October 6, 2010

Mr. Scott Daubert
Tyco Electronics
1396 Charlotte Highway
Fairview, North Carolina

SUBJECT: NRC INSPECTION REPORT NO. 99901397/2010-201, NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE

Dear Mr. Daubert,

From August 31 to September 3, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Tyco Electronics (Tyco) facility in Fairview, North Carolina. The enclosed report presents the results of this 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 Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it is described in detail in the subject inspection report. The violation is being cited in the Notice because NRC inspectors identified that Tyco failed to prescribe an appropriate procedure to initially identify a deviation for evaluation as required in 10 CFR Part 21deviations and failures to comply associated with substantial safety hazards.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice 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.

During this inspection, NRC inspectors also found that implementation of your QA program failed to meet certain NRC requirements contractually imposed on you by your customers. The NRC inspectors noted two deficiencies for: 1) failure to perform a commercial grade survey, and 2) failure to perform technical evaluations. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room 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. 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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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.

Sincerely,

/RA/

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

Docket No.: 99901397

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99901397/2010-201

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room 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. 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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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.

Sincerely,

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NOTICE OF VIOLATION

Tyco Electronics
1396 Charlotte Highway
Fairview, North Carolina

Docket Number 99901397
Inspection Report No. 99901397/2010-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted August 31 to September 3, 2010, of activities performed at Tyco Electronics (Tyco), one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

A. 10 CFR Part 21, Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," paragraph (a) requires in part that, "each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable."

   Tyco's Policies & Procedures PP-02-002, "10 CFR Part 21 – Investigation, Evaluations and Reporting," dated July 27, 2010, Section 6, "Evaluations," stated that, " If internal corrective actions are required to be taken, then Policies & Procedures PP-14-001; "Corrective Acton Request," is one of the applicable procedures to be used."

   Tyco's Policies & Procedures PP-14-001, "Corrective Acton Request," dated January 8, 2010, Section 4, "Procedure," states that, "Corrective actions must be addressed when applicable, and that Tyco Electronics Complaint Handling System (TECHS) is used for customer complaints." TECHS (customer complaints) used computerized Form 4725-9, "8-D Corrective Action work Sheet," dated March 19, 2010, for the documentation of customer complaints.

   Contrary to the above, as of September 3, 2010:

   Tyco's TECHS Form 4725-9 failed to prescribe an appropriate procedure to initially identify a deviation for evaluation, as required in 10 CFR Part 21, "Reporting of Defects and Noncompliance."

   This issue has been identified as Violation 99901397/2010-201-01.

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

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," you are 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 Director, Division of Engineering, 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: (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.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency-wide Documents 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 this 6th day of October 2010.

NOTICE OF NONCONFORMANCE

Tyco Electronics
1396 Charlotte Highway
Fairview, North Carolina

Docket Number 99901397
Inspection Report No. 99901397/2010-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted August 31 to September 3, 2010, of activities performed at Tyco Electronics (Tyco), certain activities were not conducted in accordance with NRC requirements, which were contractually imposed upon Tyco by NRC licensees.

A. Criterion III, "Design Control," of Appendix B to Title 10 Part 50, states in part that, "Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. 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."

Tyco's Quality Specification TEC-1021, "Global Quality Management System Supplement for Various International Nuclear Quality Assurance Criteria, Regulations, and Requirements," Revision B, dated December 7, 2009, Section 4, "Quality Management System," states in part that, "Commercial grade products may be converted to nuclear grade by following a documented dedication process. The site quality assurance manager is responsible for assuring records of all activities affecting nuclear product quality are maintained for a minimum of ten (10) years, in the responsible department."

Tyco's Policies & Procedures PP-10-004, "Nuclear Dedication Process," Revision 3, dated March 10, 2010, Section 6, "Technical Evaluation," states that, "A technical evaluation of each component used in a nuclear product shall be performed to determine the "safety-related" status of the component and or component characteristics as related to the finished relay by Product Engineer. As part of the evaluation, the Critical Characteristics of Acceptance (CCA) shall be determined and identified. Technical Evaluations will be documented in compliance with one or more of the following procedures: PP-04-001, "Design Control Procedure"; PP-04-006, "Equivalency Evaluation for Safety Related Items"; 102-19, "Nonconformance Materials"; Tyco "ECR" System; or other applicable procedure (CAR, Customer Return, etc)."

Contrary to the above, as of September 3, 2010:

1. Tyco's dedication program did not provide any objective evidence that technical evaluations had been performed to assure that the materials, parts, equipment and processes used for the manufacturing of the Agastat Relays (E7000) were

evaluated under the dedication program and would perform their intended safety-related functions.

2. Tyco failed to document technical justifications for design process changes.

This issue has been identified as Nonconformance 99901397/2010-201-02.

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

Tyco's Quality Specification, TEC-1000, "Global Quality Management System," paragraph 7.4.1.2, states in part that, "Quality and delivery performance ratings shall be transmitted to key suppliers based on supplier activity. Purchasing and supplier quality shall administer the evaluation of supplier performance."

Tyco's Policies & Procedures PP-17-003, "Supplier Audits Process," Revision 8, dated June 28, 2010, paragraph 3, "Policy," states in part that, "Audit frequency shall be established as follows: Product/Material Suppliers – once every three (3) years. Supplier history should be reviewed once a year; Service (Calibration) Suppliers – once every three, or "prior to use," depending on frequency of use; and Service (Testing Labs) Suppliers – prior to use audits are valid for (3) years."

Contrary to the above, as of September 3, 2010:

Tyco failed to perform a documented evaluation of any supplier's performance.

This issue has been identified as Nonconformance 99901397/2010-201-03.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Director, Division of Engineering, 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 noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid non-compliances; 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.

Because your response will be made available electronically for public inspection in the NRC Public Document Room 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, it should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the public without redaction. 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 this 6th day of October 2010.

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

Docket No.:	99901397
Report No.:	99901397/2010-201
Vendor:	Tyco Electronics 1396 Charlotte Highway Fairview, North Carolina
Vendor Contact:	Scott Daubert, Quality Manager Phone: (828) 338-1011 dauberts@Tycoelectronics.com
Nuclear Industry:	Tyco Electronics supplies the nuclear industry with commercial-grade dedicated AGASTAT E7000 timing relays for safety-related applications.
Inspection Dates:	August 31, 2010 – September 3, 2010
Inspection Team Leader:	Paul Prescott, NRR/DE/EQVB
Inspectors:	Jonathan Ortega-Luciano, NRR/DE/EQVB Aaron Armstrong, NRR/DE/EQVB (Training)
Approved by:	***/RA/*** Date: 09/30/2010 Martin Murphy, Chief: Quality & Vendor Branch Division of Engineering Office of Nuclear Reactor Regulation

ENCLOSURE 3

EXECUTIVE SUMMARY

Tyco Electronics
99901397/2010-201

The purpose of this inspection was to review selected portions of Tyco Electronics' (Tyco's) quality assurance (QA) and 10 CFR Part 21 (Part 21) programs. The inspectors focused on Tyco's activities in the area of commercial-grade dedication and supply of AGASTAT (E7000) Series Nuclear Qualified Time Delay Relays to NRC-licensed facilities. The inspection was conducted at Tyco's facility in Fairview, North 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."

There were no NRC inspections of Tyco's facility in Fairview, North Carolina in the previous five years. The results of this inspection are summarized below.

10 CFR Part 21 Program

The inspectors identified one violation of 10 CFR Part 21. Violation 99901397/2010-201-01 was cited for the lack of procedural guidance to initially document a potential deviation in customer complaints Form 4725-9, creating the possibility for the failure to perform an evaluation as required by Part 21. With the exception noted above, the inspectors concluded that Tyco's Part 21 program was consistent with the regulatory requirements.

Corrective Action

Based on the review of Tyco's corrective action and nonconformance process and implementing procedures, and a sample of Corrective Action Requests (CARs), the inspectors determined that Tyco's process met the requirements of Criterion XV and XVI of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Commercial-Grade Dedication

The inspectors identified Nonconformance with two examples. One example of Nonconformance 99901397/2010-201-02 was cited for failure to perform technical evaluation(s) for the Agastat Relays (E7000). The second example was cited for lack of documentation and engineering justification for design process changes as required by Tyco's dedication process. With the exception of the Nonconformance, the inspectors concluded that Tyco's commercial-grade dedication requirements and implementation were consistent with the regulatory requirements of Criteria III and VII of Appendix B to 10 CFR Part 50.

Audits

The inspectors identified Nonconformance 99901397/2010-201-03 for failure to periodically evaluate and document supplier performance. With the exception of the Nonconformance, the inspectors concluded that Tyco's supplier survey and internal audit program requirements and implementation were consistent with the regulatory requirements of Criteria VII and XVIII of Appendix B to 10 CFR Part 50.

REPORT DETAILS

1. 10 CFR Part 21 Program

   a. Inspection Scope

   The inspectors reviewed Tyco's Quality Specification, TEC-1021, "Global Quality Management System Supplement for Various International Nuclear Quality Assurance Criteria, Regulation, and Requirements," Revision B, dated December 7, 2009, and the associated implementing procedures that governed Tyco's Part 21 program to determine compliance with 10 CFR Part 21. Specifically, the inspectors focused on Tyco's implementing Policies & Procedures PP-02-002, "10 CFR Part 21 – Investigation, Evaluation and Reporting," Revision 8, dated July 27, 2010.

   In addition, the inspectors evaluated Tyco's Part 21 evaluations from the past two years to verify compliance with Part 21 requirements. The following evaluations were reviewed:

   - CII - 013 - CAR-100988, "The scaling was incorrect in the terminal block for both units returned from Waterford," dated November 2, 2008
   - CII - 014 - CAR-101118, "Exelon reported that some EDG004 relay failed their results," dated May 15, 2009
   - CII - 017 - CAR-101399, "Possible Contamination," dated August 26, 2010

   Finally, the inspectors reviewed Policies & Procedures PP-13-001, "Control of Nonconforming Material," Revision 20, dated January 8, 2010, Policies & Procedures PP-14-001, "Corrective Action Request," Revision 13, dated January 8, 2010, and PP-19-002, "Servicing-Customer Return Material," Revision 20, January 8, 2010.

   b. Observations and Findings

   The inspectors noted that Tyco's Policies & Procedures PP-02-002 stated that if internal corrective action is required to be taken, Policies & Procedures PP-14-001 should be used if applicable. Tyco's Policies & Procedures PP-14-001, Section 4, "Procedure," requires that corrective actions must be addressed, and the Tyco Electronics Complaint Handling System (TECHS) is to be used for customer complaints. The TECHS program uses Form 4725-9 for documentation of customer complaints. The inspectors noted that Form 4725-9 did not include a mechanism to initially identify a potential Part 21 deviation for further evaluation. The inspectors discussed, with Tyco's QA manager, the lack of procedural guidance to initially document a potential deviation in Form 4725-9, creating the possibility for the failure to perform an evaluation as required by Part 21. This issue was identified as Violation 99901397/2010-201-01.

   c. Conclusions

   The inspectors identified Violation 99901397/2010-201-01, which was cited for lack of procedural guidance to initially document a potential deviation in customer complaints Form 4725-9, creating the possibility for the failure to perform an evaluation as required by Part 21. With the exceptions of the above violation, the inspectors concluded that Tyco's Part 21 program was consistent with regulatory requirements.

2. Corrective Action

a. Inspection Scope

The inspectors reviewed TEC 1021 and the associated procedures governing the implementation of Tyco's corrective action program to ensure the procedures provided adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50 and Part 21. The inspectors reviewed a sample of Corrective Action Requests (CARs) to assess Tyco's implementation of the corrective action program.

Additionally, the inspectors reviewed Tyco's Policies & Procedures PP-13-001, "Control of Nonconforming Material," Revision 20, dated January 8, 2010 and PP-14-001, "Corrective Action Requests," Revision 13, dated January 8, 2010. Tyco informed the inspectors that there were no Nonconforming Material Reports (NMRs) available for review at the time of this inspection.

b. Observations and Findings

Policies & Procedures PP-14-001 established the system for the initiation, closure and reporting of corrective actions needed to meet Tyco's applicable quality standards and requirements. PP-14-001 stated that corrective action may be addressed by one of the following systems: Internal Corrective Action Requests; TECHS (Customer complaints); TECHS (Internal Supplier Complaints); TECHS (External Supplier Complaints); NMRs & Deviations; or Other. The requests generated from this process are verified complete and checked for effectiveness.

The inspectors noted that Tyco's Policies & Procedures PP-13-001 described the actions established for the discovery of nonconforming material. This procedure applied to all nonconforming material found in Tyco's facility. PP-13-001 also defined the segregation process for nonconforming material and acceptable rework process.

The inspectors reviewed a sample of CARs from the past Part 21 evaluations and audit activities. No findings of significance were identified.

c. Conclusion

Based on the review of Tyco's corrective action and NMR processes, implementing procedures, and a sample of CARs, the inspectors determined that Tyco's process met the requirements of Criterion XV and XVI of Appendix B to 10 CFR Part 50. No findings of significance were identified.

3. Commercial-Grade Dedication Process

a. Inspection Scope

The inspectors reviewed Tyco's Quality Specification TEC-1000, "Global Quality Management System," Revision C1, dated June 8, 2009, Tyco's Quality Specification TEC-1021, and the implementation process for commercial-grade dedication activities. The inspectors also reviewed the procedures governing commercial-grade dedication activities, interviewed Tyco's personnel, observed ongoing activities at the facility, and

the process implemented by Tyco to dedicate the Agastat Relays (E7000). The procedures, documents, and records reviewed in this area included:

- PP-10-004, "Nuclear Dedication Process," Revision 3, dated March 10, 2010
- PP-10-005, "Receiving Inspection Procedures for Commercial Grade Nuclear Related (CGNSR) Items," Revision 3, dated March 10, 2010
- PP-04-006, "Equivalency Evaluation for Safety Related Items," Revision 2, dated September 15, 2005
- PP-10-003, "Final Inspection & Testing," Revision 1, dated March 26, 2009
- ATP-TRE-01, "Audit Test Report for E7000 Relays," Revision J, dated February 17, 2010
- Production Order 200203800690, Description, "E7014ACLL004=RLY, NUC, ON, 4P, 12"
- E41315, "Operator Instruction Sheet QC Audit (Nuclear Inspection and Testing for E7000 Series 2 pole/A pole-On/Off Delay-AC/DC-Nuclear)," Revision A, dated November 11, 2008
- E41005, "Operator Instruction Sheet (Complete Nuclear Audit Check List for E7000)," Revision A, dated October 6, 2009
- TP-TRE-02, "Agastat Specification Sheet (Test Procedure for 7000 Series Time Daley Relay)," Revision S, dated May 24, 2010
- E41300, "Operator Instruction Sheet (TP-TRE-02, Calibrate and Test 700 Series Nuclear Time Delay Relay)," Revision 5, dated November 5, 2007
- Letter to Mr. Karl Kitts, dated April 16, 2008, "Subject: Product Engineering Justification of Characteristics Affecting Safety-Related Performance of Agastat EGP/EML/ETR & E7000 Series Relays by Wyle Qualification Test Report 43706."
- Training Records related to commercial-grade dedication

b. Observations and Findings

The inspectors selected the Agastat Relays (E7000) to assess Tyco's dedication process and verify how procedures are implemented by Tyco's staff performing dedication activities. The inspectors noted that the Agastat Relays (7000 series) have their own assembly line, but there is no separation between nuclear and commercial assembly of the items. Tyco purchases all of its components for assembly of Nuclear Grade Relays as "commercial grade." These "commercial grade" components, once accepted, are used in the assembly of commercial or nuclear grade relays. Tyco follows the same process for the assembly of the Agastat Relays. The difference between an E7000 (Nuclear) and a 7000 (Commercial) is explained below.

The inspectors reviewed procedure PP-10-004, which describes Tyco's dedication process that applies to the Agastat Relays (E7000, EGP & ETR) and Buchanan Terminal Blocks. Tyco uses one or more of the four methods described in EPRI NP-5652, "Guidelines for the Utilization of Commercial Grade Items in the Nuclear Safety Related Applications." For Tyco, as defined in this procedure, a piece part is considered "dedicated" at the completion of final relay testing. The process of performing 100% testing on the finished relay is considered the final acceptance in the dedication process.

The inspectors noted that Section 5, "Types of Inspections/Test Characteristics," of PP-10-004, describes the different types of characteristics that are contained in the technical drawings and their importance as part of the dedication process. The characteristics are divided in three groups:

- Critical (Safety) Characteristics (CC): shall be designated by a black dot "●" next to the criteria. These items can only be procured from suppliers on the nuclear approved vendors list. If vendor is not certified, third-party testing may be required to verify compliance of characteristics.

- Major (Safety) Characteristics (MC): shall be designated with a half black dot next to the criteria. Items can be procured from any approved vendor. Vendor certification may be used for acceptance of characteristics – without third-party verification.

- Minor (Safety) Characteristics (IC): Criteria without any dot or symbol next to it are considered a minor characteristic. Items can be procured from any vendor. Vendor certification may be used for acceptance of characteristics without third-party verification.

During the review of Tyco's dedication process, the inspectors noted that criteria having black dots "●" next to them were verified by Tyco's dedication process, which starts at receipt inspection of the piece parts for the Agastat Relays (E7000). A qualified QA inspector performs an inspection of the parts in accordance with PP-10-005. As part of this process, the QA inspector will verify if the parts will be used in the assembly of a nuclear relay. The QA inspector examines the part's technical drawing and verifies the characteristics. The QA inspector also determines if the parts came from an approved vendor. Once verified, the QA inspector determines the nature of the critical characteristics, and how to verify them by following the instructions provided in the Quality Inspection Plan (QIP). Upon acceptance by the QA inspector, a large "E" is placed on the box/container. Once the part is designated with a letter "E" by the QA inspector, the part number is also prefaced with a letter "E". For example, a set screw that contained a black dot "●" next to one of the characteristics that has been verified will be described as E123456789 Setscrew, Cup Point.

The traceability of all the parts used for the assembly of the Agastat Relays (E7000) are defined in Tyco's procedures and adequately implemented by Tyco's personnel. Tyco's relay assembly process is the same for commercial or nuclear, except the nuclear relays require additional inspections and tests. Tyco's additional activities for the nuclear relays involve verifying critical characteristics by implementing one or more of the methods described in the EPRI NP-5652 guidance. Once the critical characteristics are verified and documented, the nuclear relay assembly goes to calibration to be tested multiple times at different settings. Relays that meet the acceptance criteria are transferred to the final Audit/Inspection station. The QA inspector verifies that all the

required documentation is included with the assembly and that required steps and testing in the work order were completed in accordance with established procedures. The QA inspector performs a final visual inspection and testing on the Agastat Relay. Finally, after all tests and inspections are completed, the QA inspector generates a certificate of compliance/conformance for the dedicated nuclear relay. The QA inspector transfers the Agastat Relay (E7000), with the required documentation, to the shipping department.

The inspectors verified that the personnel involved in the dedication process were trained and certified. Tyco's process to verify critical characteristics was adequate. During the review of the implementation of the dedication process, the inspectors did not identify any findings of significance.

During the review of Tyco's dedication program, the inspectors noted that in order to maintain design configuration control, Tyco decided to place black dots "●" next to the drawing numbers to identify integral parts used in the assembly of a nuclear relays. Components that have a critical characteristic per a design specification are designated with a black dot "●"next to the piece part on the drawing.

The dedication process is considered a quality activity and a dedicating entity must be able to provide auditable records of the dedication process. The inspectors asked Tyco to provide objective evidence that the engineering process (Technical Evaluation) was followed to make the determinations of what were critical characteristics (CCs), and what methods needed to be implemented in order to verify those characteristics selected as critical for the Agastat Relay(E7000). Once these CCs are verified, they provide reasonable assurance that the Agastat Relay (E7000) will perform its intended safety function. Tyco's Agastat Relay (E7000) Product Engineer informed the inspectors that Tyco did not have any objective evidence of the technical evaluations performed to determine the CCs and acceptance methods. During the conversation, the inspectors were provided with documentation that contained the design basis for the Agastat Relay (E7000) and the engineering methodology that needed to be applied to test the relays.

According to Tyco's policies and procedures a technical evaluation of each component used in the nuclear product shall be performed and documented for a minimum of ten years. Specifically:

- TEC-1021, Section 4, "Quality Management System," subpart 4.1A4 states that, "Commercial grade products may be converted to nuclear grade by following a documented 'dedication process.'"

- TEC-1021, Section 4, subpart 4.2B states that, "The site quality assurance manager is responsible for assuring records of all activities affecting nuclear products quality are maintained for a minimum of ten (10) years, in the responsible department."

- PP-10-004, Section 6, "Technical Evaluations," states that: 1) A technical evaluation of each component used in a nuclear product shall be performed to determine the "safety-related" status of the component and or components characteristics as related to the finished relay by Product Engineer; 2) As part of the evaluation, the critical characteristics of acceptance (CCA) shall be determined and identified."

Tyco's documentation included the design basis for the Agastat Relay, but did not provide justification by Tyco on the black dots "●" designation next to the criteria considered critical. Tyco failed to document their technical evaluations required by their policies and procedures; as a result, Tyco was unable to provide objective evidence for technical evaluations performed for the Agastat Relay (E7000). This issue is identified as one example of Nonconformance 99901397/2010-201-02.

The inspectors noted that the Agastat Relay (E7000) has experienced several design changes. The inspectors asked Tyco about the design changes and how they were evaluated. Tyco was able to explain why there were changes to the design and how those changes were an improvement to the overall design. When the inspectors asked for the engineering evaluation generated as part of the design process changes, Tyco was not able to generate any documentation to support the technical evaluations. This issue was identified as a second example for Nonconformance 99901397/2010-201-02

c. Conclusion

The inspectors identified one nonconformance with two examples to Criterion III, Design Control to 10 CFR Part 50, Appendix B. One example of Nonconformance 99901397/2010-201-02 was cited for failure to perform technical evaluations for the Agastat Relays (E7000) to provide reasonable assurance that the materials, parts, equipment, and services, evaluated under the dedication program, will perform their intended safety-related functions. The second example was cited for failure to document technical justification for design process change. With the exception of the Nonconformance, the inspectors concluded that Tyco's commercial-grade-dedication requirements and implementation were consistent with the regulatory requirements and industry guidance.

4. Audits

a. Inspection Scope

The inspectors reviewed Tyco's Quality Specifications TEC-1000 and TEC-1021, related to the auditing and surveying of suppliers and the associated implementing procedures. The inspectors also reviewed the documents for the requirements associated with internal auditing of quality programs. Additionally, the inspectors evaluated a sample of internal and external audits and survey reports and corrective actions implemented by Tyco for findings identified during audits.

b. Observations and Findings

1. External Surveys

The inspectors noted that Tyco's "Agastat Nuclear Relay Program Supplier Listing," did not contain any qualified Appendix B suppliers. However, there were three suppliers that had a survey performed. The surveys of the following suppliers were reviewed:

- Applied Technical Services, Inc. of Marietta, GA. The supplier provided material testing services. The survey was done in August 2008.

- Chand Eisemann Metallurgical of Burlington, CT. The supplier provided filter discs. The survey was done in August 2010.

- Williams Plating of Asheville, NC. The supplier provided material testing services. The survey was done in July 2010.

The surveys had a combination of commercial-grade dedication survey and Appendix B audit attributes. However, the inspectors noted that the auditor's survey notes had captured and verified appropriate critical characteristics for the services provided. The inspectors discussed with Tyco personnel the appropriate method for performing a survey. The inspectors determined that Tyco personnel were aware of the requirements related to a survey. Tyco personnel gave the inspectors a new form that will be used in the conduct of a survey. The inspectors evaluated Form 5078, "Commercial Grade Nuclear Safety Related Survey Checklist," and found the document to be in alignment with industry guidance. The inspectors did not identify any findings of significance.

The inspectors asked Tyco personnel for the periodic evaluations of the suppliers discussed above. Tyco did not perform any documented periodic evaluations of the suppliers. Tyco's procedure, 102-2461, "Procedure for Performing Commercial Grade Nuclear Safety Related Supplier Surveys," Revision 0, did not provide guidance for periodic evaluations of supplier performance. The procedure did state that the industry guidance of EPRI NP-5652, "Guideline of the Utilization of Commercial Grade Items in Nuclear Safety Related Applications," (NCIG-07) constituted a part of the specifications to the extent specified. Procedure PP-17-003, "Supplier Audits Process, "Revision 8, provided guidance related to audits and their associated requirement for periodic evaluations. However, this guidance was not applied, as required, to surveys. The failure to periodically evaluate and document supplier performance was considered to be contrary to industry guidance. This issue was identified as Nonconformance 99901397/2010-201-03.

2. Internal Audits

The inspectors reviewed the last internal audit and findings, which was performed in March 2010. The inspectors also reviewed Tyco's procedure, PP-17-001, "Quality Assurance Audit System," Revision 19. The audit was performed by a lead auditor from Tyco's Fuquay-Varina facility. The audit was conducted using the Nuclear Procurement Issues Committee (NUPIC) audit checklist. There were three findings that resulted from the audit. The inspectors reviewed the following CARs:

- CAR 101297, "Operator had no way to Verify if the Timing Range was Correct"

- CAR 101298, "The Identification of Nonconforming Material is not Clear in the Rework Area," and

- CAR 101299, "Individual has not Received Formal 21 Training."

The inspectors verified that the corrective actions to address the audit findings had been completed. The inspectors did not identify any findings of significance.

c. Conclusion

The inspectors identified Nonconformance 99901397/2010-201-03 for failure to periodically assess and document supplier performance. With the exception of the nonconformance noted above, the inspectors concluded that Tyco is generally

implementing a supplier survey and internal audit program in compliance with regulatory requirements and industry guidance.

5. Exit Meeting

On September 3, 2010, the inspectors presented the inspection scope and findings during an exit meeting with Tyco personnel.

ATTACHMENT

1. PERSONS CONTACTED

R. Sinclair, Production Engineer, Tyco
S. Daubert, Quality Manager, Tyco
K. Kitts, Engine Engineering Director, Tyco
S. Fleming, Quality Engineer, Tyco
B. Berghoefer, Division of Aftermarket Sales, Tyco
S. Breswell-Zern, Lead Agastat Line, Tyco
L. Luther, QA / Receiving Inspection, Tyco
R. Hughs, Quality Engineer, Tyco
B. Lyman, Plant Manager, Tyco
J. Edwards, Reliability, Tyco
P. Clark, Manufacturing Engineer, Tyco

2. INSPECTION PROCEDURES USED

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"
IP 38703, "Commercial Grade Dedication"
IP 43004, "Inspection of Commercial-Grade Dedication Programs"

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

There were no NRC inspections of Tyco's facility in Fairview, North Carolina in the previous five years.

Item Number	Status	Type	Description
99901397/2010-201-01	Opened	NOV	Part 21
99901397/2010-201-02	Opened	NON	Criterion III
99901397/2010-201-03	Opened	NON	Criterion VII

4. LIST OF ACRONYMS USED

CAR	Corrective Action Request
CCV	Critical Characteristics Verification
CFR	Code of Federal Regulations
DE	Division of Engineering
EQVB	Quality and Vendor Branch
Tyco	Tyco Electronics
IP	Inspection Procedure
NCR	Nonconformance Report
NRC	Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NON	Notice of Nonconformance
PO	Purchase Order
QA	Quality Assurance
QAM	Quality Assurance Manual