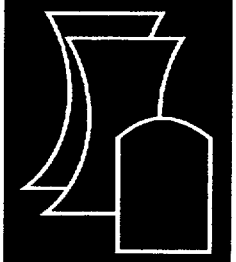
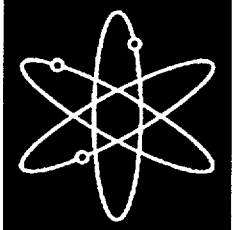
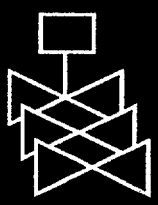
NUREG-0040
Vol. 23, No. 4







Licensee Contractor and Vendor Inspection Status Report

Quarterly Report
October – December 1999

U.S. Nuclear Regulatory Commission
Office Nuclear Reactor Regulation
Washington, DC 20555-0001

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A year's subscription of this publication consists of four quarterly issues.

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Licensee Contractor and Vendor Inspection Status Report

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October – December 1999

Manuscript Completed: June 2000
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Division of Inspection Program Management
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ABSTRACT

This periodical covers the results of inspections performed between October 1999 and December 1999 by the NRC's Quality Assurance, Vendor Inspection, Maintenance and Allegations Branch that have been distributed to the inspected organizations.

CONTENTS

INTRODUCTION

A fundamental premise of the U. S. 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 Federal government and nuclear industry have established a system for the inspection of commercial nuclear facilities to provide for multiple levels of inspection and verification. Each licensee, contractor, and vendor participates in a quality verification process in compliance with requirements prescribed by the NRC's rules and regulations (Title 10 of the *Code of Federal Regulations*). The NRC does inspections to oversee the commercial nuclear industry 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 quality verification programs.

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

The NRC 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 construction permits and operating licenses in vendor-related areas. These inspections are done to ensure that the root causes of reported vendor-related problems are determined and appropriate corrective actions are developed. The inspections also review vendors to verify conformance with applicable NRC and industry quality requirements, to verify oversight of their vendors, and coordination between licensees and vendors.

The NRC does inspections to verify 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 found, NRC ensures that affected licensees are informed through vendor reporting or by NRC generic correspondence such as information notices and bulletins.

This quarterly report 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 inspected. This information will also alert affected regional offices to any significant problem areas that may require special attention. This report lists selected bulletins, generic letters, and information notices, and include copies of other pertinent correspondence involving vendor issues.

INSPECTION REPORTS

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

November 8, 1999

Mr. Jon S. Rennie, Plant Manager
ABB Power T&D Company
North America Distribution Switchgear Group
Circuit Breaker Division
2300 Mechanicsville Road
P.O. Box 100524
Florence, SC 29501-0524

SUBJECT: NOTICE OF NONCONFORMANCE AND NRC INSPECTION REPORT NO. 99901256/1999201

Dear Mr. Rennie:

On September 27 through 30, 1999, NRC inspectors K. Naidu, S. Alexander, of this office, R. Bhatia of NRC Region I, and P. Fillion and N. Merriweather of NRC Region II, conducted an inspection at your facility. The inspection was to review ABB T&D's quality assurance program (and its implementation) intended to meet Appendix B to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50) in support of your supply of Type 5HK250 and K-Line circuit breakers to American Electric Power Company's D.C. Cook Nuclear Generating Plant; supply of spare and replacement parts to ABB Service Company, Cleveland, Ohio, and also directly to D.C. Cook in support of circuit breaker refurbishment being performed on site by personnel from the ABB Service Company shops in Charlotte (Matthews), North Carolina and Cleveland, Ohio; and supply of Type VHK(R) modular assemblies to the ABB Service Company Product Development Center in Cleveland. The inspectors also reviewed your program and its implementation established to meet the requirements of 10 CFR Part 21.

During this inspection, the NRC inspectors identified instances in which the implementation of your quality assurance program failed to meet certain NRC requirements. These instances may have contributed to deficiencies identified at D.C. Cook during receipt inspections of Class 1E circuit breakers you supplied and also resulted in inadequate corrective action for a previously cited violation. The specific nonconformances are cited in the enclosed Notice of Nonconformance and the details are discussed in the enclosed report. You are requested to 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.

In reviewing ABB's 10 CFR Part 21 program, the inspectors identified that certain records of evaluations and correspondence with licensees or affected purchasers required by Part 21 were not included in the documentation submitted to the inspectors for review and represented as being complete for the last five years. Also, not all of the notifications in the files submitted for review contained all of the information required by Part 21. These apparent deficiencies

may constitute minor violations of 10 CFR Part 21, pending your ability to produce the missing records and more complete correspondence. Therefore they were cited as Unresolved Items in the enclosed report.

In accordance with 10 CFR Part 2.790 of the NRC "Rules of Practice," a copy of this letter and its enclosures and your response will be placed in the NRC's Public Document Room (PDR). To the extent possible, your response should not include personal, private, proprietary or safeguards information so that your response can be placed in the PDR without redaction. However, should you find it necessary to include such information, you should clearly identify that which you desire not be placed in the PDR and provide the justification for withholding from public disclosure as delineated in 10 CFR 2.790.

The responses requested by this letter and the enclosed Notice of Nonconformance are not subject to the clearance procedures of 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, please contact Mr. Kamal Naidu at 301-415-2980/krn@nrc.gov or Mr. Stephen Alexander at 301-415-2995/sda@nrc.gov.

Sincerely,

Richard P Correia for

Theodore R. Quay, Chief
Quality Assurance, Vendor Inspection,
Maintenance and Allegations Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Enclosures: 1. Notice of Nonconformance
2. Inspection Report No. 99901256/1999201

NOTICE OF NONCONFORMANCE

ABB Power T&D Company, Circuit Breaker Division
Florence, South Carolina

Docket No. 99901256
Report No. 1999201

Based on the results of the Nuclear Regulatory Commission inspection conducted September 27 through 30, 1999, of activities supporting the manufacture of low and medium-voltage power circuit breakers, vacuum modular assemblies, and spare and replacement parts, it appears that certain of your activities were not conducted in accordance with NRC requirements.

A. Criterion III, "Design Control," of 10 CFR Part 50, Appendix B, states, in part, that design control measures shall include verifying the adequacy of design, including design reviews and/or a suitable testing program, that the verification must be performed by individuals or groups other than those who performed the original design, that design control measures shall be applied to delineation of acceptance criteria for inspections and tests, and that design 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.

Criterion V, "Instructions, Procedures and Drawings," of 10 CFR Part 50, Appendix B, states, in part, "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. Instructions, procedures or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Contrary to the above, ABB circumvented established design control measures by instituting a change to the specification for the control device gap for Type 5HK250 circuit breakers, which gap is defined in ABB Factory Specification TD-6931, without benefit of required design reviews, verification and approvals. The change was implemented without changing the factory specification in accordance with ABB engineering change procedures intended to implement design control measures. (99901256/1999201-03)

B. Criterion XVI, "Corrective Action," of 10 CFR Part 50, Appendix B, states, in part, that measures shall be established to assure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

Contrary to the above, ABB failed to ensure that adequate corrective action for a violation of 10 CFR Part 21, cited in the previous NRC inspection in that the posting required by 10 CFR 21.6 had been incomplete until September 27, 1999, and ABB had failed to obtain, or subscribe to, or maintain a subscription to NRC Publication NUREG-0040, that ABB committed to as part of its corrective action for the previous violation (99901256/1999201-04).

Enclosure 1

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, Quality Assurance, Vendor Inspection, Maintenance and Allegations Branch, Division of Inspection Program Management, 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.

Issued this, the 8th day of November, 1999
at Rockville, Maryland

U. S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR REACTOR REGULATION

Report No.:	99901256/1999201
	ABB Power T&D Company, Inc. North America Distribution Switchgear Group 2300 Mechanicsville Road P.O. Box 100524 Florence, SC 29501-0524
Contact Address:	Jon S. Rennie, Plant Manager
Telephone:	(843) 665-4144
Nuclear Industry Activity:	Manufacture of medium-voltage Type HK and vacuum circuit breakers and 600-V K-Line circuit breakers
Dates of Inspection:	September 27-30, 1999
Inspectors:	Kamalakar R. Naidu, Senior Reactor Engineer, NRR Stephen D. Alexander, Reactor Engineer, NRR Ram S. Bhatia, Reactor Engineer, RI Paul J. Fillion, Reactor Engineer, RII Norman Merriweather, Reactor Engineer, RII
Approved by:	Richard P. Correia, Chief Reliability and Maintenance Section, IQMB Division of Inspection Program Management Office of Nuclear Reactor Regulation

Enclosure 2

1. INSPECTION SUMMARY

On September 27-30, 1999, the NRC conducted an inspection at Asea Brown Boveri (ABB) Power Transmission & Distribution (T&D) Company, Inc., Distribution Systems Division, located in Florence, South Carolina, where ABB manufactures medium-voltage Type HK circuit breakers and vacuum circuit breakers and 600-volt-rated K-Line (metal-enclosed) circuit breakers. The inspection evaluated the ABB quality assurance (QA) program and its implementation in the design, qualification, and manufacture of these breakers and its program for implementation of 10 CFR Part 21. As part of the NRC circuit breaker task action plan, this inspection followed up on issues identified during an inspection at the Donald C. Cook Nuclear Generating Station (D.C. Cook) where ABB Service Company was performing breaker refurbishment services. Also, the inspection followed up on an inspection of ABB/Combustion Engineering, Nuclear Power (CENP), Windsor, Connecticut, which was performed to evaluate the actions taken to correct the failure of retrofit ABB vacuum circuit breakers at Baltimore Gas & Electric (BG&E) Company's Calvert Cliffs Nuclear Power Plant (Calvert Cliffs). The Calvert Cliffs issue will be pursued further in a future inspection at the ABB Service Company's Product Development Center (PDC) in Cleveland, Ohio, where the vacuum interrupters and their operating mechanisms made by ABB T&D, Florence, were converted for retrofit into existing GE Magne-Blast switchgear at Calvert Cliffs. The inspectors observed different circuit breakers in various stages of manufacture and testing and identified problems with the implementation of the ABB quality assurance program relative to 10 CFR Part 21, and to Criteria III, V and XVI of Appendix B to 10 CFR Part 50.

The inspectors also reviewed the actions taken to correct inspection findings identified in NRC Inspection Report 99901256/93-01, reviewed the manufacturing and repair records of two 4.16-kV, HK type circuit breakers that ABB had supplied to American Electric Power Company (AEP) for installation at D.C. Cook.

1.2 Violations and Nonconformances

1.2.1 Unresolved Item 99901256/1999201-01: Contrary to the requirements of 10 CFR 21.51, ABB T&D Co.'s Part 21 evaluation and notification files were determined to be incomplete, pending the vendor's location of the missing records (Section 3.1.3)

1.2.2 Unresolved Item 99901256/1999201-02: Contrary to 10 CFR 21.21(d)(4), not all required information was included in all notifications that were made pursuant to 10 CFR 21.21(d)(1), pending vendor location of complete correspondence. (Section 3.1.3).

1.2.2 Nonconformance 99901256/1999201-03: Contrary to the requirements of 10 CFR Part 50, Appendix B, Criteria III and V, ABB failed to properly change a factory specification. Also, the change was implemented without informing users. (Section 3.2.b)

1.2.3 Nonconformance 99901256/1999201-04: Contrary to the requirements of 10 CFR Part 50, Appendix B, Criterion XVI, ABB failed to take corrective action committed to for a previous violation in that ABB failed to maintain its subscription to NUREG-0040. Also, until the first day of the inspection, ABB had not posted its Part 21 procedures per §21.6(a) or the alternative notice allowed by §21.6(b). (Sections 2.1 and 3.1.1)

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

2.1 Violation 99901256/93-01-01 (Closed) Contrary to the requirements of 10 CFR 21.21(a), ABB T&D had failed to update its procedures adopted pursuant to the regulation since the substantial revision to Part 21 that became effective on October 29, 1991. Contrary to the requirements of 10 CFR 21.6(a), ABB T&D had failed to post the current revision of 10 CFR Part 21. During this inspection, the inspectors determined that the Part 21 procedures had been appropriately updated; although they contained some weaknesses as discussed in Section 3.1 below. When observed during this inspection, the current revision of Part 21 was posted along with Section 206 of ERA-1974 as required by §21.6(a). The ABB T&D procedures adopted pursuant to the regulation were not posted, but instead, as permitted by §21.6(b), there was a notice posted that described the procedures and stated where the procedures could be viewed as well as the title of the person to whom reports were to be made. However, the notice was dated September 27, 1999, the date the inspection began, and ABB admitted that neither the notice nor their Part 21 procedures had been posted previously; although, when inspected, the posting did contain at least the minimum elements required by §21.6; therefore the violation was considered corrected. Nevertheless, because neither the procedures, nor the notice had been posted prior to the inspection, and because ABB apparently had not followed through on all of their commitments for corrective action after the previous NRC inspection, the inspectors concluded that this constituted inadequate corrective action contrary to the requirements of Criterion XVI, "Corrective Action," of 10 CFR Part 50, Appendix B. Accordingly Nonconformance 99901243/ 1999201-04 was cited.

2.2 Nonconformance 99901256/93-01-02 (Open): Contrary to the requirements of Criterion V, of 10 CFR Part 50, Appendix B, ABB Circuit Breaker Division was not properly implementing its quality assurance procedures. The following examples were cited:

2.2.1 (Closed) Contrary to Paragraph 3.5 of ABB T&D Quality Assurance Procedure (QAP) 2.5, two nuclear safety-related suppliers had not been audited since 1991. During this inspection, the inspectors determined that current ABB procedures addressed supplier qualification and no further instances of untimely or missing supplier audits were noted; although one audit report reviewed in connection with another issue was of a broad-based programmatic audit and did not document supplier control of the specific attributes of interest of the supplied item. (See Section 3.4 of this report.)

2.2.2 (Closed) Contrary to Paragraph 4.4.9 of ABB's QAP 4.3, "Procurement Documentation Control System - General," Revision 1, dated October 29, 1992, ABB had purchased items from two vendors which were not listed on the Approved Vendors List and used the items in assembling nuclear safety-related circuit breakers. During review of material procurements in support of the manufacture of HK and K-Line breakers for D.C. Cook, the inspectors found no further instances of use of unauthorized sources. Disposition of the material in question and affected breakers was addressed during the previous inspection. The inspectors agreed that after this length of time with no reported failures attributable to material from the unauthorized vendors, ABB's position that final testing and successful service was evidence that the material in question was ultimately of acceptable quality was reasonable.

2.2.3 (Open) Contrary to Paragraph 3.1 of ABB's QAP 4.3, "Procurement Documentation Control System - General," Revision 1, dated October 29, 1992, ABB had not documented an evaluation to support the basis for inclusion of all vendors on its approved vendors list. This nonconformance was not reviewed during this inspection.

2.2.4 (Closed) Paragraphs 3.1.2 and 3.2.1 of ABB's QAP 7.1, "Receiving Inspection-Components," Revision 1, dated October 29, 1992, referenced "QAP 6.5," and paragraph 3.2.4.2 referenced "QAP 16.2." QAP 6.5 and QAP16.2 did not exist and therefore could not be followed. The inspectors determined that QAP 6.5 had been issued originally on April 12, 1992; therefore, it was in existence at the time of the previous inspection. Paragraph 3.2.4.2 of Revision E0 (current) of QAP 7.1 now referenced QAP 15.1, "Nonconforming Material."

2.2.5 (Closed) Contrary to Paragraph 6.2 of ABB's QAP 2.4, "Inspection and Test Personnel Qualification," Revision 1, dated October 29,1992, the log book in which job descriptions and certifications of qualifications of personnel were required to be recorded did not exist. The inspectors verified that in accordance with current procedures, these records are now kept in an electronic database.

3.0 FINDINGS AND OBSERVATIONS/REPORT DETAILS

3.1 Implementation 10 CFR Part 21

a. Inspection Scope:

The inspectors reviewed ABB's procedures adopted pursuant to 10 CFR 21.21(a), records required by §21.51, and examined the postings per §21.6. In addition, in order to evaluate ABB's identification of potential Part 21 issues under its quality assurance program, the inspectors reviewed ABB's procedures relating to nonconforming material under Criterion XV of 10 CFR Part 50, Appendix B, including handling customer complaints and equipment returned for repair/correction of problems, and procedures for corrective action under Criterion XVI of Appendix B.

b. Findings and Observations:

3.1.1 Posting per 10 CFR 21.6

ABB had properly posted Section 206 of the Energy Reorganization Act of 1974 and the latest version of 10 CFR Part 21 (1995) as required by §21.6(a), but had not posted the procedures adopted pursuant to §21.21(a); nor had they ever been posted according to the cognizant QA engineer. In addition, as allowed by §21.6(b), in lieu of the procedures, ABB had posted a notice that described the procedures and the regulation, stated where the procedures may be viewed (because the regulation was itself posted), and directed that reports be made to the QA manager. However, the notice was dated September 27, 1999, the first day of the NRC inspection and the QA engineer admitted that no such notice had been posted in lieu of the procedures previously.

The previous inspection had not identified the lack of posted procedures per §21.6(a) or the lack of the alternative notice allowed by §21.6(b), but apparently in posting the latest version of Part 21, and in preparation for this inspection, ABB discovered that neither the procedures nor an alternate notice was posted. Therefore, as posting each page of the procedure in the locked glass case used for the Part 21 posting was impractical, ABB prepared and posted the alternate notice as described above.

In reviewing the posted notice, the inspector noted that the description of the procedures was little more than a statement of their purpose. Without explaining the expectations of ABB management with regard to reporting by employees of problems identified during manufacturing, inspection and testing, or reported from the field, which could adversely affect basic components (safety-related equipment) supplied to NRC-licensed facilities, the notice was not conducive to meaningful compliance. After discussing this with ABB, the inspectors noted that the QA Engineer made the posted notice considerably more effective by revising it to state the kinds and sources of information relating to potential deficiencies or concerns about Class 1E and/or "N"-designated (nuclear) items that should be reported by employees and that they should be reported to the "Total Quality Manager" or the QA Engineer.

As part of the corrective action for the violation identified in the 1993 NRC inspection report in which ABB had not posted the latest version of Part 21 and had not updated its procedures to reflect the latest version, ABB had committed to subscribing to the NRC's quarterly publication NUREG-0040, "NRC Licensee Vendor and Contractor Inspection Status Report," in which revisions to Part 21 were published in addition to their being published in the *Federal Register*. However, the ABB Florence facility did not have NUREG-0040, nor were they receiving it, nor were they aware of it. If ABB Florence had ever subscribed to NUREG-0040, they had not maintained the subscription. As stated in Section 2.1, this was inadequate corrective action contrary to Criterion XVI of 10 CFR Part 50, Appendix B, and was cited as Nonconformance 99901256/1999201-04.

3.1.2 Procedures Adopted Pursuant to 10 CFR 21.21(a)

ABB's Part 21 procedures were contained in QAP 15.5, "Reporting Product Defects." The latest revision, Revision E01, was issued July 30, 1999. The inspectors determined that the procedures contained all the provisions required by §21.21(a) to be included in procedures adopted pursuant to the regulation. In addition, the inspectors found that the procedures were strengthened significantly by inclusion of other provisions to implement and explain in terms relevant to ABB Florence other Part 21 requirements such as, for example, notifying affected licensees or purchasers in accordance with §21.21(b) of deviations that ABB determines it cannot evaluate in accordance with §21.21(a)(1). However, the procedure also contained some weaknesses such that in certain cases, following the procedures verbatim without reference to Part 21 itself could lead ABB or allow ABB to fail to meet certain requirements of Part 21 that are not explicitly required by the regulation to be included in the procedures adopted to implement it. These weaknesses were discussed with the vendor as described in the following observations:

- The Part 21 reporting process was uniquely strengthened by including the procedures adopted pursuant to the regulation, QAP 15.5, within the group of procedures established pursuant to Criterion XV, "Control of Nonconforming Material," of 10 CFR Part 50, Appendix B. However, this advantage was diminished because QAP 15.5 did not reference the other relevant Criterion XV (and also Criterion XVI, Corrective Action") procedures such as QAP 15.1, "Nonconforming Materials" (covers nonconformance reports (NCRs)); QAP 15.2, "Production Stop Notice,"QAP 15.4, "Returned Goods Authority"; or QAP 16.1, "Corrective and Preventive Action," as prescribing activities in which potential deviations and/or failures to comply in basic components already or previously supplied to NRC-licensed facilities may be identified. QAP 15.5 also did not address other external sources of information on potential deviation or failures to comply in shipped basic components (e.g., NRC generic communications, 10 CFR Part 21 notifications or other vendor product bulletins, etc.).

- Weak procedural coordination and interface was not conducive to program effectiveness. QAPs 15.1, 15.2 and 15.4 did not provide for screening of documentation relating to nonconforming material for potential Part 21 applicability (or referring to QAP 15.5 to do so), whether information indicating the existence of potential deviation or failures to comply in shipped basic components was internal or external. QAP 16.1, governed documentation and tracking of corrective action by Corrective Action Requests (CARs). Paragraph 16.1.3.8 stated that the QA manager will determine the impact [*of the problem documented in the CAR*] on products supplied to nuclear utilities in accordance with 10 CFR Part 21. This cross reference was a programmatic strength, but the lack of any reference to Part 21 screening on the CAR form or the Corrective Action Summary Log form was not conducive to consistent implementation of this provision. QAP 16.1 also governed the Internal Complaint Review Process (ICRP) and the Customer Complaint Review Process (CCRP), but the guidance for neither process mentioned screening for Part 21 applicability. Sources of potential Part 21 issues would include ABB tests, inspections, audits, surveillances, commercial-grade surveys or source verifications, which would be captured under QAP 15.1 (NCRs) or QAP 16.1 (ICRP), from information received from the field (e.g., customer/user problems), captured under QAP 15.4 (RGA) and QAP 16.1 (CCRP); or other outside sources (e.g., NRC generic communications, 10 CFR Part 21 notifications or other vendor product bulletins,).

- In terms of corrective action incidental to the discovery of deviations and/or failures to comply (in addition to reporting requirements), ABB did not cross reference the other procedures mentioned above (and also QAP 15.3, "Scrap Procedure") in QAP 15.5 for disposition of the actual material in question, i.e., basic components with deviations and/or failures to comply that may have been identified initially under the Part 21 program itself, in parallel with the process of their being evaluated per 10 CFR 21.21(a)(1), reported to the NRC per 10 CFR 21.21(d) or reported to affected licensees or purchasers per 10 CFR 21.21(b).

- Specific detailed observations on the content of QAP 15.5 itself were as follows:

  The stated purpose of QAP 15.5 (Paragraph 15.5.1) was to define a system for evaluating and reporting deviations and failures to comply with the "Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974 (10 CFR Part 21)"; whereas the list in 10 CFR Part 21 of those things with which something may fail to comply does not include the Energy Reorganization Act of 1974 or 10 CFR Part 21 itself, but does include "any rule, regulation, order, or license of the Commission" which were omitted from the QAP 15.5 statement of purpose.

  The scope of QAP 15.5 defined in Paragraph 15.5.2 contained a good working definition of basic components in stating that the procedure is applicable to Class 1E, i.e., safety-related equipment (which it defined correctly) and services, but did not equate them to or even use the term "basic component". However, subsequent paragraphs referred to basic components without explaining that they are safety-related equipment and services; i.e., without explaining the special meaning of this otherwise non-descriptive term within the context of 10 CFR Part 21.

  Paragraph 15.5.3.1 acknowledged that ABB was a supplier of basic components and cited the requirement in 10 CFR 21.21(a)(1) for evaluation of deviations or failures to comply within 60 days of discovery, but the procedure did not explain the special meaning and specific elements of this term or refer to its definition in §21.3. Paragraph 15.5.3.1 also cited the §21.21(a)(2) requirement for an interim report within 60 days, but did not state that it must be submitted, if required, within 60 days of discovery as well.

  Paragraph 15.5.3.2 provided for informing purchasers or affected licensees when ABB determined that it could not "perform the evaluation to determine if a defect exists," which implemented §21.21(b). Although §21.21(a) does not at present explicitly include this provision among those things required to be included in Part 21 procedures, this provision made the procedure much more effective because it addresses the vast majority of cases for any supplier of basic components except perhaps the NSSS suppliers of the affected plant types, affected architect/engineers or affected licensees themselves, who would be expected to be capable of performing such an evaluation. However, the added strength was diminished because the language used did not clearly state the requirement in §21.21(b) to inform purchasers or affected licensees of the deviation or failure to comply in question, not just that it cannot perform an evaluation, which is of secondary importance, being merely the reason why the matter is being referred to the affected licensees or purchasers. Although explaining a deviation itself was implied by the phrase: "...so that purchasers or affected licensees may evaluate the deviation", the paragraph did not include failures to comply.

  This observation is not intended in any way to discourage including things in the Part 21 procedures that are requirements of Part 21, but not specifically required to be in procedures. On the contrary; all applicable Part 21 provisions

must be complied with and some might otherwise be overlooked without direct reference to the regulation itself unless included in the procedures. Rather, the observation was only intended to convey the caution that in adapting the language of Part 21 to more recognizably reflect the specific circumstances and common terminology of a particular organization, which may be more conducive to meaningful compliance, the procedure must still accurately reflect the intent of the Part 21 provisions it is intended to implement, if not restating them verbatim. Otherwise, an incorrectly or ambiguously worded procedure, if followed strictly as written without reference to Part 21 itself, could allow or even mislead the organization into violating or failing to meet certain Part 21 requirements.

Paragraph 15.5.3.3 apparently was intended to implement §21.21(a)(3) in a manner relevant to the ABB Power T&D Company by designating the "President of ABB Power Distribution Company or his designated representative" as the director or responsible officer that §21.21(a)(3) requires be notified of a defect or failure to comply associated with a substantial safety hazard within five working days of completion of the evaluation. However, the paragraph did not state that any so-called designated representative must him or herself also be a director or responsible officer as defined in Part 21; nor did it specifically designate an alternate who is also a director or responsible officer. Further, it was not clear to the inspectors that the title "President of ABB Power Distribution Company" as stated in the procedure was exactly consistent with the corporate name or organization. Finally, the paragraph failed to mention informing the designated director or responsible officer of failures to comply associated with substantial safety hazards in addition to defects.

Paragraph 15.5.3.4 implemented §21.21(d) and included the provision of §21.21(d)(5) for reporting by a designated representative (not necessarily another director or responsible officer). This was a strength, although the specific addressees for NRC notification were not given or referenced.

Section 15.5.4.1 was a significant strength, first, in that the first paragraph recognized the diverse sources of supply (other ABB divisions and outside vendors) for manufacturing ABB Power T&D Florence products and took the initiative to assign ABB Florence with the responsibility for coordinating the evaluation, notification and resolution with the NRC and the customer of problems identified in the field with ABB Florence products. However, while assuming this responsibility is commendable, the inspectors cautioned ABB that some of its suppliers (to the extent that they may supply basic components) as well as its customers (to the extent that they may use or also supply basic components) continue to be subject to Part 21 requirements. The second paragraph prescribed cooperation among the ABB Florence engineering, QA and operations departments in performing evaluation, an important concept. The third paragraph acknowledged the same responsibilities as the first, but for products from outside vendors. However, it was not made clear that for those commercial-grade items that ABB dedicates, assuming Part 21 responsibilities as the dedicating entity is required by §21.21(c)

Paragraph 15.5.4.5 was a significant strength in that it recognized the need to determine when a defect is identified in a product whether any similarly affected basic components could have reached purchasers or NRC-licensed facilities; although it should have included deviations and failures to comply as well.

Paragraph 15.5.4.6 provided some clarification of ABB's implementation of §21.21(a)(3) and §21.21(d) that was somewhat ambiguous in Paragraphs 15.5.3.3 and 15.5.3.4 respectively; although it did not provide for alternate directors or responsible officers to whom reports of defects or failures to comply related to substantial safety hazards may be reported in order to assure the ability to comply with §21.21(a)(3) should the primary designated officer not be available.

Paragraph 15.5.6.1 under QA responsibilities assigned ABB Florence QA the lead in performing evaluations of deviations to identify defects. Germane, but not mentioned was the evaluation of failures to comply to determine if they are related to substantial safety hazards.

Paragraph 15.5.6.3 established Part 21 record requirements. It required the QA manager to maintain a file "representing the product defect", but records of evaluation of and/or notifications sent to purchasers or affected licensees of deviations and/or failures to comply, per se, as required by 10 CFR 21.51 were not mentioned. In addition, although the QA manager stated that it was ABB's practice to maintain such files indefinitely, the §21.51 requirements to maintain records relating to evaluation and notification of deviations and failures to comply for a minimum of 5 years and to maintain records of the purchasers of basic components for a minimum of 10 years after delivery were also not mentioned.

Section 15.5.8 provided guidance for addressing and documenting during performance of §21.21(a)(1) evaluations (called "potential defect investigations") the types of information required by §21.21(d)(4) to be included as a minimum in notifications to the NRC required by §21.21(d)(1). However, many of the subparagraphs in Section 15.5.8 described information related to defects only and, except for 15.5.8.6 and 15.5.8.7, did not include failures to comply. Because this was the only section in which any specific evaluation guidance was provided, the inspector looked for, but did not find in the procedures, an explanation or examples of failures to comply relevant to ABB's scope of activities (e.g., seismic requirements, license technical specifications, etc.). Also absent as evaluation guidance was an explanation of deviations as departures from technical requirements in procurement documents that could be considered defects due either to their creation of substantial safety hazards or their leading to violation of license technical specification safety limits (e.g. exceeding core thermal limits due to loss of cooling capability. etc.).

The procedure also did not explain that for purposes of identifying deviations, technical requirements need not be explicitly included or referenced in procurement documents, but could be considered to be invoked implicitly. For example, specifications in published technical data upon which applications engineers rely in specifying equipment by type or model would be presumed to

be invoked by the procurement documents. Specifications, standards or other procurement document requirements certified to in certificates of conformance issued by ABB with the supplied equipment or parts could even more clearly be presumed to be invoked in the procurement documents.

In response to the discussion of the forgoing observations by the inspectors, ABB committed to revise its Part 21 procedures accordingly and also to improve procedural interfaces by revising its procedures relating to control of nonconforming material, corrective action, and complaints or returns from the field to ensure that problems identified under those procedures are effectively screened for potential Part 21 applicability.

3.1.3 Records of Part 21 Evaluations and Notifications

The inspectors requested the ABB T&D Part 21 evaluation and notification files for the previous five years as this is the minimum retention requirement in §21.51. Requested especially were any that may have resulted in no outside notifications. ABB explained that its official Part 21 evaluation and notification files were kept at the Switchgear Division facility in Sanford, Florida, so Sanford faxed copies to Florence for the NRC inspectors' review. The group of files produced was represented as complete, i.e., all evaluations and notifications, dating back to 1993. However, without a log of all Part 21 issues, and without screening all potential source documents such as NCRs, CCRPs, RGAs, CARs, etc., the inspectors could not verify that all problems or issues that would have required at least a Part 21 applicability screening, if not an actual evaluation and possible notification, were captured in the evaluation files presented. Therefore, the review was limited to determining whether the evaluations reviewed were technically sound and whether all required notifications were made and included all required information.

The group of Part 21 evaluation and notification files reviewed included 1 file from 1993, 3 from 1994, 4 from 1995, 2 from 1996, and 1 from 1997. The files are required by §21.51 to include evaluation records and any customer notifications. The inspectors found that some included lists of affected customers and that all the records asserted that the NRC and affected customers had been informed; so an assessment of the rationale for not making a report was rendered moot. However, in two cases, as discussed below, copies of the actual letters that, according to annotations in the evaluation record, had been sent to affected customers and the NRC were not present. Therefore, the inspectors could not verify that the notifications were timely or that they contained all the information required by §21.21(d)(4). In addition, in seven cases, there were no records of the evaluations that resulted in the Part 21 notifications. The 1993 file contained a record of evaluation and a copy of a notification letter to the NRC. The NRC notification was typical of most of the others in that it stated that a copy of it was being sent to affected customers, so that the NRC notification presumably also represented the notification to customers. There were no instances among the files reviewed of notifications to purchasers or affected licensees only per §21.21(b) of unevaluated deviations or failures to comply. The lack of records of evaluations in seven Part 21 files was an apparent violation of 10 CFR 21.51(a)(1); so ABB undertook to locate the missing records.

Among the two files with records of evaluation, but no copies of the notifications, the record of the evaluation of a report of oversized control wiring lugs found on ABB breakers at Southern California Edison's San Onofre Nuclear Generating Station had a margin annotation indicating that the issue was reported to the NRC and "distribution list", presumably affected customers, on May 10, 1995. As discussed further below, the evaluation record itself was not dated (completion date), but it stated that the defect had been discovered on March 14, 1995. Therefore, it appeared (but could not be confirmed without copies of the notification letters) that the 60-day maximum evaluation period requirement of §21.21(a)(1) had been met. The record was signed by the Vice President and General Manager, but his signature was not dated, so it could not be verified whether any director or responsible officer (or in particular, the "President of ABB Power Distribution"[sic] as required by QAP 15.5 had been notified of the results of the evaluation (i.e., existence of a defect in basic components supplied to an NRC-licensed facility, namely San Onofre, at least) within the 5 working days required by §21.21(a)(3). The fact that this file did not include the notifications was a violation of 10 CFR 21.51(a)(2). In addition, the lack of completion dates on the records of evaluation (and the lack of a requirement for this in QAP 15.5) would make it difficult to determine precisely within 60 days of the discovery date that was present in one case until what date the record must be retained as a minimum.

In another instance, the file on cracked and broken secondary disconnect strips, discovered in June 1995 (no exact date, also at San Onofre) contained a copy of a cover letter giving a point of contact and indicating that a Part 21 notification was attached. The cover letter, dated September 19, 1995, had an annotation indicating that it accompanied "all Part 21 reports" and that they were mailed on September 21, 1995. The record of evaluation was again not dated, nor were the review signatures, however, if the evaluation took the full 60 days from an assumed discovery date of 30 June, 1995, and if the director or responsible officer was notified of the defect five working days later, then it appeared, but could not be verified, that the notifications required by §21.21(d) had been sent within the time limit specified in §21.21(d)(3)(ii). However, since the actual notification was not on file, this was another example of the violation of 10 CFR 21.51(a)(2). ABB undertook to locate the missing notifications.

Finally, not all of the notifications reviewed contained all of the information required by §21.21(d)(4). For example, a notification to the NRC, dated June 28, 1995, did not indicate the date the information was obtained [21.21(d)(4)(v)], nor did it indicate the number and location of all affected basic components [21.21(d)(4)(vi)]. This was the case with at least two other notifications as well.

c. Conclusions

The inspectors concluded that the ABB Part 21 procedures complied with §21.21(a). The inspectors further concluded that the ABB program for implementation of 10 CFR Part 21 was strengthened significantly by locating the procedures among those addressing nonconforming material and by including provisions in the procedures to implement other Part 21 requirements in terms meaningful to ABB employees. However, related procedures were not well cross-referenced and the Part 21 procedures themselves contained some weaknesses such that in certain cases, following them verbatim without reference to Part 21 itself could lead or allow ABB to violate Part 21.

On the basis of ABB's failure to have a complete Part 21 posting until the first day of this inspection and its apparent failure to have obtained and/or maintained a subscription to NUREG-0040 as committed to as part of the corrective action for a previous Part 21 violation, the inspectors concluded that ABB's corrective action for that previous violation was inadequate and thereby constituted a nonconformance with respect to the requirements of Criterion XVI, "Corrective Action," of 10 CFR Part 50, Appendix B. Accordingly, Nonconformance 99901256/1999201-04 was cited.

On the basis of ABB's Part 21 evaluation records and notifications files presented for review not containing some of the required documents, the inspectors concluded that ABB T&D's Part 21 records did not meet the requirements of 10 CFR 21.51. The inspectors attributed this in part to the weaknesses in the Part 21 procedure regarding documentation and retention of documentation, as well as inconsistent compliance with some of those documentation-related procedural provisions that did exist. However, the inspectors further concluded that there were no identified defects or failures to comply associated with substantial safety hazards that did not appear to have been reported either to the NRC or to purchasers and affected licensees; although not all the notifications could be verified and not all of them were complete. Finally, the inspectors concluded that with regard to the records reviewed, ABB's technical corrective actions appeared to be reasonably appropriate and complete. The lack of complete Part 21 files contrary to 10 CFR 21.51 was cited as Unresolved Item 99901256/1999201-01, pending the vendor's location of the missing records. The lack of complete information in several of the notifications contrary to 10 CFR 21.21(d)(4) was cited as Unresolved Item 99901256/1999201-02, pending vendor location of complete correspondence.

3.2 Manufacture of Circuit Breakers for D.C. Cook

3.2.1 Review of Records for Breaker Serial No. CCN 0108001-010897

a. Inspection Scope:

In order to evaluate the effectiveness of ABB T&D QA controls over its manufacturing process, the inspectors reviewed the procurement, manufacture, testing, shipment and repair process for new Type HK circuit breakers. Recent purchases by AEP for D.C. Cook of two ABB 4.16-kV Type 5HK 250 breakers were used as a vehicle for this review. Areas covered included handling of incoming customer procurement documents, review of original specifications, the material requirements planning (MRP) process, preparation of "Job Packs," purchased parts, raw materials and services, process controls, and final testing. With regard to purchased materials, the inspectors focused on supplier documentation (certificates of conformance (CoCs), certified material test reports, packing lists. etc.) and dedication of commercial-grade Items (CGIs). The dedication review focused on receipt inspection and testing and final testing, including selection of critical characteristics, verification methods and acceptance criteria, supplier audits/surveys, and CoCs to the customer.

b. Findings and Observations

AEP issued PO No. 66132-040-7x, dated March 31, 1997, to ABB Power T&D Company, Columbus, Ohio (local sales office) for one ABB, 4.16-kV, Type 5HK250, Model 03, 250 MVA, 2000 amp, circuit breaker. The PO specified that the breakers should meet the same specifications as the original breakers supplied in 1971, and indicated that it was a nuclear safety-related procurement, imposed a QA program based on 10 CFR Part 50, Appendix B, and stated that 10 CFR Part 21 was applicable. The ABB Columbus sales office passed the PO to ABB T&D, Sanford where the original specifications were researched and verified. This information was then given to the ABB T&D Circuit Breaker Division in Florence. ABB Florence prepared job pack No. CCN 0108001-010897. The job pack serves as a shop traveler which follows the breaker throughout production and testing and contains QA/QC records, bill of material, etc. The breaker was completed and successfully tested on August 21, 1997. It was shipped to DC. Cook on August 29, 1997 with a CoC of that date. On January 28, 1998, AEP notified ABB, Florence of the following problems it found with the breaker:

1. All three arc chutes had cracks, misaligned bundles and mixed hardware.

2. The phase 2 primary disconnect finger had bare copper visible in one area.

3. Cadmium plating was damaged and worn on several bolt heads.

4. Phase 2 lower lead assembly was marred at pivot point.

5. Control relay was out of adjustment (improper gap).

6. Racking mechanism is out of adjustment.

7. Miscellaneous hardware and other materials found packed with the breaker.

As a result of these findings, ABB Florence issued returned goods authorization (RGA) No. 43803 to AEP to return breaker Serial No. CCN 0108001-010897 for repair. ABB performed a receipt inspection and confirmed the AEP findings. ABB's explanations and/or corrective actions were as follows:

1. ABB repaired and replaced the arc chutes as necessary.

2. ABB replaced the deficient contact finger. The ABB Returned Goods Supervisor (RGS) explained that the bare copper area on the Phase 2 primary disconnect finger did appear to have been scraped such that the copper was showing through the silver plating. Discussions of this condition with ABB staff confirmed that the apparent wear pattern was not really consistent with that expected on a breaker that had been simply racked in and out many times which would typically be less severe, more even (affecting all the fingers) and more of a burnished silver rather than scraped appearance. It would also not be consistent with a new breaker. Rather, the location, orientation, shape and size of the bare area suggested damage when being racked in not exactly straight, without lubrication of the primary disconnects or damage by mishandling. ABB also allowed that

the affected finger might not have been adequately plated, although the wear pattern was less consistent with that explanation. The inspectors also explored the possibility that an old or used finger might have been installed on the breaker, but the way that replaced parts from breakers returned for repair are segregated (mostly scrapped and recycled), the way new materials were handled and the way the assembly process is organized made this scenario very unlikely.

3. Some bolt heads did have some distortion of the finish during assembly. The RGS said that the chromate finish appeared to be slightly blistered, but the bolts still had their zinc coating. ABB did not replace the bolts because their condition did not affect the function or reliability of the circuit breaker, particularly in their relatively clean and dry nuclear plant environment.

4. The center phase lower lead assembly was confirmed to have a gouge on it. The RGS demonstrated that how during assembly, the movable bridge (moving main contact arm) may have accidentally fallen forward, and caused the gouge. ABB failed to identify this deficiency during the final inspection. ABB replaced this part.

5. With regard to the insufficient gap between the control device lever and the limit switch crank, the inspectors learned that ABB engineers had reduced the allowable range of this from 0.060-0.090" to 0.010"-0.090" for manufacturing flexibility and to avoid an excessive gap which might lead to improper operation of the control device. However, the inspectors found that the change had been effected by the cognizant product engineer simply writing what he called an "errata" for the 5HK instruction book (IB 6.2.1.7D) and instructing the factory workers to use the new gap without changing the governing factory specification (TD 6931) through the engineering change notice process and without informing customers. This issue is also discussed in section 3.2.2 of this report.

6. ABB had determined that the out-of-adjustment condition of the racking mechanism was that the gap between the manual trip bell crank assembly (Part #191725K02) and the blocking lever extension (part # 192294B00) was large enough to defeat the rack-out interlock which is intended to prevent racking the breaker out without tripping it. The necessary adjustments were made.

7. The records indicated that ABB had successfully retested breaker and shipped it back to D.C. Cook.

On August 26, 1998, DC. Cook notified ABB that it received the recently repaired breaker with shipping damage. ABB authorized D.C. Cook to return the breaker again using RGA 43942. The reported shipping damage was unique because the outside container did not exhibit any obvious signs of damage though one side of its contents had indeed suffered some damage. The RGS showed the inspector a similarly damaged breaker and explained that during transhipment, a heavy weight had been placed on one side of the breaker carton which caused one side of the breaker's insulation barrier to buckle without obvious visible damage to its carton. ABB believed the same thing had happened to D.C Cook's breaker. ABB repaired breaker, retested it and returned it to Cook once again. The damage was as follows:

1. The fiber-glass insulation barrier assembly directly behind the front cover was cracked in the top right hand corner.

2. The strap which attached two insulating pole structures (called "chair moldings") was cracked. Damaged chair moldings were replaced.

3. The epoxy attaching the flux shield to the inter-phase barriers had separated. ABB re-expoxyed and sealed the flux shield.

4. ABB replaced the bent front panel.

c. Conclusions

On the basis of review of the manufacturing and testing records for 5HK250 breaker serial number CCN0108001-010897; inspection of the returned goods area, procedures and process; inspection of the material receiving, production and testing areas and process; review of material procurement, receipt and inspection documentation; interviews with ABB personnel and examination of equipment and parts; the inspectors concluded that the breaker had been manufactured with some quality deficiencies, but that they had been adequately corrected. The inspectors further concluded that when the breaker was returned to AEP it suffered damage during shipment which ABB also corrected satisfactorily. However, the inspectors were not convinced that ABB had fully determined the root causes of some of the deficiencies (where possible) and hence, had not yet formulated preventive measures as applicable. The inspectors also concluded that ABB could improve its records handling practices in some areas as the documents associated with the repairs (as well as some others) were not readily retrievable.

With regard to the change to the control device gap, the inspectors concluded that it had been instituted without properly changing the controlling design and/or manufacturing drawing (Factory Specification TD-6931) through the engineering change notice (ECN) process prescribed in Standard Practice Procedures 600-070, "Design Control and Review" (Revision 3) and 600-050, Engineering Change Notices" (Revision 8); nor had ABB notified its customers of the change at the time of the inspection. The manner in which the change to the control device gap specification was instituted was contrary to Criterion III, "Design Control," of 10 CFR Part 50, Appendix B and to the governing ABB procedures; hence, also contrary to Appendix B Criterion V, "Instructions, Procedures and Drawings" and cited as Nonconformance 99901256/1999201-03.

3.2.2 Review of Records for Circuit Breaker Serial No. CCN 0547002-010798

a. Inspection Scope:

The inspectors reviewed the requirements that AEP imposed in its purchase order (PO) 66147-062-8x, dated May 13, 1998, to ABB Power T&D Company, Field Marketing Office (Columbus, Ohio) for one 4.16-kV Type 5HK250, 2000-ampere-rated circuit breaker, and all records associated with manufacturing, testing, and subsequent repair of the breaker supplied under that PO.

b. Findings and Observations:

PO 66147-062-8x specified Model No. 6 35 222-888-03 (00) (16) (34) (64) for the 5HK breaker and required ABB to provide a Certificate of Conformance (CoC) with the customary identifying information, e.g., PO No., Item No., description, and shop order number, attesting to the new circuit breaker's being qualified to the same requirements as those supplied under ABB's original D.C. Cook shop order, No. 33-44322, dated December 1971.

After reviewing the original order, Sanford placed an order for the breaker on Florence. On June 3, 1998, ABB Florence prepared what it calls a "Job Pack" (No. CCN 547002-010798). According to the manufacturing records, assembly of this breaker commenced on June 29, and the breaker was completed on July 02, 1998. A quality-control check list dated June 30, 1998, documented the satisfactory results of the quality control inspection of the breakers' eleven subassemblies. A medium-voltage test data sheet, dated July 24, 1998, documented successful completion of production testing prescribed by the current effective edition of Standard C37.09 of the American National Standards Institute (ANSI) and the Institute of Electrical and Electronic Engineers, Inc. (IEEE).

ABB, Florence, issued a CoC, dated July 24, 1998, certifying, that the breaker met the AEP PO requirements as well as the applicable industry standards. According to the records, an AEP QA inspector was supposed to inspect the breaker and discuss quality issues on the previously supplied 5HK250 (No. CCN 010897). On July 31, 1998, the 4-kV HK circuit breaker was released for shipment by the AEP representative. Upon receiving the breaker at D.C. Cook, AEP performed a receipt inspection and identified the following adverse findings:

1. The gap between the breaker's control relay lever and the limit switch crank was 0.010" instead of between 0.060" and 0.090" as specified in IB 6.2.1.7D, "Installation/ Maintenance Instructions Medium-Voltage Power Circuit Breakers,"(See Section 3.4)

2. The upper phenolic support between the phase 2 and phase 3 pole structures (chair moldings) appeared to be cracked.

3. The "angle iron" under the breaker frame was held with only one loose bolt and appeared to be bent.

4. The breaker had a locking device installed on it which was not on the original breaker.

5. The breaker appeared to have sustained shipping damage.

AEP completed the required information on a serialized Returned Goods Authority form provided by ABB and returned it along with the breaker to the Florence factory. Upon receipt of the breaker, ABB Florence issued Warranty Work Order No. CFR 0779 to repair the breaker. The Florence Returned Goods Department inspected the breaker and documented the following conditions:

1. The control device gap was confirmed to be 0.010" instead of 0.060" - 0.090". As discussed above regarding the other D.C. Cook breaker, the NRC inspectors determined that the factory had set the gap in accordance with the so-called "errata" for IB 6.2.1.7D, dated October 9, 1998.

2. The upper phenolic spacer between the phase 2 and phase 3 chair moldings was confirmed to be cracked, but it was the only one found to be damaged. ABB believed that the spacer was cracked during shipment. Once cracked, the spacer became loose and no longer maintained pole spacing and alignment. The cracked spacer was replaced.

3. The so-called angle iron under the frame (actually called the interference bracket) was confirmed as being held by only one of its two bolts which was loose. The bracket is a safety device to prevent a 4-kV rated breaker from being inserted into switchgear of a different voltage class. The loss of the other mounting bolt allowed the interference bracket to swing to one side making it appear to be bent. ABB properly re-fastened the bracket.

4. The breaker was confirmed to have a locking device installed on it which allows for the installation of a pad lock to prevent unauthorized operation of the breaker. The provision for a locking device is standard. ABB could only suppose that AEP had removed the padlocks and locking devices on the original breakers when they were installed in 1970s; so that the present D.C. Cook staff were not aware that the breakers normally came with locking devices.

After completing repairs on the breaker, ABB Florence issued a revised CoC dated October 9, 1998, certifying that breaker Serial No. CCN0547002 - 010798 met all the applicable requirements. ABB Sanford, Florida issued another CoC dated November 5, 1998, again certifying that the breaker had been manufactured in accordance with the requirements of the original AEP PO. The repaired breaker was returned to D.C. Cook.

c. Conclusions

On the basis of the manufacturing and repair records, interviews with factory workers, examination of the facilities and review of procedures, the inspectors concluded that the new breakers that ABB had manufactured and shipped to D.C. Cook did have some deficiencies in quality and workmanship and one had suffered damage, apparently from shipping and/or handling. As discussed in Section 3.2.1 above, the inspectors further concluded that the improperly instituted change in the control device gap set by the factory workers in accordance with the instructions by the cognizant engineer constituted a nonconformance with respect to Criterion III, "Design Control" of 10 CFR Part 50, Appendix B, because, in effect, a design change had been instituted without proper (and documented) engineering review and approval and without proper (and documented) design verification. The change was also contrary to Criterion V, "Instructions, Procedures and Drawings," because the change was made in manner not authorized by ABB procedures. Accordingly, Nonconformance 99901256/1999201-03 was cited.

With respect to the disposition of non-conforming material, either rejected during production or removed from breakers returned for repair, the inspectors concluded that these parts appeared to be consistently dispositioned in accordance with standard industry practice. Damaged or substandard production parts were captured (with a few exceptions due to sampling) and either reprocessed to meet standards if possible or, like damaged, substandard or worn parts from relatively new breakers under warranty returned for repair, deficient parts would be scrapped and the material recycled.

Finally, the inspectors concluded that breakers that have been in service for some time are sent to one of the ABB Service Company or other repair shops for repair or refurbishment. The factory did not apparently suffer from lack of timely availability of new materials and purchased parts, nor was their any significant time pressure to fill orders because of backlog or excessive work load. The factory had suffered some degradation of quality, but appeared to be genuinely concerned with improving and maintaining high quality as well as with customer perception of quality.

3.3 Replacement Parts for the D.C. Cook Breaker Refurbishment Project

a. Inspection Scope:

Using the D.C. Cook circuit breaker refurbishment project as a vehicle for review, the inspection of ABB T&D's spare and replacement parts business included review of records and interviews with cognizant personnel and touched on the following areas:

- Handling of customer orders and translation of customer requirements into job packs and procurement documents for purchased parts, materials and services
- Procurement and dedication of commercial-grade items; including selection of critical characteristics, verification methods, acceptance criteria, sampling and traceability
- Subsupplier Audits and Commercial-Grade Surveys
- Receipt Inspection and testing, handling of nonconforming material
- Manufacturing, in-process and final inspection and testing

b. Findings and Observation:

During the review of receipt inspection records for selected purchased parts, the inspectors found the following:

- On the QC Receipt Inspection Card for gear blanks for closing spring charging ratchet wheels, the concentricity of the hole with the perimeter was not specified to be checked during receipt inspection, yet the outside diameter was a finished dimension; so if the center hole is not centered, then tooth cuts could be shallow on one side, too deep on the other.

- On the QC Receipt Inspection Card for Arc Chutes which are relatively complex parts, there was no requirement to check them against applicable drawings

- The receipt inspection card for needle bearings had no direction to remove lubricant or preservative they come packed in and to repack them with Anderol 757.

- On each QC receipt inspection card, critical characteristics, verification methods and acceptance criteria needed to be hand written. The inspector was concerned that this process was conducive to the omissions noted and not conducive to effective, consistent control of purchased material. The vendor acknowledged the observed deficiencies, initiated corrective action, and agreed to consider developing standard cards (perhaps computer generated) with preprinted attributes, acceptance criteria, etc. for each type of part or raw material inspected. Then only the actual inspection results, measurements, etc. would be handwritten. This would also alleviate the need to have engineering verify the pre-positioned information on each new card.

- Electrical and performance testing of relatively complex subcomponents like the control devices, auxiliary switches, and Ryobi closing spring charging motors was being done at Florence only when those items were installed in finished breakers. For spare and replacement items, ABB had, in effect, been taking credit for sampling, i.e., the performance of the parts installed in finished, tested breakers. However, even at what amounted to a 60-80% rate, the inspectors questioned the appropriateness of sampling with such relatively complex items. ABB thought that they could in addition, take credit for verification of certain electrical and performance-related critical characteristics. However, the NRC inspectors' review of the report of the recent audit (January 15, 1999) of Ryobi, for example, ABB's new supplier of the small universal (electric drill) motor and geared drive assemblies, found it to be a broad-based programmatic audit that did not document that Ryobi controlled the critical characteristics of interest, e.g., insulation resistance, winding resistance, current draw, torque, speed, heat, etc.

For example, some of the components for the D.C. Cook breaker refurbishment project were purchased by ABB T&D Florence from ABB T&D, Coral Springs, Florida, on Florence PO No. PCO 1716, dated August 13, 1999, as follows:

- Five Type SS-14 Power Shield® solid-state over-current trip units (Part No. 60990 T 010 N)
- Five SS-14, 600A, trip units, non-safety-related part no. 609902T 010N
- Five SS-13, 600A, long-time and instantaneous, "NSR" part No.609902 T012

ABB Coral Springs then forwarded this PO to ABB, Allentown, Pennsylvania, where the components were manufactured. ABB Allentown built the trip units shipped them to ABB Florence. ABB Florence receipt inspectors verified that the parts received met the PO requirements. ABB Sanford issued a CoC to ABB Florence certifying that the trip units meet or exceed the requirements of the relays that were originally manufactured and supplied to D.C. Cook in 1971. Based on this information, ABB Florence issued its own CoC certifying that the trip units meet DC Cook's PO requirements.

The review of final breaker testing revealed that the factory test parameters were from the production testing section of ANSI/IEEE Standard C37.09-1979 that used values in Table 8 from C37.06 for *indoor* switchgear equipment. Accordingly, for 250 Vdc nominal control power equipment, for example, closing spring release coils were at tested at **200** Vdc and 280 Vdc, trip coils at 140 Vdc and 280 Vdc. However, in the IBs used by customers (usually in Table 4) control component voltage ranges equivalent to the *outdoor* values from the standard were given, i.e., **180**-260 Vdc closing, 140-260 tripping. Similarly, nominal 125-Vdc components were tested at 100 (vice 90) Vdc closing. The inspectors were concerned that key personnel in customer organizations, particularly those responsible for developing acceptance and maintenance procedures, may not know this and believe that the factory test voltages are the same as (or more instead of less conservative than) those given in the IBs; even though customers presumably have the standards cited by the ABB CoCs as well as the test reports which are provided to customers.

In reviewing manufacturing process controls, the inspectors learned, as discussed previously, that the specification for crank arm-to-lever gap on HK control devices had been changed from that specified in 5HK Instruction Book IB 6.2.1.7D as 0.060"-0.090" to 0.010"-0.090'. However, this gap in Factory Specification TD-6931 for 5HK Model "03", dated 3-20-67, Revision 3, dated 3-16-84 was 0.005-0.030" (had been 1/16" to 1/32" before). The 0.010"-0.090" specification, in use in the factory for some time, was documented in a so-called "errata" presumably intended to be published eventually for IB 6.2.1.7D. As discussed above, the factory workers had been instructed to use the specification in the errata instead of properly changing the factory specification using the engineering change notice (ECN) process as required by Standard Practice Procedures 600-070, "Design Control and Review," Revision 3, (original issue5/21/85) and 600-050, "Engineering Change Notices," Revision 8 (original issue 8/13/90). This change had been in effect for some months, yet users had not been notified.

c. Conclusions

The inspectors concluded that the spare and replacement parts QA controls had suffered some degradation and could benefit from some updating of the processes, including some automation. The inspectors further concluded that the dedication of the more complex spare and replacement parts was weak in that only those components going into completed breakers or breaker mechanisms were subjected to electrical and performance testing, that taking credit for sampling for such components was not appropriate, and that QA supplier audits or surveys were not sufficiently detailed or critical characteristic and item specific to rely on for verification of the critical characteristics in question.

Changing the IB by errata (which would normally be used for correction of an error), rather than by a formal revision or interim change was inappropriate because the change was intentional. As discussed above, it lacked proper design review and verification contrary to Criterion III of 10 CFR Part 50, Appendix B. Being instituted contrary to ABB QA and engineering procedures, the change was also a nonconformance with respect to Criterion V of Appendix B.

3.4 Observation of Manufacturing

a. Inspection Scope

The inspectors observed part manufacturing and breaker assembly for 4-kV Type HK breakers, medium-voltage vacuum breakers (e.g., Type VHK(X) for direct retrofit into HK switchgear), and low-voltage, metal-enclosed K-Line breakers, including in-process production inspections and testing. Also examined were vacuum interrupter element and breaker operating mechanism subassemblies called "modular assemblies" (in the terminology of ANSI/IEEE Standard C37.59), designated VHK(R) [for retrofit], used for building special conversion breakers designed for replacement of other manufacturers' air-magnetic type breakers using existing unmodified switchgear. These included the type supplied to the ABB Service Company Product Development Group, Cleveland, Ohio, which, under the nuclear QA and dedication procedures of ABB/Combustion Engineering-Nuclear Power (Windsor, Connecticut), is providing the converted vacuum breakers for replacement of GE Type AMH-4.16 (Magne-Blast horizontal drawout) breakers at the Calvert Cliffs Nuclear Plant.

b. Observations and Findings

The inspectors observed some of the endurance testing that each medium-voltage breaker manufactured in the plant undergoes for a minimum of 250 cycles of breaker opening and closing operations. However, the inspectors observed that during the production testing of a non-nuclear Type 5VHK-R250, 1200A, breaker (JOB NO. F131098-001), the maximum-voltage closing test was performed at 260 Vdc instead of 280 Vdc (for 250-Vdc nominal control power), as specified in ANSI/IEEE Standard C37.09 and C37.06 and as given in Table 4 of IB 6.2.7.7-4C. The test personnel acknowledged this observation, but were unable to provide a satisfactory explanation for testing at the lower voltage. ABB initiated efforts to resolve this discrepancy.

c. Conclusions

The inspectors concluded that in general, observed manufacturing process were well controlled and test records reviewed were found satisfactory except for the test voltage issue with a 4-kV VHK-R breaker intended for non-nuclear safety-related service.

3.5 Review of Medium-Voltage and K-Line Design Changes

a. Inspection Scope

During the 1999 meeting of the ABB Circuit Breaker Users Groups sponsored by the Nuclear Maintenance Applications Center (NMAC) of the Electric Power Research Institute (EPRI), ABB Service Company personnel stated that during the development of ABB's medium-voltage vacuum type circuit breakers, certain parts in the K-Line (low-voltage breaker) mechanisms that were being adapted for use in the vacuum breakers had failed prematurely due the increased stresses from greater mechanical loads caused by the greater operating forces in the vacuum breakers resulting from the

associated stronger closing and opening springs. The ABB Service Company personnel explained that as a result of these failures, ABB Florence upgraded the design and manufacturing of the affected parts (e.g., larger cross sections in parts such as mechanism latches, but with the same form, fit and function, i.e., physically interchangeable) to give these parts more strength and durability for the more severe application. The upgrades were reportedly made to all affected K-Line parts, regardless of application, for standardization.

The implication of this revelation was that the new design parts would be suitable for all types of breakers in which they could be used, but that the corresponding parts of the old design could fail prematurely if misapplied and used in a K-line mechanism installed in a vacuum breaker. The inspectors were concerned that this situation could become more probable with the increasing retrofits of conversion vacuum breakers into nuclear plant switchgear. For example, conventional medium-voltage air or air-magnetic circuit breakers of other manufacturers (particularly GE Magne-Blast) are increasingly being replaced with typically higher interrupting capacity and lower maintenance vacuum or SF6 gas circuit breakers which have been converted for retrofit into unmodified existing switchgear. The ABB Type VHK(R) unit ("R" for retrofit) being used for the Calvert Cliffs Magne-Blast replacement project (horizontal-drawout, Type AMH), has also been adapted to replace vertical-lift Magne-Blasts at Fort Calhoun. The VHK(R) is not a complete breaker, but rather consists only of the vacuum interrupting elements, the mechanism and the basic frame on which they are mounted. This configuration is called a modular assembly by ANSI/IEEE Standard C37.59-1991 which is the industry standard that governs the conversion or adaptation of such modular assemblies for use as replacements of conventional air or air-magnetic circuit breakers.

In addition, ABB has developed the Type VKH(X) breaker as a direct vacuum type replacement for its air-magnetic HK models, again using unmodified existing switchgear. Therefore, the inspectors (and the users groups as well) were concerned that with wider and wider usage of breakers with ABB vacuum interrupters and adapted K-Line mechanisms, and because the parts in question have the same part numbers and the visual differences are subtle and may not be obvious to the inexperienced eye, it could be possible for users who also have K-Line breakers in their plants to inadvertently co-mingle the older and newer designs of the affected parts, or in some other manner allow old parts to be used in an unsuitable application. The inspectors had discussed this issue with ABB Florence previously and reviewed the issue in detail, including the actual design changes and examination of the parts in question during this inspection.

The inspectors also reviewed ABB's reconciliation of design changes with breaker qualification. A principal example was use of closing spring charging motors from the Ryobi Company when the previous motors made by Ametek were no longer available.

b. Findings and Observations

With regard to the K-Line parts upgrades, using old and new design parts to illustrate, ABB stated that these upgrades were not made as a result of failures as implied by certain ABB Service Company personnel. Rather, ABB explained that they were developed to obviate many of the manufacturing tolerance issues associated with the intricate breaker operating mechanism. ABB stated that the changes were also made to

increase the design margin in the endurance limit of the K-line operating mechanism for all applications. ABB Florence denied that there had been any such failures of the type described by ABB Service Company during the adaptation of the parts for use in vacuum breakers. ABB stated that correctly manufactured older K-line parts should work in all applications as specified and design tested by ABB, but recommended that the optimized parts be used for all new breakers and refurbishment programs because they have superior endurance than the previous ones. ABB stated its intention to resolve the apparent misunderstanding of the history of the parts and also to impart this information to EPRI/NMAC for dissemination to the users groups.

c. Conclusions

The inspectors concluded that the design changes were improvements for more efficient manufacturing and for enhanced durability, but that the older designed parts were not necessarily to premature failure as long as used as designed. The inspectors further concluded that using older design parts in the K-Line type mechanisms of vacuum breakers was possible, but unlikely, that experienced technicians would likely recognize the differences, and that even if they were used inadvertently, they should function satisfactorily, but may not last as quite long as the newer designs. It had not been proved (nor should it be expected) that older design parts would last the entire service life of a vacuum breaker if misapplied.

4.0 PARTIAL LIST OF PERSONS CONTACTED

ABB Power T&D Company, Circuit Breaker Division

+		Jon S. Rennie, Plant Manager,
	*	Shannon Soupiset, P.E., Director of Engineering
	*	Robert Behl, Engineer
	*	Byron Powell, Engineer
	*	Marty Trivette, Engineer
+	*	Scott Bridges, Quality Assurance Manager (Total Quality Manager)
+	*	Richard Lubin, Senior Quality Assurance Engineer
+		Daniel Hickman, Manufacturing Manager
+	*	Thomas Woodfin, Manager of Components
+	*	John Southerland, Purchasing Manager
+		Robert Dietrich, QA Consultant (Former ABB QA Manager)
	*	Davis Ringley, Customer Service
+	*	Jill Heiden, Manager of Human Resources
+		Donald Ruedinger, Plant Accountant
		J. Parrott, Qaulity Control Inspector
		K. Smith, Quality Assurance Inspector
		J. Widdows, Quality Assurance Inspector

+ Attended entrance meeting
* Attended exit meeting

5.0 LIST OF ITEMS OPENED, CLOSED AND DISCUSSED

Opened:

99901256/1999201-01	URI	Unresolved Item: 10 FR 21.21(d)(4), incomplete information in notifications made pursuant to 10 CFR 21.21(d)(1), pending vendor location of missing records
99901256/1999201-02	URI	Unresolved Item: 10 CFR 21.51, incomplete records of Part 21 evaluations and notifications, pending vendor location of complete correspondence
99901256/1999201-03	NON	Nonconformance: 10 CFR Part 50, Appendix B, Criteria III and V, Improperly effected change in specifications
99901256/1999201-04	NON	Nonconformance: 10 CFR Par 50, Appendix B, Criterion XVI, Inadequate corrective action for previous violation

Closed:

99901256/93-01-01	VIO	Violation: 10 CFR 21.21(a), Part 21 procedures not updated to reflect major revision in Part 21 in 1991, 10 CFR 21.6, Latest version of Part 21 not posted
99901256/93-02-01	NON	Nonconformance: 10 CFR Part 50, Appendix B, Criterion V, failure to follow QAP 2.5, not all required supplier audits performed
99901256/93-02-02	NON	Nonconformance: 10 CFR Part 50, Appendix B, Criterion V, failure to follow QAP 4.3, procurement from vendors not on approved vendor list
99901256/93-02-04	NON	Nonconformance: 10 CFR Part 50, Appendix B, Criterion V, inadequate procedure, QAP 7.1, referenced QAPs 6.5 and 16.2 which did not exist and therefore could not be followed.
99901256/93-02-05	NON	Nonconformance: 10 CFR Part 50, Appendix B, Criterion V, failure to follow QAP 2.4, required log book to record qualification certifications not established

Not Reviewed:

99901256/93-02-03	NON	Nonconformance: 10 CFR Part 50, Appendix B, Criterion V, failure to follow QAP 4.3, lack of required evaluation documentation of basis for inclusion of some vendors on approved vendors list

Discussed: None

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

October 28, 1999

Mr. Blaine L. Curtis, President
Anatec International, Incorporated
930 F Calle Negocio
Post Office Box 3758
San Clemente, California 92673-3758

SUBJECT: NRC INSPECTION REPORT 999001342/1999201 (NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE)

Dear Mr. Curtis:

On August 30 through September 1, 1999, the United States Nuclear Regulatory Commission (NRC) performed an inspection at the Anatec International, Incorporated (Anatec) facility in San Clemente, California. The enclosed report presents the findings of that inspection. The inspection was conducted to review portions of your program relating to personnel training records and certifications for eddy current data analysts, and the safety-related services that are provided to commercial nuclear power plant facilities. This inspection focused specifically on activities regarding supporting documentation associated with the qualification and certification of a selective sample of Level IIA and III eddy current qualified data analyst (QDA) personnel records at the Anatec facility in accordance with Appendix G, "Qualification of Nondestructive Examination Personnel for Analysis of NDE Data," of the Electrical Power Research Institute (EPRI) Document Technical Requirements (TR)-107569-V1R5, "PWR Steam Generator Examination Guidelines," and the recommended practice of the American Society for Nondestructive Testing, SNT-TC-1A, "Personnel Qualification and Certification in Nondestructive Testing." The inspectors assessed Anatec's conformance to their customer's procurement requirements and compliance with NRC regulations.

It was found that certain of your activities appeared to be in violation of NRC requirements. Specifically, the review of a potential 10 CFR Part 21 issue regarding suspect training and certification records that was received by Anatec in May 1999 was not appropriately dispositioned in accordance with 10 CFR Part 21. The issue questioned the accuracy and validity of QDA records that were not obtained directly from the previous employer. The inspectors found that Anatec neither evaluated the issue in accordance with §21.21 of 10 CFR Part 21, nor informed the applicable licensees in order to cause the potential defect to be evaluated by the licensee as discussed in §21.21(b) of Part 21. This matter is cited in the enclosed Notice of Violation (NOV), and the circumstances surrounding the NOV are described in detail in the enclosed report. Please note that you are required to respond to this letter and should follow the instructions specified in the enclosed NOV when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, the NRC inspectors found that the implementation of your quality assurance program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the inspectors determined that your certification of certain NDE personnel did not conform to the guidance contained in Appendix G of EPRI TR-107569-VIR5 and Anatec's certification of NDE personnel procedure in that Anatec certified certain NDE personnel based upon outside organization training and certification records that were not received directly from those organizations and that were not verified by Anatec. This nonconformance could have caused an NRC licensee to be in violation of Criteria VII, "Control of Purchased Material, Equipment, and Services," and IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." This nonconformance is cited in the enclosed Notice of Nonconformance (NON), and the circumstances surrounding it are described in the enclosed report. You are requested to respond to the nonconformance and should follow the instructions specified in the enclosed NON when preparing your response.

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's Public Document Room.

Sincerely,

Theodore R. Quay, Chief, IQMB
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Docket No. 99901342

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99901342/1999201

NOTICE OF VIOLATION

Anatec International, Incorporated
San Clemente, California 92673-3758

Docket No.: 999001342/1999201

During an NRC inspection conducted at the Anatec International, Incorporated (Anatec) facility at San Clemente, California on August 30 - September 1, 1999, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of 10 CFR Part 21, requires, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to the Part 21 regulation adopt appropriate procedures to (1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of §21.21, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and (2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person. Section 21.21(b) requires that if the supplier of basic components determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination.

Contrary to the above, Anatec failed to recognize that it was required to perform an evaluation of information contained in a letter received approximately May 17, 1999, indicating that the validity and accuracy of certain non-destructive examination qualified data analyst testing personnel records were suspect. Additionally, Anatec also failed to recognize that it was required to inform the applicable utility customers if it determined that it did not have the capability to evaluate the issues in accordance with Part 21. (Violation 99901342/1999201-01)

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

Pursuant to the provisions of 10 CFR 2.201, Anatec International, 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. 20555-0001, with a copy to the Chief, IQMB, Division of Inspection Program Management, 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 for each violation:

Enclosure 1

(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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland
this 28th day of October 1999

NOTICE OF NONCONFORMANCE

Anatec International, Incorporated
San Clemente, California

Docket 99901342

Based on the results of an inspection conducted at the Anatec International, Incorporated (Anatec) facility at San Clemente, California on August 30 - September 1, 1999, it appears that certain Anatec activities were not conducted in accordance with NRC requirements.

Criterion V, "Instructions, Procedures, and Drawings," of 10 CFR Part 50, Appendix B requires that activities affecting quality be prescribed by documented instructions and procedures and shall be accomplished in accordance with those instructions and procedures.

Section 5.5.4 of Anatec Procedure ANATEC-08, "Certification of NDE Personnel," states, "Training programs administered by other companies or organizations prepared in accordance with this written practice will be considered adequate." Section 5.9, "Certification," of ANATEC-08 states, " If an outside agency is used [for certification], ANATEC executes its responsibilities for certification by assuring that training, examination and certification of NDT personnel are in accordance with this procedure, as a minimum."

Contrary to the above, Anatec certified NDE personnel based upon training and certification records from other organizations which were not verified to be in accordance with Anatec's written practice. Anatec accepted certification records from other organizations (provided by incoming Anatec employees) without auditing or otherwise assuring the other organization's training, examination and certification of NDE personnel met the requirements of ANATEC-08. (Nonconformance 99901342/1999201-02)

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001 with a copy to the Chief, IQMB, Division of Inspection Program Management, 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) the reason for the nonconformance, or, if contested, the basis for disputing the nonconformance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further noncompliances, and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland
this 28th day of October 1999

Enclosure 2

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR REACTOR REGULATION

Report No.:	999001342/1999201
Organization:	Anatec International, Incorporated 930 F Calle Negocio Post Office Box 3758 San Clemente, California 92673-3758
Contact:	Lisa T. Gardner, QA Manager (949) 498-3350
Nuclear Activity:	Anatec International, Incorporated (Anatec) provides nondestructive testing and associated activities for the evaluation of steam generator, condenser and feedwater heater tubing through eddy current testing, data collection and analysis review services to the nuclear industry.
Date of Inspection:	August 30 - September 1, 1999
Inspectors:	Joseph J. Petrosino, Lead Inspector Gregory C. Cwalina, Senior Reactor Engineer Cheryl D. Beardslee, Materials Engineer
Approved by:	Daniel H. Dorman, Chief Quality Assurance and Safety Assessment Section, IQMB Division of Inspection Program Management

Enclosure 3

1 INSPECTION SUMMARY

The NRC inspectors examined documentation related to personnel training records and certifications for eddy current data analysts, and the safety-related services that are provided to commercial nuclear power plant facilities. This inspection specifically focused on activities regarding supporting documentation associated with the qualification and certification of a selected sample of Level IIA and III eddy current qualified data analyst (QDA) personnel records at the Anatec facility in accordance with Appendix G, "Qualification of Nondestructive Examination Personnel for Analysis of NDE Data," of the Electrical Power Research Institute (EPRI) Document Technical Requirements (TR)-107569-V1R5, "PWR Steam Generator Examination Guidelines: Revision 5, Volume 1: Requirements," and the recommended practice of the American Society for Nondestructive Testing, Incorporated (SNT) - Technical Council (TC) - First Document (1A), "Personnel Qualification and Certification in Nondestructive Testing," The inspectors assessed Anatec's conformance to their customer's procurement requirements and compliance with NRC regulations.

The inspection bases were:

- 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 (CFR) (Appendix B)
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- SNT-TC-1A, "Personnel Qualification and Certification in Nondestructive Testing,"
- Appendix G of EPRI TR-107569-V1R5, "PWR Steam Generator Examination Guidelines: Revision 5, Volume 1: Requirements"

During this inspection, a violation of NRC requirements was identified and is discussed in Section 3.1 of this report. Additionally, one instance was identified where Anatec failed to conform to NRC and Electric Power Research Institute requirements contractually imposed upon them by NRC licensees. This nonconformance is discussed herein.

2 STATUS OF PREVIOUS INSPECTION FINDINGS

This was the first NRC staff inspection conducted at the Anatec facility.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 10 CFR Part 21

c. Inspection Scope

The NRC inspectors reviewed Anatec's 10 CFR Part 21 program implementation, conducted discussions with the quality assurance (QA) manager regarding 10 CFR Part 21, and reviewed and commented on the procedure that Anatec adopted to implement the Part 21 regulation.

b. Observations and Findings

b.1 10 CFR Part 21 Evaluation: On May 21, 1999, AJB Technologies (AJB), Greensburg, Pennsylvania transmitted a letter to the NRC identifying a potential 10 CFR Part 21 issue regarding suspect NDE personnel records which AJB believed were being used to certify and qualify former AJB personnel without verification of the validity of those records. A number of the individuals named in the 10 CFR Part 21 report are currently Anatec employees. The contents of this letter were also transmitted to other potentially affected NDE personnel vendors and affected licensees, including Anatec. Therefore, during the Anatec inspection, the inspectors asked whether Anatec had received the AJB information contained in the AJB letter and asked to review a copy of its 10 CFR Part 21 evaluation of the issue.

Anatec stated that they had received a copy of the information contained in the facsimile. However, Anatec stated that they had not performed the evaluation required by §21.21, "Notification of failure to comply or existence of a defect and its evaluation," of 10 CFR Part 21. The Anatec QA Manager stated that Anatec had not recognized that it was required to perform an evaluation of the potentially reportable issue in accordance with Part 21.

The inspectors determined that Anatec had failed to adequately implement the requirements of 10 CFR Part 21 and this was identified as a violation of NRC requirements. (Violation 99901342/1999201-01)

The inspectors discussed the 10 CFR Part 21 responsibilities with the QA Manager and also explained to Anatec that it was still responsible to evaluate the circumstances of the issue, as it related to Anatec's customers, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, or to provide the NRC with an interim report if the issue could not be evaluated within 60 days. Additionally, the inspectors discussed with Anatec that if they did not have the technical capability to determine if a defect exists, then they were required by Part 21 to inform any applicable nuclear power plant customers.

Anatec's Evaluation of the May 1999 letter: By letter, dated October 11, 1999, Anatec provided the NRC a copy of their Part 21 evaluation of the May 1999, AJB letter. The inspectors determined that Anatec's evaluation of the issues did not address the

significance of the deviations nor did the evaluation attempt to determine whether a particular deviation could create a substantial hazard or determine whether a failure to comply is associated with a substantial safety hazard.

The definition contained in §21.3 of 10 CFR Part 21 of "evaluation" states that it is "the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard." This aspect was discussed between the Anatec QA manager and the NRC inspectors. Nonetheless, Anatec's evaluation did not adequately address the issue of verification of previous certifications, records and experience. Additional details regarding the qualification and certification of QDAs is discussed in Section 3.2 below. For example, ANATEC's response, Page 2, EVALUATION states, "Anatec is stating that prior certifications, and/or personnel[1] records as described in ANATEC-08, Section 5.12, paragraph 5.12.4 are typically used by the hiring company as proof of prior training and experience and are normally retained by the individual in the same manner as a Lead Auditor or Welder certification would be."

However, Anatec did not verify the rap[2] sheets or certifications. If they had contacted AJB, they would have been aware that AJB's policy was to designate and maintain their personnel information, including their rap sheets or certifications, as proprietary. It was AJB's corporate policy not to provide them to the individuals. Therefore, information that was obtained directly from former AJB employees and not from AJB (or any other previous employer) should be considered suspect until substantiated with that employer.

Further, ANATEC-08 states acceptance of certifications (and not personnel records as stated in their evaluation) is sufficient. However, in the case of one QDA, no record or copy of prior certification was found in his record package; only a copy of a rap sheet that was faxed from a funeral home in Pittsburgh, Pennsylvania was found in the package. No record as to who faxed the information was noted. Additionally, the evaluation states that: "There is no prior history which would lead Anatec to believe the QDA records are inaccurate." However, the inspectors noted that there was no objective evidence in the reviewed QDA record packages indicating that Anatec took any steps to verify the rap sheet information. Instead, Anatec accepted the information provided without verification from the previous employers. Lacking any effort to validate information provided by the individuals, Anatec would not have been able to identify any concern with regard to the employee's prior history.

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[1] It was noted during review of the Anatec procedures that Procedure ANATEC-08 does not mention personnel records.

[2] The term "rap sheet" describes the data summary sheets that are used by the NDE eddy current industry to document results of certification and recertification results for each QDA.

The Anatec evaluation also states that, "all records were generated by an authorized organization, either Zetec or AJB as noted below." However, Anatec did not audit AJB and AJB does not appear on Anatec's approved supplier's list. Although, Zetec was on Anatec's approved supplier list, the inspectors noted that Zetec information was used to certify two QDAs over a month after Anatec had certified them.

b.2 10 CFR Part 21 Procedure: The inspectors reviewed a copy of the procedure which Anatec adopted to implement the provisions of 10 CFR Part 21, Procedure ANATEC-G-06, "10 CFR 21 Reporting of Defects and Noncompliance," Revision 2, dated September 26, 1994.

The inspectors identified several areas within ANATEC-G-06 that did not adequately ensure that deviations and failures to comply were dispositioned in accordance with Part 21. The procedure also did not ensure that deviations and failures to comply would be appropriately identified and evaluated. Further, the inspectors identified a few areas where Anatec's procedure could be confusing to an Anatec employee attempting to determine a course of action for evaluating deviations. Anatec's procedure required employees to notify their supervisor of applicable defects. However, since a defect is determined on the basis of an evaluation, an employee may believe that they were required to perform an evaluation prior to informing their supervision.

For example, the Part 21 procedure used the term defect, as defined in §21.3 of Part 21, throughout its procedure instead of the term deviation. The switching of the two terms mandates different Part 21 requirements for the vendor's necessary action. That is, a defect, as determined by a Part 21 evaluation process, must be reported to the NRC; whereas, a deviation is required to be evaluated in accordance with 10 CFR Part 21 to determine whether a defect or substantial safety hazard exists.

The switching of the two terms could have caused inappropriate action or no action to be performed. In the case of the violation discussed herein, Anatec did not fully understand that the issues identified in the AJB letter could have represented deviations in the Anatec quality assurance (QA) program regarding verification of personnel qualification, certification and educational requirements. Consequently, Anatec did not recognize that it was required to perform an evaluation in accordance with Part 21 as cited in NOV 99901342/1999201-01.

The general requirements stated that for those cases where reporting is required by other NRC regulations, duplicate evaluation and reporting under 10 CFR Part 21 is not required. Discussions indicated that Anatec personnel were not aware of other NRC regulations concerning reportability nor of the NRC timeliness requirements mentioned in the general requirements of ANATEC-G-06.

The definition section in ANATEC-G-06 did not contain all of the relevant definitions, such as, "discovery," and "evaluation" that would help ensure appropriate and effective implementation of the procedure. Evaluation is a significant term because it means that

a decision must be made whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

The inspectors discussed each area of ANATEC-G-06 which contained weaknesses with the QA Manager and obtained a commitment from the QA manager that Procedure ANATEC-G-06 would be revised as discussed within 120 days to ensure it provided appropriate direction to effectively implement the provisions of 10 CFR Part 21.

c. Conclusions: The inspectors concluded that Anatec failed to recognize its responsibility to evaluate deviations or failures to comply in accordance with Part 21, but committed to perform an evaluation of the issues and other related deviations and inform the Lead Inspector of the results. Anatec's established procedure, ANATEC-G-06, to implement the provisions of 10 CFR Part 21 contained numerous weaknesses that contributed to its failure to recognize the need to perform an evaluation of the deviation contained in the May 1999 information received from AJB.

Additionally, the inspectors conclude that Anatec's evaluation of the issues contained in the May 1999 letter and the evaluation of suspect records for other Anatec QDAs did not appropriately address the concerns regarding verification of records, nor address the evaluation aspects of §21.3 of Part 21.

3.2 Qualification/Certification of Qualified Data Analysts

a. Inspection Scope

The inspection team reviewed the qualification program and practices for Anatec nondestructive testing (NDT) personnel, with particular emphasis on eddy current QDAs. The inspectors reviewed the qualifications to assure conformance to licensee purchase orders, Anatec internal requirements, the recommended guidance of SNT-TC-1A, and Appendix G, of EPRI TR-107569-V1R5, Revision 5.

The inspectors reviewed the qualification documents for several employees, some of whom were qualified directly by Anatec and some of whom were qualified by Anatec based upon previous qualifications from another organization.

b. Observations and Findings

b.1 General. For each certified eddy current QDA, Anatec kept an up-to-date personnel certification summary record. The summary record included the level for which the individual was certified, the certification date and expiration date. It also included a summary of the technical examinations completed to attain certification, including the Method, Level, Date and Examiner (organization responsible for the examination), as well as the employee's test scores and copies of the written test. The summary also included a listing of the employee's experience, work history, education and training, and other documentation appropriate for qualification and certification.

The inspectors noted some inconsistencies or discrepancies in the records reviewed. For instance, some records for technical examinations listed the Examiner as the organization that actually gave the training and examination while others listed the Examiner as the employer at the time the trainee took the examination. In addition, records for required QDA annual training only consisted of verification that the QDA received the training materials and agreed to read them. There was no evidence that the trainee actually read the materials or discussed them with a trainer. The Anatec method of annual training seems contrary to the guidance provided in Appendix G of the EPRI report. Section G.4.1.3, Annual Training, states, "A record of attendance and topics covered during the training shall be maintained." The inspectors informed Anatec that they felt that wording indicated a more formal method for annual training than that implemented by Anatec. The inspectors identified, through review of older annual training records, that Anatec previously implemented a more formal process, which required discussion with a trainer.

b.2 Anatec Trained QDAs. The inspectors did not identify any additional concerns while reviewing packages for those employees who were solely trained, qualified and certified by Anatec.

b.3 Previously certified QDAs. SNT-TC-1A states that certification is the responsibility of the employer, and an employer's certification is revoked when an employee has been terminated. An employee whose certification has been terminated may be certified to the former NDT level by a new employer based upon examination, provided certain conditions are met to the new employer's satisfaction. These conditions are: proof of prior certification, employee was working in the capacity to which certified within 6 months of termination, and the employee is being recertified within 6 months of termination. As detailed below, the inspectors identified several concerns for those employees who initially received QDA training, qualification and certification while employed at another organization and were recertified by Anatec.

As stated above, SNT-TC-1A says that an individual can be recertified by a new employer based upon examination and written proof of prior certification. In all cases, Anatec administered written examinations for Level IIA or III qualification in accordance with Anatec procedures and industry guidance. However, the inspectors identified multiple packages where Anatec relied on certification and qualification test results (written and practical) from a previous employer to certify analysts as QDA qualified. [Note: Level IIA written examinations are different than QDA written examinations.] No form of practical examination was given (either for the Level IIA/III or QDA certifications). In addition, the inspectors determined that Anatec relied on certifications and QDA "Data Summary" Sheets (A.K.A. "rap sheets") that were obtained directly from the employee, not from the employee's former employer. The inspectors concluded this did not adequately meet the intent of "proof of prior certification," because Anatec did not verify the validity of the rap sheet or certification with the previous employer. In addition to the guidance in SNT-TC-1A, Section 5.5.4 of Anatec-08, "Certification of NDT Personnel,"

states, "Training programs administered by other companies or organizations prepared in accordance with this written practice will be considered adequate." Anatec did not verify that the employee's previous training was prepared in accordance with Anatec's written practice.

Specifically, the inspector identified 5 examples (See Table 1, Employees A, B, C, D, and E) where Anatec accepted a Level IIA/III and QDA certification from another organization without verifying that the paperwork supplied by the new employee (e.g., certification and/or QDA Data Sheet) was valid. In addition, Table 1 also shows that Anatec was inconsistent as to what was acceptable for qualification. In some cases Anatec used student supplied rap sheets and certifications (Employees A, and E). In others Anatec used only the rap sheet (Employees C, D, and F), or certification (Employees B and G). In all the above cases, the rap sheet or certification was a copy of the AJB rap sheet or certification. The inspectors contacted AJB and were told that AJB considered the rap sheets and certifications as the property of AJB and had not authorized their release or use as proof of prior certification. Further, AJB had not been audited by Anatec and was not on Anatec's list of approved suppliers. Therefore, there was no documented basis for acceptance of AJB rap sheets or certifications, (whether provided by AJB or the employee) to fulfill the guidance of SNT-TC-1A or Anatec's internal procedure.

The inspectors noted that, earlier in 1999, Anatec seemed to recognize the weaknesses in their certification process. In several cases, Anatec augmented their basis for certification by confirming the employee's training and/or experience. In three cases (Employees A, B, and G), Anatec contacted Zetec, Incorporated (Zetec), the provider of the training. Zetec transmitted a facsimile to Anatec stating that the employees had successfully completed their QDA training course. Although Zetec is on Anatec's approved supplier list, the training was provided under contract to AJB. Since Anatec was not aware of the specific requirements of the AJB training contract, their reliance on the Zetec facsimile is unsupported. Anatec did not provide assurance that the Zetec training was provided in accordance with the Anatec approved training and QA program. Further, the inspectors also noted that, in most cases, verification was done after the employee had been certified by Anatec and, in some cases, after the employee had performed work at a licensed facility.

In two other cases (Employees C and D), Anatec's certification was based, in part, upon an Anatec interoffice memo stating that the employees had received ET Level IIA Data Analysis training while employed at AJB. The memo does not state that the employees successfully completed the training, only that it was administered. The memo was signed by an Anatec Level III examiner who had also been employed at AJB at the time of the testing. There was no documented evidence that Anatec verified the training with the former employer.

The inspectors informed Anatec that the failure to properly verify the validity of rap sheets, certifications and other documents relied upon to perform certification, in accordance with SNT-TC-1A and Anatec's procedures is identified as

Nonconformance 99901342/1999201-02. The inspectors also informed Anatec that the potential improper certifications should be reviewed and dispositioned in accordance with 10 CFR Part 21.

The inspectors also identified a weakness in Anatec's documentation process. Through review of the QDA Data Sheets, the inspectors identified two examples (See Table 1, Employee E and F) that appeared to indicate there were errors in the QDA test taking process and contrary to the actual outcome, the QDA test should not have been passed. One employee, E, appeared to take the initial qualification test four times in quick succession before passing. Appendix G of EPRI TR-07569-V1R5 and Anatec-08 require additional training and a 30-day waiting period after failing the test the third time. A second employee, F, appeared to take the requalification test two times in quick succession before passing. For requalification, EPRI requires a full standard practical examination if the requalification examination is failed the first time. In both cases, through discussions with Anatec and documentation from the employee's previous employer, the inspectors determined the third initial qualification test and the first requalification test, respectively, were regraded, not retaken. This information should have been documented by Anatec when initially identified.

b.4 Questionable Certification: The inspectors identified a further anomaly with one data analyst (See Table 1, Employee D) in addition to the issues described above. The rap sheet indicated the employee failed the practical examination on the third attempt and took the examination a fourth time on the following day (October 20, 1998) and passed. Appendix G of the EPRI guidance and Anatec-08 require additional training and a 30-day waiting period after failing the test the third time. There was a handwritten note, dated October 20, 1998, on the rap sheet written by the test proctor which stated that an administrative error had resulted in the student's test answers being stored in the wrong location [on the third attempt]. That error resulted in the failing grade on the third attempt. The proctor's note indicated that the answers had been retrieved and regraded the following day, resulting in the passing grade. In response to inspectors questions on the note, Anatec contacted the AJB test proctor (currently employed by Anatec) who provided a detailed explanation of the issue. The inspectors visited AJB to verify the information provided by the proctor. A review of the employee's qualification file revealed that the handwritten note found on the Anatec QDA rap sheet was not on the rap sheet in AJB's files. Since the employee had taken the test while employed at AJB, the absence of the note on the AJB official records raised a question regarding the validity of the note.

Subsequent discussions conducted with a Westinghouse Level III NDE/ET QDA indicated that the Westinghouse QDA software program used was capable of introducing the anomalies that were stated to have happened. Subsequent discussions with EPRI NDE Center representatives indicated that they recalled speaking with the Level III subject Proctor regarding the anomalies encountered during the performance of the student's QDA exam with the Westinghouse QDA software program. Although neither of the two EPRI representatives stated that they had documented the date and time of the telephone call with the Level III Proctor, they distinctly remember discussing the problem with the AJB Level III QDA proctor.

Finally, this matter was discussed again with the Level III Proctor who administered the test and wrote the note on the QDA sheet. He indicated to the inspectors that his recollection of the matter was that he wrote the note on the original rap sheet and provided it to the AJB owners before he left employment with AJB in December 1998. The inspectors were unable to determine why the handwritten note found in the Anatec qualification file does not also appear in the AJB file.

The Proctor also indicated that he had provided copies of the AJB rap sheets to each of the students that he had trained and conducted the QDA exam. He explained that the rap sheets were provided to the students for their own records.

c. Conclusions

The Anatec method of annual training does not provide a positive indication of a record of attendance and topics covered. The inspectors informed Anatec that more formal method for annual training was appropriate. The failure to properly verify the validity of rap sheets, certifications and other documents relied upon to perform QDA certification, in accordance with Anatec's procedures was identified as a nonconformance. The potential improper certifications should be reviewed and dispositioned in accordance with 10 CFR Part 21.

3.2 Entrance/Exit Meetings

In the entrance meeting on August 30, 1999, the NRC inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with the Anatec QA Manager. In the exit meeting on September 1, 1999, the NRC inspectors discussed their findings and concerns.

4. PERSONS CONTACTED

Lisa Gardner	Anatec QA Manger	
Darren Howe	Anatec Level III QDA	
Delle Obazenu	Anatec Level III QDA	
Craig Smith	EPRI NDE Center	**
Gary Henry	EPRI NDE Center	**
Gary Pierini	Westinghouse NDE	**

** Contacted by Telephone

Table 1 - QDA Certification Basis

Employee ID	Date of Anatec Cert.	QDA Data (Rap) Sheet	Certification	Additional Basis for Certification
A	8/20/98	• 8/4/98 fax from employee - name handwritten - no ID of testing organization	8/5/98 fax from employee - AJB cert. of 1/22/98	• 4/16/99 fax from Zetec - successful completion of QDA training and testing
B	3/4/99	None	copy of AJB cert dated 1/22/98	• 4/16/99 fax from Zetec - successful completion of QDA training
C	3/4/99	• 1/18/99 fax from Gaines funeral home (identity of sender unknown) - no ID of testing organization	None	• copy of Zetec training certificate dated 8/2/96 for Level IIA • copy of Zetec Continuing Education Program certificate for Level IIA • 3/3/99 Anatec Interoffice Memo from Level III stating that Level IIA training was given to employee by Level III while employee and Level III examiner were employed at AJB
D	3/4/99	• Data sheet indicates test taken while employed at AJB - handwritten note dated 10/20/98 by Level III explaining basis for regrading after apparent failure on 3rd attempt • No indication of data sheet origin	None	• 3/3/99 Anatec Interoffice Memo from Level III stating that Level IIA training was given to employee by Level III while employee and Level III examiner were employed at AJB • 9/99 message from Level III examiner documenting basis for 10/20/98 regrading after failure on 3rd QDA attempt

Table 1 - QDA Certification Basis (cont.)

Employee ID	Date of Anatec Cert.	QDA Data (Rap) Sheet	Certification	Additional Basis for Certification
E	8/98	• 7/21/98 fax from employee - QDA data sheet implied the QDA test was taken 4 times in quick succession in conflict with Anatec and industry practice and guidance	7/16/98 fax from employee	• 4/1/99 fax from previous employer verifying experience hours • 8/31/99 fax from previous employer documenting basis for regrading after failure of requalification exam
F	9/98	• 9/18/98 fax from AJB Technologies - QDA data sheet implied the 1997 QDA requalification test was failed but another requalification test was immediately taken instead of a full standard practical exam		• 9/99 message from previous employer documenting basis for regrading after failure of requalification exam
G	9/21/98	None	9/18/98 fax from AJB	• 8/24/99 fax from Zetec - successful completion of QDA training

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

December 1, 1999

Mr. Craig P. Kipp
General Manager Nuclear Fuel
GE Nuclear Energy
Nuclear Energy Production
P.O. Box 780
Wilmington, NC 28402-0780

SUBJECT: NRC INSPECTION REPORT NO. 99900003/1999202
AND NOTICE OF NONCONFORMANCE

Dear Mr. Kipp:

This letter addresses the inspection of your facility at Wilmington, North Carolina, conducted by Robert Pettis, Jr. and Dr. Shih-Liang Wu, of this office on September 7-10, 1999, and the discussions of their findings with Caroline Reda and other members of your staff at the conclusion of the inspection. The inspection was conducted to review the implementation of selected portions of the General Electric Nuclear Energy (GE-NE) Quality Assurance Program Description (NEDO-11209), including 10 CFR Part 21, as it relates to the activities performed in the Chemet laboratory, and to followup on corrective actions performed by GE-NE as a result of our previous inspection.

The team reviewed technical documentation, procedures, representative records, and also interviewed GE-NE personnel. At the conclusion of the inspection, the findings were discussed with members of your staff. On the basis of this inspection, the team determined that certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Nonconformance. Specifically, a GE-NE audit of JMS Southeast, Inc. (JMS), did not objectively demonstrate that JMS's quality assurance (QA) program complied with the requirements of 10 CFR Part 21, which was imposed on JMS by purchase order. A review of the audit by the NRC inspection team identified that it did not demonstrate that JMS had adequate procedures in-place to identify and evaluate deviations, pursuant to 10 CFR 21.21, and that a recent revision to its QA manual did not address acceptance of Part 21. Over the past several years, GE-NE has placed over 10 safety-related purchase orders with JMS for thermocouple calibration services which have imposed the reporting requirements of 10 CFR Part 21.

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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for witholding the information from the public.

The response requested by this letter and the enclosed Notice of Nonconformance is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511. Should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

FOR

Theodore R. Quay, Chief, IQMB
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99900003/1999202

NOTICE OF NONCONFORMANCE

GE Nuclear Energy (GE-NE)
Wilmington, NC

Docket No.: 99900003

Based on the results of an NRC inspection conducted on September 7-10, 1999, it appears that certain of your activities were not conducted in accordance with NRC requirements.

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

Contrary to the above, an NRC review of a March 4, 1999, GE-NE audit of JMS Southeast, Inc. (JMS), did not adequately demonstrate that JMS's quality assurance (QA) program complied with the requirements of 10 CFR Part 21, which was imposed on JMS by purchase order. Specifically, the audit did not demonstrate that JMS had adequate procedures in-place to identify and evaluate deviations pursuant to 10 CFR 21.21. Section 4.13.3, "Recall Procedure," incorporated into the JMS QA manual in Revision 10, dated December 8, 1998, and later revised in Revision 11, dated February 26, 1999, was not adequate to allow for the identification and evaluation of nonconforming conditions as potential deviations pursuant to 10 CFR 21.21.

JMS revised its QA manual by adding Section 4.13.3 to address specific findings identified during a March 26, 1997, audit by GE-NE which identified several Corrective Action Requests (CARs). Specifically, CAR JMS-2 identified that JMS's QA program did not procedurally address the reporting of defects to customers pursuant to 10 CFR Part 21. Over the past several years GE-NE has placed over 10 safety-related purchase orders with JMS for thermocouple calibration services which imposed the requirements of 10 CFR Part 21. Based on the March 4, 1997, re-audit of JMS, GE-NE closed CAR JMS-2 and two others which had been open for two years without a documented resolution. Since the JMS QA manual revisions were not adequate to address compliance to 10 CFR Part 21, the NRC inspection team did not agree with GE-NE's closure of CAR JMS-2 (99900003/1999202-01).

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, IQMB, Division of Inspection Program Management, 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) the reason for the nonconformance, or if contested, the basis for disputing the nonconformance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further nonconformances, and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland
December 1, 1999

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION

Report No.:	99900003/1999202
Organization:	GE Nuclear Energy P.O. Box 780 Wilmington, NC
Contact:	Caroline Reda Manager, GE-NE Quality
Nuclear Activity:	Nuclear fuel assemblies and related components for BWRs.
Dates:	September 7-10, 1999
Inspection Team:	Robert L. Pettis, Jr., IQMB/DIPM Dr. Shih-Liang Wu, SRXB/DSSA
Approved by:	Daniel Dorman, Chief Quality Assurance and Safety Assessment Section, IQMB Division of Inspection Program Management Office of Nuclear Reactor Regulation

1 INSPECTION SUMMARY

From September 7-10, 1999, representatives of the U.S. Nuclear Regulatory Commission (NRC) conducted a performance-based inspection of the activities at the Wilmington, North Carolina, facility of GE Nuclear Energy (GE-NE). In conducting this inspection, the team emphasized technically directed observations and evaluations of GE-NE activities related to the manufacture and testing of nuclear fuel and related components. As the technical bases for the inspection, the team relied upon the following:

- Part 21, "Notification of Failure to Comply or Existence of a Defect," as defined in Title 10 of the *Code of Federal Regulations* (10 CFR)
- 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
- GE-NE Quality Assurance Program Description (NEBO-11209).

1.1 Violations

No violations were identified during this inspection.

1.2 Nonconformances

Nonconformance 99900003/1999202-01 was identified during this inspection and is discussed in Section 3.3 of this report. This issue was previously identified as Unresolved Item 99900003/1999201-02 during the March 22-25, 1999, NRC inspection.

1.3 Unresolved Items

No unresolved items were identified during this inspection.

2 STATUS OF PREVIOUS INSPECTION FINDINGS

Violation 99900003/1999201-01 (CLOSED)

During the previous inspection, the inspection team identified a violation of NRC requirements associated with the failure to identify and evaluate a potential deviation related to a laboratory analyst who failed to perform over 20 required weekly calibrations of the LECO hydrogen analyzer during the period April 1996 through March 1999. The analyzer is used to perform hydrogen tests for both zirconium fuel cladding and ceramic fuel pellets. Preliminary evaluation results performed by GE-NE during the previous inspection identified several fuel pellets which appeared to exceed the GE-NE specification limit for hydrogen. At the conclusion of that inspection, GE-NE initiated Potential Safety Concern (PSC) 9907 and Corrective Action Request (CAR) AI-2170 to evaluate the condition under the reportability requirements of 10 CFR Part 21. This issue is further discussed in Sections 3.2 and 3.4 of this report.

Unresolved Item 99900003/1999201-02 (CLOSED)

During the March 22-25, 1999, NRC inspection, GE-NE could not produce documentation to support the resolution of three open CARs identified during GE-NE's March 26, 1997, audit of JMS Southeast, Inc. During the September 7-10, 1999, NRC inspection, the team further identified this issue as a Nonconformance and administratively closed the Unresolved Item. This issue, and the Nonconformance, is further discussed in Section 3.3 of this report.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Background

The NRC inspection team reviewed the activities performed by laboratory analysts in the Chemet Laboratory. The Chemet Laboratory is an integral part of the in-process release of raw materials, process control, and final release of finished products at the Wilmington facility. The Chemet Laboratory consists of a metallurgical and wet laboratory. The metallurgical laboratory houses an environmental laboratory while the wet laboratory houses a mass spectrometer and standards laboratory. During the inspection, the team primarily focused its attention on the activities performed in the wet chemical laboratory. The wet chemical laboratory performs a wide variety of chemical and physical analyses on uranium dioxide powder and pellets and zirconium fuel cladding.

3.2 Review of Corrective Actions - Violation 99900003/1999201-01

a. Inspection Scope

The inspection team reviewed GE-NE corrective actions associated with Notice of Violation 99900003/1999201-01, which was identified during the March 22-25, 1999, NRC inspection.

b. Observations and Findings

During the March 1999 NRC inspection, the team identified a potential deviation in which a laboratory analyst failed to perform over 20 required weekly calibrations over a three year period for the LECO hydrogen analyzer. At the conclusion of the inspection on March 25, 1999, GE-NE initiated CAR AI-2170 to address the LECO calibration deficiencies. Potential Safety Concern (PSC) 9907, "Fuel Pellet/Zircaloy Hydrogen Analysis," and CAR AI-2170 were also initiated to evaluate if the deviation could cause a substantial safety hazard pursuant to the reportability requirements of 10 CFR Part 21. Since certain required weekly calibrations were not performed, the potential exists for fuel product to have exceeded either GE-NE or customer fabrication specifications, thereby resulting in the shipment of out-of-specification product.

In a letter to NRC dated May 20, 1999, GE-NE concluded that after completion of the evaluation for PSC 9907 and extending the review to all LECO methods, not just hydrogen, GE-NE concluded that the issue was not reportable. The LECO methods evaluated included pellet and Zircaloy hydrogen, Zircaloy nitrogen and oxygen, powder

nitrogen, and powder carbon. During the review, CAR AE-1104, dated May 3, 1999, was initiated to investigate a concern raised by a laboratory analyst regarding the furnace blanking method for Pellet Fluoride (PSC 9908) and Powder/Pellet Chloride (PSC 9912) methods and was documented in CAR AI-2212, dated April 16, 1999. This issue is further discussed in Section 3.4 of this report.

PSC 9907 reviewed calibrations performed during the period April 1996 through April 1999 and included a review of the LECO methods previously discussed. For each method, the calibration factors reported in the Laboratory Material Control System (LMCS), now replaced by the Laboratory Information Management System (LIMS), were evaluated back to April 1996. The review identified repeat calibration factors for all six LECO methods previously discussed. Eight calibrations enveloping each calibration in question (four before and four after the questioned calibration date) were evaluated for the maximum calibration factor. This factor, in addition to the original calibration factor, were used to correct the results using an equation derived by GE-NE. After applying the conservatively derived correction factor to all LECO methods, all corrected data was within specification limits except for several Zircaloy oxygen samples which exceeded the upper specification limit, which was attributed to an outlier which likely contributed to over correction of the data. The data demonstrated that even though a calibration may not have been performed per the required procedure, the calibration factor that was utilized was within the process control limits and that product performance during the suspect period was as expected and did not exceed specifications. As a result, GE-NE concluded that failure to perform weekly calibration did not have a negative impact on the originally reported results and as such, a product nonconformance or inadvertent shipment did not occur.

The inspection team also reviewed a parallel investigation initiated by GE-NE to determine if an employee integrity issue existed. GE-NE Integrity Case 99-005, "Falsification of Chemet Laboratory Data - Fluoride and Percent U Titrations," dated March 1999, reviewed three years of calibration constant data associated with the LECO analyzer. As a result, four laboratory analysts were identified as having questionable calibration standard results. Action taken by GE-NE included dismissal of one analyst for falsification of calibration data and written warnings for the others in accordance with company policy. When interviewed by GE-NE, none of the analysts could provide an explanation for the repeat calibration constants.

In addition to the CARs and PSC evaluations performed to determine if the falsified calibrations created a defect or failure to comply with the reporting requirements of 10 CFR Part 21, other preventive actions were taken by GE-NE to prevent recurrence. These actions included the disciplinary actions previously discussed; suspension of the pellet fluoride and powder/pellet chloride methods at the Wilmington facility pending re-qualification; performance of a "quality standown" for all Chemet Laboratory personnel; and sensitivity training on the requirements of 10 CFR 50, Appendix B, and 10 CFR Part 21. These actions were verified by the NRC inspection team during the inspection.

c. Conclusions

The NRC inspection team reviewed all available documentation, including the GE-NE Integrity Review, which evaluated the impact of the wet laboratory analyst copying the

previous week's calibration constant rather than performing the required weekly calibration. The team agreed with GE-NE's 10 CFR Part 21 evaluation which concluded that the failure to perform weekly calibrations did not have a negative impact on the originally reported results and as such, a product nonconformance or inadvertent shipment did not occur.

3.3 Review of Unresolved Item 99900003/1999201-02

a. Scope

Review additional documentation to demonstrate that GE-NE adequately resolved several open Corrective Action Requests (CARs) which were identified during a March 26, 1997, audit of JMS Southeast, Inc. (JMS). During the March 1999 NRC inspection, GE-NE could not provide sufficient documentation to demonstrate adequate resolution of the CARs, which have been open for two years. GE-NE has qualified JMS as an approved supplier of safety-related thermocouple calibration services in accordance with 10 CFR 50, Appendix B, 10 CFR Part 21 and GE-NE supplier quality requirements.

b. Observations and Findings

On March 26, 1997, GE-NE audited JMS and identified three CARs. CAR JMS-2 was of particular concern to the NRC inspection team since it identified that JMS's Quality Assurance (QA) program did not procedurally address the reporting of defects to customers pursuant to 10 CFR Part 21. Over the past several years GE-NE has placed over 10 safety-related purchase orders (POs) with JMS for thermocouple calibration services which imposed the requirements of 10 CFR Part 21. The CARs remained open through the early part of 1999 when it was determined that a followup audit needs to be performed to resolve these two year old open issues. During this time JMS revised its QA manual to address the specific findings and on March 4, 1999, GE-NE re-audited JMS. As a result of the audit, GE-NE closed all three CARs and certified JMS as an approved supplier of safety-related services and equipment.

The NRC inspection team reviewed the audit report and identified that the audit did not adequately demonstrate that JMS's QA program complied with the reporting requirements of 10 CFR Part 21, which was imposed on JMS by GE-NE purchase order. Specifically, the audit did not objectively demonstrate that JMS had adequate procedures in-place to identify and evaluate deviations pursuant to 10 CFR 21.21. Section 4.13.3, "Recall Procedure," incorporated into the JMS QA manual in Revision 10, dated December 8, 1998, and later revised in Revision 11, dated February 26, 1999, was added to address CAR JMS-2. However, the NRC inspection team did not agree since it was not of sufficient detail to allow for the identification and evaluation of nonconforming conditions as potential deviations pursuant to 10 CFR 21.21. On September 4, 1997, GE-NE placed PO No. 33497066632 to JMS for full calibration and recertification of two Type "C" thermocouples (GE-NE identification Nos. Z010003 and Z0098534) used to determine the thermal profile of the Centorr furnace. The PO required compliance to Part 21 and required the vendor to furnish Certificates of Traceability to the National Institute of Standards and Technology. The team reviewed preventive actions initiated by GE-NE to improve CAR reporting, tracking and closing, including modifications to its

Approved Supplier List effective January 1999, which should enhance the visibility of unresolved issues on a more timely basis. Nonconformance 99900003/1999202-01 was identified during this part of the inspection.

c. Conclusions

The NRC inspection team reviewed additional documentation during the inspection to support the resolution of three open CARs identified during GE-NE' s March 26, 1997, audit of JMS Southeast, Inc. However, the team concluded that the JMS audit was inadequate in several areas. Specifically, the audit failed to provide objective evidence of JMS's compliance to 21.21 of 10 CFR 21 and as such, does not support closure of CAR JMS-2. Based on the inspection team's review, the NRC has concern over JMS's ability to identify and evaluate potential deviations in light of their status as an approved supplier of safety-related services and equipment, in accordance with 10 CFR 50, Appendix B, and 10 CFR Part 21.

3.4 Review of CAR AI-2212 - Pellet Fluoride and Chloride Evaluations

a. Inspection Scope

The inspection team reviewed GE-NE CAR AI-2212 which was initiated due to a concern raised by a laboratory analyst regarding performance of the furnace blanking method for pellet fluoride and powder/pellet chloride methods. The concern resulted in initiation of PSC 9908 for pellet fluoride and PSC 9912 for powder/pellet chloride. The CAR also addressed method qualification and laboratory analyst training.

b. Observations and Findings

During performance of GE-NE Integrity Case 99-005, discussed in Section 3.2 of this report, one of the wet laboratory analysts raised a concern to management regarding the performance of the furnace blanking method for pellet fluoride and powder/pellet chloride methods. As a result, GE-NE initiated two additional investigations for reportability pursuant to 10 CFR Part 21. PSC 9908 and PSC 9912, closed on April 29, 1999, and May 11, 1999, respectively, concluded that no defect or failure to comply, pursuant to 10 CFR Part 21, existed. GE-NE also initiated CAR AI-2213, dated April 16, 1999, to address training and procedural compliance in the Chemet laboratory.

b.1 Pellet Fluorides Method (PSC 9908)

In March 1999, an employee raised an issue to management that several of the laboratory analysts were not strictly following the procedure of blanking the furnace before each fluoride sample run as prescribed in laboratory procedures. The pyrohydrolysis method, also called the blanking method, is a method to obtain analytical blank values for analysis of fluorine in fuel pellets. An analytical blank value is a fluorine concentration level obtained when the method is followed using all standard procedures, material, and equipment but without any sample present, and is described in GE-NE Calibration and Operation Instruction (COI) 253, "Determination of Fluoride in UO2 and UO2/Gd2O3 Pellets by Pyrohydrolysis and Titration," Revision 1, dated October 14, 1998. Pending evaluation to determine if a potential safety concern existed, GE-NE

suspended performance of the test. PSC 9908 was initiated to investigate the potential impact to the product quality. A second evaluation, PSC 9912 (Discussed in Section 3.4 (b.2) of this report), was also initiated to evaluate pellet chloride analysis because it also utilizes the same blanking method.

During the wet laboratory quality stand down on April 19, 1999, a laboratory analyst was interviewed for alleged falsification of pellet fluoride tests as documented in GE-NE Integrity Case 99-005. The analyst was asked to perform a series of blanking methods for a few samples in the presence of several laboratory managers. Although the tests demonstrated that the analyst did not strictly adhere to the procedures in performing the blanking method, GE-NE concluded that no falsification of data existed. The integrity review identified that the analyst performed the test "as trained" instead of strictly following the procedure. The NRC inspection team reviewed the report, including interview notes and laboratory data, and agreed with GE-NE's conclusion that no falsification of data existed.

CAR AI-2212 was issued to assess the fluoride blanking method and address potential training issues. GE-NE evaluated the effect of uncertainty in the fluoride concentration in fuel pellets in four areas affected by specification requirements: (1) fuel failures during normal operations, (2) cladding degradation during power excursions, (3) uranium content, and (4) power generation. Fuel failures during normal operation are mainly caused by primary hydride in fuel pellets that could attack cladding. However, GE-NE indicated that due to recent implementation of the dry conversion process and a strict industry requirement regarding hydrogen control, the possibility of increasing fuel failures because of the irregularity in the blanking method were very unlikely.

Cladding degradation during power excursions is affected by stress corrosion cracking of Zircaloy cladding due to pellet-clad mechanical interaction (PCMI) in the presence of fluorine. Since GE-NE has introduced a new zirconium lined cladding, the PCMI problem was basically eliminated and thus the fluorine content had no direct effect in this assessment. With respect to uranium content, GE-NE indicated that the amount of uranium could be changed by the total impurities including fluorine. They also stated that power generation is also affected by the total uranium content and higher impurities may reduce power output. GE-NE concluded that no reportable issues existed since the first two concerns related to safety were not present and the latter two concerns were commercial in nature. The NRC inspection team reviewed the assessment and agreed that the likelihood of introducing more fluorine into the fuel pellets was very small and would not effect the overall outcome.

Currently, the procedures to determinate the amount of fluoride in UO2 or UO2/Gd2O3 pellets is documented in Quality Notice (QN) F-Q-2302, "Qualification of Pyrohydrolysis and IS Detection for Pellet Fluoride Analysis," Revision 0, dated August 12, 1999. The QN describes the determination of fluoride in UO2 pellets using pyrohydrolysis followed by ion selective electrode detection. The pyrohydrolysis method is described in COI 253, "Sample Preparation for Fluoride in UO2 and (AGATE)O2 Pellets by Pyrohydrolysis," Revision 2, dated August 12, 1999, which supercedes Revision 1 of the same COI but with a different title. The ion selective electrode detection method replaced the titration method and is described in COI 252, "Determination of Fluoride in Uranium Oxides Using Selective Ion Electrode," Revision 2, dated August 12, 1999.

b.2 Pellet Chloride Method

As mentioned previously, PSC 9912 was initiated to investigate the pellet chloride method, due to the same pyrohydrolysis method, and is described in GE-NE COI 256, Revision 0, "Determination of Chloride in Uranium Oxide Pellet and Powders with and without Guideline," dated September 23, 1998. GE-NE performed a study to assess the capability of the analytical method for reliable data in chlorine concentration. They concluded that there was no safety concern since the results demonstrated that the blanking method for chlorine was adequate and that a product non-conformance did not occur. The NRC inspection team reviewed the report and agreed with the conclusion.

Currently the procedures to determine the amount of chloride in uranium powders is documented in QA F-Q-2292, "Qualification of Method for Determination of Chloride in Uranium Oxide Powders by Dissolution and Turbidimetry," Revision 1, dated June 16, 1999. In addition, COI 275, "Determination of Chloride in Uranium Oxide Powders by Dissolution and Turbidimetry," Revision 2, dated August 6, 1999, provides further detail on the pellet chloride method.

b.3 Training

As a result of PSC 9908 and PSC 9912, CAR AI-2213, dated April 16, 1999, was issued to address the laboratory training program and to develop an action plan to review current training and procedures. After management review of the current organization structure, several training courses were conducted for laboratory analysts. The training included periodic reviews, communication of procedural changes, and the new LIMS software system. On April 19, 1999, a quality standown was conducted with all available Chemet Laboratory staff in attendance. As a followup, all Fuel and Chemet Laboratory Quality staff were re-qualified into the requirements of 10 CFR Part 21. The NRC inspection team reviewed the documentation and concluded that the training program was acceptable.

c. Conclusions

During GE-NE's evaluation of Integrity Case 99-005, one of the wet laboratory analysts raised a concern regarding the performance of the furnace blanking method for pellet fluoride and powder/pellet chloride methods. As a result, GE-NE initiated two additional investigations for reportability, pursuant to 10 CFR Part 21, and initiated CAR AI-2213 to address training and procedural compliance in the Chemet laboratory. At the completion of their evaluation, GE-NE concluded that no defect or failure to comply existed. The NRC inspection team reviewed the documentation and agreed with their conclusion.

3.5. Review of Karl Fischer Moisture Analyzer

a. Scope

The inspection team reviewed the method employed at GE-NE Wilmington to determine the moisture level in uranium powder. The method, known as Karl Fischer titration, is documented in GE-NE COI 259.00, Revision 2, dated April 1, 1999, "Determination of Moisture in Uranium Powders By Karl Fischer Titration."

b. Observations and Findings

In March 1998, an allegation was brought to the attention of GE-NE management from a laboratory analyst who alleged 14 separate issues involving various activities performed in the wet laboratory. GE-NE initiated Integrity Case 98-006 to evaluate the issues which were grouped into the following categories: Falsification of Data; Procedure; Technique; Opinion; and Previously Identified Issues. Of these categories, GE-NE identified the most significant issues which involved deficiencies in the execution of Fluoride/Chloride pellet samples; improper use of test standards; and several discrepancies related to test results associated with the performance of Karl Fischer, Chloride, and Nitrogen tests.

GE-NE concluded from the investigation that although an employee integrity issue did not exist, improvements were needed in procedure interpretation and performance of laboratory standards and practices. Evidence of implementation of these improvements were later initiated through CAR AI-2170 and CAR AI-2212 in March 1999. The team reviewed the integrity report, reviewed the CARs, and concluded that GE-NE took appropriate action to resolve this allegation.

In June 1999, the wet laboratory supervisor was made aware of an issue involving a laboratory analyst who failed to report an out-of-control indication (OOCI) while performing moisture tests using the Karl Fischer analyzer. When twice encountered with an OOCI in running the test, the analyst wrote on the bench sheet "unable to stable" for the first occurrence and "underqualified" for the second occurrence and did not call attention to the supervisor. After review of the issue, the supervisor concluded that there was no immediate safety concern because the uncertainty involved in the moisture level was well within the nuclear safety specifications established by GE-NE. The analyst responsible for the test was reminded of his responsibility to report the OOCI in the future and was encouraged to use a more conservative approach while performing tests using the Karl Fischer analyzer. The NRC inspection team reviewed the supervisor's evaluation and concluded that the action taken was adequate to resolve the issue.

c. Conclusions

The NRC inspection team reviewed the evaluations performed by GE-NE in March 1998 and June 1999 and agreed with the conclusions.

3.6 Review of Fuel Rod Off-Gas Tests

a. Scope

The NRC inspection team reviewed a discontinued practice of performing off-gas tests to assure that all uranium dioxide fuel rods and internal metallic components meet the specified requirements for total volatiles and rod hydrogen content.

b. Observations and Findings

The practice of assuring that all uranium dioxide fuel rods and internal metallic components meet the specified requirements for total volatiles and rod hydrogen content (fuel rod hydrogen test) was performed by GE-NE in accordance with Product/Process

Quality Plan 4.0.4, "Uranium Dioxide Fuel Rod Outgassing," Revision 28, dated April 19, 1994. The practice of performing fuel rod off-gas tests was used primarily as an overcheck in the 1970s through 1990s to address hydrating in nuclear fuel components and to assure that moisture was not introduced into the components prior to final end plug welding. The primary test to determine fuel pellet hydrogen content is performed routinely by GE-NE for individual samples using the LECO hydrogen analyzer.

In 1996, GE-NE eliminated the need for off-gassing based on historical data which demonstrated that the fuel rod off-gas operation was stable and reliable and provided a great deal of margin for the measured attribute of hydrogenous material in fuel pellets. GE-NE QA F-D-1613, Revision 0, "Rationale for Elimination of Bi-Weekly Gumball Test," dated April 14, 1994, discussed the technical rationale for elimination of the test. Factors included documented historical data (no failures in the bi-weekly testing in the preceding nine years of running such test), enhanced training, use of administration limits, and GE-NE's conversion from the wet to the dry process. Quarterly qualification of all nine uranium dioxide furnaces and both Guideline furnaces will continue to be performed.

The practice, known as a "Gumball" test, required a test rod, filled with 80 fuel pellets, to be assembled and processed through a standard off-gas cycle in each oven on a bi-weekly basis. Fuel pellet samples are selected by Shop Operations from a minimum of 4 and a maximum of 10 production trays representative of the production run. This test rod was outfitted with a dummy rod extension and run through one cycle of the furnace qualification run. After the off-gas run is completed, the test rod is sent to the Chemet Laboratory for hydrogen analysis. A total of 24 pellets are selected for testing using the LECO hydrogen analyzer. Test results were recorded onto a "Fuel Rod Hydrogen Test Form" and entered into LMCS. Individual values must not exceed 1 part per million (ppm) and the average value for the test rod must not exceed 0.8 ppm hydrogen.

The NRC inspection team selected for review test rod 2CW0701, dated June 15, 1996, which was run through furnace 6Z. The test for pellet hydrogen utilized samples from pellets 3, 4 and 5 for all eight zones, a total of 24 samples. The average rod value reported on the form was 0.12 ppm with the highest individual pellet value reported as 0.24 ppm. The test was performed in accordance with QA F-Q-2067, Revision 73, dated June 23, 1996.

c. Conclusions

In 1996, GE-NE eliminated the need for off-gassing based on historical data which demonstrated that the fuel rod off-gas operation was stable and reliable and provided a great deal of margin for the measured attribute of hydrogenous material in fuel pellets. The test, known as a Gumball test, was an overcheck to determine if additional moisture had been introduced during the rod fabrication and loading process. Pellet hydrogen is primarily determined by testing samples of individual fuel pellets, taken from actual production runs, and testing them using the LECO hydrogen analyzer. This process differs from the Gumball test since it determines pellet hydrogen during the pellet manufacturing phase (after grinding but prior to fuel rod loading). Based on the inspection team's review of the Gumball test, the team concluded that the test, performed up through 1996, was adequate as an overcheck to determine additional moisture introduced during the off-gas process.

4 ENTRANCE AND EXIT MEETINGS

During the entrance meeting on September 7, 1999, the inspection team met with members of GE-NE management and staff and discussed the scope of the inspection. The team also reviewed its responsibilities for handling proprietary information as well as those of GE-NE. In addition, the team established contact persons within the management and staff of the applicable GE-NE organizations and discussed the results of the inspection with management and staff on September 10, 1999.

PARTIAL LIST OF PERSONS CONTACTED

C. Reda	Manager, GE-NE Quality
A. Moneta	Manager, GE-NE E'S
B. Fuller	Manager, Fuel & Chemet Lab Quality
R. Mack	Manager, PMQC/SCQC
S. Murray	Manager, Regulatory Compliance
W. Baker	Nuclear Quality Assurance
J. Ball	Team Leader/Lead Chemist
R. Bianchi	Senior Engineer
R. Hudson	Laboratory Analyst

ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Type	Description
Opened		
99900003/1999202-01	NON	GE-NE audit of JMS Southeast, Inc., did not adequately demonstrate that their quality assurance program complied with the requirements of 10 CFR Part 21. This item was previously identified as URI 99900003/1999201-02.
Closed		
99900003/1999201-01	NOV	Failure to identify and evaluate a potential deviation related to the lack of calibration of the LECO hydrogen analyzer.
99900003/1999201-02	URI	GE-NE could not produce documentation to support the resolution of three open CARs identified during GE-NE's March 26, 1997, audit of JMS Southeast, Inc. This issue has been identified as Nonconformance 99900003/1999202-01.

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

October 4, 1999

Mr. Richard L. Morley, Manager
Tennessee Valley Authority
Central Laboratories & Field Testing Services
1101 Market Street, PSC 1B-C
Chattanooga, TN 37402

SUBJECT: NRC INSPECTION REPORT NO. 99901341/99-201 AND NOTICE OF NONCONFORMANCE

Dear Mr. Morley:

This refers to the inspection conducted by Richard McIntyre of the Quality Assurance, Vendor Inspection, Maintenance, and Allegations Branch (HQMB), Jim Davis of the Materials and Chemical engineering Branch (ECMB), Hukam Garg of the Electrical and Instrumentation and Controls Branch and William Bearden and Gary Claxton of the NRC Region II Office on August 16-19 ,1999, at the Tennessee Valley Authority (TVA) Central Laboratories and Field Testing Services (CL&FTS) facilities in Chattanooga, Tennessee. The purpose of the inspection was to review the implementation of TVA CL&FTS activities for the calibration of measuring and test (M&TE) equipment and activities related to metallurgical testing and failure analysis. TVA provides these services and testing activities as safety related under their 10 CFR Part 50, Appendix B, quality assurance (QA) program to TVA nuclear plants and to other NRC licensees. At the conclusion of the inspection, the findings were discussed with you and members of your staff identified in the enclosed report.

Overall, the inspection determined that TVA CL&FTS was adequately implementing their 10 CFR Part 50, Appendix B, QA program for the areas reviewed. However, during this inspection the team found that the implementation of your QA program failed to meet certain NRC requirements in one inspection area. Specifically, the inspection identified limited examples where Nonconformance Reports (NCRs) initiated in 1998 did not receive timely resolution and disposition to completion. Also, certain closed NCRs did not include complete documentation packages and no reference was given to the other pertinent documentation associated with the particular instrument calibration .

These issues are cited in the enclosed Notice of Nonconformance (NON), and the circumstances surrounding it are described in detail in the enclosed 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 of Nonconformance.

In accordance with 10 CFR Part 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response 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,

Theodore R. Quay

Theodore R. Quay, Chief, IQMB
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Enclosures: 1. Notice of Nonconformance
2. Inspection Report No. 99901341/99-201

NOTICE OF NONCONFORMANCE

TVA Central Laboratories & Field Testing Services
Chattanooga, TN

Docket No. 99901341

Based on the results of an NRC inspection conducted August 16-19, 1999, it appears that certain of your activities were not conducted in accordance with NRC requirements.

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

TVA Central Laboratories & Field Testing Services (CL&FTS) Quality Assurance Program (QAP) Manual, QAP 7.2, "Control of Nonconformances," Section 5.2.2 requires the Manager, QA/QC staff to maintain a log of nonconformances to ensure timely resolution and disposition.

TVA CL&FTS QAP 7.2, Section 6.1.3.11, requires that the QA/QC manager or designee, perform a final review and approval signifying the NCR is complete by signature and date and forward the completed paperwork to Document Control for processing to the Electronic Document Management System (EDMS) and Records and Information Management Systems (RIMS) programs.

1. Contrary to the above, the inspectors identified the following six open Nonconformance Reports (NCRs) which were initiated in 1998 and did not include timely resolution and disposition to completion.

   - NCR 98087 - initiated on March 23, 1998
   - NCR 98097 - initiated on April 16, 1998
   - NCR 98133 - initiated on July 9, 1998
   - NCR 98163 - initiated on August 27, 1998
   - NCR 98164 - initiated on August 27, 1998
   - NCR 98165 - initiated on August 27, 1998

2. Contrary to the above, the inspectors identified the following three examples where the NCR package did not include complete documentation and no reference was given to the other pertinent documentation associated with the particular instrument calibration .

   - NCR 99035
   - NCR 99075
   - NCR 99090

(Nonconformance 99901341/99-01-01)

Enclosure 1

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, Quality Assurance, Vendor Inspection, Maintenance and Allegations Branch, Division of Inspection Program Management, 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) the reason for the nonconformance, or, if contested, the basis for disputing the nonconformance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further noncompliances, and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

Dated at Rockville, Maryland
this 4 th day of October 1999

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR REACTOR REGULATION

Report no:	99901341/1999201
Organization:	TVA Central Laboratories & Field Testing Services (CL&FTS)
Contact:	Sammy Walker, Manager QA/QStaff (408) 925-6587
Nuclear Activity:	CL&FTS provides services to TVA plants (nuclear and fossil) and to the nuclear industry for the calibration and repair of measuring and test equipment (M&TE) and also provides a wide range of metallurgical analysis and material testing services.
Date:	August 16-20, 1999
Inspectors:	Richard McIntyre, Team Leader, IQMB Jim Davis, EMCB Hukam Garg, HICB Bill Beardon, Region II Gary Claxton, Region II, OI
Approved by:	Daniel H. Dorman, Chief Quality Assurance and Safety Assessment Section IQMB Division of Inspection Program Management

Enclosure 2

1 INSPECTION SUMMARY

The purpose of the inspection was to review the implementation of TVA Central Laboratories and Field Testing Services (CL&FTS) activities for the calibration of measuring and test equipment (M&TE) and activities related to metallurgical testing and material failure analysis. TVA CL&FTS provides these services and testing activities as safety related under their 10 CFR Part 50, Appendix B, quality assurance (QA) program to TVA power plants (nuclear and fossil) as well as to other nuclear licensees.

During this inspection, one nonconformance was identified and is discussed in Section 3.3 of this report.

2 STATUS OF PREVIOUS INSPECTION FINDINGS

No previous inspection findings were examined during this inspection.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Background

TVA CL&FTS is a diverse engineering and technical service facility that has the capability to perform precision instrument calibration and repair; chemical and metallurgical analysis; nuclear qualification of commercial grade electrical equipment and other materials; specialized engineering services such as environmental qualification; and shop services such as the repair of electronic equipment.

The CL&FTS organization structure includes Instrumentation Services, Analysis and Evaluation Services, Field Testing Services Departments, and the QA/C Staff. The organization also includes the Business Development/Support Services department. All of the calibration of precision M&TE is performed by the Instrumentation Services Department. Instrumentation Services is comprised of the following five groups: Physical I; Physical II; Electrical I; Electrical II; and Laboratory Standards. The Analysis and Evaluation Services department perform a variety of technical support services, including metallurgical and material failure analysis by the Metallurgical Services Group. The Analytical Chemistry, Oil Analysis, and Environmental qualification Groups are also part of the Analysis and Evaluation Services department.

This inspection was conducted to review the implementation of the TVA CL&FTS 10 CFR Part 50, Appendix B, QA program as it relates to calibration of M&TE and as it relates to metallurgical analysis and material testing.

3.2 Metallurgical Services

a. Inspection Scope

The NRC inspectors reviewed the applicable portions of the CL&FTS QA program related to metallurgical analysis and failure analysis. QAP No. 4.10, "Analysis and

Evaluation Analysis," describes the requirements and delineates the responsibilities for management of the CL&FTS Analysis and Evaluation Analysis Department. The purpose is to ensure that all analyses/tests performed for the nuclear power industry are properly controlled and accomplished in accordance with approved methods and are within QA program requirements. Metallurgical Services is a group within the Analysis and Evaluation Analysis Department. The inspectors also reviewed selected metallurgical Quality Program Instructions (QPIs) and observed implementation of several procedures (QPIs) during actual test activities. Emphasis was placed on the use of standards traceable to National Institute of Standards and Technology (NIST) standards.

b. Observations and Findings

The following metallurgical QPIs were reviewed by the inspectors:

Instruction No.	Title
101.02-28	Metal Analysis using Varian Spectroscopy Atomic Absorption-600;
201.03-001	Determination of Total Carbon and Sulfur in Metals using Infrared Spectroscopy;
202.01-001	Determination of Hardness using a Rockwell Tester;
202.01-002	Determination of Hardness using a Portable Tester;
202.01-003	Microhardness Testing of Material;
202.01-004	Brinell Hardness of Metallic Materials;
202.01-007	Determination of Hardness using a Rockwell 556T Tester;
202.01-008	Microindentation Hardness Testing;
202.01-009	Notched Bar Impact Testing of Metallic Material;
203.02-002	Recommended Metallographic Techniques;
203.02-003	Dimensional Measurements for Metal Samples;
206.01-001	Chemical Analysis by X-Ray Flouresence Spectroscopy of Solid Metals;
327.03-002	Tinius Olsen Super "L" Universal Test Machine; and
327.03-003	Tinius Olsen 1000 Series Universal Test Machine.

During review of the QPIs the inspectors noted that revisions to the QPIs did not include the initials or the signature of the preparer as required by QAP 2.1 Section 6.2.2.2.11. QAP 2.1 provided a step-by-step procedure for preparing and approving QPIs. CL&FTS demonstrated that for newer QPI sections, the preparer's signature is electronic and the presence of the preparer's initials in the document indicates that the preparer has electronically signed the document.

There was no discussion in the QPIs on how the proving rings used to calibrate the tensile machines are calibrated and maintained traceable to NIST. CL&FTS staff demonstrated that the proving rings are sent to a CL&FTS approved supplier, Morehouse, where they are calibrated using standards traceable to NIST.

Observations Specific to the QPIs Reviewed:

QPIs 202.01-001, 202.01-002, 202.01-003, and 202.01-004, which described various methods for determining the hardness of a metallic material, interchanged the referencing of National Bureau of Standards (NBS) and National Institute of Standards and Technology (NIST) when describing the calibration blocks for these instructions. NBS officially changed its name to NIST in the mid 1980's. The TVA staff demonstrated to the inspectors that the current Wilson calibration blocks are traceable to NIST.

Instructions 202.01-001, 202.01-003, and 202.01-004 required that the calibration standard serial number be identified and that the test results from the calibration standard be included in the final report. Instruction 202.1-02 did not require that the calibration standard serial number be identified and referenced and that the test results from the calibration standard be reported. TVA staff noted that even though the QPI did not include this requirement, Section 4.10 of the QAP Manual requires that the calibration standard serial number be identified and referenced and that the test results from calibration standard be reported.

The QPIs 202.01-001, 202.01-002, 202.01-003, and 202.01-004 reference ASTM standards that are no longer valid standards since they are more than 5 years old. However, the inspectors noted that the ASTM standards referenced in the QPIs do have the year of issue specified. This ensures that if an ASTM standard undergoes a significant revision, the revised standard does not become the referenced standard, possibly without review by the TVA staff. The inspectors verified that CL&FTS has recently implemented a new requirement that all quality program instructions are revised every 4 years.

The inspectors pointed out that QPI 202.01-008 references ASTM E-384 with no year indicated. CL&FTS staff stated that the 1989 edition of the standard is being used and that no modifications to this standard have been made in later editions. CL&FTS staff also stated that when the QPI is revised, the appropriate edition of the standard will be in the revised standard.

QPI 202.01-009, on notched bar impact testing of metallic materials, states in the General Instructions that this method is used to find brittle materials. The inspectors suggested that the General Instructions be modified to state that this method can be used to determine ductile-to-brittle transition temperature, nul-ductility temperature, upper shelf energy, and toughness at any temperature.

Laboratory Environmental Monitoring

During the tour of the laboratory facilities the inspectors inquired what was the basis for the different (68°F+/- 1°F and the 72°F +/- 2°F) laboratory temperatures that are monitored in the various laboratory areas using temperature/humidity chart recorders? CL&FTS stated that QAP No. 4.1, "M&TE Calibration Program," Section 7.1, "Facilities and Environment," provided references that stated that the 68°F+/- 1°F or 20°C room is for dimensional measurements conducted in the Standard Laboratory room while the

72°F +/- 2°F is for other disciplines of metrology such as electrical standards. In addition, the relative humidity is maintained below 50 percent .

The inspectors determined that NCR 99061 was written in December 21, 1998 identifying inconsistencies between program requirements and laboratory environmental monitoring equipment performance. This issue was also identified as audit finding (Deviation Report) in the TVA Nuclear (TVAN) Supplier Audit 99V-17, dated June 4, 1999. This was an external audit of the TVA CL&FTS QA program by TVA Corporate Quality Assurance.

NCR 99061 was closed on March 22, 1999, and the remaining issues were rolled into NCR 99125. NCR 99125 was written on August 15, 1999, to address ineffective implementation of environmental monitoring described in the above Deviation Report. CL&FTS stated that a complete upgrade of laboratory environmental monitoring was ongoing as part of the corrective actions described by CL&FTS to the TVAN deviation Report 99V-17-1. These corrective action activities, if adequately implemented and completed, appear to address the TVA CL&FTS internal and TVAN Corporate external audit finding concerns with CL&FTS laboratory environmental monitoring.

Review of Implementation of CL&FTS Testing Activities

The inspectors observed a demonstration of the preparation of material samples and the testing of samples using X-Ray Fluorescence Spectroscopy to determine the chemical composition of the metal sample using QPI 206.01-001. The inspectors were also provided a demonstration of the preparation of samples and the Infrared testing of metal samples to determine carbon and sulfur. The use of calibration standards for each method was also demonstrated. The technician conducting these procedures knew the procedures in detail and had no difficulty in preforming the tests. The technician was asked what metallurgical procedures he conducted. He stated that it is CL&FTS policy that all laboratory technicians are trained to conduct all of the procedures in the Metallurgical Laboratory. The inspectors stated that this was somewhat unusual to have a technician trained on more than one or two pieces of equipment. However, the inspectors did not identify any problems with the conduct of the tests and did find that the cross-training on the various QPIs was desirable.

c. Conclusion

During the review of the QPIs the inspectors identified a number of observations and identified areas that required clarification by CL&FTS. CL&FTS was able to answer all questions and clarify the inspectors issues related to the observations. Based on this, no nonconformances were identified during this portion of the inspection. The NRC inspectors were given demonstrations of the X-Ray Fluorescence Spectroscopy test to determine chemical composition and the Infrared analysis test to determine carbon and sulfur concentration. The technician conducting the tests was well trained and was very knowledgeable in performing all the steps and procedural requirements. Finally,

the recent and ongoing long term upgrades to hardware and software for environmental monitoring of temperature and humidity should provide adequate coverage to satisfy the accuracy requirements of the QAP.

3.2 Training and Qualifications of TVA CL&FTS Personnel

a. Inspection Scope

The team reviewed training and personnel records for selected managers, laboratory technicians and calibration personnel in both the Instrumentation Services and Analysis and Evaluation Services groups to verify that those personnel were adequately trained and qualified as per TVA CL&FTS QAP requirements to perform safety-related work activities.

b. Observations and Findings

The team reviewed training and personnel history records (PHRs) for the Quality Assurance/Quality Control Manager, Instrumentation Services Manager, five instrumentation department program administrators, and the Lead Metallurgical Engineer. Additionally, training records and PHRs for one quality specialist and 10 technical personnel were reviewed. At least one supervisor and one technician from the Metallurgical Laboratory and each of the five groups in the Instrumentation Services Department were included in this review. Each individual's academic training and experience was evaluated and compared to the specific requirements stated in the associated job description to verify that these personnel were qualified to perform work activities commensurate with their responsibilities.

The team determined that, for those training records and PHRs reviewed, selection of management and technical personnel met the academic training and experience requirements contained in the associated TVA job descriptions. Each individual's level of training and previous work experience satisfied the minimum stated requirements prior to that individual being placed in the respective position. In most cases the individual's actual experience level was well above the minimum required years of on-the-job experience.

CL&FTS QAP No. 11.1, Rev. 8, "Quality Assurance Indoctrination and Technical Training", requires CL&FTS personnel to receive initial indoctrination training including training on quality assurance requirements. Additionally, each individual was required to receive an initial evaluation of on-the-job performance prior to independent performance of assigned duties. In most cases individuals had received the required level of initial indoctrination training and qualification was properly documented prior to that individual performing safety-related work activities. However, the team identified one example of a manager that had performed safety-related work activities prior to completion of initial indoctrination training.

The Instrumentation Services Manager, who had newly reported to the CL&FTS facility on August 15, 1998, had not completed initial indoctrination training until October 1,

1998. In this case, the individual had considerable experience as an instrumentation engineer and instrumentation supervisor at TVA's Sequoyah Nuclear Plant, was fully qualified in the new position. This issue had been considered after the newly assigned manager had been placed directly in the position. CL&FTS management had decided that a problem had not existed since all quality related work activities would receive additional review and signature from the Quality Manager or another qualified manager until such time that indoctrination training was completed. However, a small number of work related documents were processed without this additional level of review prior to October 1, 1998. The failure to satisfy indoctrination training requirements had occurred due to a lack of sensitivity by CL&FTS management and Quality Assurance personnel. The team noted that this had been an isolated case and that only a small number of work activities had been affected.

The inspectors determined that this problem had previously been self-identified by CL&FTS personnel and documented in NCRs 99032 and 99033 on November 6, 1998. Corrective actions included verification of completed indoctrination training and review of all potentially affected documents to determine impact on quality related work activities. CL&FTS quality assurance personnel verified that only 4 out of 183 potentially affected records had included the new manager's signature as the sole authorizing signature. Additionally, no problems were identified during the subsequent review of those records. The inspectors emphasized that the process used to qualify the newly hired manager was contrary to requirements of QAP 11.1, Section 6.1.1, but no nonconformance would be written based on the fact that it had been self-identified and corrective actions had been comlpeted.

The team determined that periodic training on revisions to CL&FTS QAP manual, procedures and quality assurance requirements was adequate. In each case, for those training records reviewed, documentation was available to show that personnel had received additional training associated with significant program or procedure changes. Additionally, each individual was required to receive an annual evaluation of on-the-job performance in order to continue to independently perform assigned duties.

c. Conclusions

Based on the information reviewed the inspectors concluded that CL&FTS personnel were adequately qualified to perform assigned duties. The team did identify one example of a manager that had performed safety-related work activities prior to completion of initial indoctrination and training. However, the one example described above was an isolated case and had been previously self-identified and included and addressed by the TVA CL&FTS NCR process.

3.3 Instrumentation Services

a. Inspection Scope

During this inspection, the NRC inspectors reviewed selected calibration reports, Quality Program calibration instructions, nonconformance reports (NCRs), and observed a

demonstration of the computerized Labmate calibration report process and the Electronic Document Management System (EDMS) and Records and Information Management Systems (RIMS) programs.

QAP No. 4.1, "M&TE Calibration Program," describes the requirements and delineates the responsibilities for management of the CL&FTS calibration program. The purpose is to ensure that M&TE calibrated for use in the nuclear power industry is properly controlled and calibrated at specific intervals.

b. Observations and Findings

Calibration Instructions

During this inspection the following two QPIs were reviewed by the inspector:

Instruction No.	Title	Rev. Date	Rev. level
308.01-009	Resistance Test Boxes	8/23/90	01
416.01-009	Scientific Columbus Transducer Calibrator	1/6/97	09

The first instruction was very simple and the second was complex. During the review, the inspector noted that the originator had not signed the instruction. The TVA CL&FTS personnel explained that when the original instruction is written the originator also signs the instruction, however, once the instructions are written by the computer, the originator is not required to sign the instruction. TVA showed the signature of the originator on the original instruction which resolved the instructor's concern. The inspector also requested the originator (J. Moore) for the second instruction to demonstrate how the instruction is used during actual calibrations. Mr. Moore demonstrated one portion of the instruction, "Voltage Calibration," to the inspector in a step by step manner. Other portions of the instruction for "Current Calibration," "Power Calibration," and "Error Meter Calibration" were also explained by the originator. Based on this demonstration, the inspector was able to determine that the instructions are adequate for these calibrations.

The inspector also noted that the format for the instructions included many sections such as, Maintenance, Data Evaluation, Final Check, and Process, but most of the instruction does not include any instruction for performing these sections. CL&FTS explained that the format is standard format and provide flexibility to add additional information when required. The inspector was satisfied with the CL&FTS's explanation.

Calibration Reports

The inspector requested CL& FTS to provide a list of calibration work which was performed for external contracts (non TVA plants) during last two years. CL&FTS provided the list and the inspector selected the following reports for two clients, Cooper Nuclear Station and Crane Movats for review.

Report No.	Date	Client	Item
1000019567	10/21/98	Cooper Nuclear Station	Deadweight Tester- Pneumatic
1000018563	9/11/98	Cooper Nuclear Station	Deadweight Tester- Hydraulic
E28473	5/18/99	Cooper Nuclear Station	Digital Multimeter
1000027403	6/10/99	Cooper Nuclear Station	Electrostatic Voltmeter
1000028453	5/13/99	Cooper Nuclear Station	Resistance Meter
1000028897	6/03/99	Crane Movats	Deadweight Tester- Hydraulic
1000028971	5/26/99	Crane Movats	Megohmmeter

During the review of the reports the inspectors noticed that some reports were signed by the originator and others were not signed by the originator. The inspector was concerned that the reports could be changed without the knowledge of the originator. The inspector requested CL&FTS to provide some calibration reports which have been revised at a later date. The inspector reviewed the following revised calibration reports:

Report No.	Date	Client	Item
1000029120	6/3/99	Peco Energy Co.	Torque Wrench (Indicating)
1000027927	4/28/99	Browns Ferry NP	Impulse Rotary Transducer
1000029741	6/21/99	Browns Ferry NP	Digital Pressure Gauge
1000027097	5/4/99	Watts Bar NP	Conductivity/ph Meter
1000024946	3/1/99	Browns Ferry NP	Sling Psychrometer

The inspector noticed the same pattern on these reports also. The inspector questioned CL&FTS to explain how the originator becomes aware of the changes made to the calibration report by the approving personnel, as it seems the originator never signs the report. CL&FTS explained that the organization is small and all personnel work in the close proximity. Therefore, if any questions or problems are identified by the approving person, he will first talk to the originator before making any changes to the calibration report. CL&FTS also explained that only the Physical I Group requires the originator to sign the calibration report. This is a requirement only in the Physical I Group and is in addition to the requirements of section 6.6.2.18.1 of QAP No. 4.1, Rev. 10, "M&TE Calibration Program," dated 1/15/99.

CL&FTS also explained that all the calibration reports are contained in EDMS/RIMS and is accessible to all personnel. CL&FTS also explained that the Labmate program which is used to generate the calibration report is also available to all technicians and managers. The inspector also observed the demonstration of the Labmate and confirmed the accessibility of the calibration report from the Labmate. However, once the technician or the originator of the calibration report signs the report he will no longer be able to access and make any changes to the report. But, if he does have any problem with the calibration report, he can raise and hopefully resolve the issue with the reviewer. During interactions with technicians, the inspectors also determined that technicians are not trained on the accessibility of the document from the EDMS. CL&FTS explained that all the management personnel were trained on the system and

were then asked to train personnel working for them. However, this may not have occurred because of time, priorities or some other reasons. The team recommended and CL&FTS management committed to conduct formal training for technicians on the EDMS. The team considered this to satisfactorily resolve the concern.

Nonconformance Reports

CL&FTS QAP No. 7.2, "Control of Nonconformances," establishes the requirements and assigns the responsibilities to ensure the identification, documentation, control, and disposition of items and activities that do not conform to the CL&FTS QA requirements. The inspector requested CL&FTS to provide a list of all Nonconformance Reports (NCRs) that had been issued during the last two years. CL&FTS provided the NCR logbooks for fiscal years (FY) 98 and 99. The inspector selected the following NCRs for review:

NCR No.	Date	Item Description	NCR Description	Completed
98079	2/27/98	Pressure Controller	Calc Error in spreadsheet	3/3/98
98102	4/29/98	Load Cell with Indicator	Incorrect Standard No.	7/23/98
98163	8/27/98	Standard Resistor	Out of Tolerance	Open
98168	9/8/98	Instruction 307.04-004 R2 Instruction 406.02.018 R0	Instructions not dated	11/12/98
99035	11/9/98	Teraohmmeter	Failed in Service	11/23/98
99075	1/25/99	Deadweight Tester	Out of Tolerance	2/2/99
99077	1/28/99	Spreadsheet	Error on Page 5	2/22/99
99106	3/24/99	DC Reference Standard	Instr Cal light not lit	6/18/99
99123	4/21/99	Proving Ring	Uncertainty Calc. does not Conform to ASTM E74-95	Open CAR99-02
99182	7/19/99	AC Voltmeter	Metcal Proc. SCR990075 R0 uses wrong voltage at Test Point No. 27.004	Open
99185	7/20/99	Spreadsheet	Out of tolerance condition	Open

The inspectors noted that the threshold used for identifying and documenting NCRs at CL&FTS was very low and consider this as an apparent strength in the NCR process . This was evident since the number of NCRs issued in FY 98 was 179 and 203 so far for FY 99. Also, QAP No. 7.2, Section 5.4.1 states that any employee can issue an NCR for any suspect deficiency in characteristic, documentation, procedure, process or method which renders the quality of an item or report data unacceptable or indeterminate and notifies the immediate supervisor and/or department manager.

NCR Disposition and Closure

CL&FTS QAP No. 7.2, Section 5.2.2 requires the Manager, QA/QC staff to maintain a log of nonconformances to ensure timely resolution and disposition. The inspector determined that QA/QC manager issues the list of all open NCRs weekly to all supervisors. The inspector requested the latest list documenting the open NCRs. Upon reviewing the list dated 8/19/99, the inspector noted that there were six NCRs which were initiated in 1998 but were still open. During the review of NCR 98163, the inspector noted that the corrective actions were identified for the closure of the NCR. However, corrective actions had not been implemented and the NCR was still open. CL&FTS explained that this NCR is applicable to Standards Laboratory and just one technician and his supervisor are assigned to work in the Standards Lab. The technician was the initiator of the NCR and the supervisor was the reviewer of the NCR. Therefore, both are quite familiar with and are following the requirements of the corrective actions. CL&FTS agreed that this NCR should have been closed in a timely manner but somehow had fallen through the cracks. The failure to ensure timely resolution and disposition of six NCRs issued during FY 98 per the above QAP requirement was identified as the first example of Nonconformance 9990134/99-01-01.

CL&FTS QAP No. 7.2, Step 6.1.3.11, requires that the QA/QC manager or designee, perform a final review and approval signifying the NCR is complete by signature and date and forwards the completed paperwork to Document Control for processing to EDMS/RIMS. However, during the review of the NCRs, the inspector identified that NCR packages, NCRs 99035, 99075 and 99090, did not include complete documentation and no reference was given to the other documentation.

CL&FTS explained that EDMS will identify all the documentation associated with the particular instrument in calibration and they produced the documentation when requested. However, the inspector concluded that the procedure requires a complete NCR package be sent to EDMS, hence, either all the document should be referenced in the NCR or should be attached to the NCR. The inspector was also concerned that the once the NCR is closed, the initiator of the NCR does not get the copy of the completed NCR package. The failure to include the complete NCR documentation package or a reference to all the documentation associated with the particular instrument calibration per the above QAP requirement was identified as the second example of Nonconformance 9990134/99-01-01.

CL&FTS explained that to the inspectors that all the NCRs are available on the EDMS and could be retrieved by anyone. The inspector observed the demonstration of EDMS and determined that the document could be easily retrieved from the EDMS but all the personnel should be trained to use it effectively. As discussed previously, the team recommended and CL&FTS management committed to conduct formal training for technicians on the EDMS.

c. Conclusions

Based on the information reviewed the inspectors concluded that CL&FTS personnel were adequately implementing the QA program requirements for the calibration of M&TE with the exception of the two NCR examples identified above in Nonconformance 9990134/99-01-01.

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Selected Generic Correspondence on the Adequacy of
Vendor Audits and the Quality of Vendor Products

Identifier	Title
Information Notice 99-34	Potential Fire Hazard in the Use of Polyalphaolefin in Testing of Air Filters

NRC FORM 335
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11. ABSTRACT *(200 words or less)*

This periodical covers the results of inspections performed by the NRC's Quality Assurance, Vendor Inspection and Maintenance Branch, that have been distributed to the inspected organizations during the period October through December 1999.

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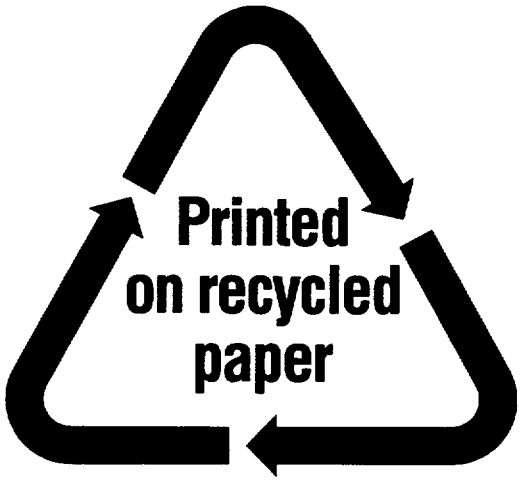

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