



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

March 31, 2009

Mr. Edward Lopez
CoreStar International Corporation
1044 Sandy Hill Road
Irwin, PA

SUBJECT: NRC INSPECTION REPORT NO. 99901380/2009-201, NOTICE OF VIOLATION
AND NOTICE OF NONCONFORMANCE

Dear Mr. Lopez

From February 24 to February 26, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the CoreStar International Corporation (CoreStar) facility in Irwin, PA. 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 are described in detail in the subject inspection report. The violation is being cited in the Notice because NRC inspectors identified that CoreStar failed to meet the requirements set forth in 10 CFR Part 21 for procedures to evaluate deviations.

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 four deficiencies for: 1) Failure of the corrective action program to identify deviations; 2) Inadequate internal audits; 3) Failure to describe the process for Certificates of Conformance in an implementing procedure and; 4) Inadequate and untimely corrective actions. 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 to withhold material 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/ D.Skeen for

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

Docket No.: 99901380

Enclosures: 1. Notice of Violation
 2. Notice of Nonconformance
 3. Inspection Report 99901380/2009-201

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 to withhold material 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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Patrick L. Hiland
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NOTICE OF VIOLATION

CoreStar International Corporation
1044 Sandy Hill Road
Irwin, PA

Docket Number 99901380
Inspection Report No. 99901380/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted February 24 - 26, 2009, of activities performed at CoreStar International Corporation (CoreStar), a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR Part 21, Section 21.21(a)(1), "Notification of failure to comply or existence of a defect and its evaluation," states 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 associated with substantial safety hazards as soon as practicable."

Contrary to the above, as of February 27, 2009:

CoreStar's 10 CFR Part 21 implementing procedure CIC-104, "Reporting of Defects and Noncompliance Pursuant to the Provisions of 10CFR21," Revision 1, dated July 14, 1997 was not an appropriate procedure to ensure effective evaluation of deviations and failures to comply associated with a substantial safety hazard. Specifically, CoreStar's procedure CIC-104 did not contain any guidance on how to evaluate deviations.

This issue has been identified as Violation 99901380/2009-201-01.

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,

ENCLOSURE 1

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 31st day of March 2009.

NOTICE OF NONCONFORMANCE

CoreStar International Corporation
1044 Sandy Hill Road
Irwin, PA

Docket Number 99901380
Inspection Report No. 99901380/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted February 24 - 26, 2009, of activities performed at CoreStar International Corporation (CoreStar), certain activities were not conducted in accordance with NRC requirements, which were contractually imposed upon CoreStar by NRC licensees.

- A. Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50, 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, on February 26, 2009:

1. CoreStar International Corporation Procedure CIC-107, Revision 2, "Non-Conformances and Corrective Action Procedure," dated August 30, 2007 did not establish measures for the identification of deviations.
2. CoreStar failed to identify deviations in safety-related purchase orders for eddy current testing services during outages at three plants between March 2004 and June 2006. The deviations related to the qualifications of a non-destructive testing (NDT) Level II personnel. This issue was identified during a review of CoreStar Nonconformance Report (CNR) Number 06-0023, dated December 1, 2006, related to the closeout of a Master-Lee Energy Services Audit finding. This audit finding identified that a NDT Level II qualification examination was improperly performed. During CoreStar's evaluation of the extent of condition they identified one individual who was qualified by the improper qualification examination. However, no deviations were identified for the work the individual performed for the outages.

This issue has been identified as Nonconformance 99901380/2009-201-02.

- B. Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, states in part that, "a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated."

CoreStar Quality Assurance Manual CIC-001, Revision 1, dated May 5, 2006, Section 21, "Audits," paragraph 21.2, states in part that, "a written report documenting the audit results and required corrective action shall be prepared and distributed to appropriate management. The report shall require the audited organization to reply within a

ENCLOSURE 2

specified time period, and to identify planned corrective actions and a schedule for implementation when corrective action is required.”

CoreStar Procedure CIC-002, “Audit Procedure” Revision 4, dated October 1, 2008, paragraph 5.4.1, states in part that, “the disposition of all audit findings and designated observations shall be documented...” Section 3, “Definitions,” of CIC-002 states in part that, “a finding is an audit result supported by objective evidence which reflects a violation of procedures or the QA program...” “An observation is an audit result supported by objective evidence, which while not a direct violation of procedures or standards, may potentially affect the quality of CoreStar’s services or products, if not monitored or addressed. Observations do not require a written response unless so directed by the auditor.”

Contrary to the above, on October 27, 2009:

The inspectors identified several examples of observations that met the definition of a finding. CoreStar failed to identify and perform any associated corrective actions. Some examples included:

- 1.) The “2006 Internal Audit Report,” dated December 11, 2006, had an observation on CIC-114, “Indoctrination, Training, & Qualification of Personnel to Quality Control (QC) Inspector Status,” in paragraph 4.1, that stated the QA manager is solely responsible for the indoctrination, training and qualification of QC personnel. There was an individual in the probe shop performing QC1 checks for calibration standards that had not been designated by the QA manager. Another observation was on CIC-112, “Document Control,” that required applicable records to have a hard copy kept in place at CoreStar’s facility and an electronic copy kept offsite. The auditor did not find copies for training, certifications, or audits kept offsite electronically.
- 2.) The “Audit Report for CoreStar International #E08,” dated December 6, 2007, had an observation on an outside agency (Wiltec) that was used for non-destructive examination (NDE) instruction. There was no evidence that CoreStar evaluated or audited the agency and that the instructor was qualified to provide this service. Another observation noted that four procedures that had been revised were not in the controlled Quality Assurance Manual (QAM) provided to the audit team.

This issue has been identified as Nonconformance 99901380/2009-201-03.

- C. Criterion VII, “Control of Purchased Material, Equipment, and Services” of Appendix B to 10 CFR Part 50, states in part that, “measures shall be established to assure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.”

Contrary to the above, as of February 26, 2009:

CoreStar failed to establish measures to assure that Certificates of Conformance provided by CoreStar conform to procurement documents. Specifically, CoreStar’s implementing procedure did not describe a certification system for safety-related

products or services provided by CoreStar. CoreStar failed to provide Certificates of Conformance to Master-Lee Energy Services for:

- 1) Safety-related standards and software as required in purchase order 5571 (CoreStar work order 3563), dated February 22, 2008, and;
- 2) Safety-related standards as required in purchase order 5589 (CoreStar work order 3641), dated March 24, 2008.

This issue has been identified as Nonconformance 99901380/2009-201-04.

- D. Criterion XVI, "Corrective Action" of Appendix B to 10 CFR Part 50, 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."

CIC Quality Assurance Manual CIC-001, Revision 1, dated May 5, 2006, Section 19, "Corrective Actions," paragraph 19.1, states in part that, "the need for corrective action is identified from sources such as nonconformances, failures, malfunctions, audits, inspections, and surveillance. Quality Assurance participates in verifying that appropriate corrective action is implemented."

CoreStar procedure CIC-107, Revision 2, dated August 30, 2007, "Non-conformance and Corrective Action Procedure," states in part that, "CoreStar management will define corrective actions during the periodic CNR reviews. Quality Assurance will verify completion of corrective actions when participating in the annual reviews."

Contrary to the above, as of February 26, 2009:

CoreStar failed to perform the corrective action identified in CNR 06-0022. CNR 060022 identified the following corrective action: revision of the CoreStar finding form by addition of a "followup" section. CoreStar failed to add this "followup" section to their finding form during the last revision of this form on October 10, 2008.

This issue has been identified as Nonconformance 99901380/2009-201-05.

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 31st day of March 2009.

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

Docket No.: 99901380

Report No.: 99901380/2009-201

Vendor: CoreStar International Corporation (CoreStar)
1044 Sandy Hill Road
Irwin, PA

Vendor Contact: Edward Lopez
President
Phone: (724)744-4094 x301
Lopez@CoreStar-corp.com

Nuclear Industry: CoreStar provides eddy current testing products and services to the commercial nuclear power industry. CoreStar is the original equipment manufacturer for safety-related eddy current testing hardware, software, and calibration standards. CoreStar provides safety-related calibration services and qualified eddy current testing personnel in support of safety-related non-destructive examination.

Inspection Dates: February 24 – February 26, 2009

Inspection Team Leader: Victor Hall, DE/NRR

Inspectors: Paul Prescott, DE/NRR
Carla Roquecruz, DE/NRR
Samantha Crane, DCIP/NRO

Approved by: Dale Thatcher, Chief
Quality & Vendor Branch
Division of Engineering
Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

CoreStar International Corporation (CoreStar)
99901380/2009-201

The purpose of this inspection was to review selected portions of CoreStar's quality assurance (QA) and 10 CFR Part 21 (Part 21) programs. The inspectors focused on CoreStar's products and services supplied as basic components to NRC-licensed facilities. The inspection was conducted at CoreStar's manufacturing facility in Irwin, Pennsylvania.

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 CoreStar's facility in Irwin, Pennsylvania in the previous five years. The results of this inspection are summarized below.

10 CFR Part 21 Program

The inspectors identified one violation of Part 21. Violation 99901380/2009-201-01 was cited for failure to adequately prescribe the process to perform an evaluation, as specified in Part 21. With the exception of the violation noted above, the inspectors concluded that CoreStar's Part 21 program was consistent with regulatory requirements.

Corrective Action

Nonconformances 99901380/2009-201-02 and 99901380/2009-201-05 were cited for failure to establish adequate measures for the identification of deviations and inadequate and untimely corrective actions, respectively. With the exception of the above nonconformances, the inspectors determined that CoreStar's corrective action program and implementation met the requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

Audits

The inspectors identified one nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99901380/2009-201-03 was cited for failure to adequately categorize audit observations as findings. As a result CoreStar did not take action to properly document and disposition the items. With the exception of the nonconformance noted above, the inspectors concluded that CoreStar's audit program requirements and implementation were consistent with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

Procurement

The inspectors identified one nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99901380/2009-201-04 was cited for failure to prescribe in implementing procedures a certification system for safety-related products or services provided by CoreStar. With the exception of the nonconformance noted above, the inspectors concluded that CoreStar's implementation of procurement document controls to sub-suppliers was consistent

with the regulatory requirements of 10 CFR 21.31, "Procurement Documents," and Criterion VII of Appendix B to 10 CFR Part 50.

Measuring and Test Equipment

Based on the review of CoreStar's control of the measuring and test equipment process, implementing procedures, and calibration records, the inspectors determined that CoreStar's process met the requirements of Criterion XII of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Training

Based on the review of CoreStar's training process, implementing procedures, and associated personnel records, the inspectors determined that CoreStar's process met the requirements of Criterion II of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Organization

The inspectors concluded that CoreStar's organizational structure was consistent with the regulatory requirements of Criterion I of Appendix B to 10 CFR Part 50. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The inspectors reviewed CoreStar's Quality Assurance Manual (QAM), Revision 1, dated May 5, 2006, and procedures that govern the Part 21 program to determine compliance with Part 21. Specifically, the inspectors focused on implementing procedure CoreStar International Corporation (CIC)-104, Revision 1, "Reporting of Defects and Noncompliance Pursuant to the Provisions of 10CFR21," dated July 14, 1997, and CIC-107, Revision 2, "Non-Conformance and Corrective Action Procedure," dated August 30, 2007.

The inspectors discussed the Part 21 process with members of CoreStar's management and technical staff to evaluate CoreStar's Part 21 program. CoreStar had not performed any Part 21 evaluations for the inspectors' review.

b. Observations and Findings

The inspectors verified that CoreStar established CIC-104 to meet the requirements of 10 CFR Part 21. The inspectors noted that CIC-104 outlined the process used by CoreStar for the reporting of defects, as well as the responsibilities of employees, managers, and the Quality Assurance (QA) Manager with respect to Part 21.

CIC-104 stated in part that the responsible manager "holds the primary responsibility for addressing defect and noncompliance issues brought to his/her attention by CoreStar personnel pursuant to 10CFR21." The procedures further stated in part that the cognizant manager "shall elevate 'substantial safety hazard' issues to the CoreStar Quality Assurance Manager, CoreStar President, customer, and/or NRC as applicable to the situation and pursuant to 10CFR21." The QA manager's responsibilities were listed in part to "assist in the evaluation of the issue and associated corrective action."

The inspectors noted, however, that CIC-104 did not address the procedural requirements of Part 21.21(a) for the evaluation of deviations. Specifically, Paragraph 21.21(a)(1) 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 associated with substantial safety hazards as soon as practicable."

The inspectors determined that CIC-104 was not an appropriate procedure to ensure effective evaluation of deviations and failures to comply associated with a substantial safety hazard. This issue was identified as Violation 99901380/2009-201-01.

The inspectors further noted that the responsibilities noted above illustrated a misunderstanding of the Part 21 process. The inspectors noted that the descriptions of the responsibilities incorrectly assumed that employees and their managers would be able to identify substantial safety hazards without performing a Part 21 evaluation. CoreStar management discussed its Part 21 process with the inspectors and noted that

Part 21 evaluations would be performed in the CoreStar Nonconformance Report (CNR) process. The inspectors identified, however, that CoreStar had not performed any Part 21 evaluations since the company's inception.

The inspectors reviewed CoreStar's process for the identification of deviations as part of the review of CoreStar's corrective action program. This review is in the Section 2 of this inspection report.

c. Conclusions

The inspectors identified one violation of Part 21. Violation 99901380/2009-201-01 was cited for failure to adequately prescribe the process to perform an evaluation, as specified in Part 21. With the exception of the violation noted above, the inspectors concluded that CoreStar's Part 21 program was consistent with regulatory requirements.

2. Corrective Action

a. Inspection Scope

The inspectors reviewed the QA procedures that govern the implementation of CoreStar's corrective action program to ensure the procedures provided adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50, and 10 CFR Part 21. The inspectors also reviewed all of CoreStar's CNRs since 2006, to assess CoreStar's implementation of its corrective action program.

b. Observations and Findings

b1. Corrective Action Program

CIC-107 defined the process by which CoreStar identified and resolved issues related to nonconformances and how CoreStar identified the need for corrective actions. This procedure outlined the issuance, disposition, filing, and review of CNRs. The inspectors verified that all of CoreStar's identified non-conformances were tracked through a CNR form, per CIC-107. The inspectors noted that CoreStar employees were trained and expected to complete a CNR when non-conformances are identified.

The inspectors noted that CIC-107 directed CoreStar management to review CNRs annually to detect trends and establish corrective actions. CIC-107 directed CoreStar management to define corrective actions during the periodic CNR reviews and for QA to verify completion of corrective actions when participating in the annual reviews.

CoreStar had revised CIC-107 on August 30, 2007, as a result of a November 2006, Nuclear Procurement Issues Committee (NUPIC) audit finding. The procedure was revised to provide a connection between the CNR process and the Part 21 procedure, CIC-104. Specifically, paragraph 5.5.4 was added to CIC-107 which stated:

"All CNR's will be evaluated for potential Part 21 violation. If a Part 21 violation is present, all reporting will be handled in accordance with CIC-104, the CoreStar 10CFR21 reporting procedure."

However, the inspectors determined that CoreStar's procedures did not assure that conditions adverse to quality were promptly identified and corrected, per Criterion XVI of Appendix B to 10 CFR Part 50. Specifically, CoreStar's corrective action procedures would not identify deviations in a timely manner. This was identified as Nonconformance 99901380/2009-201-02. The inspectors noted two examples of deviations that were not identified by CoreStar due to procedural deficiencies:

1. CoreStar failed to identify a deviation in safety-related purchase orders for eddy current testing (ECT) services during outages at three plants between March 2004, and June 2006. The deviation related to the qualifications of a non-destructive testing (NDT) Level II individual. This issue was documented in CNR 06-0023, dated December 1, 2006. This was one identified example of Nonconformance 99901380/2009-201-02.
2. A Master-Lee Energy Services audit finding identified that a NDT Level II qualification examination was improperly performed. During CoreStar's evaluation of the extent of condition they identified one individual who was qualified by the improper qualification examination and provided justification based on direct observation of the individual's work for the validity of his qualification. However, they failed to identify the deviation from the technical requirements of the purchase orders and to perform a Part 21 evaluation. This was a second identified example of Nonconformance 99901380/2009-201-02.

b2. Corrective Action Implementation

During the review of CoreStar's CNRs, the inspectors identified an instance of a CNR that was closed without completing the corrective actions. CNR 06-0022, dated December 1, 2006, was issued in response to a Nuclear Industry Assessment Committee (NIAC) Westinghouse audit deviation report (06-195-W009). The deviation report was issued for inadequate audit follow-up and closeout. The associated CNR stated the cause of the deficiency was due to the finding form used for audits. Specifically, the finding form did not have a section for follow-up. CoreStar's proposed corrective action was to revise procedure CIC-002, "Audit Procedure," to add a follow up section to the finding form. CoreStar's corrective action procedure, CIC-107, paragraph 5.5.3 stated that:

"CoreStar management will define corrective actions during the periodic CNR reviews. Quality Assurance will verify completion of corrective actions when participating in the annual reviews."

The inspectors noted that CIC-002 was revised on August 30, 2007, and CNR 06-0022 was closed on September 22, 2008. However, CoreStar failed to complete corrective actions for the identified condition adverse to quality. Specifically, CoreStar did not add a follow-up section to the finding form as required in CNR 06-0022. This issue was identified as Nonconformance 99901380/2009-201-05.

c. Conclusion

Nonconformances 99901380/2009-201-02 and 99901380/2009-201-05 were cited for failure to establish adequate measures for the identification of deviations and inadequate and untimely corrective actions, respectively. With the exception of the above

nonconformances, the inspectors determined that CoreStar's corrective action program and implementation met the requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

3. Audits

a. Inspection Scope

The inspectors reviewed Section 21, "Audits," of CoreStar's QAM and implementing procedures that govern the process for internal and external audits. The inspectors evaluated a sample of external and internal audit reports and qualification records for personnel to verify compliance with the program requirements.

b. Observations and Findings

b1. External Audits

The inspectors noted that Section 21, "Audits," of CoreStar's QAM provided a description of the process and requirements for performing internal and external audits. Implementing procedure, CIC-002, "Audit Procedure," Revision 4, dated October 1, 2008, provided specific requirements, such as audit plans, checklists, and reports for all of CoreStar's audits. The inspectors noted that CoreStar form, "Attachment 2 – Typical Audit Checklist," was of sufficient detail to provide an adequate scope for a supplier audit.

The inspectors reviewed CoreStar's Approved Supplier List (ASL). The ASL had five suppliers. The inspectors reviewed all of CoreStar's recent external supplier audits. CoreStar's audit schedule was based on a period of less than three years for the suppliers to ensure ongoing compliance with its QAM. The inspectors verified that CoreStar's recent audits of the following suppliers met the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

- Anatec International, in San Clemente, California, which supplied ECT certified nondestructive examination (NDE) personnel and lead auditor services;
- Maintenance & Inspections Services, Incorporated (MIS), in Morganton, North Carolina, which supplied ECT certified NDE personnel and lead auditor services;
- Cal Tec Labs, Incorporated, in Pittsburgh, Pennsylvania, which supplied National Institute of Standards & Technology (NIST) traceable calibration services;
- Master Lee Energy Services, in Latrobe, Pennsylvania, which supplied ECT certified NDE personnel; and
- Wiltec ET, in Big Bear Lake, California, which supplied ECT certified NDE personnel.

The inspectors' review of external audits did not identify any findings of significance.

b2. Internal Audits

The inspectors noted that CoreStar performed internal audits of each section of its QAM at least once every 24 months. The inspectors verified, in the sample of audits reviewed, that CoreStar auditors met the requirements of the QAM. The inspectors noted that the internal CoreStar audits were led by an MIS Lead Auditor with assistance from CoreStar's President and QA Manager. Findings were noted in the audit report with an associated CNR. The inspectors reviewed CIC-002, Section 5.4, "Audit Follow-up," which stated that the disposition of all audit findings and designated observations shall be documented on the appropriate audit results form. Per CIC-002, a finding is an audit result supported by objective evidence which reflects a violation of procedures, or the QA program, or directly affects the quality of CoreStar's products or services. Findings require a written response. Also per CIC-002, an observation is an audit result supported by objective evidence, which while not a direct violation of procedures or standards, may potentially affect the quality of CoreStar's services or products, if not monitored or addressed. Observations do not require a written response unless so directed by the auditor.

The inspectors identified several examples of audit observations that met the definition of a finding. The "2006 Internal Audit Report," dated December 11, 2006, had an observation on CIC-114, "Indoctrination, Training, & Qualification of Personnel to Quality Control (QC) Inspector Status," in paragraph 4.1, that stated the QA manager is solely responsible for the indoctrination, training and qualification of QC personnel. An individual in the probe shop performed QC1 checks for calibration standards although he had not been designated by the QA manager. Another observation from the same audit report had an observation on CIC-112, "Document Control," that required applicable records to have a hard copy kept in place at CoreStar's facility and an electronic copy kept offsite. The auditor did not find copies for training, certifications, or audits kept offsite electronically.

The inspectors noted that "Audit Report for CoreStar International #E08," dated December 6, 2007, had an observation on an outside agency (Wiltec) that was used for NDE instruction. There was no evidence CoreStar evaluated or audited the agency and that the instructor was not qualified to provide this service. Another observation noted four procedures that had been revised were not in the controlled QAM provided to the audit team.

The inspectors determined that CoreStar did not adequately categorize the above audit observations as findings and therefore, took no action to properly document and disposition the items. This issue has been identified as Nonconformance 99901380/2009-201-03.

Finally the inspectors verified that a sample of CoreStar's qualification records for auditors met the program requirements.

c. Conclusion

The inspectors identified one nonconformance of Appendix B to 10 CFR Part 50. Nonconformance 99901380/2009-201-03 was cited for failure to adequately categorize audit observations as findings. As a result CoreStar did not take action to properly document and disposition the items. With the exception of the nonconformance noted

above, the inspectors concluded that CoreStar's audit program requirements and implementation were consistent with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

4. Procurement

a. Inspection Scope

The inspectors reviewed the CoreStar QAM and the implementing procedures that governed the vendor's control of procurement activities.

The inspectors reviewed a sample of completed purchase orders (POs) and associated certifications provided by CoreStar to determine whether CoreStar was meeting the applicable requirements of Appendix B, contractually imposed by its customers. The inspectors reviewed the completed order packages to verify that the parts and services provided adequately matched Certificates of Conformance provided by CoreStar.

The inspectors also reviewed CoreStar Procedure CIC-105, Revision 4, "Procurement Document Control," dated September 4, 2007 and a sample of CoreStar's POs to sub-suppliers to verify the implementation of procurement document controls as required by 10 CFR 21.31, "Procurement Documents," and Criterion VII of Appendix B to 10 CFR Part 50, "Procurement Document Control."

b. Observations and Findings

The inspectors noted that all of CoreStar's activities were conducted under its Appendix B program. However, CoreStar did not have a classification system for identifying safety-related POs, parts, or services.

CoreStar performed a manual search of its POs from the previous two years to provide the inspectors with its safety-related POs. The inspectors found that CoreStar missed three POs which identified the requirement to meet Appendix B and Part 21, which should have been found during the manual search. The inspectors noted the observation as an administrative error due to CoreStar's lack of a classification system to identify safety-related POs.

In addition, the inspectors noted that CoreStar's customers did not always provide clear reasoning on why certain components should be safety-related. For example, certain customers requested that CoreStar provide ECT probes as safety-related. These probes can be used to provide safety-related services; however, the probes are not basic components. The inspectors noted that CoreStar had been audited by NUPIC for a specific scope of supply which included; ECT equipment hardware and related software, calibration standards, calibration services, and qualified NDE Technicians.

The inspectors further discussed safety classification with CoreStar and noted that it was providing Certificates of Conformance only when requested. CoreStar noted that it uses NQA-1 to meet the requirements of Appendix B. For Certificates of Conformance, NQA-1 requires, in part, that:

“The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser’s or Supplier’s quality assurance program.”

However, the inspectors found that CoreStar did not establish procedures regarding its certification. This issue has been identified as Nonconformance 99901380/2009-201-04. The inspectors noted two examples where CoreStar’s lack of procedures regarding Certificates of Conformance led to a failure to provide adequate certification:

- 1) CoreStar work order 3563 for safety-related standards and software provided to Master-Lee Energy Services (PO 5571, dated February 22, 2008,) and;
- 2) CoreStar work order 3641 for safety-related standards provided to Master-Lee Energy Services (PO 5581, dated March 24, 2008.)

The inspectors noted that CoreStar Procedure, CIC-105 outlined the requirements for the documentation of CoreStar procured products and services. The procedure included the responsibilities of the employees, QA manager, financial manager, and cognizant manager, the minimum information to be included in the PO, and requirements to impose 10 CFR Part 21, where applicable.

The inspectors noted that procurement documents for safety-related items or services specified the applicability of 10 CFR Part 21. However, three POs dated February 27, 2007, to MIS for qualified personnel to perform safety-related NDT (PO 4800, PO 4801, and PO 4802), did not specify that Appendix B to 10 CFR Part 50 applied. In each case, the POs specified ANSI/ASME N45.2, 1997, which satisfies the requirements of Appendix B. Discussions with the vendor revealed that this was an administrative oversight. A review of a PO issued to CalTech Labs for commercial calibration services, PO 4716, inappropriately specified 10 CFR Part 21. The inspectors observed this was another example of CoreStar lack of definition of safety classification. No findings of significance were noted.

c. Conclusion

The inspectors identified one nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99901380/2009-201-04 was cited for failure to describe a certification system for safety-related products or services provided by CoreStar. The inspectors concluded that CoreStar’s implementation of procurement document controls to sub-suppliers was consistent with the regulatory requirements of 10 CFR 21.31, “Procurement Documents,” and Criterion VII of Appendix B to 10 CFR Part 50.

5. Measurement and Test Equipment

a. Inspection Scope

The inspectors reviewed Section 15, “Control of Measuring and Test Equipment,” of CoreStar’s QAM and the procedures governing the implementation of the control of measurement and test equipment (M&TE) program to ensure the procedures provided adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50. The inspectors also reviewed the calibration records for all of CoreStar’s M&TE used at the facility.

b. Observations and Findings

The inspectors noted that implementing procedure, CIC-500, "M&TE Preventive Maintenance and Calibration," Revision 1, dated October 15, 2008, established the process for defining the preventive maintenance and calibration program followed by CoreStar to ensure that the equipment used for calibration and inspection met the requirements of CIC-001, "Quality Assurance Manual." CIC-500 also stated that all equipment calibrations, whether performed internally or externally, shall be traceable to NIST.

The inspectors noted that all M&TE calibrations were performed by Cal Tec Laboratories, Incorporated (Cal Tec). Cal Tec was on CoreStar's ASL and was accredited to International Standards Organization (ISO) 17025-1999. The only instrument not calibrated by Cal Tec was a thermometer. The thermometer was calibrated by Micro DAQ. The certificate of calibration stated the thermometer was calibrated using standards traceable to NIST. CoreStar's M&TE was calibrated on a yearly basis. The inspectors reviewed the last two years for all of CoreStar's calibration records. No findings of significance were identified.

c. Conclusion

Based on the review of CoreStar's control of M&TE process, implementing procedures, and calibration records, the inspectors determined that CoreStar's process met the requirements of Criterion XII of Appendix B to 10 CFR Part 50. No findings of significance were identified.

6. Training

a. Inspection Scope

The inspectors reviewed Section 5, "Quality Assurance Program," of CoreStar's QAM and the procedure governing the implementation of the training and qualification program to ensure the procedures provided adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50. The inspectors also reviewed the training records for all of CoreStar's personnel at the facility.

b. Observations and Findings

The inspectors noted that CoreStar implementing procedure, CIC-101, "Written Practice for the Training, Qualification, and Certification of Nondestructive Testing (NDT) Personnel," Revision 9, dated August 4, 2006, established the process for providing instructions and defining responsibilities for the training, qualification, and certification of CoreStar's NDT personnel for the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Section XI and V, and American Society for Nondestructive Testing (ASNT)—SNT-TC-1A. The inspectors also reviewed CIC-102, "Training, Testing, and Qualification of NDT Personnel to Qualified Data Analyst (QDA) Status," Revision 5, dated May 5, 2006, which established the process for providing instructions and defining responsibilities for the training, qualification, and certification of CoreStar's NDT personnel to Qualified Data Analyst (QDA) status.

The inspectors did not identify any issues regarding CoreStar's personnel training records.

c. Conclusion

Based on the review of CoreStar's training process, implementing procedures, and associated personnel records, the inspectors determined that CoreStar's process met the requirements of Criterion II of Appendix B to 10 CFR Part 50. No findings of significance were identified.

7. Organization

a. Inspection Scope

The inspectors reviewed CoreStar's organizational structure and functional relationships to verify compliance with Criterion I of Appendix B to 10 CFR Part 50. Specifically, the inspectors reviewed CoreStar's CIC-001 "Quality Assurance Manual," Revision 1, dated May 5, 2006, CIC-103 "Organization," Revision 1, dated May 5, 2006, associated procedures, and interviewed CoreStar personnel during this inspection.

b. Observations and Findings

The inspectors verified that CoreStar's QA program identified individuals responsible for implementation of QA procedures and instructions. The inspectors noted that CIC-103 defines the organizational structure and major responsibilities within CoreStar. This included an organizational chart, showing a direct link from the QA Manager to the company President. The inspectors verified that the organizational description adequately addressed the organizational structure, functional responsibilities, levels of authority, and interfaces.

The inspectors noted that CoreStar did not have a QA Manager at the time of the inspection. The President of CoreStar was acting as QA Manager until the company filled the open position. CoreStar management stated that they are actively seeking a QA Manager.

c. Conclusion

The inspectors concluded that CoreStar's organizational structure was consistent with the regulatory requirements of Appendix B to 10 CFR Part 50. No findings of significance were identified.

8. Exit Meeting

On February 26, 2009, the inspectors presented the inspection scope and findings during an exit meeting with CoreStar President, Edward Lopez, and other CoreStar personnel.

ATTACHMENT

1. PERSONS CONTACTED

E. Lopez, President, CoreStar
R. Casario, Office Manager, CoreStar
M. Coradi, Vice President, Hardware Operations, CoreStar

2. INSPECTION PROCEDURES USED

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"
IP 43001, "Reactive Inspection of Nuclear Vendors"

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

There were no NRC inspections of CoreStar's facility in Irwin, Pennsylvania in the previous five years.

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99901380/2009-201-01	Opened	NOV	21.21 Evaluations
99901380/2009-201-02	Opened	NON	Criterion XVI
99901380/2009-201-03	Opened	NON	Criterion XVIII
99901380/2009-201-04	Opened	NON	Criterion VII
99901380/2009-201-05	Opened	NON	Criterion XVI

4. LIST OF ACRONYMS USED

ANSI	American Nuclear Standards Institute
ASNT	American Society for Nondestructive Testing
ASME	American Society of Mechanical Engineers
CFR	Code of Federal Regulations
CNR	CoreStar Nonconformance Report
CQVP	Quality and Vendor Branch 1
DCIP	Division of Construction, Inspection, & Operational Programs
DE	Division of Engineering
ECT	eddy current testing
EQVB	Quality and Vendor Branch
IP	Inspection Procedure
ISO	International Standards Organization
M&TE	Measurement and Test Equipment
MIS	Maintenance & Inspections Services, Incorporated
NDE	nondestructive examination
NDT	Non Destructive Testing
NIAC	Nuclear Industry Assessment Committee
NIST	National Institute of Standards & Technology
NRC	Nuclear Regulatory Commission
NRO	Office of New Reactors

NRR	Office of Nuclear Reactor Regulation
NON	Notice of Nonconformance
NOV	Notice of Violation
PO	Purchase Order
QA	Quality Assurance
QAM	Quality Assurance Manual
QDA	Qualified Data Analyst