Response to Docket Number: 99901380

Inspection Report No. 99901380/2009-201

Violation Number: 99901380/2009-201-01

Severity Level IV Violation

Company:

CoreStar International Corporation

1044 Sandy Hill Road
Irwin, PA 15642

Phone: 724-744-4094
Fax: 724-744-4093
Website: www.corestar-corp.com

CoreStar

Date: April 27, 2009

To: U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington D.C. 20555-0001.

Cc: Director, Division of Engineering, Office of Nuclear Regulation

Subject: Response to NRC Violation 99901380/2009-201-01

Dear Sir or Madam:

Please find attached our response to NRC Violation 99901380/2009-201-01. Any questions regarding our response can be directed to me. I can be reached at 724 744-4094 x301.

Sincerely,

Edward P Lopez
President, CoreStar International Corp.

IE09
NRR

CoreStar International Corporation
1044 Sandy Hill Road • Irwin, PA 15642
(724) 744-4094 • FAX (724) 744-4093
24/7 Tech Support: 1-888-533-9403
E-Mail: info@corestar-corp.com

Reply to a Notice of Violation
Violation **99901380/2009-201-01**
April 25th, 2009

Text of NRC Violation 99901380/2009-201-01

> 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).

Reason for Violation 99901380/2009-201-01:

The CoreStar 10-CFR Part 21 reporting procedure (CIC-104) has only been revised one time since its inception. The NRC audit finding referred to as **Violation 99901380/2009-201-01** was the first audit to find our Part 21 procedure insufficient. This includes all of the NUPIC audits of our facility. We did not realize that simply referencing the contents of Part 21 was not adequate. The main reason for this violation is an insufficient knowledge of 10 CFR Part 21 on the part of CoreStar management.

Corrective Actions:

The CoreStar management team has read and become much more familiar with the 10 CFR Part 21 reporting requirements.

We are evaluating all safety related purchase orders that we have received since 2006. This date was suggested by our auditors during the closeout meeting. These purchase orders are being placed in a separate binder along with all future safety related purchase orders. Each of these safety related purchase orders will be evaluated for Part 21 violations. When complete, the results of this evaluation will be sent to the NRC.

Corrective Steps from this point forward:

Our corrective action procedure (CIC-107) has been directly tied to our 10 CFR Part 21 reporting procedure (CIC-104). Also, our CIC-104 has been completely rewritten. In addition, we will make sure that we carefully screen each safety related purchase order to make sure that the customer is aware and that we are aware of the implications. If we decide to accept the purchase order we will keep it and all associated documentation separate from other purchase orders. We have also created a special work order for safety related orders to ensure that we remain aware of the implications throughout the manufacturing process.

Reply to a Notice of Violation
Violation **99901380/2009-201-01**
April 25th, 2009

When any item is returned to CoreStar, or otherwise reported defective, our first step is to determine if it was purchased on a safety related purchase order. CoreStar has created a new form (attached) to facilitate the tracking of returned items for safety related issues. If there is a deviation from a safety related purchase order, our Part 21 process will be set in motion.

Attachments: CIC-107, CIC-104, Safety Related Work Order, Receipt Inspection Form

Date for full compliance:

May 31st, 2009.

This completion date will give us time to implement our procedures and complete the required indoctrination. It will also give us time to complete the evaluation of the safety related purchase orders from 2006 through 2008.

Sincerely,

Edward Lopez,
President, CoreStar International Corp.

Internal Review and Approval

	SIGNATURE	DATE	COMMENTS
ORIGINATOR: E. P. Lopez			
COGNIZANT MANAGER: M. D. Coradi			
QUALITY ASSURANCE: E. P. Lopez			

☐ Controlled Copy Number ____

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1. Purpose

The purpose of this procedure is to define the process by which CoreStar International Corporation (CoreStar) resolves issues adverse to quality as defined in the CoreStar Quality Assurance Program.

2. Policy and Scope

2.1 It is the policy of CoreStar to aggressively resolve items or processes that are adverse to quality as defined in the CoreStar Quality Assurance Program.

2.2 The scope of this procedure is limited to products manufactured by or purchased by CoreStar, critical processes performed by CoreStar, and quality related documents.

3. Definitions

3.1 CNR — CoreStar Non-conformance Report

3.2 Disposition Definitions:

Rework (RW) — A disposition that specifies the process by which a non-conforming item is made to conform to a prior specified requirement by completion, re-machining, reassembling or readjusting.

Repair (RP) — A disposition that provides for restoration of a nonconforming characteristic to a condition such that the capability of the item to function reliably and safely is unimpaired, even though that item may still not conform to the original requirements. In the case of a process, this entails repeating the procedural step(s) necessary to bring the intended results within the acceptance criteria.

Scrap (SC) — A disposition for an item that cannot be economically repaired or reworked to an acceptable level of conformance.

Accept-as-is (AC)	A disposition for a non-conformance when it is established that the discrepancy will result in no adverse conditions, and that the item under consideration will continue to meet all of the engineering functional requirements, including performance, maintainability and fit.
Return to Vendor (RV)	A disposition for a non-conformance generated by a vendor when it is deemed appropriate to have the vendor correct the error.
Hold (HD)	A disposition for a non-conformance if it is known that the part is not needed to complete an order. Management will review these during the course of the regular management review to ensure that final disposition occurs.
Void (VO)	A disposition code used for a CNR issued in error.
Documentation (DC)	A disposition code used to document errors in quality documents such as Certificates of Compliance, Calibration Standard Drawings, Quality Purchase Orders, and Tester Calibration Certificates.

3.3 Cognizant Supervisor An Engineer/Technician assigned to lead a specific function or their designee in the event that he/she is unavailable. This includes shop leads of CoreStar manufacturing areas, Design Engineers for CoreStar products, and Department Managers.

4. Responsibilities

4.2 Cognizant Supervisor

4.2.1 Must ensure that significant conditions adverse to quality as defined by this procedure are corrected and verified.

4.2.2 Dispositions all CNRs.

4.2.3 Suggests and implements corrective actions to eliminate or reduce non-conformances.

4.2.4 Review designs and processes/procedures to identify potential causes of chronic non-conformances.

4.2.5 Ensures that all CNRs are evaluated for possible 10 CFR Part 21 reporting requirements.

4.3 CoreStar Employee

It is the duty of all employees to report significant conditions adverse to quality as defined in this document.

4.4 Quality Assurance Manager

4.4.1 It is the duty of the Quality Assurance Manager to ensure that significant conditions adverse to quality are addressed and corrected in accordance with this procedure.

4.4.2 The Quality Assurance Manager must ensure that all CNRs are evaluated for possible 10 CFR Part 21 reporting requirements.

5. Procedure

5.1 When a nonconforming item or process is identified, the person who identified the situation shall make an entry in the CNR log. This process assigns a unique number to the CNR.

5.1.1 A log shall be maintained for CNR's. The individual reporting the CNR will update this log. When a CNR is issued, it is assigned the next CNR number from the log. CNR's will be numbered by the following alphanumeric sequence.

YYXXXX

The first two digits designate the year and the last four digits are the serial designators starting with 0001 and ending with 9999.

5.2 After the CNR is logged, it must be immediately reported to the Cognizant Supervisor.

5.3 Upon notification, the Cognizant Supervisor shall initiate the process of documenting and describing the issue related to the item on the CNR log.

5.4 The Cognizant Supervisor shall report the CNR to the QA Manager or his/her designee as soon as possible. In all cases this shall be within three days.

5.5 If the CNR is a deviation from a safety related purchase order, a 10 CFR Part 21 evaluation must begin immediately. The Part 21 reporting requirements are contained in CoreStar procedure CIC-104.

NOTE: Performing a 10 CFR Part 21 evaluation does not waive the internal requirements of addressing the CNR through this procedure. Both processes must be performed.

5.6 If the CNR is related to a final product, a subassembly, or a purchased item the non conforming item is identified with a Hold Tag and segregated pending the outcome of the CNR process.

5.7 If the final disposition of the CNR is AC (Accept as is) or RW (rework) the Cognizant Supervisor must also inform one of the engineers involved in the design of the non conforming item.

5.8 The Cognizant Supervisor will assign a due date for the disposition of the CNR based on the nature of the nonconformance.

5.9 Disposition of the CNR

5.9.1 The Cognizant Supervisor will document the resolution of the CNR by filling out the CoreStar Nonconformance Report and obtain QA review and signature.

5.9.2 If the disposition is to repair or rework, and the disposition was not successfully implemented, the CNR is to be reviewed by the Cognizant Supervisor for re-disposition.

5.9.3 If the CNR has been generated as a result of a vendor manufactured component, the Cognizant Supervisor determines the date by which the vendor must repair, rework, or replace the parts. Once the vendor has committed to an acceptable return date, the CNR can be signed off.

5.9.3.1 If a vendor replaces parts with parts, which are also, nonconforming, a new CNR is to be written, referencing the original CNR number in the "Ref. CNR" block of the form.

5.9.4 The CNR form includes the information below.

5.9.4.1 CNR#
5.9.4.2 Date
5.9.4.3 Name of Individual Reporting Nonconformance
5.9.4.4 Description of Nonconformance
5.9.4.5 Cause and Extent of Nonconformance
5.9.4.6 Action Taken to Correct Nonconformance
5.9.4.7 Action Taken to Prevent Recurrence of Nonconformance
5.9.4.8 10CFR21 Applicability
5.9.4.9 Expected Date of Completion
5.9.4.10 Actual Date of Completion
5.9.4.11 Signature of Cognizant Supervisor
5.9.4.12 Signature of QA Manager

5.9.5 If at any time the CNR is deemed to be in error, perhaps found to be a duplicate, the disposition field on the form and logbook are to be completed with VO for void.

5.10 CNR Filing and Review

5.10.1 CoreStar management and the Quality Assurance Manager will review CNR's annually to detect trends and establish corrective actions.

5.10.2 Outstanding CNR forms will be reviewed monthly by the Cognizant Supervisor.

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

5.10.4 When the CNR disposition is complete, the Cognizant Supervisor will file the documentation in the CNR binder. The binder is tabbed according to the CNR number and the CNR log is kept in the front of the CNR binder.

5.11 Typical Use of CNR's

5.11.1 Internally manufactured parts do not meet tolerance.

5.11.1.1 If there is single part out of tolerance the assembler or machinist will place this part in his segregated bin for "bad" parts.

5.11.1.2 The "bad" parts bin is inspected by the Cognizant Supervisor on a monthly basis. If in his/her opinion the number of non conforming parts is greater than normal a CNR will be issued.

5.11.1.3 If an entire run of parts is bad, a CNR must be reported.

5.11.2 Purchased parts fail receipt inspection.

5.11.3 Incorrect information on quality documents such as quality purchase orders, Certificates of Conformance, Calibration Certifications, Personnel Certification, and Calibration Standard Drawings.

5.11.4 Used to track and ensure timely response to audit findings.

6. References

6.1. CoreStar International Corporation, CIC-001, "Quality Assurance Manual"

Reporting of Defects and Noncompliance Pursuant to the Provisions of 10CFR21	CIC-104, Rev. 2

Internal Review and Approval

	SIGNATURE	DATE	COMMENTS
ORIGINATOR: G. M. Turley			
COGNIZANT MANAGER: E. P. Lopez			
QUALITY ASSURANCE: E. P. Lopez			

☐ Controlled Copy Number ____

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1. Purpose

This document is intended to meet the 10 CFR Part 21 requirements for defect reporting.

2. Policy and Scope

This document defines the process used by CoreStar to determine if deviations from safety related procurement documents are to be classified as defects. It also contains details on how this determination is made, reporting requirements, and required reporting times in accordance with 10 CFR Part 21. Document retention issues are covered as well. This procedure applies to all equipment and services provided on purchase orders that reference the requirements of 10 CFR Part 21.

3. Definitions

3.1. *Basic component (When applied to nuclear power reactors):* A plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) the capability to prevent or mitigate the consequences of accidents which could result in potential off site exposures.

3.2. *Basic component (When applied to other facilities):* A component, structure, system, or part thereof in which a defect or failure could create a substantial safety hazard.

3.3. *Basic component (All Cases)* In all cases, basic component includes safety related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of 10 CFR 50, whether these services are performed by the component supplier or others.

3.4. *Defect:* A deviation or departure from the technical requirements in a basic component.

3.5. *Deviation*: A departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

3.6. *Discovery:* The completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in 10 CFR Part 21.21.

3.7. *Evaluation:* The process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

3.8. *Notification:* The telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

3.9. *Procurement document:* A contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

3.10. *Responsible officer:* The president, vice-president, or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

3.11. *Safety Related Purchase Order:* A purchase order that references the CoreStar 10 CFR 50 Appendix B quality program including the requirements for 10 CFR 21 reporting.

3.12. *Substantial safety hazard:* A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of 10 CFR 50.

3.13. *Supplying or supplies:* Contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

4. Responsibilities

4.1. Employee

4.1.1. Identify and report all defects and noncompliance issues to his/her Cognizant Manager.

4.1.2. Shall immediately report all product returns and customer reports of non conforming products to the Cognizant Manager.

4.2. Cognizant Manager

4.2.1. Holds the primary responsibility for addressing defect and noncompliance issues brought to his/her attention by CoreStar personnel pursuant to 10 CFR Part 21.

4.2.2 Shall evaluate all product returns and customer reports of non conforming products brought to his/her attention for non conformance and 10 CFR Part 21 reporting requirements.

4.2.3 Shall post 10 CFR Part 21 and the Energy Reorganization Act of 1974 in the primary work area of his/her personnel.

4.2.4 Shall elevate potential 10 CFR 21 reporting issues to the CoreStar Quality Assurance Manager, CoreStar President, and customer, as applicable to the reporting requirements of 10 CFR Part 21. This means that the President or one of the Vice Presidents, which are required by 10 CFR 21.21 to report defects, must be informed as soon as is practicable and within all cases, five days from when the incident was reported.

4.3. Quality Assurance Manager

4.3.1. Shall assist in the evaluation of the deviation, the associated reporting, evaluation, and corrective action.

4.4. President or Vice Presidents (Directors)

4.4.1 If it has been determined within CoreStar that the deviation from a safety related purchase order is a defect, the President or one of the Vice Presidents of CoreStar, will report this to the NRC in accordance with the reporting requirements of 10 CFR Part 21.21.

5. Procedure

5.1 If a non conformance can be classified as a deviation from a safety related purchase order, it must be evaluated for 10 CFR Part 21 reporting requirements with this procedure. The CoreStar non conformance procedure (CIC-107) directs all such non conformances to this procedure for evaluation.

5.2 As soon as the deviation is reported, the discovery process begins. The discovery process entails writing a description of the deviation.

5.3 Evaluation is the next step in the process. Evaluation is the determination if the deviation is a reportable defect in accordance with 10 CFR 21.

5.4.1 If the evaluation is to be performed by the customer, it must be reported to them within **five** days from the initial reporting of the deviation.

5.4.2 If the evaluation is performed by CoreStar, and if it is determined that there is a defect, it must be reported directly to the NRC within **60** days of the beginning of the evaluation process. The evaluation shall include (i) All available information regarding the deviation. (ii) An analysis of the cause of the deviation. (iii) An analysis of the possible safety impact caused by the deviation.

NOTE: In most cases CoreStar will report the deviation to the customer because they are in a better position to determine the safety implications of the deviation. We will supply the customer with all necessary technical information. The items below indicate the process by which CoreStar would evaluate a deviation for 10 CFR Part 21 reporting.

5.4.2.1 Is the identified problem applicable to component hardware or software? If the answer is "NO" then STOP, Part 21 is not applicable.

5.4.2.2 Does written documentation exist indicating that the identified problem has already been reported to the NRC by an external source? If the answer is "YES" then STOP, Part 21 is not applicable.

5.4.2.3 Does the identified problem concern a basic component (plant structure, system component, or part thereof:

5.4.2.3.1 Necessary to assure the integrity of the reactor coolant pressure boundary, or

5.4.2.3.2 Necessary to assure the capability of shutting down the reactor and maintaining it in a safe shutdown condition, or

5.4.2.3.3 Necessary to assure the capability of preventing or mitigating the consequences of accidents which could result in potential offsite exposures comparable to those referred to in 10 CFR 100.11?

5.4.2.3.4 IF the Answer to any of the above questions is "YES" then continue to paragraph 5.4.2.4 of this procedure (NEXT question). IF the answer to all of the above questions is "NO" then STOP. Part 21 is not applicable.

5.4.2.4 The basic component containing the identified problem or noncompliance:

5.4.2.5.5 Has been delivered to the plant, or

5.4.2.5.6 Has been installed in a portion of the plant offered for acceptance, or

5.4.2.5.7 Creates a condition or circumstance that could contribute to exceeding a safety limit as defined in the station Technical Specifications?

5.4.2.5.8 IF the answer to any of the above questions is "YES" then continue to paragraph 5.4.2.5 of this procedure (NEXT question). IF the answer to all of the above questions is "NO" then STOP. Part 21 is not applicable.

5.4.2.5 Could the identified problem or noncompliance create a substantial safety hazard by resulting in one or more of the consequences described below?

5.4.2.5.1 Exposure in excess of the limits in 10 CFR 20.2202(a) or

5.4.2.5.2 Exposure of any individual in an unrestricted area to a total effective dose in any period of one calendar year in excess of the limits of 10 CFR 20.1301, or

5.4.2.5.3 Release of radioactive material, inside or outside of the RCA, so that had an individual been present for 24 hours, the individual could have received an intake in excess on one occupational annual limit on intake, or

5.4.2.5.4 Failure of security system equipment such that an unauthorized individual could gain undetected access to a vital area, or

5.4.2.5.5 Major deficiencies involving design, construction, inspection, test or use. "Major deficiency" means a condition or circumstance which, under normal operating conditions, an anticipated transient, or postulated design basis accident could contribute to exceeding a safety limit or cause an accident, or in the event of an accident due to other causes could, considering an independent single failure, result in a loss of safety function necessary to mitigate the consequences of the accident, or

5.4.2.5.6 A condition which could seriously compromise the ability of a confinement system to contain radioactive materials.

5.4.2.5.7 IF the answer to **any** of the above questions is "YES" then the item is reportable under Part 21. IF the answer to **all** of the above questions is "NO" then STOP. Part 21 is not applicable.

5.4.3 Initial notification by facsimile to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 within two days following receipt of information by the director or responsible corporate officer on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center.

5.4.4 Written notification to the NRC at the address specified in Part 21.5 within 30 days following receipt of information by the director or responsible corporate officer on the identification of a defect or a failure to comply.

5.4.5 The written report shall include, but not be limited to the following:

(i) Name and address of the individual or individuals informing the Commission. (ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect. (iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect. (iv) The nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply. (v) The date on which the information of such defect or failure to comply was obtained. (vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in Part 21. (vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action. (viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees. (ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

5.5 Maintenance and Inspection of Records

The following evaluation records will be kept:

5.5.1 Records on all deviations and failures to comply must be kept for a minimum of five years after the date of evaluation.

5.5.2 Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or device associated with a basic component.

5.5.3 Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including (but not limited to) any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

6. References

6.1. CoreStar International Corporation, CIC - 001, "Quality Assurance Manual"

6.2. CoreStar International Corporation, CIC – 107, "Non Conformance and Corrective Action"

6.3. 10 CFR Part 21

CoreStar International Corporation

1044 Sandy Hill Road
[redacted]in, PA 15642
(724) 744-4094
(724) 744-4093 Fax

Quality Work Order
10CFR21 Applies

DATE	Work Order #

BILL TO

Ship To	
Fedex #	

P.O. NO.	SHIP METHOD	SHIP DATE	PACKAGE SERVICE

QTY	DESCRIPTION

Procurement Requirements

- ☐ Certificate of Conformance
- ☐ Calibration Certificate
- ☐ Other

- ☐ Coilman
- ☐ Drawing
- ☐ Poly Pulled

[redacted]gnizant Manager Signature:_____

Material Return Form

Date Returned to CoreStar:_____

Customer Returning Item(s):_____

Receipt Inspected By: _____

Item/Item's Being Returned	Serial Number	Reason for Return

If there was a purchase order in the box, please attached to this form.

To be completed by Office Manager

Work Order Number Assigned:_____
If items are being returned for repair or a problem was identified by customer, research items to see if they were originally purchased on a Safety Related PO.
Were any of these items purchased on a Safety Related Purchase Order? ____
If Yes, inform Mike Coradi or Ed Lopez to start process of CIC-107
Date Mike or Ed were informed?_____

Response to deficiency #1

Statement of Deficiency:

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.

Reason for NonConformance 99901380/2009-201-02

CoreStar did not fully understand the reporting requirements of 10 CFR Part 21. The issue mentioned above was addressed as a CNR according to our program, but was not evaluated as a deviation for this reason. We did not understand what a deviation was and how to evaluate it or report it to our customer for evaluation. Our revised CIC-107 and CIC-104 procedures outline this process.

Corrective Actions:

The response to CNR# 06-0023 was technically valid. However, there was no Part 21 evaluation performed.

All data acquired by Chris Belville as a Level II was reviewed by a certified data analyst. The raw data is first calibrated by the analyst by rotating the signals from the calibration standard and normalizing the voltages. If the data was unusable or invalid in any way, it would have been detected by the certified data analyst immediately. Therefore we do not believe that a defect as defined by Part 21 could have been created by this error.

As additional follow up, we will contact the end customers that were affected to ensure that they are aware of the issue.

Corrective Steps from this point forward:

Our nonconformance reporting procedure (CIC-107) and 10 CFR Part 21 reporting procedure (CIC-104) have been rewritten to establish measures for the identification and evaluation of deviations.

Attached: Revised CIC-107 and CIC-104 procedures for non conformance and 10 CFR Part 21 reporting.

Completion Date

May 31st, 2009

The procedures are complete; they will be implemented within two weeks of this letter to allow time for the required indoctrination. However we still need to contact all of the customers involved and get a response from them.

Internal Review and Approval

	SIGNATURE	DATE	COMMENTS
ORIGINATOR: E. P. Lopez			
COGNIZANT MANAGER: M. D. Coradi			
QUALITY ASSURANCE: E. P. Lopez			

☐ Controlled Copy Number ____

☐ Uncontrolled Copy

1. Purpose

The purpose of this procedure is to define the process by which CoreStar International Corporation (CoreStar) resolves issues adverse to quality as defined in the CoreStar Quality Assurance Program.

2. Policy and Scope

2.1 It is the policy of CoreStar to aggressively resolve items or processes that are adverse to quality as defined in the CoreStar Quality Assurance Program.

2.2 The scope of this procedure is limited to products manufactured by or purchased by CoreStar, critical processes performed by CoreStar, and quality related documents.

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3.1 CNR — CoreStar Non-conformance Report

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Scrap (SC) — A disposition for an item that cannot be economically repaired or reworked to an acceptable level of conformance.

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Return to Vendor (RV) A disposition for a non-conformance generated by a vendor when it is deemed appropriate to have the vendor correct the error.

Hold (HD) A disposition for a non-conformance if it is known that the part is not needed to complete an order. Management will review these during the course of the regular management review to ensure that final disposition occurs.

Void (VO) A disposition code used for a CNR issued in error.

Documentation (DC) A disposition code used to document errors in quality documents such as Certificates of Compliance, Calibration Standard Drawings, Quality Purchase Orders, and Tester Calibration Certificates.

3.3 Cognizant Supervisor An Engineer/Technician assigned to lead a specific function or their designee in the event that he/she is unavailable. This includes shop leads of CoreStar manufacturing areas, Design Engineers for CoreStar products, and Department Managers.

4. Responsibilities

4.2 Cognizant Supervisor

4.2.1 Must ensure that significant conditions adverse to quality as defined by this procedure are corrected and verified.

4.2.2 Dispositions all CNRs.

4.2.3 Suggests and implements corrective actions to eliminate or reduce non-conformances.

4.2.4 Review designs and processes/procedures to identify potential causes of chronic non-conformances.

4.2.5 Ensures that all CNRs are evaluated for possible 10 CFR Part 21 reporting requirements.

4.3 CoreStar Employee

It is the duty of all employees to report significant conditions adverse to quality as defined in this document.

4.4 Quality Assurance Manager

4.4.1 It is the duty of the Quality Assurance Manager to ensure that significant conditions adverse to quality are addressed and corrected in accordance with this procedure.

4.4.2 The Quality Assurance Manager must ensure that all CNRs are evaluated for possible 10 CFR Part 21 reporting requirements.

5. Procedure

5.1 When a nonconforming item or process is identified, the person who identified the situation shall make an entry in the CNR log. This process assigns a unique number to the CNR.

5.1.1 A log shall be maintained for CNR's. The individual reporting the CNR will update this log. When a CNR is issued, it is assigned the next CNR number from the log. CNR's will be numbered by the following alphanumeric sequence.

YYXXXX

The first two digits designate the year and the last four digits are the serial designators starting with 0001 and ending with 9999.

5.2 After the CNR is logged, it must be immediately reported to the Cognizant Supervisor.

5.3 Upon notification, the Cognizant Supervisor shall initiate the process of documenting and describing the issue related to the item on the CNR log.

5.4 The Cognizant Supervisor shall report the CNR to the QA Manager or his/her designee as soon as possible. In all cases this shall be within three days.

5.5 If the CNR is a deviation from a safety related purchase order, a 10 CFR Part 21 evaluation must begin immediately. The Part 21 reporting requirements are contained in CoreStar procedure CIC-104.

NOTE: Performing a 10 CFR Part 21 evaluation does not waive the internal requirements of addressing the CNR through this procedure. Both processes must be performed.

5.6 If the CNR is related to a final product, a subassembly, or a purchased item the non conforming item is identified with a Hold Tag and segregated pending the outcome of the CNR process.

5.7 If the final disposition of the CNR is AC (Accept as is) or RW (rework) the Cognizant Supervisor must also inform one of the engineers involved in the design of the non conforming item.

5.8 The Cognizant Supervisor will assign a due date for the disposition of the CNR based on the nature of the nonconformance.

5.9 Disposition of the CNR

5.9.1 The Cognizant Supervisor will document the resolution of the CNR by filling out the CoreStar Nonconformance Report and obtain QA review and signature.

5.9.2 If the disposition is to repair or rework, and the disposition was not successfully implemented, the CNR is to be reviewed by the Cognizant Supervisor for re-disposition.

5.9.3 If the CNR has been generated as a result of a vendor manufactured component, the Cognizant Supervisor determines the date by which the vendor must repair, rework, or replace the parts. Once the vendor has committed to an acceptable return date, the CNR can be signed off.

5.9.3.1 If a vendor replaces parts with parts, which are also, nonconforming, a new CNR is to be written, referencing the original CNR number in the "Ref. CNR" block of the form.

5.9.4 The CNR form includes the information below.

5.9.4.1 CNR#
5.9.4.2 Date
5.9.4.3 Name of Individual Reporting Nonconformance
5.9.4.4 Description of Nonconformance
5.9.4.5 Cause and Extent of Nonconformance
5.9.4.6 Action Taken to Correct Nonconformance
5.9.4.7 Action Taken to Prevent Recurrence of Nonconformance
5.9.4.8 10CFR21 Applicability
5.9.4.9 Expected Date of Completion
5.9.4.10 Actual Date of Completion
5.9.4.11 Signature of Cognizant Supervisor
5.9.4.12 Signature of QA Manager

5.9.5 If at any time the CNR is deemed to be in error, perhaps found to be a duplicate, the disposition field on the form and logbook are to be completed with VO for void.

5.10 CNR Filing and Review

5.10.1 CoreStar management and the Quality Assurance Manager will review CNR's annually to detect trends and establish corrective actions.

5.10.2 Outstanding CNR forms will be reviewed monthly by the Cognizant Supervisor.

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

5.10.4 When the CNR disposition is complete, the Cognizant Supervisor will file the documentation in the CNR binder. The binder is tabbed according to the CNR number and the CNR log is kept in the front of the CNR binder.

5.11 Typical Use of CNR's

5.11.1 Internally manufactured parts do not meet tolerance.

5.11.1.1 If there is single part out of tolerance the assembler or machinist will place this part in his segregated bin for "bad" parts.

5.11.1.2 The "bad" parts bin is inspected by the Cognizant Supervisor on a monthly basis. If in his/her opinion the number of non conforming parts is greater than normal a CNR will be issued.

5.11.1.3 If an entire run of parts is bad, a CNR must be reported.

5.11.2 Purchased parts fail receipt inspection.

5.11.3 Incorrect information on quality documents such as quality purchase orders, Certificates of Conformance, Calibration Certifications, Personnel Certification, and Calibration Standard Drawings.

5.11.4 Used to track and ensure timely response to audit findings.

6. References

6.1. CoreStar International Corporation, CIC-001, "Quality Assurance Manual"

Internal Review and Approval

	SIGNATURE	DATE	COMMENTS
ORIGINATOR: G. M. Turley			
COGNIZANT MANAGER: E. P. Lopez			
QUALITY ASSURANCE: E. P. Lopez			

☐ Controlled Copy Number ____

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1. Purpose

This document is intended to meet the 10 CFR Part 21 requirements for defect reporting.

2. Policy and Scope

This document defines the process used by CoreStar to determine if deviations from safety related procurement documents are to be classified as defects. It also contains details on how this determination is made, reporting requirements, and required reporting times in accordance with 10 CFR Part 21. Document retention issues are covered as well. This procedure applies to all equipment and services provided on purchase orders that reference the requirements of 10 CFR Part 21.

3. Definitions

3.1. *Basic component (When applied to nuclear power reactors):* A plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) the capability to prevent or mitigate the consequences of accidents which could result in potential off site exposures.

3.2. *Basic component (When applied to other facilities):* A component, structure, system, or part thereof in which a defect or failure could create a substantial safety hazard.

3.3. *Basic component (All Cases)* In all cases, basic component includes safety related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of 10 CFR 50, whether these services are performed by the component supplier or others.

3.4. *Defect:* A deviation or departure from the technical requirements in a basic component.

3.5. *Deviation*: A departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

3.6. *Discovery:* The completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in 10 CFR Part 21.21.

3.7. *Evaluation:* The process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

3.8. *Notification:* The telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

3.9. *Procurement document:* A contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

3.10. *Responsible officer:* The president, vice-president, or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

3.11. *Safety Related Purchase Order:* A purchase order that references the CoreStar 10 CFR 50 Appendix B quality program including the requirements for 10 CFR 21 reporting.

3.12. *Substantial safety hazard:* A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of 10 CFR 50.

3.13. *Supplying or supplies:* Contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

4. Responsibilities

4.1. Employee

4.1.1. Identify and report all defects and noncompliance issues to his/her Cognizant Manager.

4.1.2. Shall immediately report all product returns and customer reports of non conforming products to the Cognizant Manager.

4.2. Cognizant Manager

4.2.1. Holds the primary responsibility for addressing defect and noncompliance issues brought to his/her attention by CoreStar personnel pursuant to 10 CFR Part 21.

4.2.2 Shall evaluate all product returns and customer reports of non conforming products brought to his/her attention for non conformance and 10 CFR Part 21 reporting requirements.

4.2.3 Shall post 10 CFR Part 21 and the Energy Reorganization Act of 1974 in the primary work area of his/her personnel.

4.2.4 Shall elevate potential 10 CFR 21 reporting issues to the CoreStar Quality Assurance Manager, CoreStar President, and customer, as applicable to the reporting requirements of 10 CFR Part 21. This means that the President or one of the Vice Presidents, which are required by 10 CFR 21.21 to report defects, must be informed as soon as is practicable and within all cases, five days from when the incident was reported.

4.3. Quality Assurance Manager

4.3.1. Shall assist in the evaluation of the deviation, the associated reporting, evaluation, and corrective action.

4.4. President or Vice Presidents (Directors)

4.4.1 If it has been determined within CoreStar that the deviation from a safety related purchase order is a defect, the President or one of the Vice Presidents of CoreStar, will report this to the NRC in accordance with the reporting requirements of 10 CFR Part 21.21.

5. Procedure

5.1 If a non conformance can be classified as a deviation from a safety related purchase order, it must be evaluated for 10 CFR Part 21 reporting requirements with this procedure. The CoreStar non conformance procedure (CIC-107) directs all such non conformances to this procedure for evaluation.

5.2 As soon as the deviation is reported, the discovery process begins. The discovery process entails writing a description of the deviation.

5.3 Evaluation is the next step in the process. Evaluation is the determination if the deviation is a reportable defect in accordance with 10 CFR 21.

5.4.1 If the evaluation is to be performed by the customer, it must be reported to them within **five** days from the initial reporting of the deviation.

5.4.2 If the evaluation is performed by CoreStar, and if it is determined that there is a defect, it must be reported directly to the NRC within **60** days of the beginning of the evaluation process. The evaluation shall include (i) All available information regarding the deviation. (ii) An analysis of the cause of the deviation. (iii) An analysis of the possible safety impact caused by the deviation.

NOTE: In most cases CoreStar will report the deviation to the customer because they are in a better position to determine the safety implications of the deviation. We will supply the customer with all necessary technical information. The items below indicate the process by which CoreStar would evaluate a deviation for 10 CFR Part 21 reporting.

5.4.2.1 Is the identified problem applicable to component hardware or software? If the answer is "NO" then STOP, Part 21 is not applicable.

5.4.2.2 Does written documentation exist indicating that the identified problem has already been reported to the NRC by an external source? If the answer is "YES" then STOP, Part 21 is not applicable.

5.4.2.3 Does the identified problem concern a basic component (plant structure, system component, or part thereof:

5.4.2.3.1 Necessary to assure the integrity of the reactor coolant pressure boundary, or

5.4.2.3.2 Necessary to assure the capability of shutting down the reactor and maintaining it in a safe shutdown condition, or

5.4.2.3.3 Necessary to assure the capability of preventing or mitigating the consequences of accidents which could result in potential offsite exposures comparable to those referred to in 10 CFR 100.11?

5.4.2.3.4 IF the Answer to any of the above questions is "YES" then continue to paragraph 5.4.2.4 of this procedure (NEXT question). IF the answer to all of the above questions is "NO" then STOP. Part 21 is not applicable.

5.4.2.4 The basic component containing the identified problem or noncompliance:

5.4.2.5.5 Has been delivered to the plant, or

5.4.2.5.6 Has been installed in a portion of the plant offered for acceptance, or

5.4.2.5.7 Creates a condition or circumstance that could contribute to exceeding a safety limit as defined in the station Technical Specifications?

5.4.2.5.8 IF the answer to any of the above questions is "YES" then continue to paragraph 5.4.2.5 of this procedure (NEXT question). IF the answer to all of the above questions is "NO" then STOP. Part 21 is not applicable.

5.4.2.5 Could the identified problem or noncompliance create a substantial safety hazard by resulting in one or more of the consequences described below?

5.4.2.5.1 Exposure in excess of the limits in 10 CFR 20.2202(a) or

5.4.2.5.2 Exposure of any individual in an unrestricted area to a total effective dose in any period of one calendar year in excess of the limits of 10 CFR 20.1301, or

5.4.2.5.3 Release of radioactive material, inside or outside of the RCA, so that had an individual been present for 24 hours, the individual could have received an intake in excess on one occupational annual limit on intake, or

5.4.2.5.4 Failure of security system equipment such that an unauthorized individual could gain undetected access to a vital area, or

5.4.2.5.5 Major deficiencies involving design, construction, inspection, test or use. "Major deficiency" means a condition or circumstance which, under normal operating conditions, an anticipated transient, or postulated design basis accident could contribute to exceeding a safety limit or cause an accident, or in the event of an accident due to other causes could, considering an independent single failure, result in a loss of safety function necessary to mitigate the consequences of the accident, or

5.4.2.5.6 A condition which could seriously compromise the ability of a confinement system to contain radioactive materials.

5.4.2.5.7 IF the answer to **any** of the above questions is "YES" then the item is reportable under Part 21. IF the answer to **all** of the above questions is "NO" then STOP. Part 21 is not applicable.

5.4.3 Initial notification by facsimile to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 within two days following receipt of information by the director or responsible corporate officer on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center.

5.4.4 Written notification to the NRC at the address specified in Part 21.5 within 30 days following receipt of information by the director or responsible corporate officer on the identification of a defect or a failure to comply.

5.4.5 The written report shall include, but not be limited to the following:

(i) Name and address of the individual or individuals informing the Commission. (ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect. (iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect. (iv) The nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply. (v) The date on which the information of such defect or failure to comply was obtained. (vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in Part 21. (vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action. (viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees. (ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

5.5 Maintenance and Inspection of Records

The following evaluation records will be kept:

5.5.1 Records on all deviations and failures to comply must be kept for a minimum of five years after the date of evaluation.

5.5.2 Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or device associated with a basic component.

5.5.3 Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including (but not limited to) any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

6. References

6.1. CoreStar International Corporation, CIC - 001, "Quality Assurance Manual"

6.2. CoreStar International Corporation, CIC – 107, "Non Conformance and Corrective Action"

6.3. 10 CFR Part 21

Response to deficiency #2

Statement of Deficiency:

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 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.

Reason for NonConformance 99901380/2009-201-03:

Since 2005 CoreStar has outsourced its internal audits to a company called Maintenance and Inspection Services(MIS). The Lead Auditor opted to call what he viewed as non major issues observations in the audit report. They were findings according to our definition of a finding, not observations. As observations, no reporting is required unless requested by the auditor.

Corrective Actions:

We will review all internal audit observations from the 2006 internal audit to the present. We will ensure that all observations are classified correctly. If they should be findings we will investigate to see if they have been responded to. If not, we will invoke our new non conformance procedure (CIC-107) to make sure that we respond correctly.

Corrective Steps from this point forward:

We will ensure that all lead auditors for our internal and external audits are properly indoctrinated on the requirements of our audit procedure (CIC-002). We will also create a letter to file stating that all members of the audit team have been made fully aware of the requirements of our CIC-002 procedure before performing any audits for CoreStar.

Completion Date:

May 31st, 2009

The review of internal audit observations from 2006, 2007, and 2008, and closure thereof will be completed by May 31st, 2009.

Response to deficiency #3

Statement of Deficiency:

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.

Reason for NonConformance 99901380/2009-201-04:

An oversight by the employee responsible for creating a Certificate of Conformance and on the part of the QA manager for not exercising proper oversight on safety related purchases.

Corrective Actions:

The above items are isolated incidents. The Office Manager will contact the end customer and will issue Certificates of Conformance.

Corrective Steps from this point forward:

A procedure has been written to control our generation and use of Certificates of Conformance. It has been attached to this response. We have created a special work order to track safety related purchases. This work order contains a checkbox to help insure that all QA requirements are met.

Attachments: New procedure controlling the issuance of Certificates of Conformance.

Completion Date:

May 31st, 2009

1.0 Purpose

The purpose of this procedure is to define the guidelines in which CoreStar International Corporation issues Certificate of Conformances.

2.0 Policy and Scope

2.1 It is the policy of CoreStar to follow applicable codes in the creation of Certificates of Conformance.

2.2 This document applies to purchase orders that request a certificate of conformance.

3.0 Definitions

3.1 *Certificate of Conformance* – A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

4.0 Responsibilities

4.1 The Office Manager is responsible for the administrative management aspects of this policy.

4.2 The President or QA Manager is responsible for the quality assurance aspects of this policy.

5.0 Procedure

5.1 When a Certificate of Conformance is requested in a procurement document, the following steps must be followed to issue the certificate of conformance:

5.1.1 The certificate shall identify the customer and purchase order number.

5.1.2 The certificate shall identify the purchased material or equipment along with their appropriate serial number(s).

5.1.3 The certificate shall state that the items in the procurement document have been met.

5.1.4 The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformance.

5.1.5 The certificate shall be signed or otherwise authenticated by a person who is responsible for quality assurance.

5.1.6 Once complete, the certificate number should be displayed in the footer. The numbering scheme is COC followed by the month, day, and year. If there is more than one certificate completed on that date, then the certificate number will be COC followed by the month, day, year, and a hyphen and the next number, for example: the second certificate of conformance performed on January 2, 2009, should be numbers as such: COC01022009-2. This is also how the file name should be stored on the quality assurance hard drive.

5.1.7 The certificate should be copied twice. The original will be filed with the Quality Assurance documents. One copy will be given to the customer which will be placed with the items to be shipped, and other will be filed with the invoice, packing slip, work order, and original customer purchase order.

6.0 References

6.1 CIC-001 "Quality Assurance Manual"

Response to deficiency #4

Statement of Deficiency:

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.

Reason for NonConformance 99901380/2009-201-05:

There were two contributing factors.

1.) Our current non conformance reporting process is very complex. This was noted in our 2009 Anatec Audit and in our response to this audit. The CIC-107 procedure rewrite simplifies the non conformance reporting process and includes an explicit test to link the non conformance to our 10 CFR Part 21 reporting procedure.

2.) The lack of a QA manager. Since 2004 we have had three different QA Managers with the President serving as interim QA manager between each of them. This change of hands in the QA department has allowed some issues to go unaddressed.

Corrective Actions:

CoreStar will complete the CNR 06-0022 by May 31st.

Corrective Steps from this point forward:

Our non conformance reporting procedure (CIC-107) has been rewritten to greatly simplify the reporting process. We are also in the process of hiring a QA Manager.

Attachments: Revised CIC-107 and associated form and log file.

Completion Date:

May 31st, 2009

Internal Review and Approval

	SIGNATURE	DATE	COMMENTS
ORIGINATOR: E. P. Lopez			
COGNIZANT MANAGER: M. D. Coradi			
QUALITY ASSURANCE: E. P. Lopez			

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1. Purpose

The purpose of this procedure is to define the process by which CoreStar International Corporation (CoreStar) resolves issues adverse to quality as defined in the CoreStar Quality Assurance Program.

2. Policy and Scope

2.1 It is the policy of CoreStar to aggressively resolve items or processes that are adverse to quality as defined in the CoreStar Quality Assurance Program.

2.2 The scope of this procedure is limited to products manufactured by or purchased by CoreStar, critical processes performed by CoreStar, and quality related documents.

3. Definitions

3.1 CNR — CoreStar Non-conformance Report

3.2 Disposition Definitions:

Rework (RW) — A disposition that specifies the process by which a non-conforming item is made to conform to a prior specified requirement by completion, re-machining, reassembling or readjusting.

Repair (RP) — A disposition that provides for restoration of a nonconforming characteristic to a condition such that the capability of the item to function reliably and safely is unimpaired, even though that item may still not conform to the original requirements. In the case of a process, this entails repeating the procedural step(s) necessary to bring the intended results within the acceptance criteria.

Scrap (SC) — A disposition for an item that cannot be economically repaired or reworked to an acceptable level of conformance.

Accept-as-is (AC)	A disposition for a non-conformance when it is established that the discrepancy will result in no adverse conditions, and that the item under consideration will continue to meet all of the engineering functional requirements, including performance, maintainability and fit.
Return to Vendor (RV)	A disposition for a non-conformance generated by a vendor when it is deemed appropriate to have the vendor correct the error.
Hold (HD)	A disposition for a non-conformance if it is known that the part is not needed to complete an order. Management will review these during the course of the regular management review to ensure that final disposition occurs.
Void (VO)	A disposition code used for a CNR issued in error.
Documentation (DC)	A disposition code used to document errors in quality documents such as Certificates of Compliance, Calibration Standard Drawings, Quality Purchase Orders, and Tester Calibration Certificates.

3.3 Cognizant Supervisor An Engineer/Technician assigned to lead a specific function or their designee in the event that he/she is unavailable. This includes shop leads of CoreStar manufacturing areas, Design Engineers for CoreStar products, and Department Managers.

4. Responsibilities

4.2 Cognizant Supervisor

4.2.1 Must ensure that significant conditions adverse to quality as defined by this procedure are corrected and verified.

4.2.2 Dispositions all CNRs.

4.2.3 Suggests and implements corrective actions to eliminate or reduce non-conformances.

4.2.4 Review designs and processes/procedures to identify potential causes of chronic non-conformances.

4.2.5 Ensures that all CNRs are evaluated for possible 10 CFR Part 21 reporting requirements.

4.3 CoreStar Employee

It is the duty of all employees to report significant conditions adverse to quality as defined in this document.

4.4 Quality Assurance Manager

4.4.1 It is the duty of the Quality Assurance Manager to ensure that significant conditions adverse to quality are addressed and corrected in accordance with this procedure.

4.4.2 The Quality Assurance Manager must ensure that all CNRs are evaluated for possible 10 CFR Part 21 reporting requirements.

5. Procedure

5.1 When a nonconforming item or process is identified, the person who identified the situation shall make an entry in the CNR log. This process assigns a unique number to the CNR.

5.1.1 A log shall be maintained for CNR's. The individual reporting the CNR will update this log. When a CNR is issued, it is assigned the next CNR number from the log. CNR's will be numbered by the following alphanumeric sequence.

YYXXXX

The first two digits designate the year and the last four digits are the serial designators starting with 0001 and ending with 9999.

5.2 After the CNR is logged, it must be immediately reported to the Cognizant Supervisor.

5.3 Upon notification, the Cognizant Supervisor shall initiate the process of documenting and describing the issue related to the item on the CNR log.

5.4 The Cognizant Supervisor shall report the CNR to the QA Manager or his/her designee as soon as possible. In all cases this shall be within three days.

5.5 If the CNR is a deviation from a safety related purchase order, a 10 CFR Part 21 evaluation must begin immediately. The Part 21 reporting requirements are contained in CoreStar procedure CIC-104.

NOTE: Performing a 10 CFR Part 21 evaluation does not waive the internal requirements of addressing the CNR through this procedure. Both processes must be performed.

5.6 If the CNR is related to a final product, a subassembly, or a purchased item the non conforming item is identified with a Hold Tag and segregated pending the outcome of the CNR process.

5.7 If the final disposition of the CNR is AC (Accept as is) or RW (rework) the Cognizant Supervisor must also inform one of the engineers involved in the design of the non conforming item.

5.8 The Cognizant Supervisor will assign a due date for the disposition of the CNR based on the nature of the nonconformance.

5.9 Disposition of the CNR

5.9.1 The Cognizant Supervisor will document the resolution of the CNR by filling out the CoreStar Nonconformance Report and obtain QA review and signature.

5.9.2 If the disposition is to repair or rework, and the disposition was not successfully implemented, the CNR is to be reviewed by the Cognizant Supervisor for re-disposition.

5.9.3 If the CNR has been generated as a result of a vendor manufactured component, the Cognizant Supervisor determines the date by which the vendor must repair, rework, or replace the parts. Once the vendor has committed to an acceptable return date, the CNR can be signed off.

5.9.3.1 If a vendor replaces parts with parts, which are also, nonconforming, a new CNR is to be written, referencing the original CNR number in the "Ref. CNR" block of the form.

5.9.4 The CNR form includes the information below.

5.9.4.1 CNR#
5.9.4.2 Date
5.9.4.3 Name of Individual Reporting Nonconformance
5.9.4.4 Description of Nonconformance
5.9.4.5 Cause and Extent of Nonconformance
5.9.4.6 Action Taken to Correct Nonconformance
5.9.4.7 Action Taken to Prevent Recurrence of Nonconformance
5.9.4.8 10CFR21 Applicability
5.9.4.9 Expected Date of Completion
5.9.4.10 Actual Date of Completion
5.9.4.11 Signature of Cognizant Supervisor
5.9.4.12 Signature of QA Manager

5.9.5 If at any time the CNR is deemed to be in error, perhaps found to be a duplicate, the disposition field on the form and logbook are to be completed with VO for void.

5.10 CNR Filing and Review

5.10.1 CoreStar management and the Quality Assurance Manager will review CNR's annually to detect trends and establish corrective actions.

5.10.2 Outstanding CNR forms will be reviewed monthly by the Cognizant Supervisor.

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

5.10.4 When the CNR disposition is complete, the Cognizant Supervisor will file the documentation in the CNR binder. The binder is tabbed according to the CNR number and the CNR log is kept in the front of the CNR binder.

5.11 Typical Use of CNR's

5.11.1 Internally manufactured parts do not meet tolerance.

5.11.1.1 If there is single part out of tolerance the assembler or machinist will place this part in his segregated bin for "bad" parts.

5.11.1.2 The "bad" parts bin is inspected by the Cognizant Supervisor on a monthly basis. If in his/her opinion the number of non conforming parts is greater than normal a CNR will be issued.

5.11.1.3 If an entire run of parts is bad, a CNR must be reported.

5.11.2 Purchased parts fail receipt inspection.

5.11.3 Incorrect information on quality documents such as quality purchase orders, Certificates of Conformance, Calibration Certifications, Personnel Certification, and Calibration Standard Drawings.

5.11.4 Used to track and ensure timely response to audit findings.

6. References

6.1. CoreStar International Corporation, CIC-001, "Quality Assurance Manual"

CoreStar Nonconformance Report

CNR#_____

Reported By	_____	**Date**	_____
Cognizant Supervisor	_____	**Date**	_____

DESCRIPTION OF NONCONFORMANCE:

CAUSE AND EXTENT OF NONCONFORMANCE:

ACTION TAKEN TO CORRECT NONCONFORMANCE:

☐ Accept-as-is ☐ Rework ☐ Repair ☐ Scrap ☐ Return to Vendor ☐ Hold ☐ Documentation ☐ Other

NOTE: *Accept-as-is* and *Rework* actions require that the Cognizant Supervisor be one of the Design Engineers for the product in question.

ACTION TO PREVENT RECURRENCE OF NONCONFORMANCE:

DOES 10CFR21 REPORTING APPLY? ☐ **YES** ☐ **NO**

DATE DUE _____

DATE COMPLETE _____

COGNIZANT SUPERVISOR _____ (**Name**) _____ (**Signature**)

QA MANAGER _____ (**Name**) _____ (**Signature**)

CoreStar NonConformance Report Request Log

CNR #	DATE REPORTED	DATE COMPLETE	REPORTED BY	SUBJECT	STATUS