December 28, 2007

Mr. Laurence Patterson
Project Manager
Areva NP, Inc.
200 West Kensinger Drive, Suite 600
Cranberry Township, PA 16066

SUBJECT: NRC INSPECTION REPORT 99901355/2007-202 AND NOTICE OF NONCONFORMANCE

Dear Mr. Patterson:

On November 27-30, 2007, U.S. Nuclear Regulatory Commission (NRC) completed an inspection at the Eaton Cutler-Hammer (ECH) facility in Greenwood, South Carolina. Areva dedicates breakers manufactured by ECH. The enclosed report presents the results of that inspection.

This was a limited scope inspection which focused on assessing your compliance with the provisions of Part 21 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 21), "Reporting of Defects and Noncompliance," and selected portions of Appendix B to 10 CFR Part 50, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Processing Plants." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance or Part 21 programs.

During this inspection, it was found that the implementation of your quality assurance program failed to meet certain NRC requirements contractually imposed on you by your customers. The findings are discussed in the enclosed Notice of Nonconformance (NON) and NRC Inspection Report. Specifically, deficiencies were noted in the following activities; (1) ECH personnel performing safety-related activities associated with final acceptance testing were not trained, (2) Areva failed to properly identify several deviations in accordance with Areva's corrective actions process guidance, (3) Areva failed to adequately control the measuring and test equipment used by ECH to conduct final acceptance testing, (4) Areva failed to document several final acceptance test results and did not perform a test for one of the identified critical characteristics, and (5) Areva lacked adequate design control documentation of engineering judgments supporting commercial-grade item equivalency evaluations.

These nonconformances are cited in the enclosed NON, and the circumstances that surround them are described in the enclosed report. You are requested to respond to the nonconformances and should follow the instructions specified in the enclosed NON when preparing your response.

CONTACT: Paul Prescott, NRR/DE/EQVB
(301) 415-3026

In accordance with 10 CFR 2.390 of the NRC's "Public inspections, exemptions, requests for withholding," of 10 CFR Part 2, “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders,” a copy of this letter, its enclosures and any associated correspondence will be placed in the NRC's Public Document Room (PDR) or from the NRC’s document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Patrick L. Hiland, Director
Division of Engineering
Office of Nuclear Reactor Regulation

Docket No. 99901355

Enclosures:
1. Notice of Nonconformance
2. Inspection Report No. 99901355/2007-202

In accordance with 10 CFR 2.390 of the NRC's "Public inspections, exemptions, requests for withholding," of 10 CFR Part 2, “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders,” a copy of this letter, its enclosures and any associated correspondence will be placed in the NRC's Public Document Room (PDR) or from the NRC’s document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Patrick L. Hiland, Director
Division of Engineering
Office of Nuclear Reactor Regulation

Docket No. 99901355

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NOTICE OF NONCONFORMANCE

Areva NP, Inc.
200 West Kensinger Drive, Suite 600
Cranberry Township, PA 16066

Docket Number 99901355
Inspection Report Number 2007-202

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted November 27-30, 2007, of activities performed at Eaton Cutler-Hammer's facility in Greenwood, South Carolina by Areva NP, Inc. (Areva) it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon Areva by NRC licensees.

A. Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50, states in part that, "A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. Test results shall be documented and evaluated to assure that test requirements have been satisfied."

Areva Quality Management Manual 56-5015885-07 issued June 1, 2007, Section 4.5.4, "Inspection and Test Status," states in part that, "The requirements placed by PLANTS on their own Units and their suppliers include the use of the inspection program or inspection plan/test plan/manufacturing sequence plan as a follow-up document which is filled in as work progresses. In this way it is possible to know, at any time, which inspection and test operations have been performed."

Areva dedication procedure, DP-01-67, "Eaton Electrical, Inc. Cutler-Hammer Type MA-VR-350-1200 and MA-VA-350-200 Medium Voltage Vacuum Replacement Circuit Breakers," Revision 5, specifies the critical characteristics that must be tested to provide reasonable assurance that the item will perform its intended safety function.

Areva Operating Instruction, OI-1580, "Acceptance Testing of Type MA-VR Vacuum Replacement Breakers," Revision 0, establishes the guidelines for performing the functional acceptance tests unique to the type of breaker.

Areva Operating Instruction, OI-1513, "Technical Evaluations and Commercial Grade Dedication," Revision 0, states that, "The acceptance inspection/tests listed in section 12 of the dedication plan will be performed and test/inspection results will be documented as Sat or Unsat."

Contrary to the above:

1. Functional acceptance testing of the truck operated contacts (TOCs) as specified in the referenced dedication plan was absent from the implementing document, OI-1580, "Acceptance Testing of Type MA-VR Vacuum Replacement Breakers," Revision 0.

2. Three functional acceptance tests required by OI-1513, Revision 0, were performed. However, the corresponding test results were not documented since the data form in OI-1580, Revision 0, lacked a block to enter the test results.

These issues have been identified as Nonconformance 99901355/2007-202-01.

B. Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, states in part that, "The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

Areva Quality Management Manual 56-5015885-07, issued June 1, 2007, Section 3.2.3, Formal Qualification," states in part that, "Within PLANTS, the personnel performing audits, inspections, tests, any specific technical process or non-destructive examination…are formally qualified according to implementing procedures."

Contrary to the above, Eaton Cutler-Hammer personnel performing testing activities in support of commercial-grade dedication of circuit breakers did not have documentation as being formally qualified in accordance with implementing procedures.

This issue has been identified as Nonconformance 99901355/2007-202-02.

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

Areva Quality Management Manual 56-5015885-07 issued June 1, 2007, Section 4.6, "Control of Measuring and Test Equipment," states in part that, "For subcontracted inspection and testing, purchase orders impose requirements on suppliers concerning the control of the measuring and test equipment they utilize."

Contrary to the above, Areva PLANTS' Purchase Order 1007003503, dated February 8, 2007, to Eaton Electrical-Vistaline, failed to impose the above requirements for the use and control of measuring and test equipment on their supplier (Eaton Cutler-Hammer). The referenced purchase order addresses the procurement of several 4160-volt circuit breakers dedicated by Areva for the Farley Nuclear Plant.

This issue has been identified as Nonconformance 99901355/2007-202-03.

D. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states in part that, "Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components." Additionally, Criterion III states in part that, "The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program."

AREVA Quality Management Manual 56-5016885-03, issued June 1, 2007, Section 4.3.7, "Control of Design and Development Changes," states, "Any change occurring during a study or design analysis, relating to documents, databases or software that are already applicable, is the subject of an analysis to assess its justification, its technical consequences, and its impact on the product and associated risks."

Section 7.5 of AREVA Operating Instruction OI-1513, "Technical Evaluations and Commercial Grade Dedication," Revision 0, states that the basis for acceptability of any critical design differences between original and replacement items, including acceptability for Seismic and Environmental Qualification requirements as applicable must be documented in the conclusion section of the Technical Evaluation or the Equivalency Determination (ED) database.

Contrary to the above:

1. Areva's Technical Evaluation, DP-01-67, "Eaton Electrical, Inc. Cutler-Hammer Type MA-VR-350-1200 and MA-VR-350-2000 Medium Voltage Vacuum Replacement Circuit Breakers," Revision 5, failed to adequately document the basis for acceptability of any critical design differences between original and replacement items.

2. Areva's review of Equivalency Determinations associated with DP-01-67, ED.136.MA-VR, Revision 3, ED.137.MA-VR, Revision 5, and ED.140.MA-VR, Revision 2, failed to provide adequate documentation to support the basis of the engineering design review conclusions. In multiple instances, the EDs merely acknowledged that an equivalent change was made to the breaker without providing information to support the justification, technical consequences, or impact on the product and associated risks.

These issues have been identified as Nonconformance 99901355/2007-202-04.

E. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states in part that, "Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Areva Quality Management Manual 56-5015885-07, issued June 1, 2007, Section 5.5.2, "Corrective Actions," states in part that, "corrective actions are carried out in order to eliminate the causes of actual nonconformances or defects. The processing of corrective actions is described in the procedure "*Corrective Actions,"* and implementing procedures."

Areva NP Inc. Administrative Procedure (AP) 1717-06, "Corrective Action Program - WebCAP," Revision 2, establishes, in part, the process for determining if issues identified in the Corrective Action Program (CAP) need to be evaluated for reporting under 10 CFR Part 21. Specifically, Section 4.3 describes the requirements for performing deviation determinations and for evaluating if the deviations are defects that are reportable under 10 CFR Part 21 requirements. Section 4.3 describes the questions in WebCAP that are required to be answered in order to complete the 10 CFR Part 21 screening process.

Contrary to the above, the instructions contained in Step 4.3.1.8 of AP 1717-06 created the potential to circumvent the performance of a 10 CFR Part 21 evaluation. This was evidenced by multiple instances of incorrect responses to the screening questions for initially identifying deviations.

This issue has been identified as Nonconformance 99901355/2007-202-05.

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 Director, Division of Engineering, 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: (1) a description of steps that have been or will be taken to correct this item; (2) a description of steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective action and preventive measures were or will be completed. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency-wide Document Access and Management System (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection, described in 10 CFR 73.21.

Dated at Rockville, Maryland this 28th day of December 2007.

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

VENDOR INSPECTION REPORT

Report No:	99901355/2007-202
Organization:	Areva NP, Inc. 200 West Kensinger Drive, Suite 600 Cranberry Township, PA 16066
Vendor Contact:	Mr. Laurence Patterson, Project Manager Areva NP, Inc. 200 West Kensinger Drive, Suite 600 Cranberry Township, PA 16066 (724) 779-9800
Nuclear Industry:	Eaton Cutler-Hammer designs and manufactures commercial breakers. Areva NP, Inc. provides dedication services for these breakers for use in the US nuclear industry.
Inspection Dates:	November 27-30, 2007
Inspection Team Leader:	Paul Prescott, DE/NRR
Inspectors:	Daniel Pasquale, DE/NRR Jason Eargle, DSS/NRR Audrey Klett, DE/NRR
Approved By:	***/RA/*** 12/26/07
	Dale F. Thatcher Quality & Vendor Branch Division of Engineering (DE) Office of Nuclear Reactor Regulation (NRR) Date

ENCLOSURE 2

1.0 INSPECTION SUMMARY

The purpose of this inspection was to review selected portions of the quality assurance (QA) and 10 CFR Part 21 (Part 21) controls that Areva NP, Inc. (Areva) has established and implemented for dedication activities it performs for breakers manufactured by Eaton Cutler-Hammer (ECH). Specifically, the inspectors focused on Areva's dedication activities associated with the replacement vacuum breakers for the Farley Nuclear Plant. The inspection was conducted at ECH's facility in Greenwood, South Carolina. The NRC 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*, and
- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

1.1 NONCONFORMANCES

- Nonconformance 99901355/2007-202-01 which identified two examples functional testing protocol deficiencies. This issue is discussed in Section 3.1 of this report.
- Nonconformance 99901355/2007-202-02 which identified the use of ECH individuals not appropriately trained and indoctrinated. This issue is discussed in Section 3.1 of this report.
- Nonconformance 99901355/2007-202-03 which identified Areva's lack of M&TE control at the ECH facility. This issue is discussed in Section 3.1 of this report.
- Nonconformance 99901355/2007-202-04 which identified two examples where Areva failed to adequately document the basis for acceptability of potential critical design differences between the original and replacement items. This issue is discussed in Section 3.1 of this report.
- Nonconformance 99901355/2007-202-05 which identified a procedural deficiency that introduces the possibility of circumventing the requirements set forth in 10 CFR 21. This issue is discussed in Section 3.2 of this report.

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

There was no recent NRC inspection of Areva's dedication activities performed at ECH's facility in Greenwood, South Carolina prior to this inspection.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 DESIGN CONTROL

a. Inspection Scope

The inspectors reviewed Areva's policy and procedures governing the commercial-grade dedication of medium voltage vacuum replacement circuit breakers at the ECH Power

Breaker Center facility to ensure those guidelines provided an adequate description of the process and implemented the requirements described in Part 21.

The inspectors also reviewed Areva's Quality Assurance Manual, a representative sample of dedication packages and related condition reports (CRs), and observed the breaker commercial-grade dedication process.

b. Observations and Findings

b.1. Commercial Grade Dedication Process

Areva's commercial-grade dedication program for medium voltage vacuum replacement circuit breakers is predominately based upon functional acceptance testing of each breaker. Functional acceptance testing of the items' critical characteristics provides reasonable assurance that the component will perform its intended safety function and meet the requirements of dedication testing as specified in Part 21. However, unlike most third-party commercial-grade dedicators, Areva's dedication plans are augmented by a review of the sub-supplier's manufacturing design changes. This additional level of scrutiny is made possible through contractual agreements between Areva and ECH, which grants Areva full access to the manufacturer's design control data. Areva performs a gap analysis between the design currently in production at the manufacturer's facility and the last design Areva qualified. If the gap analysis indicates that an attribute of a critical characteristic may have changed since Areva's last qualified design, an Equivalency Determination is performed to evaluate if the new attribute affects Areva's initial baseline Technical Evaluation. A more detailed explanation of this process can be found in the section of this report discussing technical evaluations and engineering determinations.

Areva's implementing guidelines for performing functional acceptance testing on the subject breakers are presented in two Operating Instructions (OI)-1513, "Technical Evaluations and Commercial Grade Dedication," Revision 0, and OI-1580, "Acceptance Testing of Type MA-VR Vacuum Replacement Breakers," Revision 0. OI-1513 provides guidance for performing Areva's review of the safety-related functional requirements for an assembled component as specified in the licensee's purchase order. This review includes an assessment of the component's critical design characteristics and the critical characteristics of manufacture, as determined through a Failure Modes and Effects Analysis (FMEA). The dedication plan contains a tabulation of these characteristics for the base component. Any unique features added to a base component by a licensee are verified via supplemental testing controlled by a test plan written for the specific configuration.

The inspection of Areva's dedication process at ECH included a document review, and a performance assessment of a representative dedication testing activity. Specifically, the inspection team witnessed Areva's implementation of commercial-grade Dedication Plan, (DP)-01-67, "Eaton Electrical, Inc. Cutler-Hammer Type MA-VR-350-1200 and MA-VR-350-200 Medium Voltage Vacuum Replacement Circuit Breakers," Revision 5, for the circuit breakers supplied to the Farley Nuclear Plant. The observation encompassed Areva's baseline design through witnessing of functional acceptance testing. The inspectors reviewed Areva's test processes for dedicating these breakers and identified several examples of failing to document test results. DP-01-67 lists those critical characteristics that must be tested to provide reasonable assurance that the item will

perform its intended safety function. The information as presented in the plan was interpreted to mean that all the listed critical characteristics were required to be verified in order to achieve reasonable assurance the component will perform its intended safety function since no analysis had been performed to justify not having to perform testing. Additionally, Areva utilized two lower-tier procedures working in conjunction with each other to implement the details of the dedication plan. The guidelines in OI-1580 established the requirements for performing the functional acceptance tests unique to the style of breaker. The acceptance criteria were contained in OI-1513 for the inspection/tests listed in section 12 of the dedication plan. The dedication plan required that the inspection/test results be documented as Sat or Unsat. The deficiencies identified during the inspector's review of Areva's dedication process were:

- Areva's commercial-grade dedication plan, DP-01-67 for performing the functional acceptance test did not include testing of all of the critical characteristics required by the dedication plan. Specifically, it was noted that testing of the Truck Operated Contacts (TOC) as specified in the referenced dedication plan was absent from the implementing document, Areva's OI-1580. This issue is identified as one example of Nonconformance 99901355/2007-202-01.

- The inspectors noted that OI-1513 did not have requirements to document all the test results from the final acceptance tests. The inspectors identified that even though the required testing was being performed, the corresponding test results were not required to be documented since the data form in OI-1580 lacked a block to enter the test results. This was identified during the performance assessment of a representative dedication testing activity to simulate the testing performed on circuit breakers supplied to the Farley Nuclear Plant. The tests were performed using OI-1513 and OI-1580 with Areva's commercial-grade dedication plan DP-01-67 as the bases. The attributes noted as missing documentation of the resultant test data included: 1) racking mechanism being compatible with the cell for insertion and extraction of the breaker, 2) coding plates being compatible to prevent insertion of breakers of another rating, and 3) shutter interface being able to operate properly to shield the main bus during the racking process. This issue is identified as one example of Nonconformance 99901355/2007-202-01.

The inspection also encompassed the Areva/ECH working relationship as it applies to commercial-grade dedication of ECH medium voltage vacuum replacement circuit breakers. The inspectors observed during dedication testing, that Areva was utilizing the services of ECH personnel to operate the test equipment. Upon further inspection, it was determined that these individuals had not received training or indoctrination under Areva's 10 CFR 50 Appendix B program, nor had Areva performed audits of the ECH Power Breaker Center training/qualification program. It was further observed that the Areva personnel witnessing the functional acceptance testing were not qualified by ECH to operate the facility test equipment and therefore could not fulfill the requirements of direct observation to allow ECH personnel to work independently. These activities were contrary to the requirements of 10 CFR 50 Appendix B, Criterion II, "Quality Assurance Program," which states in part that the quality assurance program "shall provide for indoctrination and training of personnel performing activities affecting quality as

necessary to assure that suitable proficiency is achieved and maintained." This issue is identified as Nonconformance 99901355/2007-202-02.

b.2. Control of Measuring and Test Equipment

Areva utilizes ECH's test apparatus to execute the functional acceptance testing on these breakers. The inspectors' review of the effectiveness of this process identified that although the ECH measuring instruments and test equipment (M&TE) were "in-calibration," and had been calibrated by an active supplier on Areva's Approved Supplier's List, ECH did not have a process in place to control and document the use of the M&TE, nor did they have an approved M&TE recall program to prohibit the use of suspect M&TE. Since Areva had not controlled the M&TE under its quality program or performed supplier audits of ECH, Areva could not take credit for any of ECH's M&TE program. This point was further substantiated by a review of Areva's purchase order to ECH for the circuit breakers dedicated for the Farley Nuclear Plant (Purchase Order 1007003503, dated 02/08/2007). This review identified that Areva had not invoked technical or quality requirements for the use of ECH's M&TE as required by Areva's Quality Management Manual (QMM) 56-5015885-07, Section 4.6, "Control of Measuring and Test Equipment," which states, "For subcontracted inspection and testing, purchase orders impose requirements on suppliers concerning the control of the measuring and test equipment they utilize." This also is contrary to 10 CFR 50 Appendix B, Criterion XII "Control of Measuring and Test Equipment," which states that, "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits." This issue is identified as Nonconformance 99901355/2007-202-03.

b.3. Design Control Processes

Areva and ECH have a unique relationship to provide for the commercial-grade dedication (CGD) of ECH's breakers. Areva has access to ECH's design documents. It is this access to ECH's design documents that imparts design control responsibilities on Areva's dedication process. The inspectors reviewed the procedural requirements and implementation of the design review process performed by Areva.

There are two different levels of design review performed by Areva. The first level of review is called a Technical Evaluation (TE), and is part of the Dedication Package. The TE is to be performed in accordance with Areva's Operating Instruction OI-1513. Areva defines a TE as, "the process used to identify, through specified technical and quality requirements, the correct item for a given application or set of applications. The technical evaluation process translates design criteria into procurement technical and quality requirements." In simplified terms, a TE is the process used to evaluate ECH's commercial-grade breaker design, and define a qualified baseline design.

To qualify a baseline design, Areva must determine the item's safety function, and critical characteristics. The critical characteristics must then be tested, and dedicated. OI-1513 states that the basis for acceptability of any critical design differences between original and replacement items, including acceptability for seismic and environmental qualification requirements as applicable must be documented in the conclusion sections of the applicable TE and/or the Equivalency Determination (ED) database.

The ED constitutes the second level of design review performed by Areva. OI-1513 states, “Equivalency Determinations (ED) involve reviewing an item’s current drawings/design back to a specific baseline, date, e.g., Qualification Report date, production date, etc. to determine if any design changes have occurred since the baseline date, thus ensuring the item’s current design complies with the customer or generic qualification requirements. The purpose of an ED is to specifically evaluate changes to fit, form, and function of the item for impact on the safety related end use and item qualification. Drawings, parts lists, and material information are reviewed. The suitability of use of the item in this application is documented in the evaluation.”

As previously stated, an ED is performed to determine if fit, form, function or material is affected by the replacement item. This acts as a screening process to see if the qualifying TE has been affected. If the item’s fit, form, function or material is not affected, then justification for the adequacy of the replacement item is documented in the ED. If the fit, form, function or material of the item is affected, then a TE must be performed to determine if the qualified baseline design must be changed.

The inspectors reviewed the associated documentation for the ECH Type MA-VR medium voltage vacuum replacement breaker that was designed to be a direct replacement for Allis Chalmers Type MA 350C air circuit breakers of various ratings. The TEs and EDs reviewed were all produced to satisfy the requirements of Project 2340-FNS for the Farley Nuclear Plant. The following is a brief overview of a completed TE and various completed EDs reviewed by the inspectors.

- The Conclusion, Section 7.5 from the TE within DP-01-67 states, “This medium voltage vacuum replacement breaker was designed specifically to be a roll-in replacement for Allis Chalmers MA air circuit breakers and reproduces the mechanical and electrical functional interfaces necessary for performance of safety related duty.” The inspectors determined that this conclusion did not adequately document the basis for acceptability of any critical design differences between original and replacement items as required by OI-1513. This issue is identified as one example of Nonconformance 99901355/2007-202-04.

- Areva Equivalency Determination, ED.136, Revision 3, was for a material change. ED.136 states, “Other manufacturing improvements included several spacers converted from machined bar stock to powder metal fabrication.” The material of the spacers was affected, yet no information was provided regarding whether the spacers are made of the same material or have the same material properties. The inspectors determined that the acknowledgement of the change failed to provide adequate documentation to support the basis of the engineering design review conclusion. This issue is identified as part of one example of Nonconformance 99901355/2007-202-04.

- Areva Equivalency Determination, ED.137, Revision 5, was for a parts addition and dimension change. ED.137 states, “The 94B3147G08 MOC Pantograph Assembly added additional bushings and mounting hardware to shift the location of the assembly by ~1/4 inch towards the rear of the breaker. The product design revisions noted above and in the attached spreadsheet may have affected form in some instances, but have not impacted fit and function of the breaker in its application.” The documentation of the change acknowledges that the form may have been affected, but does not provide any additional information as to why the change to the

form does not affect the item's safety function, or critical characteristics. The inspectors determined that the acknowledgement of the change fails to provide adequate documentation to support the basis of the engineering design reviews conclusion. This issue is identified as part of one example of Nonconformance 99901355/2007-202-04.

- Areva Equivalency Determination, ED.140, Revision 2, was for a material manufacturing process change. ED.140 states, "Another process change was the use of a vacuum heat treat process for the banana link in the mechanism. The resultant heat treatment is considered equivalent." This change affects the material properties of the item, yet there is no adequate justification of the adequacy of the new heat treatment process. The inspectors determined that the acknowledgement of the change fails to provide adequate documentation to support the basis of the engineering design review conclusion. This issue is identified as part of one example of Nonconformance 99901355/2007-202-04.

As noted above, the inspectors identified multiple examples of Areva's failure to provide an adequate engineering justification after acknowledging a potential design change. These issues are identified as examples of Nonconformance 99901355/2007-202-04.

c. Conclusion

Based on the review of documentation and discussions with Areva management and staff, the inspectors determined that Areva's program for dedication of medium voltage vacuum replacement circuit breakers at the ECH's facility in Greenwood, SC was adequate in accordance with 10 CFR 21, with the exception of:

- Nonconformance 99901355/2007-202-01 which identified two examples of functional testing deficiencies,

- Nonconformance 99901357/2007-202-02 which identified the use of ECH individuals not appropriately trained and indoctrinated,

- Nonconformance 99901357/2007-203-03 which identified Areva's lack of M&TE control at the ECH facility, and

- Nonconformance 99901355/2007-202-04 which identified two examples where Areva failed to adequately document the basis for acceptability of critical design differences between the original and replacement items.

3.2 CORRECTIVE ACTION

a. Inspection Scope

The inspectors reviewed the procedures governing the implementation of the Areva's corrective action program to ensure that those procedures provided adequate guidance consistent with the requirements Appendix B to 10 CFR Part 50 and 10 CFR Part 21 (Part 21), "Reporting of Defects and Noncompliance." The inspectors also reviewed a sample of condition reports (CRs) to assess Areva's implementation of the corrective action program.

b. Observations and Findings

b.1. Corrective Action Program

Areva's Administrative Procedure (AP) No. 1717-06, "Corrective Action Program - WebCAP," Revision 2, establishes the process for promptly identifying, investigating, reporting, tracking, and correcting conditions adverse to quality, significant conditions adverse to quality, near misses, customer/regulator-identified issues, areas for improvement identified by Areva employees, and other events or conditions as directed by Areva management. This procedure details the electronic process (by means of the WebCAP program) of identifying and documenting apparent conditions adverse to quality that fall under the scope of the Areva quality program, investigating and correcting those adverse conditions, and closing CRs upon completion of corrective action.

Condition Reports are the documents used by Areva to identify an issue, report measures and actions taken to evaluate and resolve apparent conditions adverse to quality, and track required actions through completion. The CR process includes, but is not limited to actions such as; description of the issue, screening assignment to determine significance level, initial Part 21 screening, investigation and evaluation documentation results, prescribed action(s) to be taken, and impact on related internal or external work activities or processes.

Procedure AP 1707-01, "Evaluation and Reporting of Safety-Significant Issues," Revision 35, establishes the procedures and responsibilities to ensure compliance with and execution of Part 21 requirements. Section 4.3.1.8 of AP 1717-06 references AP 1707-01 in order to establish guidance for completing deviation and defect determinations.

b.2. Review of Implementation of the Corrective Action Program

The inspectors reviewed APs 1717-06 and 1707-01 to determine how these procedures incorporated Part 21 requirements into the Areva corrective action program. AP 1717-06 requires personnel to review the issue identified in a CR and determine if a Part 21 evaluation is required. When completing a CR in WebCAP, an individual or screening team is required to answer the following screening questions, as described in Section 4.3 of AP 1717-06, to determine if a Part 21 evaluation is required:

- Is the condition a deviation to a technical requirement included in a procurement document?

- Does the condition affect a basic component designed/fabricated under a 10 CFR 50, Appendix B Quality Program or one that has successfully completed dedication?

- Could the deviation create a substantial safety hazard that could cause a major reduction in the degree of protection provided to public health or nuclear reactor power plant/facility safety?

Step 4.3.1.8 of AP 1717-06 stated that if the questions listed above are all answered "yes" or "unsure," then the fourth screening question, "Is the condition potentially

reportable under 10 CFR 21?" will be skipped, and a Deviation Determination menu option will become available in WebCAP. The inspectors identified that the first two questions listed above are necessary for determining if a deviation exists and if an evaluation for a defect should be performed. If the first two questions are answered yes, then an evaluation per 10 CFR Part 21 should be performed to answer the third question. However, AP 1717-06 did not prescribe this action. The inspectors were also concerned that the fourth question should not be skipped if the responses to the prior questions are "yes."

Step 4.3.1.8 of AP 1717-06 stated that if any of the first three questions are answered "no", then the fourth question will be asked. The inspectors identified that if any of the first three questions are answered "no," then the fourth question would always be answered "no." In addition, AP 1717-06 stated that the Deviation Determination process shall be completed in accordance with AP 1707-01. However, this procedure states that "the screening process in AP 1717-06 satisfied the review to determine if a deviation is a defect that must be reported to the NRC." AP 1707-01 instructs users to use a form to document deviations. However, AP 1717-06 instructs users to only use this form if WebCAP database is unavailable.

The inspectors reviewed a sample of CRs related to circuit breaker issues at the Farley Nuclear Plant. During this review, the inspectors identified eight instances of incorrect responses to the questions listed above in these CRs. Specifically, deviations to technical requirements included in procurement documents were not denoted as such in the "Screening" section of the CRs. In addition, the conditions described in the sample of CRs affected basic components that had successfully completed dedication, but were not denoted as such in responses to the screening questions. The CRs did not provide justification as to why the conditions were not deviations.

The inspectors reviewed CR 2007-5963 which illustrated the Deviation Determination process that is entered after completing the Screening process by answering "yes" or "unsure" to the three questions described above. WebCAP prompted users to provide information as to whether the issue has the potential to affect a safety function and to describe whether the issue has the potential to pose a significant safety hazard or a risk of violating a safety limit as defined in Part 21. WebCAP then prompted users to answer the following questions: "Is the issue a 10 CFR Part 21 Deviation," and "Is a Defect Determination Needed?" Since the Screening section of WebCAP already addressed the deviation criteria, the inspectors were concerned that the Deviation Determination could lead to an informal Part 21 evaluation process.

The inspectors identified that the instructions contained in Step 4.3.1.8 of AP 1717-06 created the potential to circumvent the performance of defect evaluations required by Part 21. In addition, the inspectors identified multiple instances of incorrect responses to the screening questions for identifying deviations. The failures to adequately prescribe the Part 21 screening process in AP 1717-06 and to accomplish the requirements of AP 1717-06 are inconsistent with the regulatory requirements of Appendix B to 10 CFR Part 50, Criterion V. This issue is identified as Nonconformance 99901355/2007-202-05.

c. Conclusion

Based on the review of the WebCAP program, corrective action process and Part 21 procedures, and a sample of CRs, the NRC inspectors concluded that strengthening the

integration of Part 21 requirements into APs 1707-01 and 1717-06 and the WebCAP program is necessary for Areva to adequately implement their corrective action program. The NRC inspectors identified Notice of Nonconformance 99901355/2007-202-05 for the failures to adequately prescribe the Part 21 screening process to accomplish the requirements in AP 1717-06.

4.0 MANAGEMENT MEETINGS AND PERSONNEL CONTACTED

4.1 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on November 27, 2007, the inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with Areva's Project Manager and ECH's Operations Manager. During the exit meeting on November 30, 2007, the inspectors discussed the inspection findings and observations with Areva personnel.

4.2 PERSONNEL CONTACTED

L. Patterson	Project Manager, Areva
H. Medsger	Engineering Manager, Areva
W. Bruce	Engineer, Areva
J. Bartleman	Manager, Corrective Action Program, Areva
T. Wideman	Operations Manager, ECH
M. Jacobsen	Engineering Manager, ECH
R. Gadagno	Senior Manufacturing Consultant, ECH
J. Dence	Inside Sales, ECH