



L-D100-2013-000007

January 10, 2013

United States Nuclear Regulatory Commission
Attn: Document Control Desk
Quality Assurance Branch
Division of Construction Inspection and Operational Program
Washington, DC 20555-0001

Shaw Modular Solutions

NRC Docket Number: 99901401

SUBJECT: REPLY TO NOTICE OF NONCONFORMANCE

NRC INSPECTION REPORT NO. 99901401/2012-201

Reference: 1. Letter from K. Kavanagh (NRC) to J. Ernst (SMS) NRC Inspection Report No. 999901401/2012-201 and Notice of Nonconformance, dated October 24, 2012

2. Email from K. Kavanagh (NRC) to J. Ernst (SMS), RE: Extension Request or SMS Reply to NON 99901401/2012-201, dated December 13, 2012

Dear Ms. Kavanagh:

In response to the Ref. 1 NRC Notice of Nonconformance (NON) and consistent with the submittal schedule extension approved in Ref. 2, Shaw Modular Solution (SMS) herewith provides the enclosed Reply (Enclosure). The Reply addresses Examples 1-4 of NON of the Notice as they relate to Section 16, "Corrective Action," of SMS Quality Assurance Manual, Revision 7, dated February 29, 2012.

SMS understands the feedback received from the NRC during the Inspection and in the published Inspection Report, including the minor findings. SMS has completed or initiated comprehensive actions to address the specific observations provided in an effort to remedy and prevent their recurrence.

SMS recognizes that an effective corrective action program is a critical aspect of a strong nuclear safety culture. As such, SMS has continued to implement process, procedure, and program improvements and has enhanced employee skills through relevant training. We believe that progress has been made in our corrective action program; however, we also acknowledge and understand that continued improvements are necessary. The findings outlined in the NRC inspection report and notice of nonconformance indicates that additional improvements and oversight of the program is necessary. SMS is dedicated to building an effective and compliant corrective action program and has implemented several immediate corrective actions.

IE09
NR0

Pursuant to the NRC's corresponding instructions specified in the Notice, the Enclosure addresses for each of the Examples of Notice of Nonconformance: 1) the reason for the nonconformance; 2) the corrective steps that have been taken and the results achieved; 3) the corrective steps that will be taken to avoid noncompliances, and 4) date when corrective actions will be completed.

Should you have questions or comments, please feel free to contact me.

Sincerely,



J. L. Ernst
Senior Vice President Quality
Shaw Modular Solutions

Enclosure:

1. Reply to Nonconformance 99901401/2012-201-01

Cc: E. H. Roach, Chief

Chief Quality Assurance Branch

Division of Construction Inspection and Operational Programs

Office of New Reactors

D. Chapman

K. Walsh

M. Faulkner

K. David

G. Grant

ATTACHMENT 1
REPLY TO NONCONFORMANCE 99901401/2012-201-01

NONCONFORMANCE

Based on the results of an unannounced U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA during September 10-14, 2012, it appears that certain of your activities were not conducted in accordance with NRC requirements that were contractually imposed on SMS by its customers or NRC licensees.

Criterion XVI, "Corrective Action," in Appendix B to Title 10 of the Code of Federal Regulation (10 CFR) Part 50, states 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. In the case of significant conditions adverse to quality (SCAQs), the measures shall assure that the cause of the conditions is determined and corrective action taken to prevent repetition. The identification of the SCAQ, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

Section 16 of the SMS Quality Assurance Manual, Revision 7, dated February 29, 2012, stated, in part, that conditions adverse to quality shall be identified and documented. The actions necessary to correct conditions adverse to quality shall be determined and implemented. For SCAQs, actions necessary to correct the root cause shall be included so as to prevent recurrence. The implementation of corrective action for significant conditions adverse to quality shall be verified and shall be assessed to determine its effectiveness.

Contrary to the above, as of September 14, 2012, SMS failed to promptly correct conditions adverse to quality and SCAQs, failed to correct a condition adverse to quality regarding documentation of late entries in a quality records procedure, failed to preclude recurrence of SCAQs related to identification and control of items, and failed to correct a condition adverse to quality associated with a nonconformance identified during a previous NRC inspection. Specifically:

1. SMS failed to promptly correct conditions adverse to quality and SCAQs. SMS failed to implement corrective actions for conditions adverse to quality in a timely manner in that there were numerous repetitive condition reports (CRs) with common causes. Additionally, SMS failed to perform root cause analyses for SCAQs within the 30 calendar days as required by Section 6.7.2.a of Procedure QP-G-16, "Corrective Action Program," Revision 6, dated June 28, 2012.
2. SMS failed to correct a condition adverse to quality. SMS opened CR No. 12-346 to address the documentation of late entries in Procedure QP-G-17, "Quality Records," and SMS subsequently closed CR No. 12-346 by publishing Revision 5 of Procedure QP-G-17. However, SMS later published Procedure QP-G-17, Revision 6, but deleted all of the guidance for the late entries incorporated in Revision 5 that addressed and resulted in the closure of CR No. 12-346.

3. SMS failed to prevent recurrence of SCAQs related to identification and control of items. SMS had a closed SCAQ CR (CR No. 12-177) related to the inadequate control of issuance of weld wires used in the fabrication of safety-related modules. However, SCAQ CR Nos. 12-272 and 12-543 were opened with the same root cause analysis as the one already closed.
4. SMS failed to perform adequate corrective actions associated with a nonconformance identified during a previous NRC inspection. SMS failed to complete procedure revisions by August 31, 2012, as committed to in its March 9, 2012, response (Agencywide Document Access and Management System (ADAMS) Accession No. ML12082A161) to a notice of nonconformance issued on January 6, 2012 (ADAMS Accession No. ML11354A389). These procedure revisions were documented as corrective actions for Nonconformance 99901401/2011-201-09, which was identified during a November 14-18, 2011, inspection for SMS's failure to perform a trend analysis of conditions adverse to quality as required by the Shaw Nuclear Services purchase orders. Additionally, some SMS staff members were performing trending analysis using a draft procedure, but there was no formal guidance provided.

This issue has been identified as Nonconformance 99901401/2012-201-01

DISCUSSION OF THE REASON FOR NONCOMPLIANCE AND ASSOCIATED CORRECTIVE ACTIONS

Issue / Condition 1.

SMS failed to promptly correct conditions adverse to quality and SCAQs. SMS failed to implement corrective actions for conditions adverse to quality in a timely manner in that there were numerous repetitive condition reports (CRs) with common causes. Additionally, SMS failed to perform root cause analyses for SCAQs within the 30 calendar days as required by Section 6.7.2.a of Procedure QP-G-16, "Corrective Action Program," Revision 6, dated June 28, 2012.

Cause and Associated Corrective Actions for the Noncomplying Condition:

Condition 1a.

Cause: The reason that SMS failed to promptly correct conditions adverse to quality, which resulted in repetitive condition reports was that:

1. The development of the corrective action plans and the implementation of those corrective actions took excessive time
2. The corrective actions failed to address causal factors
3. Effectiveness reviews for corrective actions were inadequate

Associated Corrective Actions

- 1a. Assign a Corrective Action Program Coordinator ("CAPCO") to departments to facilitate effective implementation of the CAP by performing investigations and providing support to others in performing investigations (Complete)

Results to date: Managers maintain better situational awareness of the CRs that are assigned to their departments and the status of those CRs. CAPCOs facilitate the analysis and processing of the condition reports allowing Managers to be timelier in their analysis and corrective action implementation.

- 1b. Report Daily Corrective Action Overdue status at the Morning 0730 Coordination Meeting which is attended by Senior Management (Implemented and is an ongoing activity)

Results to date: Senior management and managers maintain situation awareness of any overdue CRs. Managers monitor their CR status more closely since Senior Management is briefed daily and if needed re-prioritizes efforts in their organization to address the overdue CRs /corrective action.

- 1c. Conduct Weekly Corrective Action Oversight Meetings with the Departments/CAPCOs to discuss Corrective Actions Coming Due and that are Overdue (Implemented and is an ongoing activity)

Results to date: Highlighting upcoming corrective actions requirements and discussing any that may be overdue integrates and synchronizes the CAP Department and the Department CAPCOs understanding of CR priority. This discussion also allows CAPCOs to share their input and offer their assistance where warranted.

- 2a. Conduct a nuclear-safety related Corrective Action Program seminar for management (Manager through Executive VP Level) that reinforces the attributes necessary for an effective program

Initial "Cause Analysis for Senior Managers" training was conducted for both Senior Managers and select Managers on 17 Oct 2012. Managers are more aware of the purpose, importance and conduct of apparent cause and root cause analyses and the processes and techniques required to perform, review and approve more effective cause analyses and corrective actions. This awareness assists in their development and / or approval of the Corrective Action Plans. Additional training related to the Corrective Action Program will be conducted later in January 2013.

- 2b. Develop and conduct training for CAPCOs focusing on Causal Analysis and proper implementation of the Corrective Action Program under SMS procedures (Completed)

Results to date: By training CAPCOs on Causal Analysis on 12/20/12; CAPCOs have a common understanding of completing CR milestones in a timely manner; causal analysis techniques used in Apparent Cause Evaluations (ACE), and the elements that need to be addressed in the conduct of the ACE.

3. Perform an effectiveness review of corrective actions implemented for all SCAQs between September 2011 and 2012

CARB has reviewed all SCAQ RCAs and the recommended / identified corrective actions of all 2012 SCAQs and ensured they are sound. Effectiveness of the implemented corrective actions of the SCAQs will be conducted by Department Managers.

Condition 1b.

Cause: The reason that SMS failed to perform root cause analyses for SCAQs within the 30 calendar days as required by Section 6.7.2.a of Procedure QP-G-16, "Corrective Action Program," Revision 6, dated June 28, 2012 was that:

1. There was insufficient engagement by the Department Owner / Sponsor in the root cause analysis (RCA) investigation
2. SMS did not have a pool of staff members that were trained in root cause analysis, which caused SMS to depend on RCA teams which were largely staffed by contract personnel that were root cause qualified, but were not subject matter experts
3. Department subject matter experts were not on the root cause analysis (RCA) teams

Associated Corrective Actions

- 1a. QP- CA-216, Corrective Action Program (formerly QP-G-16), was revised to address Department Owner/Sponsor responsibilities and to provide a time limit for establishing the root cause team. (Complete)

Results to date: Team Sponsors are designated at the CARB and this identification highlights the importance of sponsorship to the designated individual. The sponsor/CR Owner for RCA 2012-1000 and 2012-1231 established the RCA Team in a timely manner. CR Owner of the SCAQs maintained situational awareness through visits or back-briefs by the RCA team leader allowing the analysis and development of the recommended corrective actions to stay on track and be briefed to the CARB within the specified timeframe.

- 1b. Executive management is notified when a CR is classified as SCAQ and provides oversight in reviewing and approving all Root Cause Analyses (RCAs). (Implemented)

Results to date: Executive Management gains situational awareness of the condition report that is designated as a SCAQ, allowing them to monitor the designation of the RCA Team Sponsor and the establishment of the RCA Team.

2. Additional employees were trained as root cause analysts to ensure sufficient subject matter expertise is available to support the root cause team (Complete)

Results to date: We no longer rely on contractors to conduct RCAs. SMS had seven individuals that had RCA Training which was conducted 20-28 Aug 2012. Eight additional personnel attended an additional RCA class conducted on 29 Oct thru 5 Nov 2012. This pool of RCA trained individuals allowed SMS to establish a Root Cause Analysis Team for SCAQ 2012-1000 and 2012-1231 in a timely manner.

3. Additional employees were trained as root cause analysts to ensure sufficient subject matter expertise is available to support the root cause team (Same as # 2 above) (Complete)

Results to date: Fifteen individuals with different subject matter background and different departments within SMS received Root Cause training (same individuals addressed in #2 above). SMS can now select their RCA team members based on the type of subject matter expertise that will be required during the conduct of the RCA.

Issue / Condition 2.

SMS failed to correct a condition adverse to quality. SMS opened CR No. 12-346 to address the documentation of late entries in Procedure QP-G-17, "Quality Records," and SMS subsequently closed CR No. 12-346 by publishing Revision 5 of Procedure QP-G-17. However, SMS later published Procedure QP-G-17, Revision 6, but deleted all of the guidance for the late entries incorporated in Revision 5 that addressed and resulted in the closure of CR No. 12-346.

Cause and Associated Corrective Actions for the Noncomplying Condition:

Condition 2.

Cause: The reason that corrective actions associated with CR 12-346 were removed from QP-G-17, "Quality Records," in revision 6 of this procedure was due to a management decision and to rescind revision 5 as a result of difficulty implementing changes made to the procedure unrelated to CR 12-346. To promptly address these difficulties, a decision was made to return the

procedure to exactly the same as it was in revision 4 without any of the changes that were included in revision 5; thus, revision 6 was the same procedure as revision 4. Knowing this was done, CR 2012-857 was initiated to ensure that these corrective actions were addressed in the next revision of the procedure.

Associated Corrective Action

1. QP-G-17 was reissued as QP-QA-217 on October 11, 2012 and included revisions to address the corrective actions associated with CR 12-346. (Complete)

Results to date: QP-QA-217 (formerly QP-G-17) is being utilized by SMS personnel.

Issue / Condition 3.

SMS failed to prevent recurrence of SCAQs related to identification and control of items. SMS had a closed SCAQ CR (CR No. 12-177) related to the inadequate control of issuance of weld wire used in the fabrication of safety-related modules. However, SCAQ CR Nos. 12-272 and 12-543 were opened with the same root cause analysis as the one already closed.

Cause and Associated Corrective Actions for the Noncomplying Condition:

Condition 3 .

Cause: The reason that SMS has failed to prevent recurrence of SCAQs related to identification and control of weld wire is that:

1. The investigation scope of the three separate root cause analysis (No. 12-002, No. 12-003 and No. 12-005) was too narrow and did not focus on programmatic or process issues.
2. The management sponsor for the investigations was not sufficiently engaged to ensure programmatic or process issues were identified.

Associated Corrective Actions

- 1a. Importance of considering programmatic and process issues when performing root cause investigations was reinforced as part of causal analysis training (Complete)

Results to date: Root Cause Analysis Teams look at programmatic and process issues using the causal analysis techniques that were discussed during RCA training. This emphasis allows the team to conduct a better RCA and develop better recommended corrective actions.

- 1b. Two types of classes were provided emphasizing cause analysis: one for those to be qualified to perform root cause analysis and one for managers (Complete)

Results to date: Root Cause Analysis Training conducted 29 Oct thru 5 Nov and the Causal Analysis Training conducted 17 Oct 2012 for Senior Managers and select Managers identified the processes and techniques required to perform, review and approve more effective cause analyses and corrective actions. This education assists in the RCA Analysis and the development of Corrective Action.

2. QP- CA-216, Corrective Action Program (formerly QP-G-16), was revised on 30 Nov 2012 to address Department Owner / Sponsor responsibilities. (Complete)

Results to date: Team Sponsors are designated at the CARB and this identification highlights the importance of sponsorship to the designated individual. The sponsor/CR Owner for RCA 2012-1000 and 2012-1231 established the RCA Team in a timely a manner. CR Owner of the SCAQs maintained situational awareness through visits or back-briefs by the RCA team leader allowing the analysis and development of the recommended corrective actions to stay on track and be briefed to the CARB within the specified timeframe.

Issue / Condition 4.

SMS failed to perform adequate corrective actions associated with a nonconformance identified during a previous NRC inspection. SMS failed to complete procedure revisions by August 31, 2012, as committed to in its March 9, 2012, response (Agency wide Document Access and Management System (ADAMS) Accession No. ML12082A161) to a notice of nonconformance issued on January 6, 2012 (ADAMS Accession No. ML11354A389). These procedure revisions were documented as corrective actions for Nonconformance 99901401/2011-201-09, which was identified during a November 14-18, 2011, inspection for SMS's failure to perform a trend analysis of conditions adverse to quality as required by the Shaw Nuclear Services purchase orders. Additionally, some SMS staff members were performing trending analysis using a draft procedure, but there was no formal guidance provided.

Cause and Associated Corrective Actions for the Noncomplying Condition:

Condition 4.

Cause: The reason that SMS failed to incorporate guidance into its procedures by the committed due date was that:

1. SMS did not allow adequate time in its time estimate for procuring and implementing the new software, understanding its trending capabilities, and gathering data to allow the organization to develop the necessary procedural guidance.

Associated Corrective Actions

1. Procedure QP-CA-303, Trending Manual was developed to provide guidance for assigning trend codes to condition reports, establishing timeframes for formal

trending reports, and identifying when a trend condition report should be initiated for investigation of a potential trend. (Complete)

Results to date: Trending procedure is in use by the Corrective Action Department. Trending CRs have been initiated.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

All actions will be completed by June 1, 2013.