix B to 10 CFR Part 50 with the purchaser assuming many of the responsibilities for ensuring quality and functionality of an item that had previously been the responsibility of the vendor. In this context, reasonable assurance consists of the purchaser controlling or verifying the activities affecting the item's quality to an extent consistent with the item's importance to safety or ensuring that these activities are adequately controlled by the supplier. For more complex items, dialogue with the original equipment manufacturer may be necessary to identify the design and functional parameters of specific piece parts. Once the dedication process is completed, the quality assurance and/or other measures applied to those aspects of the item that directly affect its safety function should result in the same level of performance as for a like item manufactured or purchased under a quality assurance program of Appendix B to 10 CFR Part 50.

5. Engineering Judgment

Engineering judgment can be used in selecting those important design, material, and performance characteristics that are identified as the item's critical characteristics. The bases for engineering judgment for this application should be documented.

TRACEABILITY

Material/Items Purchased From Distributors

Traceability can be defined as the ability to verify the history, location, or application of an item by means of recorded identification. Where the item's acceptance is based entirely or partially on a certification by the manufacturer, the traceability must extend to the manufacturer. The purchaser should ensure by survey or by other means that the manufacturer has established adequate traceability controls and that these controls are effectively implemented. For situations in which intermediaries (distributors) are included in the supply chain, the activities of these organizations may need to be surveyed to ensure that traceability and proper storage conditions are maintained. A survey of the distributor may not be necessary if the distributor acts only as a broker and does not warehouse or repackage the items or in cases where traceability can be established by other means such as verification of the manufacturer's markings or shipping records.

SAMPLING

1. Established Heat Traceability (Materials)

When heat traceability of metallic material has been established and each piece of the material is identified with the material heat number, chemical analysis and destructive testing required for the acceptance of this material may be performed on one piece of the material. The same rationale may be used for the acceptance of containers of nonmetallic materials such as lubricants providing that traceability has been established and each container is identified with a unique mix or batch number.

2. Established Lot/Batch Control (Items)

When lot/batch (defined as units of product of a single type, grade, class, size, and composition, manufactured under essentially the same conditions and at essentially the same time) control is established through a commercial grade survey, the party performing dedication of such items can use sampling prescribed by standard statistical methods that are based on homogeneous product lots. Such sample plans should be identified and should provide for the verification of the critical characteristics with confidence level consistent with the item's importance to safety. Other means of demonstrating adequate lot/batch control may include satisfactory performance history and the results of receipt inspection/testing. When such methods are used as a basis for developing product sampling strategy, they should be supported by documented objective evidence.

3. Material and Items With No Lot/Batch Control

When lot/batch control cannot be established, sampling plans need to be considered on individual, item-specific basis and ensure that they are capable of providing a high level of assurance of the item's suitability for service. There may be situations where each item needs to be tested.

COMMERCIAL GRADE SURVEYS

1. Verification of Vendor's Control of Specific Characteristics

A commercial grade survey should be specific to the scope of the CGI(s) being purchased. The vendor's controls of specific critical characteristics to be verified during the survey should be identified in the survey plan. The verification should be accomplished by reviewing the vendor's program/procedures controlling these characteristics and observing the actual implementation of these controls in the manufacture of items identical or similar to the items being purchased.

2. Identification of Applicable Program/Procedures

The vendor must have a documented program and/or procedures to control the critical characteristics of the item or items being procured that are to be verified during the survey. When many items are being purchased, a survey of a representative group of similar items may be sufficient to demonstrate that adequate controls exist. If the vendor's controls are determined to be satisfactory, purchase orders for these items should invoke these controls as contract requirements by referencing the applicable program/procedure(s) and revision. If multiple working level procedures are applicable to the vendor's activities, which affect the item's critical characteristics and these procedures, in turn, are controlled by a higher level document, it may be appropriate to reference that document in the purchase order. It is important to ensure that the specific controls reviewed and accepted during the survey be applied during the manufacturing process. Upon completion of the work, the vendor should certify compliance with the purchase order requirements.

3. Documentation of Survey Results

Commercial grade survey documentation should include the identification of the item or items for which the vendor is being surveyed, identification of the critical characteristics of these items that the vendor is expected to control, identification of the controls to be applied (program/procedure and revision), and a description of the verification activities performed and results obtained. Critical characteristics that are not adequately controlled should be addressed by contractually requiring the vendor to institute additional controls or by utilizing other verification and acceptance methods.

4. <u>Survey Frequency</u>

Commercial grade surveys should be conducted at sufficient frequency to ensure that the process controls applicable to the critical characteristics of the item procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial grade surveys include the complexity of the item, frequency of procurement, receipt inspection, item performance history, and knowledge of changes in the vendor's controls. The survey frequency should not exceed the audit frequency established for 10 CFR Part 50, Appendix B, suppliers.

ACCEPTANCE OF CERTIFIED MATERIAL TEST REPORTS (CMTRs) AND CERTIFICATES OF COMPLIANCE (CoCs)

<u>Validity Verified Through Vendor/Supplier Audit or Testing</u>

When the verification of critical characteristics is based on vendor CMTRs or CoCs, the validity of these documents should be ensured. This can be accomplished through a commercial grade survey or, for simple items, periodic testing of the product on receipt. Such verifications should be conducted at intervals commensurate with the vendor's past performance. If the item's supply chain includes a distributor, a survey of the distributor's activities may be necessary (see "Traceability").

USE OF INDUSTRY GUIDANCE

The Electric Power Research Institute (EPRI) NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)," defines critical characteristics as "identifiable and measurable attributes/variables of a CGI, which once selected to be verified, provide reasonable assurance that the item received is the item specified." NRC's conditional endorsement of EPRI NP-5652 by Generic Letter 89-02 was based on interpreting that in the EPRI definition of critical characteristics the "item specified" encompassed those attributes that are essential for the performance of the item's safety function. This interpretation is consistent with the definition of "critical characteristics for acceptance" found in EPRI NP-6406, "Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants," which notes that critical characteristics for acceptance are a subset of "critical characteristics for design." The EPRI NP-6406 definition of "critical characteristics for design" includes those attributes that ensure the performance of the item's design function.

Published NRC guidance does not differentiate between design and acceptance critical characteristics and the CGI dedication guidance provided in Generic Letters 89-02 and 91-05 does not suggest that all design requirements of an item need to be verified during the dedication process. Rather, the licensee is expected to identify the item's design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function and select from these characteristics a set of critical (or acceptance) characteristics that, once verified, will provide reasonable assurance that the item will perform that function. Consistency in the definition of critical characteristics can be improved by equating the NRC's definition of critical characteristics to the EPRI definition of "critical characteristics for acceptance."

END

APPENDIX B

DEFINITIONS

The following terms are listed to provide the inspectors with working definitions of important terms used during the procurement and dedication of commercial grade items (CGIs). These terms are defined only in the context of the CGI dedication process and are solely to aid the inspector in the inspection process.

Basic Component - A plant structure, system, component, or part thereof necessary to ensure one of the following:

- the integrity of the reactor coolant pressure boundary
- capability to shut down the reactor and maintain it in a safe shutdown condition
- the capability to prevent or mitigate the consequences of accidents that could result in offsite radiation exposures comparable to those referred to in 10 CFR Part 100.11

Certificate of Compliance - A written statement attesting that the materials are in accordance with specified requirements.

Certified Material Test Report - A document attesting that the material is in accordance with specified requirements, including the actual results of all required chemical analyses, tests, and examinations.

Commercial Grade Item - An item satisfying all the following criteria:

- not subject to design or specification requirements that are unique to nuclear facilities
- used in applications other than nuclear facilities
- ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., catalog)

Commercial Grade Survey - Activities conducted by the purchaser or its agent to verify that a supplier of CGIs controls, through quality activities, the critical characteristics of specifically designated CGIs, as a method to accept those items for safety-related use.

Critical Characteristics - Those important design, material, and performance characteristics that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedication - The process by which a CGI is designated for use as a basic component. This process includes the identification and verification of critical characteristics. (Also refer to definition in 10 CFR Part 21.3(4)(c-1))

Engineering Judgment - A process of logical reasoning that leads from stated premises to a conclusion. This process should be supported by sufficient documentation to permit verification by a qualified individual.

Source Verification - Activities witnessed at the suppliers' facilities by the purchaser or its agent for specific items to verify that a supplier of CGIs controls the critical characteristics of that item as a method to accept the item for safety-related use.

Traceability - Is the ability to verify the history, location, or application of an item by means of recorded identification.

END

APPENDIX C

CONTENTS OF DEDICATION PACKAGES

The dedication packages compiled by the licensee may contain the following items, as applicable, depending on the item chosen and the dedication methods used.

- Purchase requisitions and purchase orders.

- Other pertinent vendor/licensee correspondence.

- Design specifications - original and updated to verify certain important parameters, such as original design pressure of a system or degraded pickup voltage of a solenoid or relay.

- Catalog specifications.

- Procurement basis evaluation - like-for-like, equivalency, plant design change packages, drawing and specification updates.

- 10 CFR Part 50.59 safety evaluation, if required.

- Material receiving reports, packing lists/invoices, and other shipping documents.

- Receipt inspection reports and any related test reports.

- Other documents to trace the item from the time it was dedicated to the time it was installed, tested, and accepted.

- Certificates of conformance/compliance/quality.

- Vendor test and inspection reports.

- Third-party or subvendor test and inspection reports.

- Shelf life information.

- Vendor dedication/partial dedication information.

- Design/material/process change history information.

- Completed commercial grade dedication document including:

  - safety classification

  - identification of safety functions/application requirements

  - identification of critical characteristics

  - identification of verification methods and acceptance criteria for the critical characteristics

  - evaluation of credible failure modes (if applicable)

- Any deviation from design, material, and performance characteristics relevant to the safety function (nonconformance dispositions).

- Documents showing objective evidence:

  - special test and inspection procedures and results

  - commercial grade survey reports - item, design, material, and specific performance characteristic (relevant to safety function)

  - source inspection reports

- Completed post-installation test procedure and results.

- Completed stock or material issue forms and installation work orders or reports.

- Historical performance information.

END

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 25, 1994

Mr. Stanley P. Johnson
Chief Executive Officer
The Johnson Gage Company
534 Cottage Grove Road
Bloomfield, CT 06002

Dear Mr. Johnson:

I am responding to your letter of March 8, 1994, to Chairman Selin concerning the use of certain equipment for identifying dimensionally nonconforming fasteners in the nuclear power industry. We are quite familiar with the controversy surrounding the use of System 21 for thread gauging as a means of identifying dimensionally nonconforming fasteners. Although System 22 verifies additional thread characteristics such as the pitch diameter, the NRC staff does not consider System 21 or the use of go-no-go gauges to be inappropriate ("flawed") for accepting certain fastener threads based on the following discussion.

Because of an increase in the number of bolting failures during the 1970s, the U.S. Nuclear Regulatory Commission (NRC) established a generic safety issue on bolting in 1982 to study the potential safety implication of these failures. The scope of Generic Safety Issue (GSI) 29, "Bolting Degradation or Failure in Nuclear Power Plants," included all safety-related bolts, studs, embedments, machine/cap screws, other special threaded fasteners, and all their associated nuts and washers. The Atomic Industrial Forum (AIF), the Metals Properties Council (MPC), and the Electric Power Research Institute (EPRI) conducted major studies on bolting. As a result, EPRI issued a number of documents addressing NRC's concerns about bolting. Further, the NRC conducted two independent assessments of the probable risk of bolting failures in nuclear power plants. Both assessments indicated that the probability of a core meltdown caused by a bolting failure was low because of the highly redundant design of bolted connections and because the bolted connection would leak and the leakage would be detected before the connection completely failed. The NRC staff published NUREG-1339, "Resolution of Generic Safety Issue 29: Bolting Degradation or Failure in Nuclear Power Plants," in June 1990, which documented the staff review of studies by AIF, MPC, and EPRI and recommended the closure of GSI 29. On October 17, 1991, the NRC staff officially closed GSI 29 by issuing Generic Letter 91-17, "Bolting Degradation or Failure in Nuclear Power Plants."

The NRC has resolved this issue without having developed any new requirements, because of industry's initiatives in this area. It was found that the primary causes of these failures were stress corrosion cracking of overly hard fasteners, boric acid corrosion of steel fasteners, and metal fatigue. There is no evidence to indicate that the failures were directly attributable to dimensionally nonconforming fasteners.

Notwithstanding the closure of the generic safety issue on bolting, the NRC staff continues to be vigilant regarding any bolting problems. Through regulatory requirements in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR), the NRC requires that each licensee establish a quality assurance program to ensure that items, such as fasteners used in safety-related applications, conform to applicable specifications. The NRC conducts periodic inspections of licensees to ensure that they are effectively implementing their quality assurance programs. Part 21, "Reporting of Defects and Noncompliance," of 10 CFR requires the reporting of defective items to the NRC. The NRC then assures that other nuclear facilities that may have also received the defective items are informed. The NRC staff has reviewed the Part 21 submittals since 1990 and has not identified any bolting failures directly attributable to dimensionally nonconforming fastener threads.

In addition, nuclear power plant licensees are required to report any safety-significant problems including fastener failures to the NRC in licensee event reports (LERs). The staff has reviewed LERs submitted since the mid-1980s and has not found any reports of fastener failures that could be attributed to dimensionally nonconforming fastener threads, giving additional credence to the conclusion that this is not a safety concern.

The NRC staff is examining the relative merits of System 21 and System 22 for the gauging of fastener threads. Its preliminary conclusions indicate that, although System 22 may be an improvement over System 21, there is no sufficient basis to make its use a requirement for NRC licensees. The staff has also reviewed the documents you provided in your letter and notes that the referenced military standards and much of the correspondence from the National Institute of Standards and Technology address safety issues associated with the acceptance of Class 3 (interference fit) fastener threads using the System 21 plug and ring/go-no-go methods. The use of Class 3 fasteners in the commercial nuclear industry is minimal, and we know of no safety issues associated with their use.

In summary, the NRC staff has not found evidence that failures due to dimensionally nonconforming fasteners are occurring and therefore, does not consider it to be a safety concern.

I hope this letter adequately addresses your concern.

Sincerely,

Frank J. Miraglia

for William T. Russell, Director
Office of Nuclear Reactor Regulation

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 3, 1994

Kirsten A. Burger, Assistant People's Counsel
State of Maryland
Maryland People's Counsel
6 St. Paul Street, Suite 2102
Baltimore, Maryland 21202

Dear Ms. Burger:

SUBJECT: REQUEST FOR PART 21 REPORT NOTIFICATIONS

In your letter to Mr. Walter P. Haass dated January 7, 1994, you requested to be placed on the mailing list for all 10 CFR Part 21 reports, unless it was possible to separate out those that apply to the plants that supply power to Maryland consumers. These plants include Calvert Cliffs, Peach Bottom, and Salem. Your request apparently arises from our recent decision to issue Part 21 Monthly Reports directly to nuclear plant licensees.

Part 21 reports are received by the NRC from the issuing organizations including licensees, vendors, and other entities. These reports are made available to the public by their placement in the Public Document Room (PDR) in Washington, D.C. and in public document rooms local to each nuclear plant. At the time of their receipt and placement in the PDRs, it is not known in most cases to which plants the defect notification may apply. This information may be obtained during the course of review and evaluation of the issue. Resolution of the issues generally involves informing the affected licensees unless they have been previously notified by the vendor. In cases where the affected licensees can not be identified, an information notice from the NRC may be issued to all licensees, if appropriate.

We believe it would not be cost effective to attempt to develop another distribution list for outside organizations to receive Part 21 notifications or to separate out those applicable to certain plants. All the information you requested is already available in the PDRs and it is suggested that you avail yourself of that source of data.

Should you require additional information on this matter, please contact Mr. Walter P. Haass who can be reached at 301-504-3219.

Sincerely,

Leif J. Norrholm, Chief
Vendor Inspection Branch
Division of Reactor Inspection and
Licensee Performance
Office of Nuclear Reactor Regulation

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Division of Reactor Inspection and Licensee Performance
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

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Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

This periodical covers the results of inspections performed by the NRC's Vendor Inspection Branch that have been distributed to the inspected organizations during the period from January through March 1994

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