March 26, 2010

Mr. William M. Arnold
President
Century Industries
P.O. Box 17804
Bristol, VA 24209

SUBJECT: U. S. NUCLEAR REGULATORY COMMISSION (NRC) INSPECTION REPORT NO. 71-0947/2010-201

Dear Mr. Arnold:

This letter refers to the team inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on February 23 and 24, 2010, at the Century Industries (CI) facility located in Bristol, VA. The purpose of the inspection was to assess the status of CI's implementation of their NRC-approved Quality Assurance (QA) program in the functional areas of QA program management, packaging design, fabrication, and maintenance, in preparation for CI's intention to become an NRC 10 CFR Part 71 Certificate of Compliance (CoC) holder and for subsequent fabrication of packagings to be used domestically within the United States.

The NRC inspection team terminated the inspection early because it was apparent that, except for the area of design control, CI did not implement effective programmatic controls in the functional areas of QA program management, fabrication, and maintenance. As detailed in the enclosed inspection report, CI had not effectively implemented their QA program as described in their submittal to the NRC, and that formed the basis for NRC approval of the program description.

The NRC is concerned that, to date, CI has not adequately implemented its QA program, particularly given that the CoC approval process for the Versa-Pac packaging designs is nearing an end and package fabrication activities could commence soon. As such, I have directed my staff to work with you to arrange for a management meeting to he held at NRC headquarters in Rockville, Maryland, at a date soon to be determined. At that meeting, you should be prepared to discuss the reasons for the inadequate implementation of your NRC approved QA program and the actions you will take to assure full and proper implementation in the future, in particular, prior to packaging fabrication.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/

David W. Pstrak, Chief
Rules, Inspections, and Operations Branch
Licensing and Inspection Directorate
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0947

Enclosure: NRC Inspection Report No. 71-0947/2010-201

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Docket No. 71-0947

Enclosure 1: NRC Inspection Report No. 71-0947/2010-201

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U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Spent Fuel Storage and Transportation

Inspection Report

Docket:	71-0947
Report:	71-0947/2010-201
Certificate Holder:	Century Industries P.O. Box 17804 Bristol, VA 24209
Date:	February 23-24, 2010
Inspection Team:	Earl Love, Team Leader, Safety Inspector, SFST Jim Pearson, Senior Safety Inspector, SFST
Approved by:	David W. Pstrak, Branch Chief Rules, Inspections, and Operations Branch Licensing and Inspection Directorate Division of Spent Fuel Storage and Transportation Office of Nuclear Material Safety and Safeguards

EXECUTIVE SUMMARY

On February 23-24, 2010, the U.S. Nuclear Regulatory Commission (NRC) performed an announced team inspection of Century Industries (CI), at its facility at Bristol, VA. The purpose of the inspection was to determine if CI's activities associated with the transportation of radioactive material were being performed in accordance with the requirements of 10 CFR Parts 21 and 71, applicable proposed Certificate of Compliance (CoC), related Safety Analysis Reports (SARs), and the NRC approved quality assurance (QA) program.

The NRC inspection team terminated the inspection early because it was apparent that, except for the area of design control, CI did not implement effective programmatic controls in the functional areas of QA program management, fabrication, and maintenance. As detailed in the enclosed inspection report, CI had not effectively implemented their QA program as described in their submittal to the NRC, and that formed the basis for NRC approval of the program description.

The term "observation" as used in this report means a non-conforming condition or activity that, had it concerned packagings with an NRC CoC, the observation would have been a violation of the applicable requirement in 10 CFR Part 71.

REPORT DETAILS

1.0 Inspection Scope and Background

In October 2009, Century Industries (CI) was granted an NRC 10 CFR Part 71 Quality Assurance (QA) Program Approval as a prerequisite to its submittal of a Type AF radioactive material packaging design for which it is seeking an NRC CoC. The inspection focused on how CI is implementing its NRC-approved QA program with respect to QA program management, packaging design, fabrication, and maintenance, in preparation for CI's intention to become an NRC 10 CFR Part 71 CoC holder and for subsequent fabrication of packagings to be used domestically.

As noted above, the term "observation" as used in this report means a non-conforming condition or activity that, had it concerned packagings with an NRC CoC, the observation would have been a violation of the applicable requirement in 10 CFR Part 71. Observations have been listed in these inspector notes so that CI can take appropriate actions for these non-conformances consistent with their QA program requirements.

1.1 Inspection Procedures/Guidance Documents Used

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings," NUREG/CR 6314, "Quality Assurance Inspections for Shipping and Storage Container," Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material."

1.2 List of Acronyms Used

AVL	Approved Vendor List
B&W	Babcock & Wilcox
CFR	Code of Federal Regulations
CoC	Certificate of Compliance

METS	Montgomery Engineering Technical Services
NCR	Nonconformance Report
NRC	U.S. Nuclear Regulatory Commission
QA	Quality Assurance
QAM	Quality Assurance Manager
QAPM	Quality Assurance Program Manual
SCAQ	Significant Condition Adverse to Quality
SOP	Standard Operating Procedure

1.3 Persons Contacted

The individuals present at the entrance, de-briefing meetings and exit meeting were as follows:

Entrance and Exit Meetings Attendance

NAME	AFFILIATION	ENTRANCE	EXIT
Earl Love	NRC	X	X
Jim Pearson	NRC	X	X
William Arnold	Century Industries	X	X

2.0 Management Controls

2.1 Quality assurance organization / program

2.1.1 Scope

The team assessed the adequacy of management controls in the areas of CI's Standard Operating Procedures (SOPs) implementation, nonconformance controls, documentation controls, and audit program. The team reviewed CI's practices and procedures, and their implementation, to determine the effectiveness of management controls.

2.1.2 Observations and Findings

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 c) 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 operating 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.

2.1.3 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 Part 71 in regard to quality assurance independence.

2.2 Nonconforming materials, parts, or components and Corrective actions

2.2.1 Scope

The team reviewed selected records and interviewed selected personnel to verify effective implementation of the nonconformance control program, and that corrective actions for identified deficiencies were technically sound and completed in a timely manner.

2.2.2 Observations and Findings

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.

2.2.3 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 Part 71, Subpart H.

2.3 Documentation

2.3.1 Scope

The team reviewed CI's documentation control program to determine the effectiveness of the QA program in controlling quality-related documentation and records. The team reviewed procedures and drawings for adequacy and approval signatures. In addition, the team reviewed records of fabrication for a prototype Versa-Pac 55 container such as inspection and test procedures, nonconformance reports, SOPs, and packaging drawings.

2.3.2 Observation and Findings

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.

2.3.3 Conclusions

CI's implementation of documentation controls 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.

2.4 Audits

2.4.1 Scope

The team reviewed CI's audit program to determine whether plans, procedures, and records were available. The team determined whether CI scheduled and performed internal QA audits and vendor audits in accordance with approved procedures or checklists; whether qualified, independent, personnel performed the audits; whether CI management reviewed audit results; and whether CI took appropriate follow-up actions in those areas found to be deficient.

2.4.2 Observations and Findings

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 qualifications (e.g., surveys or audits) prior to services being rendered.

2.4.3 Conclusions

Overall the team assessed that CI's control of the 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 Part 71, Subpart H.

3.0 Design Controls

3.1 Design

3.1.1 Scope

The team reviewed selected design documentation (drawings, procedures, and records) to determine if adequate design controls were implemented. The team reviewed design organization interfaces, use of appropriate regulatory requirements and quality standards in design activities, and design deviation control. The team also reviewed design modification controls to ensure that modifications made to the design received the same level of review as the original design, and that the modifications were correctly reflected in the design documentation.

3.1.2 Observation and Findings

The team reviewed SOP 2.3, Revision 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.

3.1.3 Conclusions

The observations represented 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.

4.0 Fabrication Controls

4.1 Fabrication & assembly

4.1.1 Scope

The team reviewed documentation of fabrication activities affecting safety aspects of the packaging to verify if they were performed in accordance with approved methods, procedures, and specifications.

4.1.2 Observations and Findings

Since no fabrication was occurring during the inspection the team reviewed the CI SOPs 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 non-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 the need for special controls and processes and skills to attain the required quality, and the need for verification of quality by inspection and test.

4.1.3 Conclusions

From a procedural standpoint, the team assessed that CI SOPs 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 SOPs 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 Part 71 packaging fabrication activities.

5.0 Meetings

The team performed an entrance and exit meeting on February 23 and 24, 2010, respectively.