



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION II
SAM NUNN ATLANTA FEDERAL CENTER
61 FORSYTH STREET, SW, SUITE 23T85
ATLANTA, GEORGIA 30303-8931

June 10, 2009

Mr. Mark Capallo, President
Energy & Process Corporation
2146-B Flintstone Drive
Tucker, GA 30084-5000

**SUBJECT: ACKNOWLEDGEMENT OF ENERGY AND PROCESS' ADDITIONAL
RESPONSE TO REACTIVE VENDOR INSPECTION – NRC TEAM
INSPECTION REPORT 99900866/2008-001 AND NOTICE OF
NONCONFORMANCE**

Dear Mr. Capallo:

This letter is in reference to your November 21, 2008, and January 14, 2009, additional responses to the five nonconformances referenced in Nuclear Regulatory Commission (NRC) Inspection Report 99900866/2008-001, dated May 20, 2008. Your initial response was sent on June 9, 2008, and did not provide sufficient corrective actions to the identified nonconformances. Our July 8, 2008, letter provided specific items to be addressed by Energy and Process Corporation to allow closure of the nonconformances.

Your response to our July 8, 2008, letter was sent on August 18, 2008, and did not adequately address three of the five nonconformances. Nonconformances 99900866/08-01-01 (inspections) and 08-01-03 (design control) required additional corrective actions and/or additional information and you were still in the process of providing an additional response to Nonconformance 99900866/08-01-02 associated with the implementation of your external and internal audit programs. Our October 28, 2008, letter provided specific items to be addressed by Energy and Process Corporation to allow closure of the remaining three nonconformances.

We have completed our review of your additional responses and are advising you of the results. Details of our review are provided in the enclosure to this letter. Our review has determined that your additional response does not adequately address Nonconformance 99900866/08-01-02. Your responses to Nonconformances 99900866/08-01-01 and 99900866/08-01-03 were reviewed and found to be adequate and will be closed.

In our July 8, 2008, letter we pointed out that Energy and Process's response to Nonconformance 99900866/08-01-02 needed to address basic audit processes, including how the process for planning audits will develop scopes and establish audit criteria to assess the effectiveness of the programs being audited. That letter further identified that Energy and Process needed to address how the audit program would meet the broad scope of a 10 CFR Part 50 quality program with respect to root cause assessment and the specific requirements of 10 CFR 50 Appendix B, Criterion XVI, "Corrective Action."

In your January 14, 2009, letter you provided copies of your expanded internal and external audit checklists as well as a copy of a commercial grade survey/audit checklist. It appears that some careful consideration was given to the internal audit checklists. However, the external

audit and the commercial grade audit guidelines appear to be very general and lack specific information regarding acceptance criteria for the items contained in the checklists. Without criteria, it is uncertain how auditors reach conclusions regarding program adherence to audit requirements. Given the broad range of quality programs and processes used by vendors and suppliers, it is imperative that these programs receive quality audits that can provide clear criteria regarding acceptance or non-acceptance of quality program elements and identified deficiencies.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," this document may be accessed through the NRC's public electronic reading room, Agency-Wide Document Access and Management System (ADAMS) in the Internet at [http: www.nrc.gov/reading-rm/adams.html](http://www.nrc.gov/reading-rm/adams.html). Should you have any questions concerning this letter, please contact us.

Sincerely,

/RA/

Charles R. Ogle, Deputy Director
Division of Construction Inspection

Docket No: 99900866

Enclosure:
NRC Response to Energy and Process Letter
dated November 11, 2008 and January 14, 2009

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Enclosure:
NRC Response to Energy and Process Letter
dated November 11, 2008 and January 14, 2009

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 ADAMS: Yes
 ACCESSION NUMBER: ML091620248
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OFFICE	RII:DCI	RII:DCI	RII:DCI				
SIGNATURE	MSL	JOC	Via email				
NAME	MLesser	JCalle	BBurgess				
DATE	6/10/2009	6/10/2009	5/26/2009				
E-MAIL COPY?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO

Letter to Mark Capallo from Charles Ogle dated June 10, 2009

SUBJECT: ACKNOWLEDGEMENT OF ENERGY AND PROCESS' ADDITIONAL
RESPONSE TO REACTIVE VENDOR INSPECTION – NRC TEAM
INSPECTION REPORT 99900866/2008-001 AND NOTICE OF
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**NRC Response to Energy and Process Letters dated
November 11, 2008 and January 14, 2009**

Nonconformance 99900866/08-01-01

10 CFR 50, Appendix B, Criterion X, "Inspection," requires, in part, that "a program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity." Contrary to the above, from January 2007 through February 2008, Energy and Process performed surveillances (inspections) of fabricated reinforcing steel purchased from Commercial Metals Company (CMC) Rebar Carolinas that did not verify conformance to specified documents, including the American Concrete Institute (ACI) 349, "Code Requirements for Nuclear Safety-Related Concrete Structures." The failure of Energy and Process to perform adequate surveillances that verified conformance to quality during fabrication of reinforcing steel resulted in a large quantity of nonconforming reinforcing steel, approximately 892 tons, sent to the Mixed Oxide Fuel Fabrication Facility for installation into items relied on for safety structures.

Energy and Process Additional Response to Nonconformance 99900866/08-01-01

Energy and Process issued revision 4 to QCP 11, Commercial Grade Dedication, which implemented the following:

- clarified the control of quality during manufacture or fabrication of safety related or QL-1 parts
- clarified responsibilities and methodology for documenting critical characteristic selection and verification
- required that the customer approve in writing the attributes to be verified by E&P during fabrication
- required training relative to identification and compliance to referenced specifications
- specified that agreements between E&P and the customer regarding the control of supply for basic components as part of the purchase of safety-related, items relied on for safety, or NQA- 1 parts not included in the purchase specification be in writing by the customer

Evaluation of Energy and Process' Additional Response to Nonconformance 99900866-01-01

The NRC finds that the Energy and Process response to this nonconformance is adequate.

Nonconformance 99900866/08-01-02

10 CFR 50, Appendix B, Criterion XVIII, "Audits," requires in part, that "audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program." Contrary to the above, for the period January 2007 through February 2008, audits conducted by Energy and Process were inadequate for determining the effectiveness of the quality assurance (QA) program being audited. Specifically, the audits did not contain the audit scope, objective evidence and review and summation documentation required to determine audit program effectiveness.

Enclosure

Energy and Process' Additional Response to Nonconformance 99900866/08-01-02

Energy and Process' (E&P) response contained checklists for internal and external audits and a commercial grade survey/audit.

Evaluation of Energy and Process' Additional Response to Nonconformance 99900866-01-02

In reviewing the checklists, the format for each audit contains a center section that is used to determine acceptability, unacceptability and not applicable (N/A) in evaluating each audit aspect. For the checklist that is used for internal audits of E&P, the use of not applicable raises a concern. The audits, in order to meet NQA-1 and Appendix B requirements, must be developed to evaluate all aspects of the quality assurance program and are also to evaluate the effectiveness of the program. The use of not applicable, or N/A implies that some aspects of the E&P Quality Assurance program are not applicable for an audit. All aspects of the E&P QA program are auditable. A similar consideration should be given to the commercial grade survey/audit checklist, as the general aspect of each audit line item would seem to apply to any supplier or vendor providing commercial parts.

In evaluating the specific audit checklists, there are a number of audit aspects that are very general in nature. For example, one external audit aspect was to examine procurement documents for inclusion of specific technical and quality requirements, to include those quality requirements and controls that must be further extended to subcontractors and suppliers such as: 10 CFR Part 21, flow down requirements, rights of access, and reporting and dispositioning nonconformances. It is unclear what qualifications E&P quality assurance personnel have that would provide for an independent determination of technical requirements applicable to a vendor or supplier. If E&P is referring to flow-down requirements, these requirements are typically specified by the purchaser/customer in the purchase specification, and could be confirmed by E&P to be applicable to a vendor or supplier subcontracted to the customer. Moreover, an audit of a Part 21 program requires specific knowledge of the reporting requirements of Part 21 and of the typical manufacturing and fabrication defects and nonconformances that would require application of the Part 21 program. Nonetheless, if E&P proposes to audit technical requirements and Part 21 programs, E&P should provide the training and implementing procedures used to ensure that each E&P QA inspector consistently audits these complex programs to commonly accepted audit standards.

Given the numerous general requirements contained in both the internal and external audit checklists, E&P, to fully support evaluation of its audit program, should provide all of the audit implementing procedures and training programs that would be necessary to complete these audits successfully and in conformance with commonly accepted standards and requirements. Furthermore, the external audit and the commercial grade audits appear to be very general and lack specific information regarding acceptance criteria for the items contained in the checklists. Without criteria, it is uncertain how auditors reach conclusions regarding program adherence to audit requirements. Given the broad range of quality programs and processes used by vendors and suppliers, it is imperative that these programs receive quality audits that can provide clear criteria regarding acceptance or non-acceptance of quality program elements and identified deficiencies.

The external E&P audit checklist for design control has numerous elements for auditing design. If E&P determines that an audit is needed involving design, then personnel with appropriate expertise and experience in quality assurance/quality control practices related to

design should be used, and this limitation should be documented in the implementing procedure or controlling document for this audit. Given that no implementing procedures were provided, E&P should provide the implementing procedures or controlling documents that would restrict audit of design to a third party with the expertise and experience hired by or contracted to Energy and Process.

A review of the commercial grade survey/audit raises several concerns. First, a survey usually differs from an audit and is controlled by virtue of the definition of a survey contained in the quality assurance program definitions and/or description. During the exit, the NRC made specific comments about the potential for confusion if audits and surveys were not properly defined in the quality assurance program description. As a reiteration, surveys are nominally narrowly focused, and address processes and specific components that are usually completed by a single individual in a day or two. In contrast, audits are nominally reviews of portions of or the entire program at a particular entity, and usually are completed by a team of individuals in several days or weeks, depending on scope and documentation requirements.

The second concern addresses the specific audit of commercial grade supplier, which is highly program oriented in nature. NP-5652 provides specific elements of a commercial grade program that must be met to dedicate a part for application into a safety-related or item relied on for safety system. Key in any commercial grade program (and any audit of a commercial grade program) is the identification of critical characteristics, and the analysis, source verification, tests and inspections that are used to verify that the components selected critical characteristics are acceptable before installation into a safety related application. In reviewing the commercial grade survey audit, no review of critical characteristics or their dedication is provided. In order to audit an entity's program that dedicates a commercial part as safety related or an item relied on for safety, it is critical that the analyses, test, source determinations, or inspection aspects be evaluated by the engineering organization that maintains the design standards to determine that the part is acceptably dedicated prior to installation.

Finally, a review of both the internal and external audits regarding corrective actions provided no evidence of a program adequately addressing the conduct of root cause assessment and actions to preclude repetition in cases of significant conditions adverse to quality.

Nonconformance 99900866/08-01-03

10 CFR 50, Appendix B, Criterion III, "Design Control," requires, in part, that "measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components." Contrary to the above, for the period January 2007 through February 2008, the commercial grade dedication processes for the procurement of piping material procured from Outokumpu, for plate steel procured from Claymont Steel, and for reinforcing steel procured from Commercial Metals Company Rebar Carolinas were inadequate in that these materials were supplied to MFFF for use in items relied on for safety structures, systems and components without adequate review for suitability of application.

Energy and Process Additional Response to Nonconformance 99900866/08-01-03

Energy and Process issued revision 4 to QCP 11, Commercial Grade Dedication, which implemented the following:

- clarified the customer's ownership of design responsibility

- evaluated separately simple components or commodities from more complex or unique items
- required the customer to acknowledge E&P's plan for dedication. If a procured "off the shelf" (customer inventory) item were to be evaluated to a unique application at any time in future by the recipient of material supplied, the documentation confirms critical characteristics previously identified and accepted.

Evaluation of Energy and Process' Additional Response to Nonconformance 99900866-01-03

The NRC finds that the Energy and Process response to this nonconformance is adequate.