

April 14, 2010

U.S. Nuclear Regulatory Commission
Mr. David W. Pstrak, Chief
Rules, Inspections and Operations Branch
Licensing and Inspection Directorate
Division of Spent Fuel Storage and Transportation
Office of Nuclear Safety and Safeguards
Washington, D.C. 20555-0001

RE: USNRC Inspection Report No. 71-0947/2010-201 Response and Plan of Action

Century Industries Statement

Dear Mr. Pstrak,

Although, Century Industries is presently a small organization with a few people wearing many hats, we have been, are and will continue to place the quality of any product produced by the company at the forefront of importance. Century Industries, has thru the years depended upon maintaining its reputation as a designer and manufacturer by producing quality products for its customers and industry. It is our goal to meet and exceed the requirement of both its customers and regulations that have successfully guided the industry.

Century Industries remains committed to meeting all requirements of 10 CFR 71 with regard to Quality by providing the necessary items and personnel for success. Our personnel are trained in accordance with outlines developed to ensure that a thorough understanding of their job function and requirements are part of their daily operation. It is impressed upon our employees by instructions and guidelines that are transferred to them thru the use of QA Plans, Standard Operating Procedures (SOP's), Route Sheets, Fabrication Control Records (FCR's) and drawings that the product safety and the quality provisions of our QA Program must never be compromised under any circumstances regardless of cost or schedule.

Our thanks to the Inspection Team and NRC staff for taking the time to meet with us, as we work to correct these items discussed and bring our program implementation up to the standards required and expected of a package manufacturer within our industry.

Respectfully submitted,



William M. (Mike) Arnold
President
Phone: 423-646-8164
E-mail: CenturyIndWMA@aol.com

Attachment No. 1 - Century Industries Response and Plan of Action
Attachment No. 2 - Resume of Mr. Andrew Ross - New QA Manager

File Cc: QA File

Century Industries

P.O. Box 17084, Bristol, Virginia 24209

Phone: 423-646-1864/276-628-7553

RE: USNRC Inspection Report No. 71-0947/2010-201 Response and Plan of Action**NRC Inspection Report**

On February 23 and 24, 2010, the U.S. Nuclear Regulatory Commission Quality Assurance Inspection Team conducted an inspection to assess the status of Century Industries implementation of our NRC approved Quality Assurance program and determined that Century Industries (CI) was lacking in full implementation of the areas inspected.

Plan of Action Table

Needed Action	NR & Corrective Action Report	Required Action	Date Completion Due	Progress and/or Date Completed
Review NRC Inspection Team Report and Initiate NR and CAR's	Non-Conformance Report # 1008	Write Non-Conformance Report & Associated Corrective Action Reports	April 02, 2010	Completed 04-02-10
Independent Review of Report, QA Manual & SOP's	N/A	Independent Reviewer Sent Materials	April 20, 2010	Arrangements made and review In-Process
Management Controls	CAR# 0001	Hire a QA Manager to provide Independence & Separation	April 09, 2010	Pg. 5 of this Report Completed 04-08-10
Non-Conforming Items & Corrective Action	CAR# 0002	Provide a more technically basis when dispositioning non-conforming items, Investigate and review records to assure that NR's are properly entered into the NR Record Log and that Accountability Los and reports are properly disseminated to the appropriate management,	April 10, 2010	Pg. 6 of this Report Completed 04-08-10
Documentation	CAR# 003	Complete a full review & update of all SOP's for missing and incomplete information. Hire QA Management and duly review the SOP's and other documentation to correct the observations. Review all training records and logs for completeness	May 07, 2010	Pg. 7 of this Report Work is progressing with the SOP's fully reviewed and updated. A QA Manager has been

		and accuracy. Ensure that all controlled copies of the QA Manual are the appropriate revision. Establish a shop location for SOP's to be easily accessed by employees.		hired and is working to complete his review of all documents. The auditor Participation Log is reinstated. Training outlines and records are up to date.
Audits	CAR# 0004	Provide explanation for failure to complete the 2009 internal audit. Complete new audit once program adjustments and corrections have been made. Update the AVL to include all safety related service contractors and services.	May 07, 2010	Pg. 8 of this Report The 2009 audit was postponed to accommodate a move to a larger facility, a move has not yet been accomplished. The AVL has been updated to include the services of outside contractors and service providers.
Design Controls	CAR# 0005	Review all design records and make any necessary corrections to provide missing information (e.g. Signatures) in the design records. Review and correct any failure in the design interface where failure to comply with SOP 2.3 exist and make needed adjustments	April 20, 2010	Pg. 9 of this Report A review of the design record found that the individual firm (METS) had not been clearly defined. A separate PO was written but failed to provide full responsibilities required of the contractor. The PO has been amended and placed in the Design and Input Record. Records for checking the adequacy of design by section have been reviewed and missing signatures are currently being gather and will become part of the

				design record as required.
Fabrication Records	CAR# 0006	Update all procedures and SOP's concerning fabrication to ensure that individuals are properly trained and records available, review all welding procedures and qualification records for completeness. Also review all special process procedures and fabrication processes.	May 07, 2010	Pg. 10 of this Report CI has hired a QA Manager, updates SOP's reviewed both the welding procedures and welder qualification records to assure compliance and is working to revise Fabrication Control Records as may be needed due to any licensing drawing changes and associated fabrication drawing revisions that may have occurred.

Inspection Team Observations and Conclusions

1. Management Controls

The team noted that CI has failed to: a) establish a quality department necessary to assure organizational freedom to identify quality problems; b) initiate solutions; c) verify implementation of solutions; and d) assure sufficient independence from cost and schedule. Specifically, the team noted that the individual assigned the responsibility for assuring effective execution of CI's entire quality assurance program is CI's President.

The team noted that CI had no established structured operation departments (e.g. Engineering, Welding, Purchasing and Production) to fulfill roles and responsibilities as defined within CI's QA Program Manual and Operating Procedures. The Team noted that said activities were performed by a single individual.

Conclusions

The team determined that CI has not adequately implemented its QA program. In addition, the team noted that most activities directly involve a single individual (CI President) and are essentially part of the overall operation of CI. The team assessed that some of the activities currently performed would not provide the independence required to meet the requirements of 10 CFR 71 in regard to quality assurance independence.

CI Response and Actions – Action Completed

A Corrective Action Report No. 0001 was initiated under NR Report No. 1008 on April 02, 2010 to address the need for separation of the quality assurance functions within the CI QA Program. As stated in the Observations and Findings by the inspection team the management of CI has consisted of only one individual wearing many hats, including the Quality Assurance Managers position. However it has been the intention of CI to hire an individual for the position prior to the beginning of fabrication in order to establish a formal separation of the QA function and operations, with the hiring of Mr. Andrew Ross (Resume' Attached) we believe that the independence and separation of the QA Program needed, has been reestablished. Mr. Ross has been hired as an interim QA Manager until a full time individual can be adequately accessed and hired.

Mr. Ross will have the full support and authority of Century Industries President to implement and update the program as needed to meet the requirements of the regulations. In accordance with our Program he is given the authority to halt work to assure compliance with contract requirements and/or 10CFR71 Subpart H and the QA Program. As President of Century Industries, I retain the overall responsibility for quality compliance within the company.

Most all of CI's engineering work is sub-contracted to individuals or companies with the appropriate credentials, as was the case in the development of the Versa-Pac Shipping Container, those credentials and surveys of the engineering services have been added to the AVL as contractors providing their services to Century Industries. Welding procedures and welder qualification have been part of our QA Manager position's function. We have a separate production supervisor that presently reports to the President. Purchasing responsibilities will soon be conducted by a different individual.

With the hiring of Mr. Ross we have completed the implementation portion of Corrective Action Report No. 0001 as of 04-08-10.

2. Nonconforming materials, parts or components and Corrective Actions

The team reviewed CI's process for documenting and resolving nonconforming product by reviewing six (6) nonconformance reports (NCRs) written since 2005 and noted several NCRs that were dispositioned as "Use-As-Is" without documenting an acceptable technical basis for continued use.

Further, the team noted that non-conformances were not documented by entry into CI's corrective action system and that procedures lack guidance in determining significant conditions adverse to quality (SCAQ). The team was concerned that in the absence of immediate entry of an issue into the corrective action system that the cause and preventative measures to preclude repetition could go undetected, particularly in the absence of a quality assurance manager.

Conclusions

Overall, the team assessed that CI's controls on non-conformance controls and corrective actions were not adequate in addressing the applicable requirements of 10 CFR 71.

CI Response and Actions

A Corrective Action Report No. 0002 was initiated on April 04, 2010 to address the observations reported and make the necessary corrections. As with any non-conforming item it is the practice of Century Industries to seek the appropriate concurrence and provide an acceptable technical basis for the disposition either in the use as is, repair or scraping of any item, we will endeavor to provide a more technical basis for dispositions on future Non-Conforming items and seek the required approvals either by the customer and/or any regulatory requirements.

We have reviewed our records to ensure that all Non-Conformances have been properly documented and entered into NR Record Log L22, and reported on form D21 which provides direction and instructions to properly see the non-conforming item to its proper resolution. We have reviewed our records to ensure that all NR's have been recorded onto form D115 (Non-Conformance Accountability Log) and forwarded to the QA Manager on a monthly basis for review. We also verified that the NR's have been summarized on Form D116 (Non-Conformance Accountability Summary) to determine if trends or significant condition adverse to quality are detected for evaluation and correction. No adverse conditions or trends were found.

Corrective Action Report No. 0002 has been completed.

3. Documentation

The team interviewed CI's President in regard to how the CI document control system functioned and how the distribution and receipt occurred for document users. The team also discussed the importance of version control since many documents were available for use in a central location. The team noted that SOPs are originated, reviewed and approved for release by a single person and noted certain omissions such as Auditor Participation Logs, Training Outlines, Attachments, Forms and Text, as required by procedure. The team noted that CI failed to effectively implement Quality Assurance Program Manual (QAPM), QA-1, dated October 27, 2009, (NRC approval No. 0947) such that controlled copies of the QAPM in effect at the time of this inspection were dated May 8, 2009. The observations in the document control area represent a non-conformance with regard to the requirements of 10 CFR 71.111 and 113.

Conclusions

CI's implementation of documentation control was assessed to be inadequate. Several observations were identified with regard to CI not following prescribed activities or missing or incomplete documentation as described within procedures.

CI Response and Actions

A Corrective Action Report No. 0003 was initiated to address the observations provided by the Inspection Team and corrections began and continuing to completion. Century Industries has since the receipt of the Inspection Teams Report as previously noted, completed a full review of its SOP's to ensure that forms, text and attachments are in place within the SOP as required. These SOP's once reviewed and accepted by our new QA Manager will be signed and properly distributed. Multiple signatures will be found on all SOP's denoting separate reviews. Multiple locations within the shop will be established and a designee named and recorded for control of those SOP's. This will provide a station for shop personnel to review and have access to SOP's in more convenient location.

An Auditor Participation Log has been reinstated to comply with both the Inspection Team observation and applicable SOP's.

Training Outlines are established and personnel trained in accordance with those Outlines. The training records are in place and available for review. The new QA Manager will be reviewing those records as part of his responsibilities.

The QA Program Manual QA-1 Revision 3 bears the date of 10-22-09, which was the date it was last revised and updated. We will adjust the Approval date to the October 27, 2009 date for consistency with the NRC Approval No. 0947, effective date following a review of the QA Manual by both our outside reviewer and our new QA Manager. This action is planned for completion by April 30th.

We have reviewed all issued copies of the QA Manual to ensure that the latest date of 10-22-09 is properly reflected in each copy.

At the time of inspection, we made available copies of the QA Manual to the inspection team that did have the incorrect front cover attached; this error was noticed during the inspection.

The Corrective Action Report No. 0003 is scheduled to be completed once the internal audit has been implemented on or about May 07, 2010.

4. Audits

The team reviewed CI's internal audit process and determined that 2004, 2005, 2006 and 2009 internal audits were not performed. In addition, internal audit reports and associated checklists for 2007 and 2008 were incomplete and failed to adequately assess the effectiveness of the overall QA program. Both these factors combined leave the adequacy of the program as indeterminate and should have been a significant indicator to CI management for the need for corrective action.

The team reviewed CI's Approved Vendor List (AVL) and noted that important to safety services (e.g., calibration, audit, nondestructive examination and design/engineering) were performed without appropriate vendor qualification (e.g., surveys or audits) prior to services being rendered.

Conclusions

Overall the team assessed that CI's control of external audit program and both internal and external audit planning were not adequate in addressing the CI procedure requirements and applicable requirements of 10 CFR 71, subpart H.

CI Response and Actions

A Corrective Action Report No. 0004 was issued to address the observation noted by the inspection team and resolve the findings. The 2009 internal audit was postponed to incorporate a move to a larger facility, we have as of this date been unable to facilitate the move. Once the QA Manager has made adjustments that may be needed to the QA Program during his review process, we will conduct a new internal audit. We have discussed the need for a more intense audit action with our previous outside auditor, so that we will have a better picture of the program implementation.

Our Approved Vendors List (AVL) has been updated to include the safety related services including calibrations, outside audit personnel, nondestructive examination subcontractors and our design/engineering services. Surveys to incorporate these services have been conducted and will be reviewed as part of the internal audit process.

Closure of Corrective Action Report No. 0004 will be completed when the above discussed actions have taken place and are scheduled to be completed with the internal audit planned for 05-07-10.

5. Design Controls

The Corrective Action Report No. 0005 was written to address the non-conformance regarding the failure to fully provide interface controls and missing signatures on the review records for the design. The team reviewed SOP 2.3, Rev. 0, dated September 15, 2001, "Design Control" and noted a requirement to identify and control design interface efforts such that all participating organizations shall have responsibility assigned and procedures established. The team noted that responsibilities among participating design organizations (e.g. subcontracted engineering services and quality assurance) has not been clearly defined. Further, the team reviewed records of design input performed by Montgomery Engineering Technical Services (METS) and noted incomplete records (e.g. missing signatures) for checking the adequacy of the design.

Conclusions

The observations represent a non-conformance with regard to the requirements of 10 CFR 71.107 in that implementation of SOP 2.3 had not occurred relative to design interface efforts and design verification.

CI Response and Action

In review of the Team's observation, it was found that although a letter outlining the design control and input for the Versa-Pac, which describes the basis for the design, areas of responsibility, materials and specifications used in the design and manufacturing requirements, that the individual firm, in this instance METS was not clearly defined. A separate Purchase Order was written for METS but not included or clearly detailed in the design file as is required. The purchase order for METS has been corrected to fully describe the responsibility, operating procedures and specifications for METS as the engineering contractor for Century Industries Versa-Pac Shipping Container design process. This purchase order has been included as an attachment into the letter of design control and input.

Missing signatures on the required forms for all revisions, reviewing the adequacy of the design, are being reviewed, completed and will become part of the design record as required.

This Corrective Action Report No. 0005 will be completed by April 20, 2010.

6. Fabrication Controls

Since no fabrication was occurring during the inspection the team reviewed the CI SOP's that place controls on fabrication activities. Instead, the team reviewed test series prototype Fabrication Control Record No. 30104, applicable to Versa-Pac 55 container, serial number 10553, and noted that nondestructive visual examination was accomplished by a no-qualified person. In addition, the team noted that development of the weld procedure that was used; along with the welder qualification process (e.g. pre and post specimen testing) was performed by the same person. The team noted that the need for special controls and processes and skill to attain the required quality, and the need for verification of quality by inspection and test.

Conclusions

From a procedural standpoint, the team assessed that CI SOP's were not adequately implemented for packaging fabrication activities. The team noted that actual fabrication processes were not observed during this inspection and that the overall efficiency of the implementation of SOP's could not be fully assessed. Such an assessment will be made at such time as the NRC performs an inspection of future CI 10 CFR 71 packaging fabrication activities.

CI Response and Action

Corrective Action Report No. 0006 was prepared to provide response and action to correct those items where observations were noted.

Since the inspection, CI has been working on the update of its procedures concerning points of fabrication activities.

Our welding procedures have been taken from pre-qualified procedures within the AWS Specification; our welders are qualified in accordance with AWS D1.1 by prescribed test methods. Records have been reviewed and are maintained within the QA Department.

All special process procedures and fabrication processes are being reviewed and will be corrected as needed to assure that a quality product is provided in accordance with the requirements.

The items within this Corrective Action Report No. 0006 have been completed and will be considered implemented with an acceptable internal audit, due on May 07, 2010.

ANDREW ROSS
717 McFee Rd. Knoxville, TN 37934

SECURITY CLEARANCE

Active Q, Department of Energy

EXPERIENCE SUMMARY

Mr. Ross has more than thirty years in Quality Assurance/Quality Control, serving nuclear power utilities, Department of Defense (DOD) suppliers, Waste Management, commercial construction, manufacturing and nuclear environmental industries. He is qualified as an **ASQ Certified Quality Manager, an ISO 9000 RAB Registered Auditor, an ASME NQA-1 Lead Auditor, an ASME Section XI In-Service Examiner, and as an AWS Certified Welding Inspector.** Mr. Ross is experienced in technical writing, quality system development, auditing, employee training and training program development, including vendor qualification and management. Mr. Ross has developed, implemented, and supported ISO 9000 programs for the manufacturing industry. He has also developed welding process procedures and welder qualification programs. Mr. Ross is experienced as an ASNT NDE Technician and ANSI Mechanical Equipment Inspector. His areas of expertise extend to include the assessment and verification of customer contract requirements, including D.O.E and D.O.D. projects, the inspection of ASME Section III power piping, Section VIII pressure vessels, DOT transportation tanks, ISO shipping containers and radioactive and hazardous waste shipment packaging and waste shipment auditing.

PROJECT EXPERIENCE

Project Quality Assurance, Y-12 National Security Complex – Responsibilities include development and application of quality assurance requirements for construction and D&D projects. This includes contractor and supplier compliance to specifications and D.O.E. standing orders.

Project Quality Manager, Fairfield Service Group / K25/27 D&D Project - Responsibilities include Quality Program implementation for the Non-Destructive Analysis (NDA) subcontract in support of Phase 2 of the D&D project. Developed required pre-mobilization procedures. Additional responsibilities include implementing the detector calibration program, performing internal Management Assessments, Corrective Action tracking and implementation, Document Control, and Employee Training. Developed the Software Quality and Configuration Control procedures, and implemented other aspects of the subcontract Exhibit K – Quality Assurance Requirements.

Project Quality Manager, Duratek Federal Services / K25/27 D&D Project - Responsibilities included Quality Program Implementation and assessments during Hazardous Material Removal (Phase 1) of the K-25 D&D project. Additional responsibilities included managing the nonconformance control tracking corrective action implementation. Successfully completed a project review by the DOE.

Project Quality Manager, CH2M Hill / EMWMF Landfill / K25/27 D&D - Construction of D.O.E. EMWMF project, a radioactive / hazardous waste landfill. Responsibilities include Quality Program Development, verification of regulatory compliance, inspections, procedural training and system auditing. Required to interface with regulatory and client QA Personnel.

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Quality Manager, FBF Nuclear Containers, Inc. - Small Business. Certification testing of DOT 7A TYPE A containers. Manufacturer of DOT TYPE B containers. Holder of U.S. NRC approved quality program – 10 CFR-71 Subpart H, and ASME NQA-1. Primary customers included the DOE and DOD, commercial nuclear facilities, nuclear environmental remediation and the medical nuclear device industry. Responsible for all aspects of Sales, Purchasing, Quality, Manufacturing and Shipping.

Division Quality Manager, Aqua-Chem, Inc. - Manufacturing Facility. ASME VIII Pressure Vessels. ASME S, U, R Stamps. Also ISO 9001 Registered, Dept. of Defense Contractor. Nuclear Sub Safe and Level 1 Reactor Water Systems. Commercial and Naval Vessel Water Desalinating Systems. Successfully developed program and led an effort to achieve the China Import Safety Quality Licensing Stamp for the importation of pressure vessels into China.

Quality Consultant, Aerotek Engineering. - CNC Machining. Contracted to U.S. Pipe in Chattanooga, TN. Quality Program Development. Developed quality program for a successful ISO 9002 certification effort.

Quality Manager Heil Trailer International - Development and implementation of an ISO9001 Quality Management System. Investigated Customer Complaints, and developed and implemented corrective actions resulting from Warranty Investigations. Participated in Kaizan Manufacturing Process Improvement. Developed Corporate Internal Auditor Training Program. Managed 5 QC Personnel. Achieved a Fifty percent reduction in warranty costs over an eighteen month period through employee training and process engineering.

Quality Engineer Scientific Ecology Group - Nuclear Environmental Services - Audit Program Manager, Vendor Auditing, Project Surveillance including D.O.D and D.O.E. projects. Developed audit program procedures. Managed vendor audit program. Developed welder qualification program and welding procedures.

Contract Quality Assurance/Quality Control, Various Contract Firms - Quality Assurance surveillance and verification, Quality Control inspections at nuclear power and commercial construction sites. Trained in civil and structural construction materials testing, structural steel fabrication and erection.

Quality Control Inspector, Quality Assurance Examiner, Fluor Daniel Construction Co. - Contract surveillance, review and inspection - Nuclear power plant construction (Shearon Harris Nuclear Power Plant) and power outage support. NDE technician, ASME XI In Service Examiner, ANSI Mechanical Inspector - Piping, Pumps, Valves, Pipe Supports and Seismic Structural Steel.

Contract Nuclear Quality Control Inspector - United States Testing, Universal Testing - Nuclear Power Plant construction: Port Saint Lucie, Nine Mile Point II

Engineering Aid, Tennessee Valley Authority - Bellefonte Nuclear Power Plant. Successful completion of six month jobsite training program.

ORAU / Union Carbide Y-12 Plant - Student - Training and Technology Program - Nondestructive Testing.